The Feasibility and Potential Effectiveness of a Conventional and Exergame Intervention to Alter Balance-related Outcomes including Fall Risk:

A Mixed Methods Study

A thesis in fulfilment of the requirements for a Ph.D. degree

Candidate: Christine Rogers SLSCHR001 Peoplesoft number: 1267062

Department of Health and Rehabilitation Sciences

Faculty of Health Sciences

Supervisors:

Prof. Delva Shamley, Clinical Research Centre, Faculty of Health Sciences, University of Cape Town

Em. Prof. Seyi Amosun, Department of Health and Rehabilitation Sciences, Faculty of Health Sciences, University of Cape Town

CONTENTS

List of Tables xii

List of Figures xiii

Plagiarism Declaration xiv

Acknowledgements and Dedication xv

Funding Declaration xviii

Declaration/conflict of interest xix

Dedication xx

List of Abbreviations xxi

General abbreviations xxi

Abbreviations of outcome measures xxv

Symbols xxvi

Abbreviations of trial guidelines xxvi

Glossary of Terms xxvii

Statistical terms xxxii

A note regarding spelling of terms xxxii

Abstract 1

Introduction 2

Outline of the Introduction 2

Purpose of the study 3

Unique aspects of the study. 4

Outline of the present thesis. 5

Background and context for the study. 6

Role of Rehabilitation. 12

Chapter I. Fall Risk Factors in Older Adulthood 18

Introduction 18

Ageing and falls 18

Factors Contributing to Fall Risk in Community-dwelling Older Adults 19

Intrinsic risk factors for falls. 20

The Contribution of Dizziness and Balance to Fall Risk 25

Vestibular ageing. 26

Prevalence of dizziness in older adults. 29

Modifiable fall risk factors: impact of PA and sedentary behaviour. 31

South African fall risk factors. 32

Intrinsic fall risk factors pertinent to the African context. 33

Chapter II. Prevalence of Falls in Community-dwelling Older Adults 35

Global Fall Prevalence Data 35

African Challenges 37

Extrinsic fall risks 37

Impact of falls in the African context. 37

Impact of Falls: Mortality and Morbidity 38

Mortality. 38

Morbidity 39

Ageing in an African Context 42

Planning for ageing in Africa. 45

Chapter III. Prevention of Falls 48

Introduction 48

Part One: Role of Prevention and Health Promotion 49

Screening. 50

Prevention. 53

Resources for fall prevention and intervention programmes 54

Part Two: Exercise-based Interventions in Community-dwelling Older Adults 57

Introduction. 57

Evidence that Exercise-based Interventions Improve Balance: A Critique of Systematic Reviews. 58

Recommendations arising from critiques of research on exercise-based interventions to reduce falls. 66

Chapter IV. Conventional Exercise-based Interventions and the Otago Exercise Programme for Reducing the Risk of Falls 70

Introduction 70

Conventional Fall Prevention Programmes 70

Otago Exercise Programme 72

OEP design and evidence. 74

OEP in LMIC. 75

Feasibility Considerations 80

Recruitment and attrition for OEP trials. 80

Safety and adherence for OEP trials. 81

Costs of fall prevention programmes including the OEP. 81

Chapter V. Exergames and Evidence for the Wii Balance Board and Fall Prevention 85

Introduction 85
Part One 86
Serious Games in Context 86
Motivation to use an exergame intervention in this study. 88
Research on the Wii Fit for Balance Rehabilitation and Fall Prevention 89
Introduction to the Wii Fit and Balance Board. 89
Balance theory, Conventional Vestibular Rehabilitation and the Potential for Exergames to be an Effective Intervention for Balance Deficits 91
Introduction. 91
Conventional VRT and fall programmes. 92
Theoretical constructs supporting the use of exergaming. 93
Psychological Contributions to the Efficacy of Exergames 103
Part Two 105
Evidence Supporting the Use of Exergames to Improve Balance and Prevent falls. 105
Older Adults' Adherence to Exercise-based Fall Prevention Programmes 106
Chapter VI. Methodology 109
Introduction 109
Aim of the Study 113
Objectives. 113
Study Design 116
Feasibility cluster RCT. 116
Participants 117
Site selection criteria. 117
Sampling and randomisation of clusters. 118
Selection of individual participants within clusters. 118
Sample Size 122
Recruitment and Enrolment 122
Recruitment of clusters. 122
Recruitment of individual participants. 122
Equipment, Materials and Instruments 123
Equipment and materials. 123
Instruments. 123
Research Procedures 127
Ethical clearance, trial registration, and permissions. 127

Induction of participant into the study. 128
Eligible OEP and WBB participants receive interventions 130
Repeated measures and monitoring. 131
Participants exit trial. 133
Reliability and Validity 133
Randomisation, allocation concealment and blinding 133
Training for physical endpoints. 134
Sources of bias and efforts to manage them. 135
Research personnel. 137
Participant Safety and Monitoring 137
Data Management 137
Data Analysis 139
Triangulation of results. 140
Ethical Considerations 140
Confidentiality. 141
Risks and benefits for participants. 141
Justice 142
Competence of researcher and staff. 142
Referral 143
Insurance for research-related injuries 143
Qualitative Component 144
Aim 144
Objectives 144
Study Design 144
Framework for focus group design. 144
Sampling Plan 146
Sampling strategy and selection criteria. 146
Sample size. 146
Recruitment 146
Focus Group Setting 146
Procedure 147
Permissions and consent 147
Focus group procedure. 147
Facilitator Preparation and Management of Group 148

Assistant facilitator's role. 149
Materials 149
Rigour and Trustworthiness 149
Data Analysis 152
Phases in the analysis process. 152
Ethical Considerations 153
Chapter VII. Results 155
Results of Aim 1 155
Objective 1. Site and Participant Recruitment 155
Failure to enrol sites. 155
Procedures linked to site initiation. 156
Description of sites. 156
Site and protocol feasibility checklist. 157
Issues Impacting Potential Enrolment 173
Eligibility and recruitment fractions. 173
Refinement of eligibility criteria. 173
Objective 2. Issues Related to Cluster Randomisation 174
Sources of potential bias. 174
Use of a cluster design. 174
Safety, Adverse Events and Falls. 177
Sample size for future trials. 178
Objective 3. Adherence 179
Adherence, exercise regimens and relationship to best practice guidelines. 179
Relationship between adherence and intervention efficacy (i.e. falls). 183
Objective 4. Costs of the Feasibility Study and a Future RCT 184
Costs of feasibility RCT. 184
Objective 5. Utility of Physical Outcome Measures 185
Intraclass correlation coefficients results. 185
Appropriateness of outcome measures. 185
Results of Aim 2 190
Endpoints related to physical activity and balance. 190
Falls. 193
Fall risk, fall events and changes in physical endpoints between intervention groups. 196
Experience of the Interventions 197

Quantitative data. 197
Domain 1: Research Team and Reflexivity 200
Personal characteristics and facilitator's relationship with participants. 200
Domain 2: Study Design 201
Theoretical framework. 201
Participant selection, recruitment, and study settings. 201
Data collection and management. 201
Domain 3: Analysis and Findings 202
Data coding. 202
Participants' attitudes towards falls and fall prevention. 203
WBB participants' experience of the intervention. 207
Barriers and facilitators to participation in the WBB intervention. 211
Chapter VIII. Discussion 216
Introduction 216
Feasibility of the Trial and Interventions 217
Site and participant recruitment. 217
Suitability of participant eligibility criteria. 220
Participants' fall risk profile. 221
Implication of fall prevalence for planning and policy in South Africa. 227
Issues Related to Use of a Cluster RCT Feasibility Design 231
Sample size calculations. 231
Between-group differences at base-line. 231
Missing data. 232
Randomisation, allocation concealment, and blinding. 233
Safety issues. 234
Statistical considerations. 235
Proposed changes to protocol. 236
Preliminary Evidence for the Interventions 253
Reduction of falls in the exercise intervention groups. 254
Participants' experience of WBB. 257
Fiscal Motivation for a Large Scale RCT 259
Costs of a future RCT. 259
Implications of the Study 260
Training implications. 260

Clinical implications. ... 261
Policy implications. ... 263
Recommendations for Future Research ... 264
Conclusion ... 266
Appendices ... 267
Appendix A Exercise intervention programmes (OEP and WBB) ... 267
Appendix A.1 Summary of exergame systematic reviews ... 267
Appendix A.2 Permission to use Otago Exercise Programme. ... 293
Appendix A.3 Otago Exercise Programme. ... 294
Appendix A.4 Permission to use WBB exercise programme. ... 302
Appendix A.5 Wii Fit Balance Board Programme. ... 305
Appendix B Supplementary Tables to Support Literature Review ... 319
Appendix B.1 Fall prevalence in LMIC referenced to USA data. ... 319
Appendix B.2 OEP eligibility, enrolment, recruitment and attrition data from trials in high and LMIC. ... 324
Appendix B.3 Trials of OEP: adherence, safety and outcome measures. ... 326
Appendix C Documents Pertaining to Site Recruitment ... 328
Appendix C.1 Information sheet provided to site managers after initial meeting. ... 328
Appendix C.2 Consent Form granting permission for use of facility to recruit participants. ... 331
Appendix C.3 Information letter to invite site managers to be participants. ... 332
Appendix C.4 Concept Protocol used with site managers who agreed to participate. ... 335
Appendix C.5 Protocol Feasibility Checklist (see Results). ... 337
Appendix C.6 Pre-study site selection visit checklist. ... 339
Appendix C.7 Site assessment and feasibility questionnaire. ... 342
Appendix C.8 Study initiation checklist. ... 346
Appendix C.9 Invitation to recruitment presentation to attract potential participants to study. ... 348
Appendix C.10 Indication of interest and response slip.* ... 349
Appendix C.11 Letter of welcome to study and eligibility screening appointment.* ... 351
Appendix C.12 Matters Pertaining to Recruitment of Older Adults ... 352
Appendix D Informed Consent Documents for Individual Participants ... 354
Appendix D.1 Information sheet and Informed Consent document for the Otago Exercise Programme.* ... 354
Appendix D.2 Information sheet and Informed Consent Document for Wii Fit programme*. ... 363
Appendix D.3 Information sheet and Informed Consent Documents for Focus Groups. ... 372

Appendix E MiniBESTest Balance Evaluation Systems Test 376
Appendix E.1 Introduction. 376
Appendix E.2 MiniBESTest procedure instructions and score sheet (604). 377
Appendix E.3 MiniBESTest Equipment and scoring descriptors. 382
Appendix E.4 Timed-up-and-Go. 385
Appendix F Dynamic Gait Index 386
Preferred walking speed. 386
Number of steps for 360° pivot turn and stop. 388
Dynamic Gait Index method and instructions 388
Appendix G Monitoring Logs 392
Appendix G.1 Exercise Log. 392
Appendix G.2 Log of falls, injuries and expenses incurred. 394
Appendix H Cognitive screening and Mini-Cog 398
Appendix H.1 Introduction. 398
Appendix H.2 Permission to use Mini-Cog. 399
Appendix H.3 Mini-Cog™ 401
Appendix I Geriatric Depression Scale (short form) 403
Appendix I.1 Introduction. 403
Appendix I.2 Geriatric Depression Scale (short form, 15 item). 404
Appendix I.3 Geriatric Depression Scale (short form, 15 items) Scoring Instructions. 405
Appendix J Case History 406
Appendix J.1 Case history questionnaire including Functional Comorbidities Index. 406
Appendix J.2 FRAT-up webpage screenshot. 411
Appendix K Euro-QoL EQ-5D-3L Health Questionnaire English version for South Africa 413
Appendix K.1 Permission to use Euro-QoL EQ-5D-3L. 414
Appendix K.2 Euro-QoL EQ-5D-3L Health Questionnaire English version for South Africa. 416
Appendix L Self-efficacy for Exercise Scale (592) 418
Appendix L.1 Reliability and validity of the SEE. 420
Appendix M Physical Activity Scale for the Elderly (PASE) 421
Appendix M.1 Permission to use the PASE. 421
Appendix M.2 Physical Activity Scale for the Elderly© 422
Appendix M.3 Additional information and normative data for PASE. 427
Appendix N Systems Usability Scale 428
Introduction 428

Appendix N.1 Scoring the System Usability Scale [903]. 428
Appendix N.2 System Usability Scale. 429
Appendix O Borg Rating of Perceived Exertion Scale 432
Appendix P Five Times Sit to Stand Test 433
Method and instructions 433
Appendix Q Frailty and Injuries: Cooperative Studies of Intervention Technique (FICSIT-4) 434
Changes for this study 434
FICSIT-4 method and instructions 434
STEADI 4-Stage Balance Test. 436
Appendix R Ethical Clearance and Trial Registration Documents 438
Appendix R.1 UCT Human Research Ethics Committee clearance for RCT. 438
Appendix R.2 Annual Progress Report/Renewal. 439
Appendix R.3 Registration with Pan African Clinical Trials Registry. 440
Appendix R.4 UCT Human Research Ethics Committee clearance for focus groups. 441
Appendix R.5 Certification of Good Clinical Practice qualification. 445
Appendix R.6 Confidentiality agreement for research staff 447
Appendix R.7 Singapore Statement on research integrity. 449
Appendix R.8 Application for UCT No-fault insurance. 450
Appendix S Record of Unmasking of Intervention Allocation Group 454
Appendix T Reporting of Adverse Events 455
Appendix U Capacity of Individuals to Participate in Decision-making 458
Appendix U.1 Strategies to enhance the informed consent process. 459
Appendix U.2 Beneficence. 460
Appendix U.3 Non-maleficence. 460
Appendix V Example of Participant Referral for Further Services 461
Appendix W Focus Groups 463
Appendix W.1 Thank you letter to site managers and permission to hold focus group. 463
Appendix W.2 Interview schedule for focus group discussions. 466
Appendix X Additional Data for Results Chapter 467
Appendix X.1 Site recruitment. 467
Appendix X.2 Procedures completed at site initiation visits. 471
Appendix X.3 Demographic and self-assessment scores collected at base-line and their impact on adherence 473
Appendix Y 476

REFERENCES 480

LIST OF TABLES

Table 1. Methodological issues highlighted in Cochrane review and strategies to address them in the current study design. 61
Table 2. Methodological concerns from literature review and strategies to address them in this study. 68
Table 3. Features of Otago Exercise Programme (OEP) and adaptions to Wii Balance Board (WBB) for this study. 79
Table 4. Hypotheses underpinning therapeutic strategies* to improve balance using conventional VRT and exergaming programmes. 94
Table 5. Aims and objectives of the study. 114
Table 6. Participant exclusion criteria, method of detection and rationale for exclusion. 121
Table 7. Schedule of endpoints. 132
Table 8. Sources of bias and strategies to manage them. 136
Table 9. Endeavours to promote trustworthiness. 150
Table 10. Site and protocol feasibility checklist. 158
Table 11. Recruitment of participants at each site. 164
Table 12. Participants' demographic data. 168
Table 13. Functional Comorbidity Index results. 172
Table 14. Between group differences in self-assessment scales. 176
Table 15. Number and severity of falls during trial. 177
Table 16. Minutes and exercise sessions/week for both interventions. 182
Table 17. Participants meeting/exceeding norms for physical endpoints. 187
Table 18. Participants achieving MCID on physical endpoints. 189
Table 19. Between-group differences in physical endpoints over time. 192
Table A.1. Summary of exergame systematic reviews. 267
Table B.1. Fall prevalence in LMIC referenced to USA data. 319
Table B.2. OEP eligibility, enrolment, recruitment and attrition data from trials in high and LMIC. 324
Table B.3. Trials of OEP: adherence, safety and outcome measures. 326
Table E.1. Normative data for TUG by age and sex. 385
Table F.1. DGI scores per decade of life. 386
Table F.2. Results from meta-analysis demonstrating impact of age and sex on preferred walking speed. 387
Table Q.1. Normative data for static tests of balance per decade of life 437
Table X.1. Recruitment processes from initial contact to recruitment presentation. 467
Table X.2. Details of site inspection and enrolment procedures. 471
Table X.3. Demographic and SAS data and impact on adherence. 474
Table Y.1. Breakdown of feasibility study costs. 476

LIST OF FIGURES

Figure 1. Flow chart of organisation of Introduction. 2
Figure 2. Global burden of falls in 2016 [127] 10
Figure 3. Organisational flow of Chapter I. 18
Figure 4. Intrinsic risk factors contributing to fall risk in community-dwelling older adults. . 22
Figure 5. Age-related factors influencing balance and postural control. 26
Figure 6. Organisational flow of Chapter II. 35
Figure 7. Organisational flow of Chapter III. 48
Figure 8. Organisational flow of Chapter IV. 70
Figure 9. Organisational flow of Chapter V. 85
Figure 10. Schema of design and methodology. 109
Figure 11. Flow chart showing organisation of Chapter VI. 112
Figure 12. Decision tree for participant enrolment. 129
Figure 13. Numbers of participants available at follow-up points. 166
Figure 14. CONSORT flow diagram for intervention participants. 167
Figure 15. Intervention minutes spent exercising per week. 183
Figure 16. SUS results for user-friendliness of WBB (number, %). 198
Figure 17. WBB participants' views of the intervention. 199
Figure 18. WBB participants' views on SUS (cont.). 200
Figure 19. Steps towards abstracting data to a theme. 203
Figure 20. Word cloud of participants' constructs of falls. 205
Figure 21. SWOT analysis of cluster design. 236
Figure 22. Root cause analysis of factors associated with good adherence. 251

PLAGIARISM DECLARATION

This thesis/dissertation has been submitted to the Turnitin software and I confirm that my supervisor has seen my report and any concerns revealed by such have been resolved with my supervisor.

Name: Christine Rogers

Student number: SLSCHR001

Peoplesoft number: 1267062

Signature: Signed by candidate

Date: 18 December 2019

ACKNOWLEDGEMENTS AND DEDICATION

- **To the participants**

Thank you for your gracious participation in this project. Whatever your motivation to participate, it has resulted in making this work possible and I will always be grateful for your time and cooperation. I hope to honour you with a contribution to knowledge, which will promote an agenda of care for older adults in this country.

- **To my colleagues and friends**

Thank you all so much for the listening ears, hearing hearts and supportive words and actions. The corridor moans and generalised whining; escapes for coffee, ups and downs were all better shared with such wonderful people. Grateful thanks.

- **To my supervisors**

> You gave me the gift of time, the most thoughtful gift of all.
> *- Dan Zadra*

Thank you to **Dunay Taljaard** for the 'incubation period', love, friendship and holding me in your heart! I gratefully acknowledge Professor Emerita Susan Herdman, for your kind interest and support; and for allowing me to visit you at Emory University.

To Dele and Delva:

Thank you for your support and guidance during my Ph.D. journey. You were most gracious when I came to you with a 'ready-made' idea.

Dele, you have seen me at probably the lowest point in my life and you went far beyond what supervisors can be expected to do. You will never know how much your kindness meant to me.

Delva, your great manner, warmth and encouragement, and willingness to accept me as your student; plus, your very constructive suggestions, were pivotal to my completion.

To you both, your insight, academic prowess and ability to stimulate my thinking and growth were much appreciated. You are the dream team! **Thank you.**

- **To my husband and family**

Gratitude makes sense of our past, brings peace for today, and creates a vision for tomorrow.
- Melody Beattie

Thank you for your love, interest, support and the many practical ways you have shown that you believe I can do this!

Mum, my earliest memory is sitting by your side and realising I was reading myself! Thank you for instilling a love of reading and language in me. **Dad**, I think your work ethic, tenacity and urge to provide for your family has rubbed off on me! You grew from very simple roots and I hope I have honoured you by rising to the challenge of pursuing my own career and education. I hope I've made you proud, dearest Mum and Dad. I love you both so much! You did what every parent should do – your very best for me! Thank you.

To my lovely brother and sister-in-law, thank you for the fun, holidays when needed (England, Christmas 2015, Romania 2019 in particular!) and laughs. You make me remember my inner child! **David**, thank you for the hours of proof-reading and great input! **Anna**, you are the sister I didn't know I wanted! Thank you for being part of our family! The Fab Four continues their professional and personal adventures!

To darling **Peter**, you always knew what I needed and when I needed it (including keeping the coffee supply regular!). Thank you for all your help with the “P and P” of this work! We got through the M, a massive mid-career change and this degree as we do everything else – talking and loving together, as one, for always. Your love, kindness and generosity of spirit is an example to us all. Thank you.

FUNDING DECLARATION

This work is based on research supported in part by the National Research Foundation of South Africa (Grant Number: 110802) and the Harry Crossley Fellowship, 2017, University of Cape Town.

The researcher thanks the reviewers of the applications and funders, respectively.

DECLARATION/CONFLICT OF INTEREST

No conflict of interest. All research expenses including student fees, tests, equipment, research assistant salaries, database construction and analysis were paid for by the researcher. Interventions and all tests were used with respect to their developers' intellectual property and copyright issues. Permissions and proof of purchase respectively, are attached in the Appendices. The researcher has no relationship, beyond collegial, with any paid research staff. She does not hold shares with Nintendo® nor any related company.

The researcher has previously acted as a consultant to a medical communications company and prepared continuing professional development materials for their client, a naturopathic company. She has previously worked for an equipment manufacturer and produced newsletters on management of dizzy patients on their behalf. She has not been involved in marketing any equipment for that company. The researcher has and continues to work as a consultant/ expert witness for several insurance companies and the Insurance Ombudsman of South Africa. Appearances at congresses as an invited speaker have been paid for by congress secretariats or funded from the researcher's personal research funds. None of these roles present a conflict of interest.

DEDICATION[1]

FIRST, THIS WORK IS DEDICATED TO MY BELOVED HUSBAND AND FAMILY.

SECOND, IT IS DEDICATED, WITH THE DEEPEST RESPECT, TO THE MEMORY OF PROF BONGANI MAYOSI, DEAN OF THE FACULTY OF HEALTH SCIENCES, UNIVERSITY OF CAPE TOWN, WHOSE UNTIMELY PASSING DURING THE FINAL WRITE UP OF THIS WORK ROCKED THE UNIVERSITY COMMUNITY AND COUNTRY AS A WHOLE.

CLINICIAN, RESEARCHER, ACADEMIC GIANT, HUMAN BEING.

HAMBA KAHLE, SIR

[1] *Hamba kahle* is an isiXhosa term meaning goodbye, go well, or farewell, particularly in the case of death. Reference: Retrieved 25.4.2019 from https://www.collinsdictionary.com/dictionary/english/hamba-kahle

LIST OF ABBREVIATIONS

General abbreviations

Abbreviation	Definition
ADL	Activities of Daily Living
AE	Adverse events
ASEAN	Association of South East Asian nations, comprising member states of Brunei, Cambodia, East Timor, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam (1)
AUC	Area under curve
BPPV	Benign Paroxysmal Positional Vertigo
CACE	Complier average causal effect
CDC	Centers for Disease Control and Prevention
CI	Confidence interval
cm	Centimetres
cm/s	Centimetres per second (velocity)
CNS	Central nervous system
CPOA	Cape Peninsula Organisation for the Aged
DALY	Disability Adjusted Life year
EO	Eyes open (during balance tests)
EC	Eyes closed (during balance tests)
GBD	Global Burden of Disease

Abbreviation	Definition
GP/s	General practitioner/s. In South Africa, this term is used for graduates entering the medical profession, while the term physician implies a post-graduate specialisation in internal medicine. Typically, GPs are the entry point into the healthcare system and are engaged in family practice
HIV/AIDS	Human Immune Deficiency Virus/Acquired Immune Deficiency Syndrome
HREC	Human Research Ethics Committee
ICC	Intra-class/cluster (where relevant) coefficient. ICC is a relative measure of reliability (2)
ICF	International Classification of Functioning, Disability and Health
ITT	Intention-to-treat (analysis)
LMIC	Low- and middle-income countries
m	Metre
m/s	Metres per second (velocity)
MA	Meta-analysis
MCID	Minimum clinically important difference
MD	Mean difference
MDC	Minimum detectable change. MDC is the amount of change in a given measure which represents a true change between two testing opportunities (3)
MeSH	Medical Subject Headings
MMSE	Mini-Mental State Examination
MRC	Medical Research Council (United Kingdom)

Abbreviation	Definition
NCD	Non-communicable diseases
NHANES	National Health and Nutrition Examination Survey (United States of America)
NICE	National Institute for Clinical Excellence (United Kingdom)
NNS	Number needed to screen (to randomise one individual to an intervention)
OEP	Otago Exercise Programme
OR	Odds ratio
P	Participant
PA	Physical activity
PICOS	Participants, interventions, comparisons, outcomes, study design
PRoFaNE	Prevention of Falls Network Europe
PP	Per protocol (analysis)
QoL	Quality of life
RCT	Randomised control trial
ROI	Return on investment
RPE	Ratings of perceived exertion (for exercise). This study used the Borg RPE
s	Second/s
SAS	Self-assessment scales
SD	Standard deviation
SEM	Standard error of measurement. SEM is an absolute index of reliability (2)
SMD	Standardised mean difference/s

Abbreviation	Definition
SR	Systematic review
SUS	Systems Usability Scale
UCT	University of Cape Town
USA	United States of America
US$	United States of America dollars
VOR	Vestibulo-ocular reflex
VRT	Vestibular rehabilitation therapy
WBB	Wii Fit Balance Board
WHO	World Health Organisation

Abbreviations of outcome measures

Abbreviation	Definition
ABC	Activities-specific Balance Confidence Scale
BBS	Berg Balance Scale
DGI	Dynamic Gait Index
FICSIT-4	Frailty and Injuries: Cooperative Studies of Intervention Techniques
EQ-5D-3L	EuroQoL Five Domain/dimension Three Level Quality of Life scale
EQ-5D VAS	EuroQoL Five Domain/dimension Visual Analogue Scale
FTSST	Five Times Sit to Stand Test
GDS	Geriatric Depression Scale
M-CTSIB	Modified Clinical Test of Sensory Integration of Balance
Mini-BESTest©	Mini Balance Evaluation Systems Test
PASE©	Physical Activity Scale for the Elderly
SEE	Self-efficacy for Exercise Scale
SF-36 and SF-12	Short Form evaluations measuring self-reported health
SLS	Single Leg Stance test
TUG	Timed-Up-and-Go test. Two measures were used to assess participants in this report, TUG-simple and Tug-Cognitive

Symbols

Symbol	Definition
/	Per
>	More than
<	Less than
≥	Greater than or equal to
≤	Less than or equal to
≈	Almost equal to
≠	Not equal to
=	Equal to

Abbreviations of trial guidelines

Abbreviation	Definition
CONSORT	Consolidated Standards of Reporting Trials [4]
COREQ	Consolidated Criteria for Reporting of Qualitative Research [5]
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials [6]

GLOSSARY OF TERMS

Activities of Daily Living (ADL): routine everyday activities, which require functional mobility and facilitate personal care, such as washing, toileting, dressing and meal preparation [7].

Adaptation: exercises used in vestibular rehabilitation therapy to promote recovery of vestibulo-ocular gain. Lost function is not restored, but replaced by new operating systems in the brain, induced by active learning processes [8].

Adverse events: defined by the Good Clinical Practice guidelines as any unfavourable and unintended sign, symptom or disease, which was absent at baseline (i.e. trial induction); or becomes worse than at baseline and is temporally associated with a treatment or procedure, regardless of attribution [9]. The relationship of the event to the treatment or procedure does not require proof [10]. Adverse events are not necessarily linked to participation in a clinical trial [10].

Audiometry (pure tone): the evaluation and measurement (via testing) of hearing acuity across variations in sound intensity and pitch [11].

Balance: the ability to maintain the body's centre of mass over a small base of support provided by the feet. Also termed postural control. The vestibular apparatus senses gravity and head acceleration and is an important sensory system which contributes, along with vision and proprioception, to controlling posture [12]. A balance disorder is common in older adults, affecting approximately one third of all older adults; and may or may not be vestibular in origin [13].

Benign Paroxysmal Positional Vertigo (BPPV): BPPV is the most frequently diagnosed vestibular disorder [14]. Vertigo is induced by moving the head into different gravity-dependent positions [14]. Provocative tests identify the semi-circular canal affected and treatments involving repositioning. Repositioning treatments are evidence-based and effective at one week when compared with sham manoeuvres [15]. BPPV has a good spontaneous recovery rate of 50% within three months of onset [16].

Cawthorne-Cooksey exercises: Cawthorne-Cooksey exercises were introduced in 1946 for patients with head injury, and consist of generic, graded activities to stimulate the vestibular system [17]. Cawthorne-Cooksey exercises are essentially habituation exercises, VRT in contrast, has refined and customised rehabilitation strategies based on physiological and behavioural rationales [18].

Community-dwelling older adults: there is confusion regarding the definition of community-dwelling [12]. In the context of this report, community-dwelling older adults are independent and capable of self-care [19]. They do not meet the pre-requisites for frailty, that is: vulnerable to increased risk for adverse outcomes, at risk of admission to a residential facility such as a nursing home, experiencing difficulties in the activities of daily living, and death [20, 21]. Participants in this report were living completely independently, with no assistance from carers or adult children, in retirement villages. Most had a cleaner one morning per week, who undertook heavy domestic chores such as washing floors and bathrooms. Otherwise, participants managed self-care and running their homes independently.

Cultural competence/sensitivity: cultural competence demands the effective provision of healthcare with due consideration of the social, cultural and linguistic requirements of the recipient [22]. Cultural awareness includes openness to methods of healing other than Western medicine [22].

DALY: disability adjusted life year. The potential number of years lost due to premature death [23]. DALYs are the sum of two measures: years of life lost and years lived with disability [24]. DALYs represent a health gap between the state of the population's health compared to a normative goal [22]. The concept has been extended to include the equivalent number of years of "healthy" life lost due to states of poor health or disability [22]. DALYs express the burden of disease and aggregate total health loss at a population level [25, 26].

Dizziness: a subjective perception of disorientation present either during movement or at rest [27].

Dual-tasking: maintaining postural control/ walking speed as the primary task while doing a secondary task, which may be cognitive or manual. Convincing evidence suggests that ageing increases the cognitive demands necessary for posture, balance and gait [28].

Dynamic visual acuity test: a test which quantifies gaze stability between static (ability to read optotypes on visual acuity chart with head stationary) and dynamic (head moving) conditions. The test is a functional measure of the vestibulo-ocular reflex [29].

Error signals (in the context of vestibular rehabilitation therapy): vestibular hypofunction results in alterations in vestibulo-ocular reflex (VOR) gain. When the VOR is unable to maintain gaze stability due to deficits, head movements frequently result in visual blurring frequently. Thus, images slip off the fovea of the retina, a phenomenon known as retinal slip. Such slip creates an error signal perceived by the brain. Error signals prompt the modification of neural processes in the angular VOR pathway. Exercises such as X1 and X2 are prescribed in vestibular rehabilitation therapy, which foster alternative gaze stability strategies [30].

Exergaming: also referred to as serious games, exergames are games played for exercise or rehabilitation purposes, with an interactive programme such as the Wii Fit^{RT} Balance Board or an X-Box Kinnect™ system. The Wii Fit Balance Board was used as the experimental intervention in this report.

Fall/s: definitions in the literature vary [31]. A fall may be defined as unintentionally and involuntarily moving towards the ground or other lower level [32]; which is not the result of a major medical intrinsic event or hazard, such as being struck by a vehicle [33]. The definition is explored further in the Introduction.

Fall risk factors: may be intrinsic, which are related to the health and socio-demographic status of the person at risk for falls [34, 35]; or extrinsic, related to environmental hazards such as uneven pavements [36].

Fatalism: a collection of beliefs concerning predestination, pessimism and the attribution of life events, including health issues, to luck or fate [37]. Health fatalism may result from religious convictions, where illness and recovery are solely at the decree of God [38] or a supreme being.

Frailty: frailty is an increased vulnerability to poor health outcomes, including mortality and morbidity, due to a decline in physiological reserves [39, 40]. While frequently considered to represent a downward spiral of declining function, frailty is in fact dynamic and may improve [39].

Global North: grouping of countries based on political and socio-economic categorisations [41]. The Global North comprises North America, Western Europe, and developed parts of East Asia [34]. Countries or regions where English is an official language or with Anglo-Saxon ties are considered parts of the global North (e.g. parts of Oceania) [34]. The global South comprises Africa, Latin America, developing regions of Asia and the Middle East [34].

Habituation: repeated exercises, which provoke symptoms in patients with an aim to acclimatise them to those symptoms and ultimately eliminate them [42]. Habituation aims to programme the vestibular system to not respond, as opposed to adaptation, where the aim is to induce the vestibular system to respond differently [35].

Hawthorne effect: alterations in behaviour resulting from observation of such behaviour [43].

International dollars ($): one International dollar would buy, in a specified country, a comparable amount of goods or services that a US$ could purchase in the USA [44].

Imbalance: dysequilibrium and postural instability that is present standing and walking [27].

Labyrinth: collective term for a structure located in the inner ear comprised of three parts: the cochlea, whose function is hearing; the semi-circular canals, and the connecting vestibule, which is located between the cochlea and semi-circular canals and contains the utricle and saccule [45]. The latter structures are concerned with vestibular function and balance [38].

Low- and middle-income countries (LMIC): South Africa is regarded economically as an upper-middle income country [46]. However, the population health profile is more consistent with a low-income nation [39].

Morbidity: disability resulting from chronic illness or disease, associated with reduction in quality of life [47]. Linked with eventual mortality [40].

Mortality: death of large numbers [48].

Older adults: cognisant of the American Psychological Association's recommendations [49], the terms *elderly* and *senior* have been avoided and instead the term older adult/s has been used throughout. While generally accepted to indicate adults over 60-65 years of age, it is acknowledged that in LMIC, particularly for women from poor socio-economic circumstances, old age and its attendant issues may commence when the reproductive years end [50]. In the present thesis, older adults were defined as those ≥ 60 years of age, as per the South African Human Rights Commission[2].

Orthostatic hypotension (also referred to as postural hypotension): a prevalent condition in older adults, sometimes associated with autonomic nervous system dysfunction and more recently with falls [51]. A drop of ≥20mmHg on systolic and/or ≥10mmHg on diastolic within three minutes of having moved from supine to standing allows a diagnosis to be made [52].

Otago Exercise Programme: an evidence-based [53] fall prevention programme, which works on improving balance and strength. Used as the gold standard in the present thesis. (See Appendix A).

[2] Reference: https://www.sahrc.org.za/index.php/focus-areas/disability-older-persons/older-persons Retrieved 7 October 2019.

Physiotherapist: UK/South African terms for the professional referred to in the USA as a physical therapist. These professionals apply physical agents (heat, water, light) in treatment [54]. They perform tests examining nerve, muscle and skin conditions and reactions [45]. Physiotherapists prescribe exercise and massage among other treatment modalities [45]. Physiotherapists specialise in movement sciences, and are leaders in rehabilitating balance and gait disorders [55].

Polypharmacy: polypharmacy is the simultaneous use of multiple drugs by an individual and is thought to be present in ≈40-50% of all older adults in high-income countries [56]. There is little consensus as to the quantity of drugs to constitute polypharmacy [57] and thresholds of ≥3 - ≥6 have been cited [58]. A conservative value of ≥4 drugs was used as a definition of polypharmacy in the present thesis. Polypharmacy has been linked to falls [57] and increased frailty in numerous studies [58].

Presbyacusis: increasing hearing loss experienced with ageing [59]. Presbyacusis is the result of a summed deterioration of hearing linked with environmental, sensory, metabolic and neural causes that all contribute to age-related hearing loss [49].

Responsiveness: sensitivity to change, or the ability of a test to detect change over time when a participant/patient has truly experienced an improvement or deterioration in function [3].

Romberg (test): commonly used balance test which has been shown to be helpful in predicating risk of falls in a LMIC [60]. Standardisation of the clinical test is somewhat lacking [50]. For this study, the test was conducted with the feet positioned tightly together, with the Jendrassik manoeuvre (arms flexed, and fingers hooked together, using tension to try to pull them apart) and eyes open then closed for 30 seconds. This is referred to as a standard Romberg test. Failure to hold the pose for 30 seconds with eyes closed is commonly attributed to neurological disease [50]. A sharpened (sometimes referred to as tandem) Romberg test is conducted with the individual's feet in a heel-to-toe position and is similarly held for 30 seconds in eyes open and then closed conditions [61]. In the eyes open condition, sharpened Romberg is a valid and reliable test [62] and could be useful to predict fall risk [62]. Sharpened Romberg with eyes closed is much more demanding and subject to greater variability in high functioning older adults [60]. It is likely that the latter condition measures a different construct than that involved in the eyes open condition [50].

Sedentary behaviour/time: time spent in a seated or reclining position with low energy expenditure (for example, reading, working seated at a computer or watching television). Sedentary time is an important predictor of healthy ageing as well as being a modifiable determinant of health [63].

Sensory substitution/re-weighting: after a vestibular or balance deficit, the comparative 'weight' of each of the incoming sensory cues (vestibular, visual, somatosensory) is re-evaluated and changed [64]. During vestibular rehabilitation therapy (VRT), patients are trained to use visual and somatosensory inputs to improve postural control and stability during motion [42, 64]. Sensory substitution is not a predictable process [65]; however, when combined with adaptation, results of VRT may be better than habituation alone [42].

Serious games: computer games whose main purpose is not entertainment and such games have applications in health, corporate and military training and education [66].

Social desirability bias: research participants may give socially desirable responses to surveys in preference to responses which accurately reflect their true feelings. Drivers for social desirability bias may include ego and self-deceptive behaviours, and may lead to high no-response rates [67].

Syncope and pre-syncope: syncope is a temporary real or apparent loss of awareness or consciousness due to cerebral hypoperfusion. It is characterised by rapid onset, short duration and spontaneous, complete recovery. Causes include vaso-vagal, orthostatic and cardiac issues. Pre-syncope refers to the symptoms and signs before the loss of consciousness [68].

Ubuntu: an Nguni word that can be represented by the phrase "I am because we are" and encompasses an African moral philosophy of embracing compassion, humanity and social responsiveness [69]. The interests of community are placed ahead of individual aspirations [70].

Vestibular system: sensory and motor system which accomplishes the following:

- Perception of body position and self-motion.
- Orientation of the trunk to vertical.
- Control of the body's centre of mass, for both static and dynamic positions and movements by working with the body's postural responses.
- By using the vestibulo-ocular reflex pathways, stabilisation of the head/visual fields during movement [71].

Vestibulo-ocular reflex (VOR): a three-neuron arc from the receptors and primary neurons in the vestibular inner ear, to the extra-ocular muscles of the eyes [72]. The primary purpose of the VOR is to uphold retinal stability when the head is moving, and to prevent visual blurring (retinal slip) [59].

VOR gain: the ability of the VOR to stabilise an image on the fovea of the eye and to match head movement with an opposite (but equal in term of amplitude and velocity) eye movement [73]. In perfect health, VOR gain = 1 [60].

Vestibular rehabilitation therapy (VRT): compensatory, physical activity-based training to assist in the recovery from vestibular and balance lesions [64]. Key principles underpinning VRT include adaptation, habituation and sensory reweighting/substitution [42].

Vertigo: a sensation of self-motion when no self-motion is occurring. The term is derived from the Latin meaning turning, spinning or rotating [74]. The symptom of vertigo is mostly caused by peripheral vestibular disorders [75].

Wii Fit and Wii Fit Balance Board (WBB): the exergaming equipment and intervention programme used in this research. It is described in the Literature Review.

X1 and x2 exercises: adaptation exercises prescribed in vestibular rehabilitation therapy programmes. These exercises require the achievement and maintenance of gaze stability when the head is moving. Exercises produce retinal slip and error signals, which are resolved by neural plastic processes in the brain [76].

Statistical terms

Ceiling effect/floor effect: ceiling and floor effects exist when a considerable proportion of subjects (e.g. 15%) score either best/maximum (ceiling) or worst/minimum (floor) scores. Floor and ceiling effects renders a test unable to discriminate between subjects at either extreme of the scale [77, 78].

Number of patients needed to be screened (NNS): the number of patients who needed to be screened in order to randomise one patient, calculated as $\frac{1}{recruitment\ fraction}$ [79].

Odds ratio (OR): an odds ratio may be defined as the "ratio of probability that an event of interest (in this case, a fall) occurs to the probability that it will not" [80p.1468]. An odds ratio of 1 signifies no relationship between event occurrence and the risk factor [67].

Sensitivity: the ability of a test to correctly identify patients with a disorder, diagnosis or event occurrence (for example, a fall). The test's true positive rate [8].

Specificity: the ability of a test to correctly identify patients without a disorder, diagnosis or event occurrence. The test's true negative rate [8].

A note regarding spelling of terms

This report is written using South African English, which is modelled on United Kingdom English. For example, the spelling *ageing* is used in preference to the USA spelling aging. Where institutions based in the USA are cited, the USA spelling is used, e.g. Centers for Disease Control, USA National Council on Aging.

ABSTRACT

Introduction: Fall risk, occurrence and injury is increasing as the world ages, and Africa and other emerging regions will not be spared. Similarly, the rise of non-communicable diseases, compressed morbidity and lack of physical activity present major challenges. This novel feasibility study explored the use of an exergaming technology compared with a conventional, evidence-based exercise programme (Otago Exercise Programme) to reduce fall risk by improving balance, and to inform a future large-scale randomised control trial.

Methodology: Mixed methods study in independent older adults with established fall risk. The quantitative component employed feasibility Randomised Control Trial methodology. Cluster-randomisation assigned interventions to sites. Single blinding was used. Both interventions were offered for six months. A variety of balance-related endpoints (e.g., Timed Up and Go, Dynamic Gait Index, Mini-BESTest) were used to find the most applicable. Patient-centred variables included questionnaires regarding depression, physical activity levels, quality of life and estimates of self-efficacy for exercise. Qualitative focus groups explored participants' experiences of falls and the exergaming intervention using a phenomenology lens.

Results: Site and participant recruitment was simple and readily achievable, with low numbers needed to screen required. Eligibility criteria were confirmed and more added. Adherence and attrition were major challenges. Cluster randomisation appeared to exacerbate between-group differences at baseline. The exergaming intervention produced preliminary evidence in its favour, with a marked reduction in falls and results approaching Minimal Clinically Important Difference. The experience of the exergaming intervention was regarded as positive by focus group participants. Barriers and facilitators are reported.

Discussion: Methodological issues in the literature have prevented firm consensus on the use of exergaming in falls prevention, although studies are abundant. The current study used rigorous methodology in the novel context of a developing region, which offers numerous challenges for older adults. Implications for a large-scale, fully funded RCT are discussed. Lessons learned can be used to scale up service delivery for an under-served population; and promote the aim of well-being for all at all ages.

INTRODUCTION

Outline of the Introduction

This chapter introduces the study's aims, objectives, research design, and outlines the main sections of the present thesis. The Introduction is divided into four sections, addressing different aspects of the research. First, there is a brief discussion of ageing and the global burden of falls. Morbidity and mortality aspects are highlighted. A focus on the economic impact of physical inactivity and sedentary behaviour follows. The need for exercise-based interventions to reduce the risk of falls prompts a brief consideration of the role of rehabilitation and, finally, the audiologist as a stakeholder in fall prevention.

Figure 1 shows an organisational chart of the Introduction.

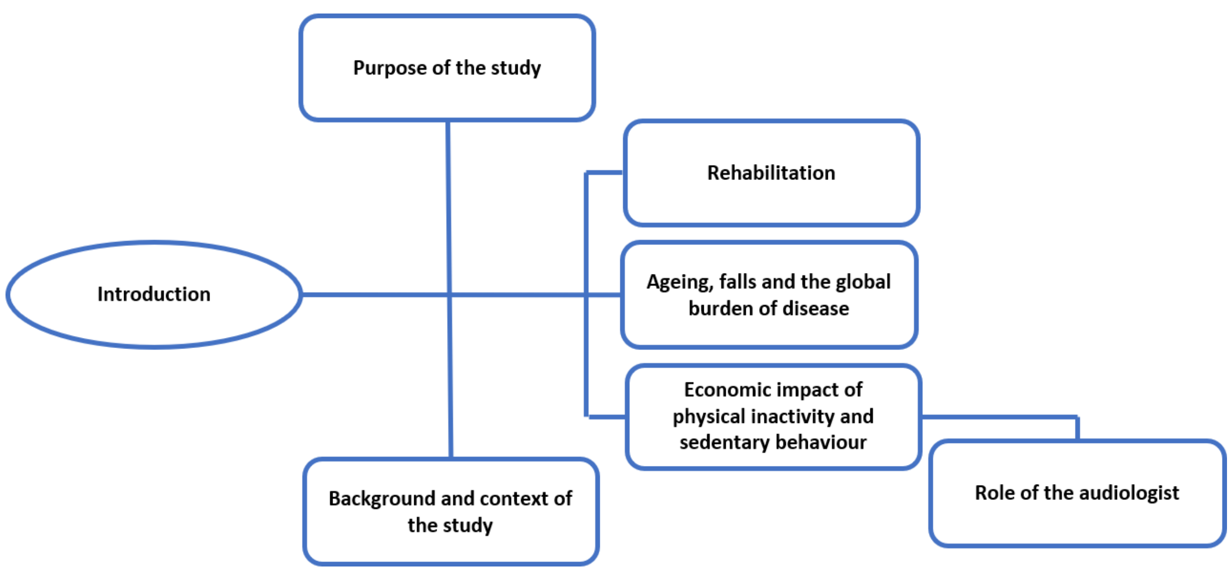


Figure 1. Flow chart of organisation of Introduction.

> Population ageing…is arguably one of the most significant social transformations of the 21st century; with direct and obvious implications to healthcare and health policy…
>
> …Ageing, of course, is inevitable and older people are more likely to have multiple, coexistent, and interrelated health problems. This fact, together with geriatric syndromes, frailty and impaired cognition, continence, gait, and balance, suggests the need for a more thorough "retooling" of the healthcare system and workforce to meet the health challenge of ageing.

(81p. 309)

Purpose of the study

Calls to maximise the potential of technology for rehabilitation, including exergaming[3] in low-and-middle-income countries (LMIC) have been made [(82)]. However, the focus of emerging nations, including China [(83)], Latin America,[(84)] and, South Africa [(85, 86)] has been on the young, or populations with movement disorders such as Parkinson's disease [(71)]. This report is the first to compare a proven exercise-based intervention, the Otago Exercise Programme (OEP), to reduce fall risk in older adults by improving balance, with a novel intervention using interactive videogaming technology, specifically the Wii Fit Balance Board® (WBB), in a LMIC context (see Appendix A Exercise intervention programmes (OEP and WBB) for OEP and WBB description).

Quantitative feasibility methodology employed a cluster randomised control trial (RCT) design to inform a potential, large, fully funded RCT. Feasibility endpoints included recruitment of sites and participants, refinement of eligibility criteria, retention, and adherence. Sample size and costs for a future RCT were calculated. Preliminary evidence was explored regarding changes in participants' falls status and balance. Evaluation of participants' experiences, particularly of complex

[3] See Glossary of Terms.

interventions, assists with interpreting trial outcomes [87]. Thus, mixed methodology was implemented. Qualitative methodology used a phenomenological lens and focus group design with content analysis [88]. Blending the two research approaches enhanced the understanding of participants' engagement with the interventions, and explored pertinent barriers and facilitators to both exercise programmes.

Lessons learned could potentially inform the design of a possible future RCT of exercise-based fall prevention in different communities of older adults in emerging regions, where population ageing is a cause for concern.

Unique aspects of the study.

There are several unique aspects presented in this report. First, there is a dearth of falls research from LMIC. While there is scanty knowledge of fall prevalence[4], few trials concerning fall prevention have been conducted. Recently, Malaysian researchers have conducted RCTs evaluating the OEP [89-92]. However, their multi-factorial, individualised interventions in specialised populations and research settings [76-80] prompt concerns regarding generalisability and suitability for large-scale application. Moreover, South Africa's healthcare delivery and infrastructure closer resembles a low- [46] rather than an upper-middle-income country such as Malaysia [93]. Thus, gaps in the literature exist, with applications of readily implemented fall prevention programmes suitable for implementation at a population level not having been evaluated in LMIC.

Second, the report's mixed methodology is among the first of a new generation of research designs into fall prevention. Increasingly, the focus in healthcare research considers end-users' views and preferences [94]. This study solicited such opinions. Third, it offered an analysis of exergaming through a

[4] See Chapter I. Fall Risk Factors in Older Adulthood.

vestibular rehabilitation perspective, not previously described in the literature (see Chapter V. Exergames and Evidence for the Wii Balance Board and Fall Prevention). Fourth, it used the OEP as gold standard, compared with the WBB. Rigorous comparison of these two interventions is lacking. Indeed, much of the critique of exergaming literature describes methodological issues; likely exacerbated by a lack of feasibility studies to prepare for appropriate RCTs. Hence, a body of exergaming literature seeks to answer efficacy questions prematurely, leading to a lack of clear evidence. The present thesis considers all these concerns and attempts to respond to them.

Finally, this research recognises repeated calls for audiologists to position themselves[5] as members of a multi-disciplinary team to address the global crisis of falls. Fall-related research and intervention has been largely ignored by the profession. RCTs are extremely rare in audiology and mostly focus on tinnitus management[6]. It is hoped that this work will encourage audiologists to embrace RCT methodologies and evidence-based practice [95].

Outline of the present thesis.

The Introduction explores aspects of the global pandemic of falls in older adults. The role of rehabilitation and the audiologist is discussed. Chapters I–V comprise a Chapter I. Fall Risk Factors in Older Adulthood, which interrogates fall risk, prevalence, and prevention. Where available, reports from LMIC are included, with a focus on Africa. Later chapters discuss exercise-based interventions to prevent falls. Evidence for the OEP is discussed first, prior to interrogating exergaming and specifically the WBB.

[5] Discussed later in this Chapter.
[6] Search using MeSH terms randomised control trial + audiology on Trip database (https://www.tripdatabase.com/search?criteria=randomised+control+trials+%2B+audiology) conducted 27.4.2019 yielded 12 RCTs, mostly focused on tinnitus treatment.

Chapter VI. Methodology, commences with frameworks for the designs chosen. Quantitative and then qualitative design, material and procedures are described. Ethical considerations are discussed and expanded upon in the Appendices. Chapter VII presents the Chapter VII. Results with quantitative results, followed by qualitative analysis of data from the focus groups. Chapter VIII concludes the thesis with a Chapter VIII. Discussion, which explores the results further and contrasts them with established literature. Implications and recommendations for future research follow.

Background and context for the study.

Globally, falls are a serious economic and public health concern (96). Falls present a significant morbidity and mortality threat across the lifespan, from early infancy (97) to young, middle (98, 99) and late adulthood (100). The following section introduces falls and ageing, and references falls to the global burden of disease and public health contexts.

Construct of falls.

The construct of a fall is complex, with fall definitions varying in the literature (31, 101). Definition differences obfuscate the generalisability of clinical trials, treatment strategies and outcome evaluation, including meta-analyses (102, 103). Thus, researchers have been urged to use a standardised definition of falls, such as the one promulgated by the Prevention of Falls Network Europe (PRoFaNE[7]) (104). PRoFaNE's classification has been successfully adopted, with compliance in up to 75% of RCTs (105).

[7] PRoFaNE was a European collaboration of researchers focusing on falls and the effectiveness of prevention interventions.

A fall describes an individual unintentionally and involuntarily moving towards the ground or other lower level [106], which is not the result of a major intrinsic event or hazard [32]. Intrinsic events are idiosyncratic health-related issues, such as visual acuity or balance deficits [107] and may include age, sex, and ethnicity [108]. Loss of consciousness due to syncope or stroke are examples of major intrinsic events excluded from this definition of a fall [12, 31]. The definition excludes major extrinsic events like pedestrian traffic accidents [33].

PRoFaNE suggested that a fall definition should be simple [32]. Moreover, lay perspectives should be sought when asking research participants about falls [29]. Questioning fall occurrences should include slips, trips, and losing balance [29]. Both these recommendations were adopted for this study, as they concur with recommendations from the American and British Geriatrics Societies, World Health Organisation (WHO), and the UK National Institute for Clinical Excellence (NICE) [31].

Falls and the Global Burden of Disease (GBD).

Falls are an important clinical issue for older adults, associated with increased morbidity and mortality, as well as having major implications for public health [107, 109, 110]. Although controversial, GBD studies often guide policy, prioritise spending and direct management strategies in public health [111]. GBD reports cluster major causes of morbidity and mortality into three large categories: communicable diseases (including maternal, perinatal health and nutritional disorders), non-communicable diseases (NCD), and injuries [97]. Falls are an important contributor to unintentional injuries [85].

GBD reports signal a reduced occurrence for almost all injuries, suggesting the world has become a safer place [25]. The exception to this decline is falls. The GBD ranking of falls increased from 24th to 15th place in importance between 1990 and 2010 [24]. Furthermore, the WHO cites falls as the second leading cause of accidental or unintentional injury deaths worldwide, exceeded only by transportation and road traffic incidents [23]. In the United States of America (USA), falls are the leading cause of injury across almost all ages [112]. An American older adult falls every second, requires emergency services for fall-related injury every 18 seconds, and there is a fall-linked death every 20 minutes [113]. Data extracted from the USA National Vital Statistics database support European findings by demonstrating a marked increase in deaths due to falls in individuals ≥75 years of age [114]. The crude mortality rate increased from 51.6 per 100 000 in 2000 to 122.2 per 100 000 in 2016 [102]. LMIC are not spared the phenomenon of injurious falls. Data from 17 countries across four different income rankings suggest that falls are associated with rural settings, increasing age[8], female sex, and current or previous alcohol use [115]. In South Africa, alcohol represents a significant health and social ill, with one of every three adults consuming alcohol and one in seven binge-drinking [116], making it a good location for the current and future studies on falls.

Differences between the 1990 baseline and 2015/2017 GBD reports indicate improvements in overall health worldwide [117, 118]. The net result is longer life expectancy [117]. South Africa follows international trends as the number of deaths decrease, combined with a concurrent increase in older adults' (≥60 years of age) absolute numbers and proportion of the overall population [119-121]. The Western Cape of South Africa, the setting for this research, now has the highest life expectancy in the country [120]. While mortality figures vary between countries, life expectancy predictions ignore the challenges of functional ageing, such as morbidity

[8] Note the referenced study only considered ages between 30 and 70 years.

[118, 122, 123]. Variations in the onset of markers of morbidity are explored in the next section.

Recent (2017) GBD reports highlight differences in the onset of age-related disease globally [124]. For example, the health status of a 76-year-old in Japan is better than the global average for age-related disease at 65 years of age; while an individual from Papua New Guinea achieves the same global level for age-related disease at just 46 years of age [111]. Such data suggest that ageing in LMIC without adequate wealth and health, should raise concerns as nations "grow old before they grow rich [122p.310]." Thus, Global North and South disparities should be identified and rectified to ensure greater health equity [118].

A disability adjusted life year (DALY) represents a year of healthy life lost due to disability and expresses the burden of disease at a population level [25]. Of primary concern is that falls were responsible for a 50% increase in DALYs in the USA, according to the GBD 2010 report [24]. Thus, falls are associated with marked morbidity. Similar to deaths, falls are the second leading cause for a loss of DALYs after road accidents, with the incidence showing a clear upward trend [125]. Living longer can be conceived as the postponement of mortality [117]. However, increasing longevity may imply more years in which loss of functional capacity is experienced, that is, living with more morbidity [105]. The effect of having less years in good health is compounded by the earlier onset and rise in NCD [126]. Africa has not been spared such changes, and the years living with a loss of functional health have increased with life expectancy [117]. Thus, the likelihood of populations living longer, but with more disability, is real and requires address. In the context of falls, injury may have profound implications for both the individual and society.

An example of falls causing an increase in DALYs with age is shown to good effect in Figure 2, extrapolated from GBD 2016 data [127].

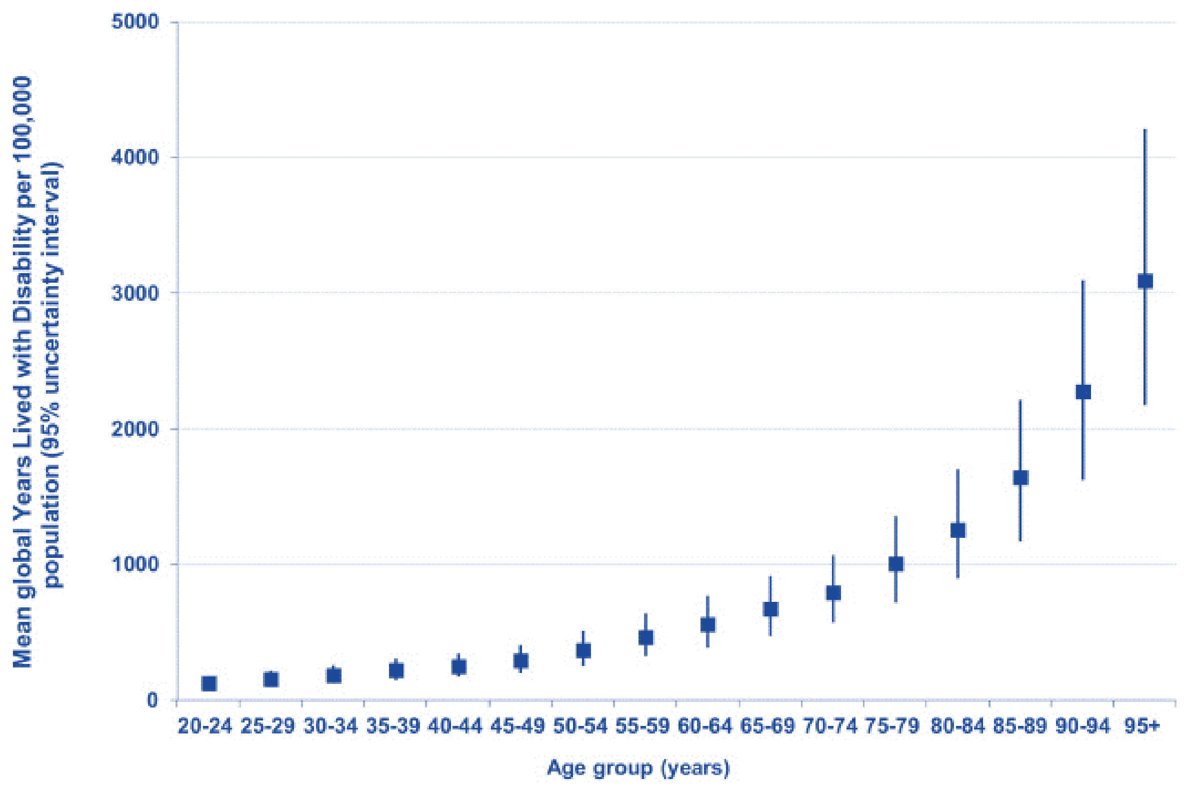


Figure 2. Global burden of falls in 2016 [127].

Reprinted with permission from publisher

Thus, concerns regarding the contribution of fall injury to DALYs are warranted [25]. In terms of global health and public policy, efforts to reduce falls would result in healthcare savings at a population level [127]. Before proceeding to examine rehabilitation and the professionals involved in such efforts, the impact of physical inactivity, a remediable fall risk factor [128] will be discussed briefly in the following section.

Economic impact of physical activity and sedentary behaviour.

Research has suggested that less than half (49%) the population in the USA meet the recommended guidelines for physical activity (PA), and 15% of the population are completely sedentary [129]. Sedentary behaviour is marked in older adults, with 60-70% of older adults' waking hours consumed with sedentary occupations [130]. These behaviours translate into a concurrent loss of physical function in adults over 65 years of age, with two thirds experiencing some limitation in the activities of daily living (ADL) [116]. Populations in Africa are not exempt from sedentary behaviour and physical inactivity, although the extent ranges between countries [131]. Furthermore, quality data regarding PA in Africa is lacking [132]. South African studies have cited rates of physical inactivity as high (≈ 50% of study participants, including older adults, failed to meet exercise targets for health), although contexts such as rural/urban settings caused variations [123, 133-135].

Exercise is key for the management of sedentary behaviour [136]. With physical inactivity being a modifiable health risk, and indeed a contributing factor to falls in older adults, methods to promote change should be explored [123]. Most countries in Africa have policies promoting PA; however, there is little evidence to support their effectiveness and it is likely that cultural perspectives require address [131]. Post-apartheid healthcare policy in South Africa is concerned with redress and equity of services [137]. Promotion of healthy lifestyles, including exercise, gained prominence with the government in 2009 [124]. South Africa has a National Strategic Plan for the Prevention and Control of NCD, which aims to reduce physical inactivity by 10% by 2020 [134]. However, infrastructure and personal safety issues may well inhibit efforts to promote exercise in public spaces [137].

Exercise-based fall prevention strategies were the interventions used in the present thesis. The targeted population was older adults, as this group is at high risk of falls[9]. Research is required in a South African context prior to informing policy regarding fall prevention in older adults, with a view to expansion to younger

[9] See Chapter I. Fall Risk Factors in Older Adulthood

populations. Public health interventions must be effective, feasible and sustainable [138]. The use of technology, specifically with reference to PA, has been suggested [129] and is explored in the present thesis.

Fall prevention exercise programmes have frequently been offered by healthcare practitioners such a physiotherapists and other rehabilitation professionals [139]. Rehabilitation aims to facilitate people living with impairment [140] and will be discussed next.

Role of Rehabilitation.

The foundation of (re)habilitation services is to allow individuals to reach and maintain their full potential, despite possible deteriorating conditions such as ageing[81]. Rehabilitation services should share a continuum of care with curative and health promotion interventions [68]. While GBD studies indicate better control of communicable diseases with cures and prevention, NCD with their attendant morbidity and mortality are on the rise in LMIC [141]. Furthermore, despite the intentions of the 1978 Declaration of Alma Ata [142], rehabilitation is still regarded as a putative 'luxury' health service in many LMIC [140 p.314]. In South Africa, although epidemiological data are lacking, it is estimated that one in three adults live with at least one chronic health challenge, and large numbers experience physical challenges linked to chronic disease [143]. Furthermore, many disorders are not addressed by South African policy-makers, which combined with a lack of spending on rehabilitation, results in well-being compromise [128].

Estimates [144] indicate that the cost of physical inactivity in terms of health care expenses in Africa was 0.6 billion in 2013 International $[10]. Loss of productivity due to death was a similar figure [129]. It bears consideration that effective promotion,

[10] See Glossary of Terms.

prevention and rehabilitation services could have a positive impact on these figures. The role of audiologists' contribution to rehabilitation, prevention and health promotion is expanded upon in the following section.

The audiologist's role in fall prevention.

There are several arguments supporting audiologists' roles in fall prevention, and these include:

- *Hearing loss is linked to falls*. As humans age, sensorineural hearing loss (presbycusis[11]) develops [(59)]. Hearing impairment is strongly correlated with falls. Meta-analysis findings demonstrated that the presence of audiometrically[12] proven hearing loss resulted in an almost seven-fold increased risk of falling [(145)]. Other correlates of hearing impairment in older adults relevant to fall risk include sedentary behaviour, slower gait speed [(146)], social isolation and withdrawal [(147)], and cognitive decline [(148)]. With an ageing population, the number and rate of individuals seeking audiology services will increase [(149)]. Thus, audiologists have extensive access to older adults, and are in a pivotal position to at least screen for falls and fall risk factors. Disappointingly, in practice, at least in the USA, less than one third do [(150, 151)].
- *Audiologists assess vestibular disorders, which can and should extend to concerns regarding balance and falls.* Historically, audiologists had a role in assessing vestibular integrity, likely due to the location of the end-organs in the inner ear and correlations between labyrinthine[13] disorders, which may affect both hearing and balance. Increasing numbers of audiologists are involved in the assessment and management of patients with vestibular

[11] See Glossary of Terms.
[12] See Glossary of Terms.
[13] See Glossary of Terms.

dysfunction [152, 153]. Services include hearing assessments, clinical and laboratory vestibular evaluations, and vestibular rehabilitation therapy [154]. Decades ago, calls were made for audiologists to concern themselves with the 'balance' system rather than purely vestibular function and evaluation [155]. Further, most examinations for the assessment of fall risk are within the scope of audiologists' practice [140]. For example, audiologists performing vestibular assessments for American Medicare beneficiaries have been mandated to conduct fall risk assessment and formulate plans of care [156], firmly positioning the audiologist in the multi-disciplinary team.

In South Africa, vestibular and balance assessment and rehabilitation has been legislated as mandatory audiology degree programme exit level outcomes since 2011 [157]. Previously, practitioners had their post-graduate training portfolios reviewed and accepted by the regulatory/licensing body prior to practice [142]. Notwithstanding this progress in developing audiologists' skills in vestibular management, audiologists in South Africa have been slow to embrace vestibular work into their scope of practice [154]. The present thesis is the first by a South African audiologist to promote interest in balance and falls, rather than a strict vestibular focus.

- *Dizziness and vertigo are common, often associated with vestibular dysfunction, and may be managed by several professionals, including audiologists.* Extending the notion above, dizziness and vertigo are common complaints in older populations [158], many of whom may consult an audiologist. Abundant studies describe the anatomical and physiological impact of ageing of the vestibular system[14]. Thus, knowledge of structural changes is easily accessible to all health care professionals. However, less is known regarding the functional impact of such changes on daily living [(159)], although more holistic and rehabilitation-orientated texts exist[15]. Granting that the relationship between vestibular impairment, ageing and falls has been rather under-researched [(161)], the following explores this relationship.

A case control study [(162)] demonstrated that 80% of older adult participants with clinically significant vestibular impairment fell. Interestingly, most participants did not report the presence of dizziness or vertigo [(147)], which would alert clinicians to the possibility of vestibular deficits [(163)]. Thus, even asymptomatic vestibular lesions likely to have compensated, may still underpin falls. Another study with patients with vestibular impairment and associated dizziness suggested an increased the risk of falling by a factor of 12.3 [(164)]. Similar to Liston and colleagues' [(147)], participants with asymptomatic vestibular dysfunction still had a six-fold increase in fall risk [(148)]. Consider results from a study of 185 patients referred to a clinic for fall management, rather than the investigation of dizziness [(165)]. Almost three quarters (73%) of the participants demonstrated signs of either peripheral or central vestibular dysfunction [(149)]. It should be noted that over the last decade, more extensive testing of the vestibular pathway has become possible, leading to greater diagnostic accuracy [(166)]. Therefore, it is possible that early findings [(149)] correlating vestibular lesions and fall risk are underestimations. Overall, these studies support the view that audiologists

[14] For example, see (E. R. Anson et al., 2016; Bermúdez Rey et al., 2016; Hall & Meldrum, 2016; Li et al., 2015; Smith, 2016; Xie et al., 2017).
[15] For example, see seminal work such as 160. Herdman SJ, Clendaniel R. Vestibular rehabilitation. 4th ed. Philadelphia: FA Davis; 2014.

should be questioning all older adults regarding falls, not just those who complain of dizziness. Indeed, it is argued that failing to evaluate fall risk is a significant omission in the duty of care to audiology patients.

- *Audiologists have a moral and ethical obligation to act as agents for change, particularly in LMIC settings.* Embedded in the key roles of an audiologist are disease prevention and health promotion at all levels of health care [167]. Internationally, calls for audiologists to include fall prevention in their scope of practice have been made by influential leaders of the profession over the last four decades [147, 149, 150, 155, 165, 168-174]. Moreover, audiologists have been urged to play a pivotal role in falls research [147]. However, significant progress is required before falls become part of audiology practice in South Africa. The current research hopes to address some of these barriers.
- *Audiologists are qualified and licenced rehabilitation professionals*. The profession experiences a challenge in that audiologists do not necessarily embrace rehabilitation [175] as do other professionals such as physio- and occupational- therapists [176]. Current practice has a diagnostic focus, rather than deeply engaging with patients and building strong therapeutic alliances [175].

  There is convincing evidence that vestibular rehabilitation is effective in managing symptoms of vestibular deficits [177] and this would include reducing fall events and risks [158]. Gaze stability exercises are one of the key tenets of vestibular rehabilitation [42]. Such exercises have been found to reduce dizziness and fall risk [178] even in patients in whom no vestibular pathology has been demonstrated, although later work questioned this [179]. Evidence that exercise-based fall interventions are effective will be discussed in detail.

Thus, programmes based on vestibular rehabilitation and applied in a fall prevention context could be argued to be relevant to audiologists and their patients.

This section has examined the audiologist's possible role in fall prevention. Fall risk factors pertinent to audiology patients have been outlined. The strength of evidence, the desire to practice using an evidence base and the need for audiologists to embrace their role as agents of change and rehabilitation professionals, behoves audiologists to expand their practice by engaging with fall prevention.

CHAPTER I. FALL RISK FACTORS IN OLDER ADULTHOOD

Introduction

This chapter discusses older adults' risk factors for falls. The focus is on *intrinsic fall risks*, which are unique to an individual, such as their health and medical profile. The contribution of vestibular and balance disorders to fall risk is emphasised. The African and South African milieu is described.

Figure 3 shows a flow chart of Chapter I.

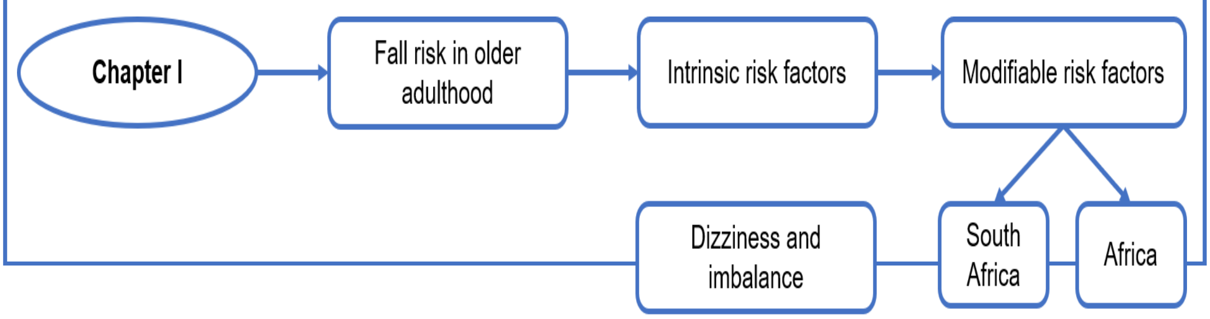


Figure 3. Organisational flow of Chapter I.

Ageing and falls

It takes a child one year to acquire independent movement and ten years to acquire independent mobility. An old person can lose both in a day.

(180p.64)

Ageing presents as an accumulation of intrinsic fall risk factors, including detrimental changes in the systems that sub-serve balance and postural control [(181)]. Sensory mismatches from age-related physiological decline interact with reduced ability to negotiate environmental hazards, increasing fall risk [(182)]. Older adults at risk of falling generally do not have one predominant problem. Rather, several smaller deficits across multiple systems combine and will likely result in a fall [183]. The factors contributing to fall risk are expanded upon in the following section.

Factors Contributing to Fall Risk in Community-dwelling Older Adults

> For those individuals who fall and are subject to one or more risk factors, their bodies not only fall *down* but also fall *out* of the social sphere's functional spaces of certainty, utility and mobility.
>
> *Italicised by CR.*

(184p. 166)

The likelihood of falling may be attributed to a variety of underlying chronic problems, the collective result of which is referred to as fall risk [185]. Over four hundred risk factors for falls exist [186]. As an individual's number of risk factors increase, so does the risk of falling [187].

Several fundamental issues exist when considering fall risk literature. First, it is incorrectly assumed that intrinsic risk factors (e.g., balance and gait deficits) are stable [188]. Second, intrinsic and extrinsic fall risk factors co-exist, and interaction between them is frequently overlooked [188]. For example, activity such as walking (itself a 'controlled fall') and the environment in which walking occurs, is influenced by issues like lighting and surfaces [188]. Third, interactions between risk factors are complex, and differ between individuals with isolated or recurrent falls [186]. Finally, fall risk factors are not necessarily predictive. To illustrate, a study of community-dwelling older adults demonstrated 30% of low risk participants falling during one year; while almost half (46%) of those assessed as high fall risk fell [189]. The number of falls encountered in the putative low-risk group would suggest that assessment of risk is somewhat lacking in precision. The following section discusses intrinsic risk factors in community-dwelling older adults.

Intrinsic risk factors for falls.

While all older adults should be regarded as being at risk of falling [(8)], specific risk factors for falls have been researched extensively; and studies have prioritised different aspects of fall risk as most important [(102)]. However, numerous researchers and reviews consistently identify imbalance and impaired gait as among the primary risk factors for falls [(190-193)]. Balance disorders may affect approximately one third of all older adults [(13)]; interestingly, a similar figure to the percentage of those who fall. Research continues to demonstrate associations between vertigo, dizziness, vestibular disorders, and falls [(165, 194-199)] and thus stimulate audiologists' interest in fall prevention [(171)].

Deandrea and colleagues [(200)] conducted a meta-analysis (MA) of prospective studies concerning risk factors for falls in community-dwelling older adults. Papers written in most of the major European languages were included, reducing metabias to some extent. Studies' sample sizes had to exceed 200 participants, with at least 80% of participants residing in a community setting [(200)]. The endpoint was one or more falls during the follow-up period [(200)]. These selection criteria are important in that the sample sizes were reasonable; and the results are not biased by a large percentage of dependent individuals, a potential confounder. Results were reported as odds ratios (OR)[16]. The MA found OR of 2-3 for: a previous history of falls, dizziness and vertigo, gait problems, the use of assistive devices for walking, diagnosis of Parkinson's disease, fear of falling, and the use of anti-convulsants [(200)]. Expressed more persuasively, only a previous history of falls was a stronger predictor of falls than dizziness and vertigo, the presence of which increased the chance of falling three-fold [(200)]. A finding relevant to the present thesis, was the role

[16]See Glossary of Terms.

of balance-related issues among the leading predictors for falls [200]. One of the strengths of Deandrea et al.'s MA is that only prospective studies with a rigorous method of recording falls, for example, on a calendar or using interviews were included. A limitation of the analysis is the width of the confidence intervals, caused by the heterogeneity of the studies. However, such heterogeneity is common in literature on falls and fall prevention. Results were organised according to the risk factors classification system proposed by Lord and co-workers [201]. Risk factors are categorised into: socio-demographic factors, balance and mobility issues, sensory and neuro-muscular factors, psychological issues, medical issue and medication, and finally environmental factors [200]. Figure 4, abstracted from Deandrea et al., highlights some of these areas and the OR are shown.

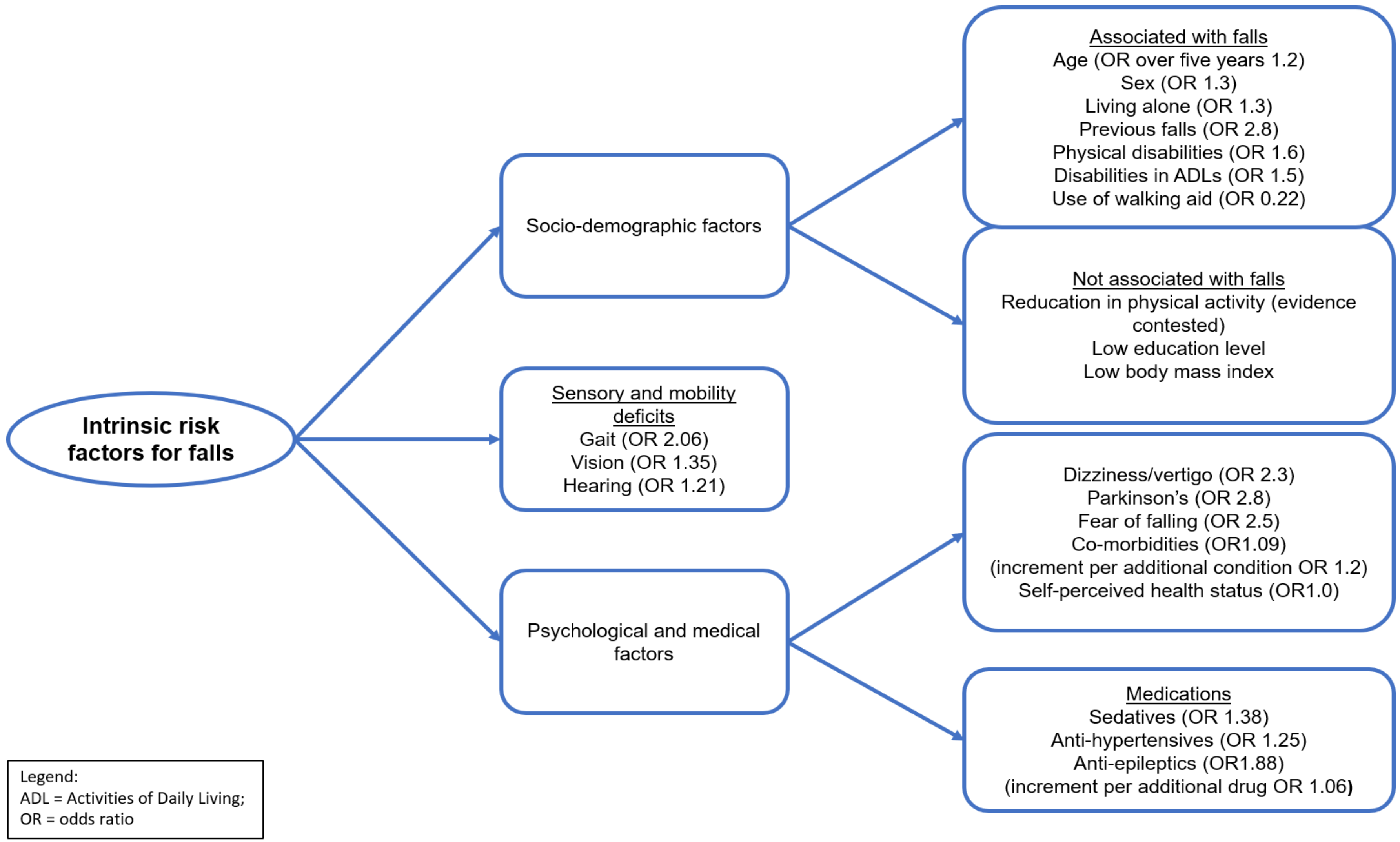


Figure 4. Intrinsic risk factors contributing to fall risk in community-dwelling older adults.

Data extracted from Deandrea et al.

While balance deficits are significantly and consistently associated with increased fall risk in community-dwelling older adults [13], the precision of such findings bear further examination [202]. There is confusion in defining the term community-dwelling, and a lack of consensus regarding residential facilities obfuscates the literature [12]. For example, the residential setting and support within it, could be argued to influence research findings of fall risk and occurrence. Thus, reviews including participants residing in supported living facilities or institutions may have overestimated the level of fall risk, as it is likely that substantial functional and cognitive differences exist between individuals residing in their own homes and assisted living [202]. The removal of institutions from Muir and colleagues' data yielded an overall reduction of fall-related risk ratios and OR values. However, the finding that balance impairment results in a moderate increase in fall risk in community-dwelling older adults remained [202]. Muir and colleagues described studies' methodological quality as low to poor. Finally, differences in choices of measurement instruments, many of them subject to ceiling effects [203], methods of recording fall outcomes, and length of follow up all had the potential to impact on the magnitude of the association between balance impairment and falls [202]. Thus, while researchers attempt to take an evidence-based approach to fall risk literature, results remain varied.

Tinetti and Kumar's [204] systematic review (SR) of fall risk factors produced some differences compared with Deandrea et al. Examples include risk associated with low body mass index (OR 3.1) and a higher OR for female sex (OR 2.3) [204]. Three pertinent points arose from Tinetti and Kumar's findings and establish concurrence with other SRs. First, the most robust risk factors were a previous history of falls, impairments impacting strength, gait and balance, and the use of certain medications [204]. Second, many of the risk factors applied to the risk factors for injurious falls resulting in fractures [204]. Third, unsurprisingly, the risk of falling increased with the number of risk factors present [204].

Lusardi et al.,[8] interrogated sensitivity and specificity for fall risk factors identifiable from medical case history information, self-assessment scales (SAS), and performance-based outcome measures. Studies in the MA were either retro- or prospective with samples comprising >30 community-dwelling adults >65 years of age [8]. No single measure had the ability to predict falls [8]. Given the multi-factorial nature of falls, this finding is to be expected. However, five key questions used in combination, were found to have predictive ability and thus, useful to screen fall risk [8]. These were:

- previous falls;
- presence of psychoactive medications;
- the need for assistance in the activities of daily living (ADL);
- fear of falling; and
- the need to use an assistive ambulatory device such as a cane/walking stick or walker [8].

These items were adopted in the design of the case history questionnaire used in the present thesis.

Tests with the best sensitivity and specificity to predict fall events were: Timed-Up-and-Go test (TUG), Five-Times-Sit-to-Stand Test (FTSST), Single Leg Stance (SLS), Berg Balance Scale (BBS), and preferred walking speed [8]. While these tests appeared to be supported the most by evidence, the authors noted that all required further evaluation before they could be used with confidence to predict falls [8]. All tests, except the BBS, were adopted for the present research.

The rationale for excluding the BBS includes a lack of normative data [(205)] and floor and ceiling effects [(206)], which challenge the responsiveness of the BBS as an outcome measure [(207)]. The BBS may not be suitable for high functioning older adults and could miss the effect of subtle balance deficits [(207)], which arguably contribute to fall risk. Further, there are few dynamic balance activities in the BBS [(207)]; and previous reviews have suggested mixed results for the BBS's predictive ability regarding falls [(208)]. Since the design of this research, an MA [(209)] has concurred with the view of Lusardi and colleagues [(8)] that the BBS is an appropriate fall risk screening tool for adults of all ages. Moreover, the BBS along with the Mini-BESTest were recommended for research and broader clinical use in a Core Outcome Set for measuring standing balance in adults, although reservations were noted by the consensus panel [(210)]. Having reviewed fall risk and predictive tests, dizziness and balance will be discussed next.

The Contribution of Dizziness and Balance to Fall Risk

> The high prevalence of dizziness and falls in the elderly is a growing and immediate medical concern…
>
> …For dizziness and balance impairment to reach such epidemic proportions, the question remains as to whether the medical community will be prepared to effectively handle such an overwhelming number of balanced-impaired patients. The current projections of the number of audiologists, physicians, physical therapists, occupational therapists, and kinesiologists working in clinical vestibular environments would suggest a disproportionate patient-to-provider ratio, with the number of patients far outweighing the number of clinical providers.

(197 p.175)

Either a general progressive loss of function or specific pathologies may affect any or all of the three senses (vision, proprioception and vestibular) contributing to postural control and balance [(13)]. In addition to the sensory systems, central areas in the brain and brainstem integrate incoming signals, control stepping behaviours and drive motor outputs (211). All brain function depends on adequate levels of brain perfusion, so deficits will impact on balance (211). For example, syncope and pre-syncope may result in cerebral hypoperfusion, provoking a fall (211). In addition, the literature has highlighted diffuse, age-related micro-vascular brain disease as an important contributor to balance difficulties and falls (212). Age-linked physiological changes in the visual and proprioceptive inputs to balance and postural control are outlined in Figure 5. Vestibular issues will be discussed next.

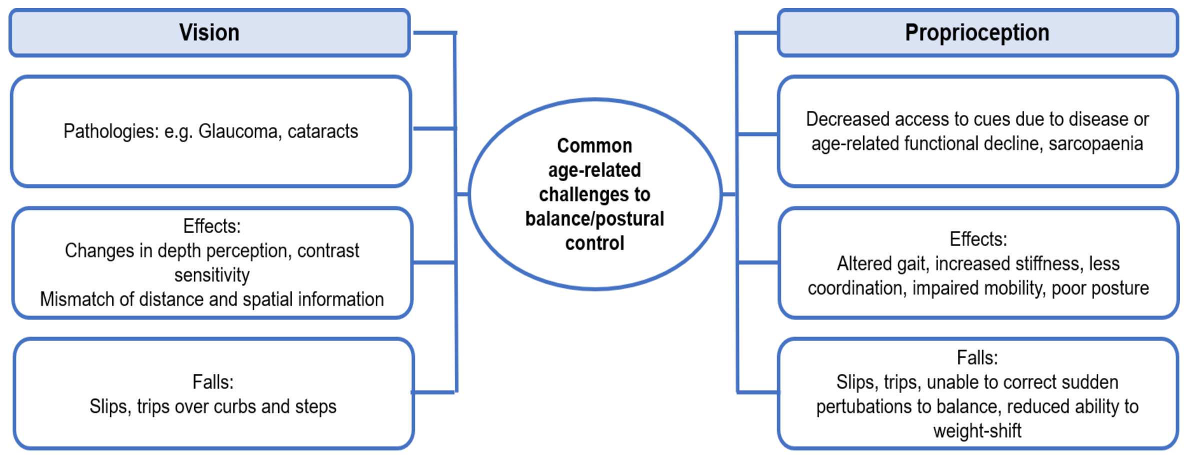


Figure 5. Age-related factors influencing balance and postural control.

References for Figure 5: (102, 164, 213, 214).

Vestibular ageing.

It is known that vestibular dysfunction contributes to the risk of falls, but not the extent of such a contribution (161), although some studies examining the link are presented. Vestibular ageing literature has been published since the 1970s (215) and is discussed briefly in this section. Several issues confound research into vestibular ageing. First, difficulties exist when attempting to link age-related histological and anatomical changes to clinical findings (197). A central compensatory process occurs in response to vestibular dysfunction, therefore, objectively proven damage does not necessarily correlate with symptomatology (216). Furthermore, the symptoms of dizziness and imbalance may be due to numerous diverse and multi-factorial disorders, for example, neurological deficits, medications and cerebrovascular issues [216, 217].

Terms such as presbyvertigo, presbyastasis, and presbyataxia [218] describe symptoms and not a diagnosis, phenotype or finding [217]. New (2019) diagnostic criteria for presbyvestibulopathy have been compiled [219]. Presbyvestibulopathy is a chronic vestibular syndrome characterised by unsteadiness, impaired gait, falls, and mild, bilateral vestibular deficits on specialised investigations [219]. However, to confine the impact of ageing to specialised investigations of the vestibular end-organs is an over-simplification. While there is undisputed evidence supporting ageing of inner ear vestibular hair cells from birth, which becomes more marked after 70 years of age [217], degeneration also occurs in the vestibular nuclei and nerves [219]. Recent research has investigated visuo-spatial capacity, a higher brain function dependent on vestibular inputs, and ageing [215]. Links between vestibular dysfunction and cognitive impairment have also been explored, with the suggestion that any type of vestibular deficit, particularly in older adults, may possibly result in cognitive impairment [220]. A brief discussion of age-related vestibular system deficits follows.

Age-related hair cell loss occurs in the sensory epithelium of the labyrinth [221]. There is a concurrent reduction in signals regarding head movement and orientation to the brain [194, 222]. This reduction of signals may not be met with adequate sensory re-weighting[17]. Re-weighting permits attention to be shifted from the impaired vestibular signals to more reliable inputs from the other senses [159], and can help prevent falls. Vestibular neglect, a subjective hypo-responsiveness to vestibular

[17] See Glossary of Terms.

stimulation, is due to deterioration in central vestibular pathways [223]. Vestibular neglect is associated with postural instability in older adults [223], thus elevating fall risk. Therefore, vestibular loss, irrespective of site of lesion, may present as staggering, unsteadiness on turns and postural instability, all of which increase the risk of falls [194, 221].

Of concern is that functional vestibular decline is thought to commence earlier in life than previously assumed. The National Health and Nutrition Examination Survey (NHANES), a large national population survey in the USA [194] used putatively objective screening tests of assumed vestibular function. The test was what clinicians consider a Modified Clinical Test for Sensory Integration of Balance (M-CTSIB), although was not described as such [224]. Over one third (35%) of the sample ≥40 years of age had signs of reported vestibular dysfunction [194]. It has been argued, quite correctly, that the test used in the NHANES study is not suitable to screen for vestibular lesions [224]. Ceria-Ulep and co-workers noted that the NHANES battery was too easy and lacked discrimination between levels of function in healthy adults. However, the difference in ethnicity in the latter's [225] sample of Japanese descent Hawaiians and the NHANES study is noted. Nonetheless, many individuals failed the NHANES tests and had indications of imbalance, if not true vestibular disorder. Such imbalance is a risk factor for falls. Interestingly, the NHANES participants who failed the screen and reported dizziness, had an eight-fold increase in the risk of falling [194].

Perhaps more important than a strict focus on proof of vestibular deficits associated with ageing, is the presence of vestibular symptoms and links with fall risk. There is evidence that the presence of vertigo, a complaint suggestive of peripheral vestibular disorder [75], correlates with falls, but its role is frequently underestimated [196]. The researcher acknowledges and is acutely aware of the differences between dizziness and vertigo[18]; however, the following section will focus on the prevalence and impact of dizziness, irrespective of its origin.

Prevalence of dizziness in older adults.

Vestibular disorders are responsible for almost half (48%) of all dizziness in older adults [226] and the prevalence of dizziness and imbalance increases markedly with advancing age [227]. Indeed, dizziness is the most common reason for patients over 75 years of age to consult their doctors [228]. Over half (54%) of people 90 years of age have experienced dizziness within the last three months [229]. The relationship between dizziness and ageing has been established in several regions. Kammerlind and colleagues [230] noted that 41% of their community-dwelling sample of Swedish older adults reported dizziness, and their results are discussed in more detail below. A similar (40%) prevalence was found in Brazil [231]. Another very large population-based survey in Brazil demonstrated that dizziness was the third most frequent symptom reported among all adults surveyed [232]. Only headache and fever out-ranked dizziness [232]. Prevalence increased over the age of 50 years and peaked in the eighth decade of life [232]. A small household survey of older adults in Egypt reported that 33.3% of the respondents experienced dizziness [233]. It is reasonable to suggest that dizziness prevalence in LMIC, at least in older adults, is similar to the global North.

Continuing the focus on symptomatology, in many older people dizziness may be non-specific and multi-factorial, rather than being attributed to discernible vestibular pathology [197]. Therefore, it is more reasonable to consider the impact of dizziness symptoms on fall risk, rather than seeking to prove causal links between

[18] See Glossary of Terms.

dizziness, vestibular disorder and falls. By way of example, Kammerlind et al., sought links between the presence of dizziness and falls in Swedish adults between 75 and 90 years of age (mean age 81 years). Almost one third (30%) of participants with mild dizziness reported a fall, with a marked increase to 46% of participants with substantial dizziness having fallen [230].

While the NHANES study discussed above [194] had instrumentation issues, nevertheless the results are a cause for concern. To summarise, 75% of participants over 70 years of age had abnormal test results for balance [194, 234]. This figure increased to 88.5% once participants were over 80 years of age [194, 197, 234]. Living below the poverty line made balance problems 15% more likely [194, 234]. The latter finding is consistent with the studies from LMIC (above), in that low socio-economic status impacts on reports of dizziness.

In terms of functional outcomes, the presence of dizziness has been shown to be associated with:

- A reduction in exercise at moderate intensities and a less active lifestyle [230, 235];
- Decreased likelihood of taking a walk [235];
- Increased falls [235];
- Increased fatigue [235];
- Poorer performance on balance-related outcome measures such as gait speed, stair climbing and SLS [235];
- Increased impairment in the ability to perform the ADL [236]; and
- Decreased quality of life (QoL) [230].

It is striking that all the issues noted in the tabulated list are in themselves risk factors for falls. The contribution of imbalance and dizziness to falls is beyond dispute; thus, efforts to improve balance to reduce the risk of falls are urgently required. Such programmes should meet the basic requirements of public health interventions and be feasible, sustainable, accessible and affordable (138) and it was with these issues in mind that this feasibility study was designed. As the study used physical activity (PA) programmes as the intervention, PA's impact is introduced next.

Modifiable fall risk factors: impact of PA and sedentary behaviour.

Interestingly, a large volume of research has focused on fall risk factors which are either not ameliorable (e.g., age, sex and ethnicity), or medical concerns, such as medication reviews. Few of the authors in the preceding sections examined sedentary behaviour and challenging this lifestyle with PA, as a potentially treatable cause of falls (237). Thibaud and colleagues' MA (237) considered the role of PA and falls. Results indicated that for older adults, PA is a protective factor for falls, particularly injurious falls (237). PA may address intrinsic risk factors for falls by improving balance and gait speed, muscle, and physical strength (237). Sedentary behaviour was at least as important as other fall risk factors, such as medication profile (237). The reviewers noted the risk of publication bias and that few studies were included in the MA; however, the large number of participants (7 343 for PA and 4 279 for sedentary behaviour) made the results generalizable to older adults (237). Therefore, the use of PA in the management of fall risk should be prioritised, and two programmes which promote such activity are the focus of the present research. Further evidence to support the use of exercise to prevent falls is offered in later Chapters.

Little attention has been awarded to fall risk factors in the South African milieu. The sparse literature is discussed in the following section.

South African fall risk factors.

A small (837 participants) epidemiological survey of fall risk factors and prevalence among adults (≥65 years of age) was conducted in Cape Town [(238)]. Self-reported history of falls, dizziness and vertigo, along with ethnicity, were found to be predictive of falls in a one-year period [(238)]. The presence of dizziness had an OR of 2.52 [(239)], similar to that of international reviews already discussed in this Chapter. Kalula and colleagues had previously demonstrated that for at least some sectors of the population, fall prevalence was similar to rates in high-income regions [(240)]. An overall fall prevalence of 26.4% was found, like that of other countries, but with marked differences within ethnic groups [(240)]. Prevalence was highest in Caucasians (42.9%) and people of mixed ancestry (42.9%) [(240)].

Both the cross-sectional studies referred to above could be subject to several sources of bias. Recruitment bias was possible, in that only ambulant participants were included [(238)]. A social desirability bias is possible as no consideration was given to the stigmatising effect of falls [(241)], leading to possible under-reporting and increasing no response rates [(67)]. Finally, recall bias is possible. Falls were not recorded on an on-going basis using a diary or similar, no reminders were given, and participants were simply asked if they had fallen in the year between the two data collection points [(239)].

A small unpublished study examining PA levels and fall occurrence in older adults, set in Cape Town, demonstrated that 30% of participants recalled falling in the preceding year [(242)], consistent with local and international fall prevalence data. A second study exploring fall prevalence in 150 independent community-dwelling adults over 40 years residing in Cape Town reported that 40% had fallen within the last year [243]. Neither of the studies examined ethnicity nor socio-economic status as outcomes, however participants were from diverse backgrounds.

Collectively, the South African studies suggest some evidence that for at least certain sectors of the South African population, fall risk resembles worldwide data. Having established that falls are an important issue for older South Africans, the following section presents additional considerations for fall risk in an African setting.

Intrinsic fall risk factors pertinent to the African context.

Besides health issues faced by older adults, including the highlighted role of imbalance and gait deficits, it is apparent that socio-economic circumstances and socio-demographics may elevate fall risk [244]. The contribution of ethnicity, socio-economic- and educational- status to fall risk has been markedly under-researched [245], although these issues are gaining attention more recently [246-248]. Rubenstein and colleagues [35] suggested that adults from a low-income group, with low levels of education and literacy, and who live in poor environmental conditions may be at greater risk for falls. However, additional research is required as some of the evidence is indirect. For example, it is already established that low income is related to poor health status, which in turn will increase the risk of falls [35]. Contrary to the notion of poor circumstances amplifying fall risk, a large Nigerian study suggested that falls occurred more frequently as individuals' socio-economic status increased [249]. It could be argued that as incomes improve, work might shift from physical/manual to more sedentary occupations. PA is thought to be a protecting moderator of fall risk [237] and thus, by spending more hours inactive as work demands change, fall risk should increase. As noted, ethnicity may also have a role in fall risk [33, 240]; however, this has not been conclusively established [238, 250]. Despite the tensions noted when considering socio-economic and similar factors, falls in LMIC are a concern and efforts should be made to reduce the risk of falls with sustainable interventions.

CHAPTER II. PREVALENCE OF FALLS IN COMMUNITY-DWELLING OLDER ADULTS

Chapter II examines fall prevalence. Challenges in the literature are described, followed by global fall prevalence data. African aspects are outlined as they pertain to extrinsic and possible intrinsic fall risk factors. The impact of falls is considered in terms of morbidity, mortality and cost. The Chapter concludes with a discussion on ageing in Africa. Figure 6 shows a flow chart of the Chapter's organisation.

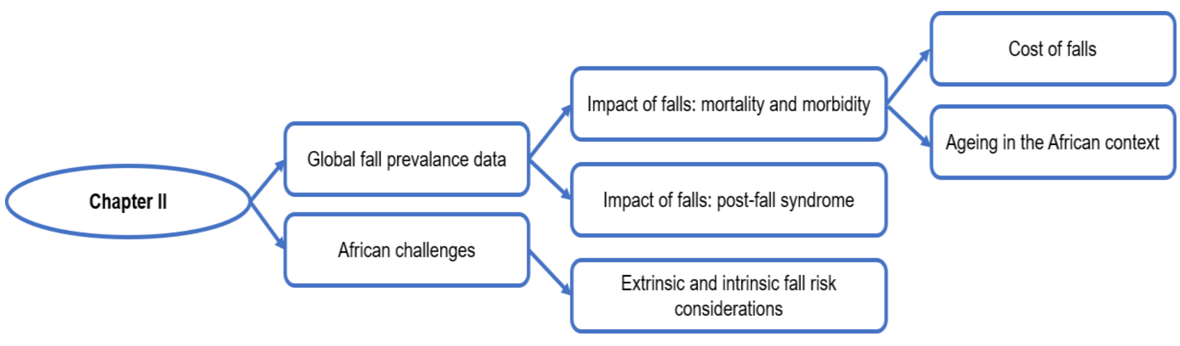


Figure 6. Organisational flow of Chapter II.

Global Fall Prevalence Data

Fall prevalence research has been complicated by several factors, which include:

- Methodological challenges: a lack of appropriate prospective designs exists. Cross-sectional or retrospective studies permit recall bias, and likely under-reporting of fall events. Older adults who have fallen repeatedly may not report their falls, possibly due to denial or even poor memory [(251)]. Participants may also only report injurious falls [(252)], instead of all falls, making falls estimates inaccurate. Prospective recording of falls in falls diaries or calendars is the preferred method compared with relying on recall [253].

- Falls are regarded as negative, stigmatising events, with those who have fallen reporting feeling anxious, isolated and fearing a loss of independence [254-256], all of which contribute to social desirability bias.
- Large-scale community-based surveys in low- and middle-income countries (LMIC) are lacking due to the expense and lack of resources, although recent efforts have been made in Brazil [231, 232]. Studies exploring the prevalence of injurious falls may be given preference. For example, injurious falls were surveyed during a WHO study on ageing and adult health [257]. While the latter was an epidemiological study that surveyed households in varied settings, many others involve simple record reviews of injurious falls, due to the convenience of auditing hospital or clinic records. Considering the use of bone-setters in regions in Africa [258, 259], Asia [260], and South America [261], it is highly probable that the number of injurious falls in LMIC is under-reported.
- Moreover, due to the challenges of collecting data in diverse geographical regions, unequal access between urban and rural settings is likely. It could be argued that fall prevalence could easily be related to location and the rigours of living in different environments.

Table B.1 reflects prevalence data from a sample of research undertaken in LMIC. Briefly, fall prevalence rates are sparse in many emerging regions. A conservative annual incidence of falls (22.1%) from a USA study [262] was used as a comparator. Results of fall prevalence vary, with rates of 21-34% in Latin America

[263], 11-34% in China [264], and 33% in Egypt (33%) [233]; the variance likely linked to the methodological issues presented above. However, the table highlights that the prevalence in Africa is analogous with other continents. Two studies from Africa, which examined recurrent falls and had previous falls as an eligibility criterion were excluded [249, 265].

African Challenges

It is feasible that the prevalence of falls, and their risk factors, may be different between world regions; however, firm evidence is lacking. Nonetheless, the phenomenon of ageing, and its attendant public health concerns, warrants global attention from researchers. Moreover, LMIC could be less well equipped and resourced to plan for the public health issues an ageing population presents [266]. The following sections focus on issues pertaining to Africa.

Extrinsic fall risks

Several researchers from LMIC have described fall extrinsic risk factors pertinent to these regions. Ghodsi [267] suggested poverty and poor health may confine individuals to their homes, where safety issues may arise during bathing and toileting. Environmental hazards include poor street design, maintenance, lighting, and the presence of holes and ditches [267]. Amin [268] noted cultural and religious issues such as rising during the hours of darkness for morning prayers, ablutions at ground level, and finally, long traditional dresses of several layers, which could cause trips and slips.

Impact of falls in the African context.

In the African context, although the point is arguable, many of the population will already have inherent fall risks due to their poor socio-economic and health status. Disadvantage, coupled with lack of access to interventions to address fall risk, makes the current research particularly relevant. Increasing resilience to falls could make a valuable contribution to quality of life (QoL). The impact of falls in the older population in Africa should not be ignored. Older individuals are often required to assume additional familial responsibilities, such as attending to adult children dying from HIV/ AIDS, or care of young children orphaned by the AIDS pandemic [(269)]. While progress has been made, management of HIV/AIDS remains a significant challenge in Africa and other regions [(270)]. Loss of mobility, or increased dependence as a result of a fall, would have profound consequences on communities relying on the contributions of the older generation to care for the sick and vulnerable. The impact of falls is explored further in the following section.

Impact of Falls: Mortality and Morbidity

Falls have a detrimental and long-term impact on QoL [(271, 272)] and are life-changing events for older adults [(273)]. There is compelling evidence that the health status of adults who fall, in terms of physical, cognitive and mental function, is fundamentally different from older adults who do not fall [(183)].

Mortality.

The WHO estimated 646 000 fall-related adult deaths each year; 80% of which occur in LMIC [(274)]. As described, evidence suggests that death rates from falls have risen precipitously in the last decade [(109, 275)]. Most deaths related to falls occur in individuals over 65 years of age [(274)]. Morbidity is similarly linked to falls, with injurious falls predicted to double by the year 2030 [(276)]. However, as individuals age, the outcome of injury is more likely to be fatal, even if the injuries are similar between young-old and oldest-old [(277)]. For example, an injury in the seventh decade of life carrying a 2.5% risk of death doubles to 5.4% in the tenth decade, due to a lack of physiological reserve to manage the same injury [(277)]. Even apparently uncomplicated falls have been shown to lead to high rates of mortality and morbidity [278].

Morbidity.

Health-related sequelae of falls.

Older adults' recurrent falls are problematic. Of those who fall, half will fall at least twice in the same year [279]. For example, Pohl and colleagues [280] monitored a small (230 individuals) cohort of Swedish community-dwelling older adults prospectively, and reported that 48% fell at least once during a one-year period. More compelling is that during a five-year follow-up, those who had at least one injurious fall requiring emergency treatment, had an almost three-fold risk of another injurious fall during prolonged surveillance [280]. Another group's results of adverse events experienced within six months of a post-fall visit to an emergency department are even more convincing [275]. Over half a cohort of 350 older adults experienced a subsequent adverse event [275], including recurrent falls (23%), repeated visits to the emergency department (43%) and hospitalisation (32%) [275]. Thus, falls should not be regarded as once-off accidents in older adults, but rather herald repeated, potentially serious and costly health issues.

Older adults are at increased risk for head, neck and pelvis injuries compared with their younger counterparts [278]. For example, falls are the leading cause of traumatic brain injury and are heavily implicated in hip fractures in older individuals [281, 282]. Frequently, survivors of the immediate post-fall period have guarded outcomes in terms of morbidity and mortality. To illustrate, one third of patients with hip fractures will die, and more than half of those alive at twelve months will have significant mobility challenges [283, 284]. It is not possible to overstate the devastating effects of an injurious fall for an older adult, nor the cost to public health budgets (284, 285).

Functional sequelae of falls.

Results from a small South African study into osteoporotic hip fractures demonstrated the most common risk factor as falls (286). Of the 130 participants followed prospectively for one year, 45 (34.6%) died, congruent with data above. For survivors, deterioration in the ability to perform the activities of daily living (ADL) noted at three months, persisted at one year (286). In the South African setting, the latter finding could well be explained by a lack of rehabilitation services (287). International studies exploring reductions in ADL capacity after a hip fracture vary between one third to almost one half of individuals impacted (288, 289). This loss of executive function frequently prompts altered living circumstances, for example having to move to assisted housing. In the four to six months following treatment for a hip fracture, between half to two thirds of individuals required support in terms of living arrangements (289). Importantly, this loss of autonomy is a major risk factor for falls, with evidence suggesting that difficulty in accomplishing at least one ADL doubles the risk of falling (244). Thus, there are profound physical and psychological sequelae from falls, which may lead to reduced ability to participate in ADL and the capacity to live independently (290). The psychological issues related to falls are discussed briefly in the following section.

Post- fall syndrome and fear of falling.

Post-fall syndrome, also known as fear of falling, describes a loss of confidence and self-imposed restriction of activity after a fall, which is disproportionate to any injuries sustained (291). Post-fall syndrome has been described as a specific health problem and a geriatric syndrome (292). Fear of falling encompasses concerns regarding loss of independence, or fear of becoming dependent on others [293]. Furthermore, fear of falling is linked to older adults' apprehension regarding physical injury, not being able to get up after a fall, partial or complete loss of mobility, and anxiety regarding institutionalisation [293]. Fear of falling may be a predictor of future falls [292]. Consequences include an increased risk of mobility disability and poor physical performance [294]. Aged adults who have fallen may behave differently to prevent another fall. For example, they may deliberately reduce walking speed, even though this puts them at greater risk for falling, and is associated with increased mortality rates should another fall occur [295]. The result of fear of falling has been associated with a declining course of reduced physical and social activities, frailty, further falls and loss of independence [244, 288].

Costs associated with falls.

Falls constitute an important economic drain on society [296]. In high-income countries, where fall-related costs range between 0.85% and 1.5% of the total health care expenditure, it is likely that with ageing societies the total burden will increase [296]. Injurious falls are the most important cause for hospitalisation in the older population [297]. The cost of hospitalisation after a fall is substantial, although dependent on the severity of the injury [296]. Numerous studies have reported the direct health related costs of fall induced injuries [298]. Aggregated costs of falls in 2015 in the USA were US$25 487 for a fatal fall and US$9 463 for a non-fatal fall [247]. Estimates in 2012 suggested that a total of US$54.9 billion (in 2007 US$) would be required for health care expenses due to the direct and indirect cost of falls in 2020 in the USA alone [113]; and a mere ten years after that, US$101 billion [299]. The figure of US$50 billion was in fact reached by 2015, up from US$38 billion (adjusted to 2015 US$) in 2013 [193]. Almost 99% of the expenditure was on non-fatal falls (193). Thus, it is evident that falls are a significant risk factor for an increase in healthcare spending should efforts at fall prevention fail. There is a body of evidence which suggests that the implementation of fall management strategies is far from optimal (109, 299); and so the need for further research, particularly into effective prevention, continues.

In line with the situation in the USA, recent reports concerning ageing in Ireland predicted major growth in the cost of falls. O'Connell and colleagues (183) reported that €402 million was spent on older adults' falls in 2006. More impressive is the prediction that expenditure will grow to €922-€1077 million by 2020, should an intervention to manage fall risk not be implemented (183). Like predictions from the USA, Irish forecasts are probably underestimates, as they do not include extended costs, for example, of carers, medication, and institutionalisation (183). In Sweden, a country of under ten million, costs of falls in 2009 equated to €1.4 billion, with the majority (€900 million) of the spending addressing QoL issues for fall survivors (300). Thus, those who have fallen use resources which could otherwise be allocated (183), a relevant issue in emerging regions. The following section continues to explore the impact of falls in an African context.

Ageing in an African Context

> Older persons in Africa are not to be taken for granted; they are Africa's greatest resource yet. Africa needs their wealth of knowledge, variety of skills, and the strength and ties that they offer to hold together a family, particularly in times of crisis.

(301, no page number)

Ageing is a worldwide phenomenon, and not exclusive to the global North. In LMIC it is predicted that by the year 2050, one in five individuals will be ≥60 years of age [302]. In Africa, the total population of older adults will triple from approximately 53 million in 2009 to 150 million in 2050 [302]. By the end of the century it is predicted that Africa's aged population will have grown 13-fold, more than any other world region, and there will be 716 million older adults on the continent [303]. In sub-Saharan Africa alone, the population of older adults is predicted to double between the years 2000 and 2030 [304]. Several factors have contributed to population ageing, including reduced levels of fertility, a decline in infant and child mortality and increased longevity [305]. For example, if an individual reaches 60 years of age, s/he will have a longer life expectancy than ever before [306]. The notion of longevity and its equivalence with the success of humanity persists [307, 308] and indeed should be celebrated [301]. However, such progress is remarkable only if living longer is associated with improved QoL, health and well-being, which is not necessarily the case in Africa [307].

In LMIC, including those in Africa, there has been an assumption that families will care for their elders within multi-generational households [302]. However, attitudes towards ageing are changing [301], and the circumstances in which older adults live are diverse. First, consequent to urbanisation and migration, older adults may no longer reside in the traditional extended family environment, where three generations share a home [309]. Younger, economically active adult children may support older parents financially, but either due to working long hours or having moved away, are unable to provide physical assistance [310]. In addition, more women are entering the work force, couples are having fewer children and intergenerational spacing is increasing, all impact on traditional family arrangements [311].

Furthermore, family structures have been profoundly changed with the HIV/AIDS pandemic, leaving older adults to first nurse their adult children when they are ill, and then to tend their orphaned grandchildren as primary carers [309, 312]. More than twelve million children in sub-Saharan Africa have been orphaned by HIV/AIDS [269], and sizable numbers are cared for by their grandparents [312]. Thus, there has been a substantial change in the roles and responsibilities of older adults in the region [309, 312]. Fiscal strain is common in grandparent-led households [269, 309], leaving less likelihood that older adults can seek and pay for health care. Finally, it has been suggested that respect for older adults in the African context is no longer assumed [310, 313, 314], which could add to older adults' disempowerment. These changes in the traditional fabric of society in Africa would suggest that care of, and finance for, older adults will shift from familial responsibility to public institutions [311].

Research in South Africa has demonstrated many challenges faced by older adults [309, 312, 315]. The majority of South Africans over 60 years of age receive a monthly social pension provided by the state and have no other financial support for their retirement [46, 316]. While increased numbers of citizens are receiving social grants, poverty alleviation and improved health status remains elusive [315, 317]. For instance, pensions are often used to support others in the older individual's household, rather than to improve the recipient's ability to live independently [309, 312]. While older South African adults usually 'age in place'[19], significant challenges arise concerning healthcare services. First, services are regarded as under-developed and dysfunctional [318] and access to such healthcare facilities has not improved since democracy in 1994 [319]. Tensions exist between managing major

[19] Facilitation of allowing older adults to reside in their homes and communities for as long as possible.

communicable diseases, such as tuberculosis and HIV/AIDS and a rising epidemic of non-communicable diseases (NCD) [318]. Furthermore, there are substantial indications of a bias towards younger populations when developing policies and services in emerging regions [304]. Needs of older adults are often ignored, with the result that in South Africa, they experience reduced access to health services compared with their younger counterparts [303, 320].

Older adults are likely to have several chronic conditions with the potential to result in disability [303]. Thus, services are required to move from 'once-off' clinical encounters to long term management. Specific to accessing health services, South Africans encounter problematic travelling distances to clinics and long waiting times once there [321]. Finally, research has suggested that older individuals using health care services perceived either a lack of quality of the service, or that the required assistance is not available [303, 312, 315]. Thus, it could be argued that the majority of older South Africans remain disadvantaged, have less financial and health care resources should they require interventions resulting from having fallen, making efforts at fall prevention a convincing priority.

Planning for ageing in Africa.

In contrast with high-income countries that have experienced a gradual ageing of their populations, and have been able to anticipate strategies around care for the aged, LMIC are relatively unprepared in terms of planning policy [307]. It is predicted that within the next 20 years, emerging nations will have a high percentage of older individuals whose health needs will not be met [302]. Thus, LMIC have much less time available to formulate and implement policies to respond to the challenges of ageing populations and create infrastructure [306]. When the Millennium Development Goals were discussed, issues regarding older adults were not mentioned (310). Progress has been made with the new Sustainable Development Goals specifying the need for optimal health at all ages (46), implying that concerns affecting older adults must be considered.

The United Nations placed ageing populations at the forefront of a World Assembly agenda in Madrid in 2002 (322). Signatories, including South Africa, pledged to develop strategies to improve health services for older adults (322). In 2003, the African Union produced a Plan of Action on Ageing, in which the need to prevent disease and subsequent disability, and for policies to promote access to health care was highlighted (322). Implementation of the Plan of Action on Ageing has been slow and uncoordinated in Africa (310, 322-324). In 2006, South Africa introduced legislation to uphold older individuals' constitutional rights, and further indicated a need to shift services for older adults to community-based care (312, 315, 325). However, 1998 legislation had reduced budgets for older adults' services, resulting in the closure of amenities, community centres and residential care for the aged (312). In the Western Cape of South Africa, where the present study is situated, service centres for older adults exist and provide hot meals and health-related information (325). However, facilities are characterised by inconsistencies in staffing, capacity, funding and infrastructure, with the quality varying from very good to poor (325).

Of relevance to the question of falls and their consequences, trends in high-income countries suggest that of older adults who were hospitalised due to an injurious fall, 40% of them are discharged to a nursing home, 15% required home health or hospice care, and less than one third (29.6%) returned home with no assistance (326). The changing circumstances of older adults in an African context suggests that there may not be capacity to manage those who have fallen within their home setting. Older adults who have fallen may be caring for others (325), with a subsequent risk of further fragmentation of traditional systems of familial support. Moreover, residential care facilities for older adults are sparse [312] and overall healthcare provision quality has decreased [320]. The need for community and social housing for older adults is at a critical point; and yet the State perceives its only obligation is to provide support to older adults in need of residential frail care [320]. These issues signal necessity to prepare, at a national and policy level, for the needs of older and possibly frail individuals. The following Chapter describes fall prevention measures, and with a focus on exercise-based programmes and the evidence to support them.

CHAPTER III. PREVENTION OF FALLS

Introduction

Chapter III comprises two parts. *Part One* focuses on disease prevention and health promotion. Key to prevention is screening activities, discussed in terms of fall risk. Fall prevention guidelines are introduced, and the lack of implementation described. Approaches to fall prevention, and contextual issues in Africa are discussed. *Part Two* presents fall prevention programmes. Non-exercise-based interventions are mentioned briefly. Evidence concerning exercise-based interventions underpins *Part Two.* Methodological issues arising from the literature, and how these will be managed in this research, are described. The organisational flow of the Chapter is depicted in Figure 7.

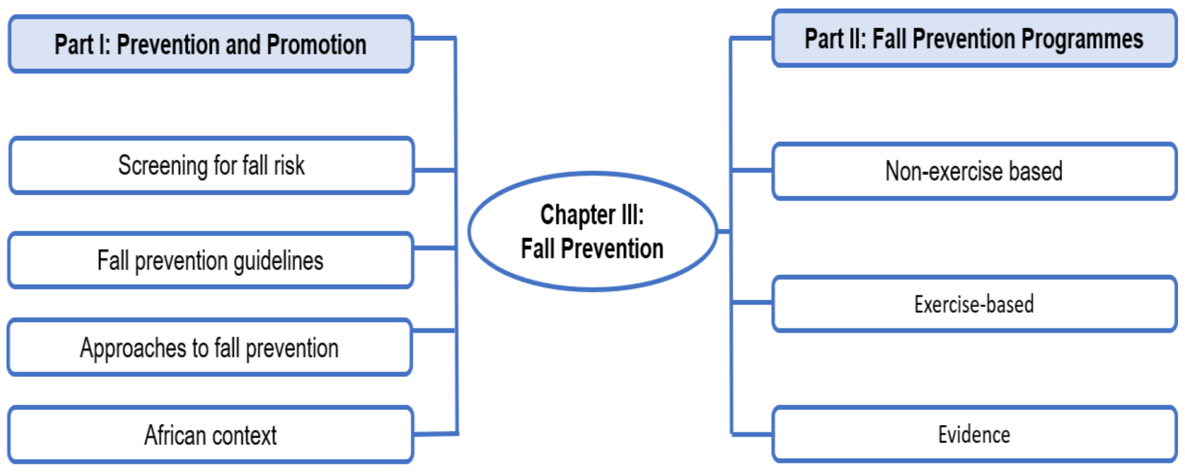


Figure 7. Organisational flow of Chapter III.

Part One: Role of Prevention and Health Promotion

> On average, an older adult falls every second of the day. With the number of older adults and fall death rates rising, the situation will decline without active participation from all health sectors, especially primary care… no matter where you live and practice, at least one in five older adults report falling.
>
> We are at the point of putting what we know about the issue into action. In other words, not “What should we do?” but “How should we do it?” for the best (patient) outcome.

(327 p.121)

Ageing is associated with physiological decline; age-related diseases and their attendant risk of falls already described. However, it should not be assumed that falls are an inevitable consequence of ageing. Instead, fall risk is remediable and thus lends itself to activities included in disease prevention and health promotion programmes [(326)]. Africa has been tardy in addressing the escalating problem of ageing. Indeed, a review by Kalula and colleagues [(328)] failed to find any evidence of effective fall prevention strategies in a LMIC context. In contrast, increasing numbers of randomised control trials (RCTs) exploring fall prevention programmes have been conducted in Asia [(329)]. Trials including adaptions of the OEP, an intervention in this report, have been conducted in Thailand [(330)] and Iran [(331)]. Yet, Kalula noted a persistent lack of knowledge regarding falls in Africa [(239)]. The South African Department of Health’s fall prevention guidelines were issued almost two decades ago [(332)], but no research has been conducted on their uptake or efficacy [(333)]. No evidence of an update to the guidelines could be found[20], which could speak to falls not being a priority, despite the increased ageing population. It is argued that the entire topic of fall prevention and management has been neglected

[20] As of November 2019.

on this continent. The current and predicted expansion of the aged portion of the population, and the lack of organisational responses to the attendant complications this will bring, presents a major public health concern. Health care system reform in LMIC is required, with a focus on disease prevention, health promotion, early screening, and finally, effective intervention programmes at a community level [(306)].

Historically, public health efforts were concerned with the prevention of disease in society [(334)]. In high-income countries, attention has shifted to the promotion of health and individual responsibility to maintain health, and these concepts have driven public health reform [(334)]. Conversely, LMIC maintain a dual responsibility, with communicable diseases such as tuberculosis and HIV/AIDS poorly controlled in some regions [(335)], and the growth of non-communicable diseases (NCD) [(336)]. Prevention programmes are a viable method to control the costs and consequences of NCD, and can impact positively on public health issues [(337)]. Notwithstanding the potential of health promotion and prevention activities to reduce incapacity and to improve QoL for older adults, such programmes have often overlooked this population as a target for services [(338)]. However, comprehensive efforts, including fall prevention programmes, have been made in the USA [(339)] and other high-income countries. The following sections discuss activities in promotion efforts regarding falls.

Screening.

One of the key aspects and first steps of prevention strategies is screening, in which people at risk of falling are identified [(340, 341)]. Screening programmes offer the opportunity for early detection and management of disorders, combined with a public education component [(311)]. Conceptually, screening should be differentiated from diagnosis in that the aim is to categorise a population into two groups, that is, those with and without an increased risk of a condition [342]. Individuals who are screened positive for increased risk then proceed to further tests to diagnose and treat their condition [341]. Screening settings vary from medical facilities to community centres or home-based services; and staff may originate from diverse professional backgrounds [343, 344]. Home- and community-based care providers may be well-placed to offer such services and then refer at-risk individuals for further assessment and management [344], making services more accessible.

Guidelines for screening older adults for fall risk emanate from the American and British Geriatric Societies, adopted for use in programmes such as Stopping Elderly Accidents, Deaths and Injuries (STEADI) [345]. Briefly, the guidelines recommend that all adults over 65 years are asked about falls each year by their health care provider. Patients are questioned about perceived walking or balance difficulties, and if the visit to the health care practitioner is due to a fall. Finally, an office-based test of balance such as the Timed-Up-and-Go (TUG) is conducted. Individuals with positive results on the self-reported items or the balance test should be referred for a comprehensive fall risk assessment [341].

While recommendations for balance and fall risk screening exist, implementation has been extremely slow and problematic [109, 346, 347]. Despite their importance to identify individuals with fall risk [348], guidelines appear to be under-utilised in routine health care assessments [346, 347, 349]. However, a modest improvement in uptake has occurred in the last decade [350]. Furthermore, due to the multi-factorial issues comprising overall fall risk, screening for falls is fraught with difficulty [103].

While guidelines suggest questioning patients regarding falls, this strategy may be inadvisable, as many older adults fail to report falls [351]. To illustrate, an

Australian study of fall-reporting behaviour in older adults suggested that fewer than three in ten patients initiate talking to their doctors regarding falls [352]. Of those who did, 75% received either no or unhelpful advice [352]. Moreover, counselling was not in accordance with the evidence base; for example, patients were told to apply more caution when moving around and to move slowly [352].

Supporting the lack of appropriate management referred to above, a small USA study suggested that only 8% of GPs based their fall prevention practices on recognised clinical guidelines [349]. Johnson, Newman, Danhauer, and Williams [151] proposed that failure to screen for balance disorders could be linked to lack of awareness of vestibular rehabilitation as an effective strategy for imbalance in the older population. One could posit that the same lack of knowledge extends to the efficacy of exercise-based interventions to prevent falls. Thus, ignorance of appropriate therapeutic paradigms for falls, and their association with balance disorders, could be a disincentive to screening activities. Other possible challenges to implementation of clinical guidelines and screening for falls include a lack of time and training [109, 347], the latter probably integral to both studies cited here.

For practitioners who employ screening, concerns arise regarding the sensitivity and specificity of tests to identify those with fall risk [103]. There is little consensus on which screening methods are most appropriate. The predictive value of screening tests has not been well described, and the recommendations of the professional societies are thought to be only of moderate clinical utility [353]. Several authors have suggested there is some proof that simple enquiries regarding history of falls and perceptions of abnormal gait and balance are effective, and may be as robust as more sophisticated screening tests [341, 354]. Moreover, the heterogeneity within age-bands of older adults, and differences in the settings in which they live, implies that no single instrument for screening will be appropriate for all sub-populations [346].

Prevention.

Some fall risk factors are modifiable, and others responsive to therapy. Moreover, for health care practitioners, falls are both predictable and preventable. Thus, the possibility exists to reduce the individual cost of falling, both physical and psychological, and the cost of falls in public health terms. Previous studies have reported that reduction of even one fall risk factor impacts positively on fall events and morbidity [344]. Prevention of falls is a pressing medical, public health, and social issue [355, 356].

There are two main approaches to fall prevention. A selective approach identifies high-risk individuals and refers to dedicated fall prevention services. While this approach is expensive, the benefit is individualised risk assessment and targeted advice and referrals [357]. The second approach is non-selective and includes attention to environmental issues, fall avoidance education, recommendations for physical exercise, and promotion of awareness of fall risk [357]. Non-selective approaches have appeal for population-based, public health types of interventions.

While selective and non-selective approaches have been described in the fall prevention literature, a model from the Institute of Medicine in the USA would perhaps allow for a better conceptualisation of fall prevention. Winston et al., [358] described a three-tier intervention system. The first, universal level [358] would address the public health problem of falls, and target a population-based audience. Sub-groups within the population, for example, frail adults and those in long-term residential facilities may receive a special focus. Campaigns would raise awareness and promote healthy responses to fall risk, in a similar way that public health campaigns have influenced smoking risk-taking behaviour [359]. The second, selective level of intervention would allow for targeted minority groups with higher risks to be addressed. Increased risk prompts more intensive intervention [358]. Individuals with risk, but who have not yet experienced an adverse event such as a fall, would receive these interventions. The top tier would be the smallest group and would already have experienced falls, likely injurious or recurrent falls, and would require more intensive and individualised management [358]. In a resource-constrained setting, and a region in which there has been no sustained fall intervention, adoption of a tiered approach could be argued to make best use of economic and human assets.

Resources for fall prevention and intervention programmes.

The focus of this research was to extract and evaluate one element of successful fall risk reduction programmes, namely, physical exercise. An exercise programme, making use of commercially available interactive video gaming technology, the WBB, was used in a novel way to reduce fall risk by improving balance and compared with a proven programme (OEP). While a feasibility design considered issues to inform a larger randomised control trial (RCT), the effect of the interventions was assessed. Should the WBB improve balance and strength, it has the possibility to be adapted so that there is the least possible drain on skilled health care professionals. If successful, the intervention could be either self-directed or implemented with minimal assistance from ancillary staff, leaving health care professionals, for example, physiotherapists, audiologists, nurses, or occupational therapists to oversee and evaluate the programme, rather than deliver each component of it.

Human resource challenges in Africa.

Further motivation for the research is provided by the African context. Several challenges affect the availability and effectiveness of health care professionals and their services to older people. For example, migration has resulted in skilled health care professionals working in predominantly urban areas, leaving older individuals in rural areas with fewer available fewer services [302, 304]. There is a need for a larger cadre of health care professionals to service the entire population, including older adults, particularly in rural areas [360]. In addition, attrition and emigration of skilled health care professionals from LMIC, including South Africa has been well described [361-364]. A contributing factor to international migration of health care personnel is the mounting health care needs and funding for the ageing epidemic in high-income countries [365]. It is possible that better payment packages at home, and stringent rules regarding entrance into destination countries abroad may have slowed migration from South Africa [363]. Nonetheless, to stabilise the number of GPs at the current ratio to the South African population, which is critically under-serviced, the number of medical graduates needs to double within the next fifteen years [361]. GPs could be targeted as gate-keepers regarding fall occurrence in older adults.

Furthermore, the nature of health care professionals' training should shift, so that older people and their health are more of a focus [303]. Geriatric medicine is an unpopular speciality, even in high-income countries [366]. Gerontology is not part of the core undergraduate curriculum in South Africa or many other African countries [333]. Indeed, in 2015, only one of 25 medical schools in 11 countries in sub-Saharan Africa included geriatrics training in their curricula [367]. Specific to a lack of attention to the fall-related needs of older adults, Kalula and colleagues [368] presented interesting data. Their study, set in the emergency unit at one of South Africa's leading academic hospitals, suggested that the focus of casualty staff was primarily to assess and treat fall-related injuries. Emergency department staff failed to question risk factors which contributed to the fall [(333)], suggesting a missed opportunity to manage fall risk. Referrals were not made for evaluation and follow up of fall risk, despite geriatric services being available at the hospital [(368)]. Interestingly, the same hospital has a multi-disciplinary vestibular and balance service, which has never received a referral for falls evaluation and management from the emergency department. Thus, more emphasis should be placed on prevention, rehabilitation, appropriate follow-up within a multi-disciplinary team and more long-term care for older adults [(311)].

In the South African context, plans are underway to introduce mid-level, community-based rehabilitation workers to bridge the gap between doctors and nurses, and to address the human resource crisis in health care professions [(361)]. These mid-level workers would be orientated to community-based care [(362)] and could perform a pivotal role in disease prevention and health promotion activities, including falls and fall risk. Training such a corps would require a shift in attitude towards true prevention, as in many instances, health promotion education in South Africa commences only after the patient presents with a problem, rather than targeting whole communities [(328)]. Finally, primary health care facilities must be orientated to older adults, ensuring better accessibility [(50)]. Thus, unless implemented with care, fall prevention policies and interventions could be set for failure.

Part Two: Exercise-based Interventions in Community-dwelling Older Adults

> Exercise is medicine and physicians need to prescribe it!

(369 p.3)

Introduction.

Falls have been described as a “quintessential” geriatric syndrome [370] and thus, a chronic health condition which affects some older adults [370-372]. The construct of a geriatric syndrome clearly indicates that more than one factor contributes to the propensity for falls, and thus, diagnosis and treatment should be rational and focussed [373]. However, the label of a geriatric syndrome should not suggest an inevitable outcome of ageing, nor that the condition is not treatable and even reversible [373].

Of the numerous chronic health conditions common in older adults, there is quality evidence supporting the implementation of fall prevention and management strategies [343]. Considerable literature has investigated the impact of exercise programmes in independent older adults to prevent falls and associated functional decline [53, 374]. Although the role of exercise in the maintenance of health and prevention of falls and disability is accepted, Davis and co-authors [375] suggested that exercise seems not to be prescribed in clinical settings. Referring to exercise-based fall prevention programmes, the same authors criticised clinicians’ lack of universal adoption of exercise as therapy, and the dearth of widespread public health spending to this end [375].

The following section outlines the role of physical exercise to improve balance and reduce fall risk. Specific attention is given to Cochrane reviews and other meta-analyses.

Evidence that Exercise-based Interventions Improve Balance: A Critique of Systematic Reviews.

There is no other group in our society that can benefit more from regularly performed exercise than the elderly.

(376 p.864)

Cochrane review.

Howe and colleges, on behalf of the Cochrane Collaboration [377], conducted a systematic review (SR) of exercise-based intervention programmes to improve balance in older adults. Quasi-randomised and randomised control trials (RCT) were included. Cross-over designs were excluded due to the potential of the intervention/s to have a long-lasting effect [377]. Trial participants were over 60 years of age and resided in a variety of setting including institutions [377]. The inclusion of institutionalised participants is an important issue [378] and likely responsible for some skewing of the results. For example, Sherrington, Tiedemann, Fairhall, Close, and Lord [379] examined the effect of exercise-based interventions in nursing home type residential settings as part of their meta-analysis (MA) and found no statistically significant reduction in fall events. Howe et al.'s SR excluded participant groups with diagnoses of Parkinson's disease, stroke, vestibular lesions, hip fractures, and cognitive impairments [377].

Interventions had to involve muscle exercise, and could be either individually, self- or group- supervised. A variety of health care professionals and fitness instructors implemented the programmes, and in some cases the qualifications of the supervisors were not stated [377]. The diversity of settings, supervision, and commitment to group or individual exercise regimens may have an impact on adherence and thus outcomes of interventions [378]. Experimental groups were compared with either usual standard of care, or attendance at recreational or educational groups [377]. Care was taken in that control groups' contact with the research team was the same as those in the experimental interventions [377]. Hence, a positive feature of the review is that issues of therapeutic alliance [380] were similar between intervention and placebo groups, a feature adopted in the present thesis.

While diverse outcome measures were used, balance performance tests were an inclusion criterion for the SR. Howe and co-workers [377] divided endpoints into primary (e.g., TUG, Single Leg Stance, gait speed, Berg Balance Scale) and secondary (e.g., functional reach, four square step tests, figure of eight, standard, and sharpened Romberg tests) measures. The psychometrics of these measures will not be analysed here, but justification for the measures used in the present thesis is included in the Chapter VI. Methodology Chapter and related Appendices. Trials recording fall rates or the number of participants who fell, but did not include balance as a primary outcome, were excluded [377].

Exercise interventions were categorised according to ProFaNE guidelines and were:

- gait, balance, co-ordination and functional activities;
- strengthening, three-dimensional (e.g. Tai Chi, dance, yoga);
- general PA (e.g., walking or cycling);
- computerised balance training using visual feedback;
- vibration platforms; and
- multiple interventions, which were a combination of the above [377].

Intervention duration varied from one to 12 months, with the most common period of intervention being three months. Most often, exercise sessions were conducted three times per week and lasted one hour in duration [377].

Some fundamental methodological issues were revealed by Howe and co-workers. These concerns are shown in **Error! Reference source not found.** along with efforts to address them in this report.

Table 1. Methodological issues highlighted in Cochrane review and strategies to address them in the current study design.

Issue	Strategy for this report
Lack of clarity regarding randomisation.	Cluster randomisation of sites.
Difficulty blinding participants to intervention.	Cluster randomisation of sites lessened participant anxiety regarding group allocation and whether individuals were receiving the control or experimental intervention. It is not always possible to blind participants to a non-pharmaceutical intervention (381), but the nature of which intervention was experimental was concealed.
Lack of detail regarding blinding of assessors.	Single blinding was achieved in most assessments. Outcome assessor was not involved in the initial intake of participants. At follow ups, participants were shown a brightly coloured sheet, with large font, asking them not to discuss the nature of the exercise programme, and their adherence to it, with the outcome assessor. The researcher was present throughout to remind participants regularly.
Incomplete data management not described.	The design envisaged per protocol and intention to treat (ITT) analysis; thus, permitting inclusion of individuals with incomplete follow ups.
Lack of long term follow up in a sizable proportion of the studies.	Six-month follow-up planned, as this was reasonable given the age of the participants.
Attrition of participants.	As the design was a Phase II feasibility study, adherence and attrition were specific objectives to be described.
Small sample size in many of the included studies.	The feasibility study design may inform suitable future trials regarding sample size.

Results of the Cochrane review.

Exercise programmes focussed on gait, balance co-ordination and functional tasks produced statistically significant differences (signalling improvements) in primary outcome measures such as the TUG, gait speed, and Berg Balance Scale (BBS) when compared with controls [377]. Similarly, strengthening programmes showed statistically significant improvements in the TUG, Single Leg Stance (SLS) with eyes closed, and gait speed [377]. Multiple exercise interventions achieved statistically favourable results with the TUG, SLS with eyes open and closed, positive changes in gait speed, and the BBS [377]. Key recommendations were that exercise programmes had to:

- Pose at least a moderate challenge to balance;
- Have an exposure of 50 hours, that is, two hours per week; and
- Be on-going, as the positive effects are rapidly lost upon cessation [377].

Overall, Howe, and colleagues [377] concluded that there was evidence that some exercise types were moderately effective, as measured in the immediate period post intervention, resulting in clinical balance improvements in older adults. Other authors, for example, Nyman and Victor [382], have argued that the evidence to support exercise to prevent falls presented in the Cochrane review is 'robust'.

Evidence from other systematic reviews.

In contrast with Howe et al.'s [377] somewhat cautious conclusion regarding efficacy, Sherrington and colleagues' [383] meta-analysis (MA) of 54 trials, 85% of which were based in the community, provided strong evidence in favour of exercise reducing fall rates in older people. Their evidence of an overall fall reduction rate of 17% based on 9 603 participants was felt to be applicable to broad populations of older adults [383]. Note that the two reviews examined different outcomes, specifically, balance improvements versus reduction of fall rates. Differences in exercise regimens might be responsible for varied results in MAs. In Sherrington et al.'s analysis, exercise exposure was calculated as the number of exercise sessions per week, multiplied by the length of the programme. This measure was able to discriminate between more and less effective programmes and was superior to examining the weekly exercise frequency or programme length in isolation [(383)]. The minimum effective dose was found to be twice weekly sessions in a programme of 25 weeks [(383)]. Recalling that in many of the trials included in the Cochrane review [(377)] the programme duration was 12 weeks, this could go some way to explaining the difference in strength of evidence offered between the two reviews.

Balzer, Bremer, Schramm, Lühmann, and Raspe [(384)] expressed concern regarding methodological issues, with compromise of internal validity in half of the 37 RCTs in their SR. Supporting concerns outlined by the Cochrane Collaboration, shortcomings included lack of details regarding allocation of participants to groups, and lack of blinding (or reports of blinding procedures) of both the participants and investigators [(384)]. Despite these caveats, the authors found that exercise programmes may be effective if conducted consistently over a longer period of time [(384)]. The included studies comprised healthy, high functioning participants. Finally, it was suggested that the variations in the exercise intensity and delivery mode, professional backgrounds of the trainers, and length of follow-up made firm conclusions regarding the effectiveness of one type of training over another difficult [(384)].

Hill and co-workers [(378)] evaluated falls, time to fall events, and physical performance in their MA. Of relevance to this research, only home-based programmes were included [(378)]. This setting is an important selection criterion, as adherence may be different between individuals performing exercises at home as opposed to a group, centralised setting (378). Twelve trials yielded a total of 2 999 participants. Unlike the Cochrane (377) design, Hill et al.'s (378) review included groups of participants with Parkinson's disease, post-hip fracture individuals and dementia. Some of these groups could be argued to be at a higher fall risk due to the presence of a movement disorder, and likely previous injurious falls. Seven OEP trials were included in the MA (378).

Several outcome measures reviewed (378) are used in the present thesis, thus, results are presented here. The Physical Activity Scale for the Elderly (PASE)[21] is a questionnaire evaluating leisure physical activities in older adults. Questions consider the frequency and duration of activity. Low scores indicate sedentary behaviour, while high scores reflect high level PA demands being met (385). In the intervention groups, the PASE demonstrated significantly higher PA levels than for the control groups (378). Two studies examined balance outcome measures used in this report. The TUG is commonly used to evaluate fall risk in clinical and research settings (386). Analysis of TUG scores failed to demonstrate a difference between groups in Hill et al.'s (378) review. The Five Times Sit to Stand Test (FTSST) evaluates functional lower limb strength and functional changes of transitional movements between sitting and standing, and is an important predictor of falls and future disability in older adults (387). Hill and colleagues' (378) review demonstrated exercise improved scores on the FTSST. Overall, although there was no difference in the number of people who fell, levels of PA and measures of balance improved in individuals who participated in exercise-based interventions (378). Highlighted design features which enhanced success in the MA (378) were applied in the present thesis,

[21] (©New England Research Institutes, 1991)

and included a physiotherapist to supervise the exercises, home visits, and completion of exercise diaries. A cautionary note was that individualised programmes lacked the social component of group exercise classes, and required more self-efficacy from the participants [(378)].

Like Hill et al.'s [(378)] review, where a focus was fall events, Tricco and collaborators [(388)] examined the number and rate of falls, and injurious falls as key endpoints. However, all single and multi-factorial interventions were included, rather than exclusively exercise-based programmes [(388)]. The large (41 596) population pooled in the network MA were older adults from diverse settings [(388)]. While exercise interventions were found to reduce the rate of injurious falls (OR 5.1) and overall number of falls (OR 0.83); interestingly, there was no positive impact on either the number of fractures or hip fractures [(388)].

Stubbs, Brefka, and Denkinger [(389)] conducted an umbrella review of MA, which included the Cochrane reviews. The focus was independent community-dwelling older adults, and specialised populations (e.g., Parkinson's disease, stroke) were excluded [(389)]. In contrast to several reviews already cited, there were no restrictions regarding the reporting language of the initial trials or reviews of trials [(389)]. Therefore, the chance of publication bias, problematic in SR and MA [(390)], was somewhat mitigated. Another positive feature is that a standardised definition of a fall event was used [(389)]. Results were encouraging, with a reduction in fall rate, risk, and odds of falling with exercise-based interventions [(389)]. The quality of the MAs included in the review was found to be moderate to high, although poor reporting of harms, and adverse events was found [(389)]. Efforts were made to adopt a rigorous reporting strategy for injury or harm experienced during the present research.

Michael and colleagues' (391) SR similarly commented upon the small number of trials that were explicit in reporting adverse effects. However, there was no increase in falls across any of the active groups in exercise intervention trials (391), suggesting that exercise-based interventions to reduce fall risk are safe. Reduction in fall risk due to an exercise-based intervention, conducted in settings which could be used in primary care of community-dwelling older adults, was found to be 13% in the pooled analysis (391), similar to Stubbs et al. (389). Effect size was resistant to age, sex, history of previous falls and fall risk (391).

Further Cochrane reviews have been published. Sherrington and co-authors (392) updated their previous (2008) review, motivated by the proliferation of new trials. Their MA examined endpoints like the number and rate of falls (392). Special populations, including those recently discharged from hospital were incorporated but analysed separately (392). Strong evidence was found in favour of the effects of exercise to reduce falls (392). Of relevance to the present thesis, while the results were felt to be generalisable, few studies had emanated from LMIC (392). Sherrington and colleagues (393) published another review in 2019. Findings revealed that exercise-based interventions reduced the rate of falls by 23% and recurrent falls by 15% (393). Adverse effects were examined in several trials in the MA, and a median of three (range 1-26) was computed over a total of 27 RCTs involving 6 019 participants (393). The following section summarises issues arising from the critique of research already offered, and strategies to address them in this study.

Recommendations arising from critiques of research on exercise-based interventions to reduce falls.

Howe et al., **(377)** suggested that future research should conform to CONSORT guidelines, and that outcome measures should be clinically relevant. Measures correlated to functional activities should be emphasised, as these are of importance to participants in terms of ADL performance [377]. Indeed, there is little point in reducing fall risk if concomitant QoL is not similarly improved, so patient-related outcomes are valuable. In this report, outcome measures were carefully selected as participant-orientated, and not requiring the use of sophisticated equipment or intensive training for assessors, making them relevant in a LMIC context. Further considerations have emerged from literature [374, 379, 383] and influenced the design of this project. Mention is made of how the recommendations influenced study design for both the conventional (OEP) and WBB interventions. These are described in Table 2. The following chapters focus specifically on the interventions used in this feasibility study.

Table 2. Methodological concerns from literature review and strategies to address them in this study.

Methodological concern	Strategies implemented in this study
Lack of clear superiority of any one exercise intervention [374].	• Use of evidence-based intervention Otagoe Exercise Programme (OEP) for control group. • Implementation of experimental Wii Balance Board WBB intervention to evaluate feasibility and seek preliminary evidence.
Lack of consistency of fall definition [374].	• PRoFaNE guidelines for definition and description to participants implemented.
Falls and injuries should be reported, due to their implications for the individual who has fallen and use of health resources [374].	• Participants were asked regarding falls, their circumstances and consequences at every follow-up. A formal system of categorising injuries [394, 395] was implemented: □ A – Serious injury: admission to hospital/accident and emergency unit with fractured bones, head or internal injuries. □ B – Moderate injury: wounds, bruises, cuts requiring a health professional's examination such as physical examination, X-ray, sutures. □ C – Minor injury: minor bruises or cuts not requiring health professional assistance, reduction in physical activities for at least three days □ D – No injury: no physical injury detected □ E – No injury, but afraid of falling again
Activities need to progressively challenge balance abilities [374].	• Both interventions permitted progression of the complexity of the exercises.

Table 2 continued.

Methodological concern	Strategies implemented in this study
Challenge to balance should be either moderate or high [379].	• Exercises should reduce the base of support, allow movement of the centre of gravity and decrease the need for upper limb support when exercising [379]. Both interventions permitted adoption of all these recommendations.
Activities must promote rapid reactions [374] and dual tasking [396].	• WBB required participants to maintain balance, generate motor responses and cognitive engagement. • Rapid reactions are required for perturbations of balance in the control intervention. Some level of concentration is required and was encouraged by the therapist.
Recommended dose should be a minimum of two hours per week for six months, i.e. 50 hours [379, 383].	• OEP and WBB met this criterion. Participants were required to complete an exercise log and adherence was monitored with telephone calls and home visits.
Use of walking training. Walking programmes are simple for older adults to implement and are not equipment or cost intensive [374].	• Exercise models have been successful in fall reduction, whether they have included a walking component or not. However, walking may reduce the time and attention older adults give to the more targeted balance and co-ordination components of the programmes [379]. Furthermore, while walking programmes may improve overall PA levels in older adults, research is divided as to its role in fall prevention [397]. • The OEP includes a walking programme; to standardise this component a similar walking requirement was added to the WBB. • The OEP (control intervention) must be given exactly as prescribed [398] thus, no adaptations or exclusions were made.

CHAPTER IV. CONVENTIONAL EXERCISE-BASED INTERVENTIONS AND THE OTAGO EXERCISE PROGRAMME FOR REDUCING THE RISK OF FALLS

Introduction

Chapter IV is the first of two Chapters to discuss the interventions used in this feasibility study. Conventional fall prevention programmes are outlined, followed by a description of the OEP. Evidence to support the use of the OEP is offered, with a brief review of its application in high-income and LMIC. Outcomes aligned to feasibility studies, namely recruitment, attrition, safety, and adherence are considered, followed by costs of OEP interventions. Figure 8 shows the organisational flow of Chapter IV.

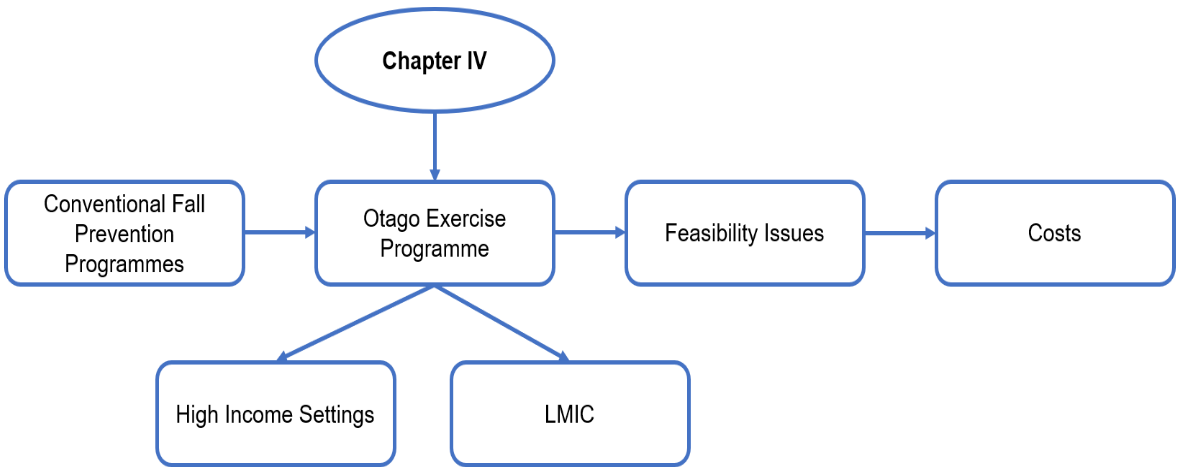


Figure 8. Organisational flow of Chapter IV.

Conventional Fall Prevention Programmes

As discussed, increasing rates of falls, injurious falls, and death-related falls are pressing concerns. For example, age-adjusted data for adults over 65 years of age in the USA showed that between 2007 and 2016, the rate of death due to falls increased by 3% per year, yielding an overall increase of 31% in a decade [247].

Should this exponential rise not be addressed, by 2030 there will be seven fall-related deaths per hour in the USA alone [298]. At the same time, exercise-based interventions which improve strength, gait, and balance successfully reduce fall risk and rate, and death-related falls [327]. One SR [391] suggested that exercise-based programmes reduced the risk of falls by 13%, while other large reviews [383, 399] cite up to a 40% reduction of fall risk. Recommendations based on moderate evidence (level B) from the USA Preventive Services Task Force, have been made in favour of exercise for community-dwelling older adults at risk for falls [400].

Efforts to introduce large-scale exercise-based fall prevention programmes have been made, particularly in the global North. In the USA, strategies include falls advocacy groups, such as the Falls Free® Initiative and a number of programmes including: the OEP [401], Matter of Balance exercise and education classes [402], Stepping On [299] and STEADI (Stopping Elderly Accidents, Deaths and Injuries) toolkits for health providers [299, 403, 404]. In Europe, regional resources include professional networks such as PRoFaNE and the Falls Prevention network [405]. National policies and efforts at screening, fall prevention and management are underway in countries such as Scotland and Eire [406, 407]. While various programmes are available, the focus is the OEP.

Some caveats regarding the literature exist. These are:

- Falls have multi-factorial causes [408] and thus, addressing one aspect, like balance, may not be the sole reason for change in fall risk status. For example, gains in cognitive function associated with the OEP may, at least partially, explain fall risk reduction [409]. Improvements in cognitive skills are noted in the following Chapter, which discusses the WBB.

- Differences in fall definitions and exercise components, end-points, and effect sizes explain variance in results from clinical trials [327]. Furthermore, specific outcomes may not be suited to collation of quality evidence, synthesis, and interpretation [408], leading to exclusion of potentially important results.
- Exercise programmes, even those focused on one type of intervention, may have different results in RCTs due to variations in the method of delivery (group vs. individual) and level of exposure (frequency, duration, and intensity) [410].
- Clinical trial populations may not resemble those for whom fall risk is typically greatest. Often, selection criteria for trials are strict, leading to exclusion of certain groups or individuals [109]. For example, there has been little attention for individuals >85 years of age, referred to as the oldest-old [411], and populations with multi-morbidities or limited English [109].

Otago Exercise Programme

The OEP is a home-based exercise programme to reduce the risk of falls in community-dwelling older adults [409]. Developed in New Zealand in the late 1990s, initial results over four trials with 1,016 participants aged between 65-97 years of age suggested a 35% reduction in fall events and fall related injuries over 12 months [53, 396]. The programme has been implemented across the world, and favourable results continue to be obtained in diverse settings [401].

The OEP was selected as the programme of choice by the Centers for Disease Control and Prevention (CDC) and USA National Council on Aging to undergo pilot studies in three American states in 2012 [396, 412]. The process to select the OEP was rigorous. The second review of fall interventions by the CDC found 22 interventions effective for reducing the rate of falls [413]. The OEP was one of three physical exercise interventions chosen based on the strength of evidence [412, 414]. American training systems enable the OEP to be delivered at a community level, while maintaining standards for efficacy [413]. Research continues regarding the OEP's implementation [401], with modifications such as using non-physiotherapist instructors [415]. Group- and video-supported OEPs have been evaluated in several countries [414, 416-418], along with adding specific vestibular exercises to a modified OEP [162]. The OEP has been implemented in trials in LMIC, where preliminary results are emerging [89, 330, 331]. The latter RCTs are discussed briefly after the efficacy of the OEP has been reviewed.

Although initially developed for community-dwelling older adults with fall risk, the OEP has been used in diverse populations. These include balance deficits [419], stroke survivors [420], patients with osteo- [92] and rheumatoid- arthritis [421], and younger adult groups with developmental and intellectual disabilities [422]. Studies have compared the OEP with different class-based exercises aimed at fall risk reduction [423], and with other forms of exercise described to be effective at reducing falls, such as Tai Chi [424]. A recent SR examined the use of video exercise and virtual-reality based programmes to improve physical performance, rather than fall risk per se, in older adults and none of the included studies compared a classically-delivered OEP with an intervention using the WBB [425]. This report, which considers the feasibility of a large RCT comparing outcomes (in terms of balance and fall risk) of the OEP with the WBB is unique.

OEP design and evidence.

OEP components include leg muscle strengthening exercises, balance retraining and a walking schedule, which increase in intensity and level of challenge over the duration of the programme [(409, 416)]. A physiotherapist delivers the OEP to an individual at risk for falls, and adjustments are made by the therapist at follow-up visits [(416)]. The OEP meets the following requirements:

- *Structured exercise intervention.* Warm up, balance and gait training are delivered consistently [(396)];
- *Evidence-based programme.* Clinical trials have shown an effect regardless of setting or instructor [(396)]; and
- *Primary fall prevention,* in that it prevents falls in those without a history of falls [(416)].

A key construct underpinning the success of the OEP is that the moderate to high intensity challenges to balance have a protective effect on the rate of falls, amounting to approximately 25% [(383)]. The precise mechanisms by which programmes such as the OEP reduce falls remain unclear [(410)].

It is possible that the OEP may reduce falls by improving executive function, for example, working memory [(409)]. Liu-Ambrose and colleagues [(409)] conducted a well-designed, albeit underpowered RCT of the OEP and a control group of frail older adults with a history of falls. Measures included several selected for the current study, such as the PASE, Functional Comorbidities Index and TUG. The OEP group experienced a 47% decrease in fall events at one year [(409)]. Interestingly, there was no significant changes in functional mobility (TUG) after six months, suggesting the gain experienced by the OEP individuals was not exclusively physiological [(409)]. This reduction in fall risk was attributed to improved cognitive and executive function [409], a construct later referred to as the central benefit model [426]. The evidence from MA of the OEP is presented next.

One of the early publications concerning the OEP demonstrated a reduction in falls and injurious falls of 35% in community-dwelling older adults, with maximum benefit experienced by participants ≥80 years of age [394]. A 2010 MA [53] explored single-blinded RCTs of the OEP, four of which originated from the intervention developers. All the trials used a standard definition of falls as per PRoFaNE's recommendations. Seven studies, with a total of 1 503 participants, were included. Sources of bias were at times unavoidable [53]. For example, it is frequently not possible to blind participants and therapists to the nature of the intervention in non-pharmacological trials [427]. The MA did not focus on outcome measures which concerned balance, gait or QoL; rather, endpoints were programme adherence, adverse events, falls, attendant injuries, and mortality [53]. Thomas, Mackintosh, and Halbert's [53] findings noted a significantly reduced risk of falls and death in older adults participating in the OEP. Unlike previous findings [394] the rate of injurious falls did not decline [53]. The included trials were high quality, but a homogeneous population was likely due to the origin of some of the reports [53]. Adherence and safety will be discussed under a separate heading.

OEP in LMIC.

There is scant literature regarding the OEP in LMIC, although studies have emerged from India [428], Iran [331], and groups in Thailand [330, 429] and Malaysia [89, 430]. The results from Malaysia await publication [215, 431]. A small (30 participants) pre-test post-test study from India [428] had several apparent methodological challenges. These included a short (six week) exposure to the programme, a lack of details regarding power and effect size, lack of blinding and a control group, and no prospective recording of falls. However, the authors declared findings as clinically significant, with improvements in balance and strength and reduction in over fall risk from moderate to low [428].

An appropriately powered and well-designed RCT was conducted with Iranian adults ≥60 years of age with a history of falls [331]. In contrast with the studies conducted in Thailand (described below), positive results were found in the OEP group. Statistically significant improvements were found in key endpoints, such as the TUG, BBS, and 30 second sit-to-stand test, as well as the rate of falls [331]. Possible contributing factors to success in the Iranian study include a physiotherapist-delivered programme, an unmodified OEP, younger participants, and finally the presence of a female care-giver who was judged to have appropriate levels of health literacy [331]. Such a care-giver may positively impact adherence.

Studies from Thailand were similarly well designed and found poor results in terms of benefit. Boongird, Keesukphan, Rattanasiri, and Thakkinstian [330] used stringent procedures for their RCT. A standardised definition of falls was provided; and outcome measures were those commonly used in falls research (fall events recorded on a calendar; TUG, BBS, FTSST, and QoL measures) [330]. The OEP was modified by combining and simplifying the exercises, and a video and training with a nurse was provided [330]. Although recruited from a primary care service at a university hospital, participants were community-dwelling older adults with a mild to moderate balance disorder [330]. The presence of a balance disorder was implied by either the use of a cane to walk, or abnormal functional reach and FTSST scores. A previous fall was not a selection criterion [330].

A non-statistically significant reduction in the rate of falls was found in the intervention group [330]. No differences between groups were found for the physical endpoints or QoL measures, but fear of falling was reduced in the OEP participants. Adherence to the OEP was poor, with less than one third (29.6%) of the 219 participants recording over 120 minutes/week (good adherence) at three months post trial induction. Very few (13%) OEP participants received home visits [(330)]. The lack of home supervision is likely a sizable contributor to the results, as supervision is a key component of the OEP; as is delivering the programme precisely as outlined by its developers [(398)]. A positive feature of the study is that the participants were heterogeneous [(330)] and represented a typical profile for older adults, in terms of multi-morbidities and medications.

Another RCT from Thailand recruited participants ≥60 years of age and provided a four-month OEP intervention with home visits by a physiotherapist [(429)]. Falls and exercise sessions were recorded. Physical endpoints included functional reach, FTSST, and TUG including dual-tasking. Results were analysed on an intention to treat (ITT) basis [(429)]. Unlike Boongird et al.'s [(330)] study, high levels of adherence to the programme were noted. Despite this, and a multi-factorial intervention including medication review and home hazard modification, no significant difference in fall events was found between the OEP and controls [(429)]. The researchers posited that programme duration and younger, presumably fitter, participants may account for the differences between their and other published favourable results [(429)]. Thus, well-designed RCTs conducted in LMIC did not produce congruent results, leaving questions as to its applicability in such regions. All trials presented here raised contextual issues, which may be applicable when considering adoption of conventional exercise-based programmes in South Africa.

The OEP has several features which made it suitable for implementation as the control intervention in this research and these are tabulated in Table 3. Adaptations to the WBB are suggested to make the two interventions comparable in certain aspects. The following section will present feasibility issues which are pertinent to this trial.

Table 3. Features of Otago Exercise Programme (OEP) and adaptions to Wii Balance Board (WBB) for this study.

Requirements of the interventions	OEP (Control intervention)	WBB programme (Experimental intervention)
Non-selective intervention.	Single, exercise-based intervention.	Single, exercise-based intervention.
Home-based programme aimed at community-dwelling older individuals.	Programme designed as such.	Programme given as such.
Level of customisation.	Important concept in programme.	While not customisable, the WBB programme was made more challenging each week.
Ideal regimen is 50 hours.	30-minute sessions at least three times per week PLUS two walks per week.	Sessions were compiled with the same frequency and a walking component added.
Progression in level of challenge to balance – e.g. more repetitions, more difficult exercises, more time walking.	Guidelines laid out in programme.	Games have increasing levels of complexity/difficulty to allow progression.
Effect of contact with therapist.	Five home visits, monthly telephone contact.	Implemented with same level of contact.
Tracking of adherence.	Specified in programme with monthly calendar on which exercise sessions and walks are indicated. Reminders given either at follow-up visit or phone call.	Identical to OEP.
Falls diary.	Provided along with the exercise calendar, and used classification of serious, moderate and no injury [53].	Identical for all groups.

Feasibility Considerations

Recruitment and attrition for OEP trials.

One of the endpoints of Thomas et al.'s [53] MA was attrition. Attrition was generally low, with data being available for at least one of the key outcomes in more than 80% of the participants [53]. Table B.2 in Appendix B shows enrolment and attrition data extracted from a sample of OEP studies from the global North and LMIC. The following definitions were used to calculate the data:

- Target population: the pool of potentially eligible candidates for the trial [79]. The target population speaks to the generalisability of a study [432].
- Eligibility fraction: the proportion of the target population who undergo screening and are found eligible to enrol [79].
- Enrolment fraction: the number who are eligible, give informed consent, and actually enrol in the trial [79, 432].
- Recruitment fraction: the number of potential participants who actually enrol in the trial [79], calculated by the product of the eligibility, and enrolment fractions [432].
- Number of patients needed to be screened (NNS): the number of patients who needed to be screened in order to randomise one patient, calculated as $\frac{\mathbf{1}}{\boldsymbol{recruitment\ fraction}}$ [79].

Of interest in Table B.2 is the highly variable NNS, which ranged between 1.26 – 5.88. Having to screen almost six potential participants to recruit one is expensive and time-consuming, an important consideration in clinical trials. Studies' attrition rates varied. Most encouraging was a Canadian study which reported OEP participant attrition of 9.6% and 14.2% for the controls [426]. A trial in the UK reported 30% attrition [162]. Data from LMIC were similar or worse, with an Iranian study, which coincidentally had the highest NNS, having well over one in three participants (41.9%) not available at the endpoint (331). With the exception of one Thai (429) study, there is little difference in attrition between experimental and control groups.

Safety and adherence for OEP trials.

Safety and adherence were addressed in Thomas, Mackintosh, and Halbert's (53) MA. In the studies which discussed safety, overall six adverse events occurred; which included three falls, pain related to exercise, and one moderate injury which was not the result of a fall (53). Six of the seven included studies presented adherence data. Of 747 participants who were retained at 12 months, over one third (36.7% ± 15.8%, range 18 – 63%) were exercising three or more times per week. Over half (55.9% ± 14.8%, range 36-72%) were exercising twice per week at the 12-month point (53). However, safety and adherence data are inconsistently reported in the literature. For example, Patel, and Pachpute (428) failed to mention either. Table B.3. Trials of OEP: adherence, safety and outcome measures. outlines previously-mentioned studies in terms of adherence and safety/adverse events. Outcome measures are shown and are discussed in the Methodology Chapter and Appendices.

Costs of fall prevention programmes including the OEP.

Frick, King, Parrish, and Narrett (433) noted the dearth of research on the cost-effectiveness of fall prevention interventions. Indeed, at a time where there are increasing calls to introduce population-level interventions (109), evidence for their cost-effectiveness must be proven. Despite guidelines (434) recommending methods to evaluate fall prevention programme costs, this aspect remains under-developed.

The OEP was one of three evidence-based fall prevention programmes subjected to a cost-benefit analysis, where key considerations included feasibility, effectiveness and return on investment (435). The following calculations were computed:

- Average cost of programme per participant calculated by:

$$\frac{Total\ cost\ of\ intervention}{Total\ number\ of\ participants}$$

- Net benefit (benefit from averting medical costs attributed to an injurious fall after subtracting the intervention costs).
- Average expected benefit, a subtraction of the direct medical (fall-related) costs for an intervention participant from the direct medical costs of a non-intervention individual.
- Return on investment (ROI) is the percentage of return for each invested dollar. The magnitude is the extent to which the programme benefits exceeded the programme costs, expressed in a percentage (435).

The average cost of delivering the OEP was US$339.15 in 2012 US$; average expected benefit was US$461, while net benefit was US$121.85 per participant (435). A positive ROI was found with a 36% return for every dollar invested. When individuals over 80 years of age were analysed separately, results were even more impressive. Due to the increased likelihood of falls, and more serious injurious falls, average expected benefit increased to US$768.33; the net benefit rose to US$429.18 and ROI to 127% (435).

Although the participants included in a cost-benefit analysis in the United Kingdom had rheumatoid arthritis, the average age was 62 years (421). Here, the cost of delivering the OEP amounted to US$314.34 in 2016 US$ for one year; average expected benefit was US$1304, and the ROI amounted to over 100% (421). Costs were similar to those incurred in the USA study cited above, and high levels of ROI were apparent in both studies. Thus, research suggests the OEP has been shown to be effective, cost-saving in terms of net benefits and offers a substantial return on investment.

While the few studies specific to the cost-effectiveness of the OEP have been discussed, results of reviews of programmes such as the Matter of Balance programme are relevant to the context of this study. The Matter of Balance programme was developed as a high priority prevention and health promotion programme to improve health and reduce medical expenses of Medicare recipients in the USA [(436)]. Reductions in unplanned hospitalisations, decreased spending on health-related expenses and service utilisation resulted from the programme [(436)]. In challenging healthcare settings such as South Africa [(437)], the ability to plan for service supply and demand is essential. Other key lessons from a review of the Matter of Balance programme of relevance for South Africa include:

- Targeting of programmes in areas where a high concentration of older adults reside [(402)]. Thus, programmes might commence in centres for older adults before being replicated on a scalable level.
- Training of volunteers to deliver the programme [(402)]. Volunteerism is influenced by cultural norms, which in turn may facilitate or obstruct volunteering [(438)]; however, in the South African milieu, the collectivist spirit of *Ubuntu*[22] could have a positive influence of volunteerism [(439)].
- Advocacy for completion of programmes, by managing barriers of individuals' capacity for adherence [(402)].
- Commitment to large scale, population-based fall prevention programme delivery [(402)]. Such commitment requires political will, present in the global North and discussed in previous Chapters; but as yet, not implemented

[22] See Glossary of Terms.

well in South Africa. It is hoped this study and subsequent work may generate data to place falls in older adults on the agenda.

CHAPTER V. EXERGAMES AND EVIDENCE FOR THE WII BALANCE BOARD AND FALL PREVENTION

Introduction

This Chapter is arranged in two parts. *Part One* introduces serious games and exergames as a rehabilitation tool. Motivation for the use of technology is considered in an international and local context. One of the commonly used commercial applications of exergames, the WBB is explored in detail. A novel aspect of *Part Two* is the comparison between knowledge of principles underpinning the success of vestibular rehabilitation therapy (VRT) and how these might contribute to the putative success of exergames for improvements in balance and reduction of fall risk. *Part Two* examines the evidence for WBB with reference to balance and falls and highlights methodological issues with published studies. Figure 9 depicts the organisational flow of Chapter V.

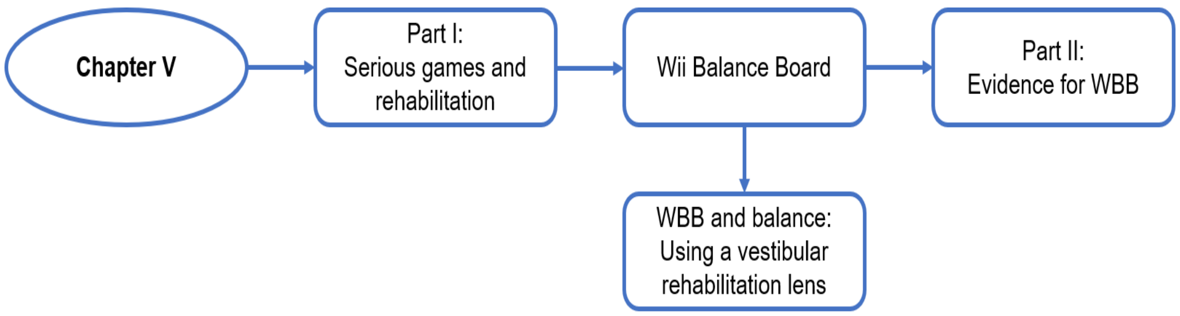


Figure 9. Organisational flow of Chapter V.

Part One

Serious Games in Context

> Technology is nothing. What's important is that you have faith in people, that they're basically good and smart, and if you give them tools, they'll do wonderful things with them.
>
> Steve Jobs

Serious games are computer games with functions other than pure entertainment and have applications in health, corporate and military training, and education (440). In the health and rehabilitation context, serious games refer to the use of commercial games, such as the WBB, as therapy tools (441). Active video games, also referred to as exergames, are interactive video games which require physical activity (PA) from the player to drive the game (425, 442). Exergames provide a combination of exercise, fun and entertainment (443), the latter two being appealing features for users. The following discussion focuses on the WBB, used in this report, and no other products using similar technology, such as the Xbox Kinect™. Furthermore, custom-designed immersive virtual reality paradigms have been excluded from this section. True virtual reality systems are more expensive than commercial exergames and are often only available in specialised settings (441), making them unsuitable for the context of the present thesis. The WBB was in common use[23] during the design phase of the study, as evidenced by SR discussed below. The Wii Fit Plus programme was hugely successful, with over 22.67 million units sold worldwide by 2018 (444).

[23] However, Nintendo has since announced its production has been halted in Japan and Europe. A brief search of commercial online stores such as Amazon conducted 25.11.2019 showed continued availability. Nonetheless, it is hoped that the results of this report may be useful in planning interventions using similar devices in future.

The advent of serious games has attracted new audiences previously disinterested in videogaming, for example, women and older adults [(66)]. The introduction of the WBB was an attempt to challenge perceptions of videogaming as exclusive to sedentary young people [(445)]. Nintendo® specifically targeted an older adult audience with the Wii, as the company perceived this population as a growing market with spending power [(445)]. While the use of digital games by adults over 50 years of age varies according to the country, the possibility of using technology as a sustainable way to potentially treat the sensory-motor decline of older adults should be explored as an accessible and legitimate form of intervention [(446, 447)].

By using interactive technology to sharpen cognitive, sensory-motor abilities and even socio-emotional well-being, successful ageing, and maintenance of independence could be promoted at a population level [(417, 448-450)]. In countries like the USA and United Kingdom, more than half the population of older adults have internet access and use digital game technology [(451, 452)]. Individuals with high incomes may well have better access to technology to improve their health; therefore, it is important that technological interventions are delivered with care, to avoid exacerbating the disparity between well-resourced and underserved populations [(453)]. Rural and disadvantaged populations are at risk of being excluded from technology, a phenomenon described as the digital divide or digital exclusion [(454)]. Global efforts strive to increase access to the internet and telecommunications [(455)]. In South Africa, a country plagued by inequality and a heterogenous society [(456, 457)], policies such as South Africa Connect, instituted in 2013, aim to provide broadband capacity to all South Africans by 2030 [(455)]. South African legislation prioritises access to information technology as a key measure in poverty alleviation [(458, 459)]. Even in settings where technology may not be currently accessed by large sectors of the population, particularly poor socio-economic groups such as South Africa [459], the potential for computer-assisted rehabilitation exists. In the case of the WBB, there is no reliance on internet connectivity or dedicated computers, rather a console and balance board interface with a television. Equipment could be placed at community centres, clinics, churches, and other meeting places to ensure maximum use by a cross-section of people.

Motivation to use an exergame intervention in this study.

There is an abundance of research concerning the use of exergames [460]. Research reports have considered exergaming for the rehabilitation of numerous conditions, including traumatic brain injury [461], Parkinson's disease [462, 463], stroke [464], multiple sclerosis [465, 466], balance and vestibular issues [467-471], and fear of falling [472]. Amelioration of balance issues in older adults has been a key focus for exergaming interventions [460]. SRs have demonstrated supervised balance training using exergames to be efficacious, with results suggesting outcomes at least as good as conventional balance exercises [441, 473]. However, valid concerns remain regarding varied outcomes and reporting, methodological issues, and cost-effectiveness [417, 450, 474]. Feasibility is particularly poorly described [475]. This research hoped to address some of these questions.

Routine rehabilitation exercises given in physiotherapeutic treatment can be repetitive and uninteresting for patients [473]. Boredom may contribute to poor motivation and adherence levels [476]. In contrast, the fun element of incentivises individuals and encourages physical activity (PA) [474]. Enjoyment and the engaging nature of exergames [477] may allow patients to focus less on their physical conditions, and more on their continued interaction with the games [449, 478]. Exergames may promote self-efficacy [474], a concept explored later. Active videogaming may allow for increased and more accurate repetitions of exercises [473, 478] without the onset of tedium. Importantly, overall training time may be augmented [478]. Sufficient exposure to rehabilitative exercises is necessary for forging changes in neural plasticity [449] and in this instance, improving balance.

Persuasive reasons to evaluate the role of technology in rehabilitation exist. Issues of access, resources, and costs have the potential to be delineated in research. In high income countries, the use of technology to deliver intervention programmes can be cost effective and easily accessed by individuals in their own homes [479, 480], an important consideration with older people who may have difficulty accessing formal services. Numerous questions arise when such programmes are introduced in LMIC, some of which the present study hoped to address. Although Africa and South Africa trail behind other regions towards progress for technological innovations to be made available to all, the wide (90%) access of the population to mobile telephones, a similar figure to the USA [481], holds promise as a delivery method for health information. Overall, using technology as a tool for rehabilitation has potential to change the face of health care, as acceptance of tele-health continues [482-484].

Research on the Wii Fit for Balance Rehabilitation and Fall Prevention

Introduction to the Wii Fit and Balance Board.

The Nintendo Wii Fit (2006) was one of the earliest videogame consoles, which used the motion of the player's body to drive the game [441]. The Balance Board™, a force plate which measures the centre of pressure of the body, was added a year later [441]. The WBB was the first commercially available gaming system to use a built-in sensor in its balance board, which gives real-time feedback to the player by detecting his/her weight-shifting [485]. The WBB system is connected to a television, and the user stands on the balance board while holding a wireless remote control [486]. A 3-dimensional accelerometer responds to changes generated by the player's direction, speed, and acceleration of movements [485]. WBB activities and games are designed to enhance balance, promote adaptation of visual inputs, strength, and aerobic function [486, 487]. Players use unanticipated movements to play the games [487, 488]. Games include yoga, balance activities, and aerobic and strength programmes, which have progressive levels of difficulty [489]. Scores for each game are given on completion of the activities, so users can evaluate their progress [489]. An avatar gives the player further auditory and visual feedback and encouragement [480]. The system was introduced in the United States in 2008 and proved popular, selling over five million units within the first nine months [490]. The WBB has been favoured by rehabilitation professionals and is thought to be widespread in implementing therapy for diverse patient populations [491-493].

The manufacturers of the WBB marketed the system as a tool to improve fitness, and there is some evidence to support this. Fitness video games have been shown to result in energy expenditure similar to a moderate intensity PA [229, 494], and thus, can be effective in promoting physical health [495]. Importantly for older adults, exergames could prompt sedentary individuals to commence more PA as part of an active lifestyle [496].

While the moderate energy expenditure measured during active videogames is recommended for older adults [229], certain challenges remain when using exergames as a fitness intervention in this population. These include:

- Historically, manufacturers have not targeted older adults as audiences for videogames [448], so some features could be unsuitable. Games do not necessarily consider the diversity of older adults' physical and functional capabilities or diseases [497].

- High-intensity games tend to require more videogaming skills [496]. Older adults who are not computer-literate may experience difficulty playing exergames [498]. Recent research into older adults' gaming experiences, preferences and design recommendations has been conducted [499]. It is likely that such research interest has been motivated by older adults' acceptance of gaming.
- Commercial games have not been created for rehabilitation purposes [448] and thus, benefit may be less than customised therapy provided by a rehabilitation professional.

Despite these concerns, the low cost, ability of exergames to increase PA in older adults [500] and ease of access, warrants thorough interrogation into benefits. The following section considers how exergames foster improvements in balance capabilities, prior to reviewing the evidence for the use of the WBB to improve balance and postural control.

Balance theory, Conventional Vestibular Rehabilitation and the Potential for Exergames to be an Effective Intervention for Balance Deficits

Introduction.

This section introduces conventional vestibular rehabilitation therapy (VRT) and the core physiological processes contributing to patient improvement. It is likely that programmes using the WBB incorporate similar processes, but not exclusively. Theoretical hypotheses which could be responsible for improvements in balance due to the WBB are outlined. Literature has not cohesively described such constructs, nor have they been presented with reference to VRT principles. Doing so may further understanding of the putative mechanisms for exergaming's success.

Conventional VRT and fall programmes.

The objective of rehabilitation is to provide training, which will result in functional improvements (140). VRT[24] aims to reduce symptoms of balance deficits like dizziness and oscillopsia, improve gaze and postural stability, and reduce the risk of falls (501). The ultimate success of VRT depends on a combination of stimulation of motor and sensory systems, cognitive, and psychological process, and not exclusively muscle and strength training (502). Most VRT programmes utilise exercises which enhance recovery processes by driving responses to error signals[25] (503). Key physiological processes underpinning recovery from vestibular and balance deficits include adaptation, sensory substitution/reweighting and habituation[26] (42, 64, 65). There is a strong body of evidence to support the use of VRT as treatment of choice for various vestibular and balance conditions (163, 504, 505). Moreover, VRT has been shown to be effective in reducing fall events in older adults (506).

Conventional fall prevention programmes including the OEP specifically target balance and gait difficulties, and prescribe exercises to improve both (507). Many of the OEP exercises resemble components of VRT programmes, such as walking exercises (e.g., walking and turning, walking backwards and heel-toe) and standing exercises (e.g., single leg stance) designed to challenge balance (508). However, OEP and WBB are not synonymous with VRT, rather, they include components typical of VRT treatment plans. The inclusion of the balance and gait exercises in

---

[24] All concepts referred to are defined in the Glossary of Terms.
[25] See Glossary of Terms.
[26] See Glossary of Terms.

the OEP is fundamental to its success. The benefit of the walking component is controversial. Sherrington and colleagues' [383] meta-analysis suggested that walking programmes increased fall events. As previously noted, the populations in the reviewed trials included groups particularly vulnerable to falls. Research from Japan challenged Sherrington and colleagues' [225] findings by suggesting that walking reduced falls, but increased the rate of trips, when compared with a balance programme alone [509]. The participants' balance programme incorporated exercises from the OEP and Tai Chi [509]. Stringent selection criteria made the study less generalisable. Although not specifically commented upon, Okubo and colleagues' [368] participants appeared to have body mass indices (average 22.7) within a healthy weight range [510]. This demographic is likely different to the global North and some emerging nations including South Africa, which face an obesity epidemic [511, 512]. Moreover, obesity is associated with reduced likelihood of participating in fall prevention exercises [513], and thus, adherence may be different in the Japanese cohort.

Theoretical constructs supporting the use of exergaming.

Similar to the discussion of the OEP in previous Chapters, the precise mechanism behind the WBB improving fitness, psychological wellness and fall risk is mostly unknown [514]. As noted, the light [515] to moderate [477] energy expenditure playing exergames is unlikely to reduce falls by a simple improvement in fitness alone. One way to evaluate exercise-related energy expenditure is to use a rating scale, such as the Borg Ratings of Perceived Exertion (RPE) [516]. Individuals rate how hard exercise is on a 16 point linear scale [517]. The selected level is then multiplied by a factor of ten to give an approximate heart rate [517]. The Borg RPE has been shown to be a valid tool for use with WBB exercise programmes [518].

Taylor et al., (514) examined participants' physiological effort using WBB contrasted with conventional physiotherapy-based fall prevention exercises. Energy expenditure for the WBB programme was approximately one third less than that required for VRT (514). Interestingly, RPE has been shown to be reduced compared with physiological findings (e.g., heart rate) when playing WBB, putatively linked to the visual and auditory distractions involved in the interactive process (518), which may have partially accounted for Taylor et al.'s (373) findings.

Central, brain, and psychological processes could contribute to improvements. Exergames may promote learning, in terms of neuroplastic adaptation (519), discussed further in Table 4, as well as training, that is, musculoskeletal adaptations (378). Some exergames resemble exercises incorporated in balance training and Tai Chi, both of which have been proven to reduce the risk of falling (479, 520). WBB stepping, weight-shifting, Tai Chi-, and yoga-like poses extend the players' centre of pressure and mass and could well be a mechanism behind balance improvements. Furthermore, rapid head movements and changes of fixation to maintain steady visual fields when playing might enhance gaze stability in similar way to conventional VRT. Gains made with exergames might be transferable to real-life movements (521). Reviewing of established VRT principles and proposing translations into WBB interventions is expanded upon further in Table 4.

Table 4. Hypotheses underpinning therapeutic strategies* to improve balance using conventional VRT and exergaming programmes

	Neural reorganisation.
Hypothesis	• (Hebbian principle of neuronal network plasticity) [65] • Sensory systems are prompted to interact and integrate within the central nervous system (CNS); and produce the correct cues and responses necessary for postural control and movement. • Active training and PA promote structural and functional reorganisation in the brain [64, 65, 73, 448, 522].
Advantages of a conventional VRT programme	• Customised therapy identifies an individual's deficit/s and prescribes exercises to promote neural reprogramming and recovery [73]. • Issues such as fatigue or induction of symptoms [523] may be monitored by the therapist, and activities varied allow for recovery within a session. • Reorganisation is experience-dependent [65].
Disadvantages of a conventional VRT programme	• Literature suggests Cawthorne-Cooksey exercises are still prescribed as part of VRT [524]; or instead of VRT [17] however, they must be customised to be most effective. • Although evidence is not conclusive, customisation of therapy appears to optimise results [525]. • Should the therapist lack the training or skills to make such adjustments, outcomes may be sub-optimal. Close monitoring of VRT patients results in better outcomes [527]. • Limited interaction with the therapist due to resource constraints (time, costs, therapist availability) may result in less exposure and thus, reduced adherence, as well as a lack of precision when doing exercises [528]. There is evidence that poor adherence negatively affects outcomes in VRT [529].Adherence to VRT is under-reported, but likely to be low when done at home [528].
Advantages of an exergames programme	• Exercises are demonstrated for the player to copy or respond to, and real-time feedback is provided [485]. • Repeated modelling and feedback may prevent mal-adaptive behaviours commonly adopted due to fear of falling [448, 526]. • Visual cues from the WBB provide feedback and reduce postural sway [502]. • The fun component may enhance motivation to play[521].
Disadvantages of an exergames programme	• Programmes are non-customised and not designed as therapy [448], nor are they developed in accordance with basic exercise principles [500]. • Games may lack levels of adaptation and integration, which would make them suitable as therapeutic tools [522]. • Fatigue during games may lead to abandonment of the session.

Table 4 continued

	Dual-tasking.
Hypothesis	• Dual-tasking is the performance of two different, but interacting tasks, which share attentional functions, for example, balance control and a cognitive task (530). An example pertinent to older adults is walking while talking (531), • which declines with age (532). • CNS balance integrators pool resources with centres for higher cognitive processing (533). Ageing may cause cognitive-motor interference, affecting reactive balance (533). In particular, cognitive demands hamper motor tasks (538) and postural stability is governed by the ability to allocate attention to the balance task (539). Thus, walking with an additional dual task has a negative impact on walking stride, cadence and gait (215). • Prolonged response times for self-initiated perturbations of balance and reactive balance increase fall risk, and both are exacerbated with dual tasking (220).
Advantages of a conventional VRT programme	• Therapists interact with the recipient during therapy. Having to engage with the therapist while doing balance-related tasks could be a form of dual-tasking.
Disadvantages of a conventional VRT programme	• Therapist-patient exchanges may be superficial and clinician-dominated, and potentially not fully engage the patient (534). Trivial conversation requires little cognitive effort (535) and as such dual-tasking may not be assured.
Advantages of an exergames programme	• Having equipment accessible might promote activity at home, overcoming common mobility problems experienced by older adults (536). • Dual-tasking is fundamental in exergaming (e.g. having to focus on the avatar and respond appropriately with body movement in a sustained way). Dual-tasking interference causes smaller centre of mass excursions (533). • These may be addressed by being forced to play on the balance board, capable of sensing such movement Interaction with the games may promote plastic changes, due to having to manage balance interference along with additional cognitive loads (533). Needing to respond quickly to the avatar may help reduce prolonged reaction times caused by dual-tasking in ageing (533). • Videogaming has been shown to improve task-switching, response speed and reaction times (519), all of which would be helpful when dual tasking. There is some evidence that employing techniques of dual-tasking during therapy improves results when compared with conventional therapy for fall prevention (540); and exergaming requires constant dual-tasking.
Disadvantages of an exergames programme	• If tasks are too complex, and not suited to older adults' interests, they may cease to play (537).

Table 4 continued

	Adaptation** (exercises to increase vestibulo-ocular reflex [VOR] gain) [42, 76].
Hypothesis	• Mismatch of signals is important to prompt adaptation to sensory loss [64]. • Speed of head movement may have an impact on outcomes. • High velocity, short bursts of x1 exercises with forced use balance and gait exercises have proved successful [542].
Advantages of a conventional VRT programme	• Achieved by using exercises such as x1 and x2 [76]. Exercises are prescribed, demonstrated and monitored by therapist to ensure they are performed correctly.
Disadvantages of a conventional VRT programme	• Patients do not necessarily continue to exercise correctly at home. Frequent, recurrent practice is necessary, and this requires perseverance from the patient.
Advantages of an exergames programme	• Retinal slip may be caused by realistic visual environments in games, thus, encouraging adaptation [541]. • Rapid head/eye body re-fixations could mimic traditional adaptation exercises. • Games may improve visual-motor performance and increase contrast sensitivity of the eye [519]. Visual information is effective in prompting reorganisation of sensorimotor circuits [541]; and exergames provide rich inputs.
Disadvantages of an exergames programme	• Mechanism of how information is processed by the CNS is not fully understood [502] and thus, could inhibit optimal design of targeted programmes. • The amount of exposure required to promote and maintain recovery is not well described[541]. • Speed of head/eye movement is uncalibrated and may not be within therapeutic range. For example, if visual smearing caused by very rapid head movement occurs [543], then adaptation will not be promoted.

Table 4 continued

	Sensory reweighting.
Hypothesis	• Feedback regarding body motion is correlated by the CNS with input from intact senses [502]. • Each incoming signal's importance is evaluated and changed to reduce awareness of the deficient signals [64]. • Strong evidence for sensory reweighting is lacking [502].
Advantages of a conventional VRT programme	• Managing sensory input should be specific to the patient population and individual [6, 544]; thus, avoiding complications such as visual dependence in patients with vestibular deficits [545].
Disadvantages of a conventional VRT programme	• VRT is most effective when customised [529, 544]. Exercise prescription must be tailored to accommodate individual and pathological considerations (e.g. older adults, vestibular deficits) [6]. • Thus, therapists require enough training and knowledge to ensure a patient-specific programme is prescribed.
Advantages of an exergames programme	• Visual cues provided during play may decrease postural sway [502]. • Virtual reality (and by extension, WBB games) can drive discordance between visual- vestibular stimuli. Interaction between vision and inertial detectors in the vestibular and somatosensory systems may promote autonomic motion responses [6]. • Games encourage centre of pressure displacement and feedback given may reduce reaction times positively.
Disadvantages of an exergames programme	• Designers of exergames may lack knowledge of physiological processes which drive improvements in balance. Games need to produce movements which are specific to the function requiring rehabilitation/training [502].

Table 4 continued

	Sensory substitution.**
Hypothesis	• Pre-programming of saccadic eye movement in vestibular deficits may be important, especially in cases of bilateral vestibular hyperfunction [64, 529]. • Vestibular loss in old age is presumed to be bilateral, although there is some evidence of asymmetry in older adults who have sustained injurious falls [546].
Advantages of a conventional VRT programme	• Therapist can ensure exercises (e.g. 'remembered' target) are done correctly to foster sensory substitution using gaze stability strategies [547]. The therapist may use measures like visual analogue scales during treatment sessions to monitor induction/ exacerbation of symptoms [505], and modify exercises where appropriate.
Disadvantages of a conventional VRT programme	• Many exercises in conventional VRT use static visual cues [64, 529]. • Tracking eye movements, combined with moving the head and body, are experienced in daily life, and exercises should mimic this scenario [529]. Thus, complexity is required and may be difficult to emulate in a conventional therapy setting.
Advantages of an exergames programme	• Exercises encourage eye tracking of targets combined with body movement. Level of challenge can be increased.
Disadvantages of an exergames programme	• As above, if games are too rapid then gaze stability will be lost, and positive plastic changes may not occur. Games may be frightening for older adults [42].

Table 4 continued

	Postural stability.
Hypothesis	• In motor-adaptive behaviour theory, feedback systems require sensory input [538]. Reactive and anticipatory responses are driven by the feedback system and control stability [538]. • Feed-forward circuitry uses predictive mechanisms and thus require previous experience [538]. Feed-forward capability can foster new or adapted movement patterns [387]. • Older adults are vulnerable to impaired reactive adaptations and walking becomes negatively affected [538] . • Sensory systems referred to above have intrinsic redundancy and share properties of the feedforward mechanisms which contribute to postural control [64]. Feed-forward models are generated by ADL and can be enhanced with postural training [64].
Advantages of a conventional VRT programme	• Postural stability is dependent on the ability to attend to the balance task [539]. Balance, postural stability and gait training are incorporated into VRT [160]. • Should treatment exacerbate symptoms [528] or produce near fall, the therapist can tailor programme to maintain the patient's confidence.
Disadvantages of a conventional VRT programme	• Training is effective, but five supervised therapy sessions are required to produce a clinically significant improvement [528]. It is likely most patients receive two sessions and 'do it at home' is less effective [528].
Advantages of an exergames programme	• Challenging exercises requiring postural control may train sensory systems integrated in the CNS to produce correct cues for posture and motion [64]. These skills could be transferable to daily life. • Sessions are likely to be repeated frequently due to the fun aspect [443]. • Cognitive processes required during play may assist with predictive control and improve motor tasks [538].
Disadvantages of an exergames programme	• The lack of a therapist to direct attention to balance specifically may result in sub-optimal activation of feedback responses. • Loss of interest and difficulty remembering routines may limit exposure and thus improvement [548]. Fear of falling and injury may inhibit play.

Table 4 continued

Hypothesis	**Cognitive and psychological aspects including fear of falling.**
Advantages of a conventional VRT programme	• Evidence that VRT can improve cognitive function (visuo-spatial ability, tracking tasks, attention and executive tasks) exists [549]. VRT has a positive effect on psychological aspects of anxiety and depression [550].
Disadvantages of a conventional VRT programme	• VRT outcomes in patients with concurrent psychological issues may be more guarded than in those without anxiety and depression [551].
Advantages of an exergames programme	• There is low quality evidence in support of exergaming having a moderate significant difference for tracking tasks requiring cognitive function, but not for fear of falling [417, 480]. • Cognitive components can be added to exergames easily, such as introducing forced choices while exercising [552]. • Players focus on the outcome of the game and not the required movements, mimicking daily life where task achievement is the goal, rather than maintaining balance [534]. • Theoretically, the shift of focus reduces anxiety and fear of falling [397]. Improvements due to exergames are most apparent on measures of reaching and dynamic balance [397].
Disadvantages of an exergames programme	• The focus of exergames is on what action should be done and not how (i.e. method that could be conducive to therapeutic change) actions are completed [552]. Mindfulness, encouraged during VRT, is not stressed. • Issues such as self-management are crucial when exercise programmes are essentially unsupervised [553]. Prolonged exposure is required but engagement may be • sub-optimal if there are low levels of self-efficacy [417]. Self-motivation and efficacy is explored below. • Meta-analysis of 16 studies provided very low-quality evidence of no significant effect on exergaming's impact of fear of falling [417, 480]. Thus, exergames do not address this component of fall risk

Table 4 continued

Hypothesis	Therapeutic alliance
Advantages of a conventional VRT programme	• The presence of a therapist may improve results and ensure the patient is engaged, giving full attention to the tasks prescribed [65]. Close monitoring of the individual receiving therapy results in better outcomes than a ‘do these at home’ approach [527]. • Positive therapeutic alliance is a goal in conventional physiotherapy [554] and may be central to patient outcomes and engagement [527]. Essential to building such a relationship are good communication skills; which have been largely under-researched in physiotherapy [534, 554].
Disadvantages of a conventional VRT programme	• Therapists prescribe appropriate exercises, ensure they are done appropriately and correct patients during the session. • Poor communication techniques like frequent interruptions may make exchanges superficial [555] and not foster a good relationship.
Advantages of an exergames programme	• Competition with oneself or the computer game/avatar may to some extent foster a working alliance [554] but there is no constant human element. • Adherence to physiotherapy interventions is frequently sub-optimal [556], so the potentially motivating aspects of exergaming could enhance the success of rehabilitation programmes.
Disadvantages of an exergames programme	• No empathy or understanding is possible. However, an assistant at the beginning of training could address this to some extent. • A therapist is likely to have to be available for safety and to ensure the programme is effective [552]. However, this control could be from a remote site [416]. It may not be possible for a therapist to supervise the user adequately [416].

*note habituation is not discussed in this Table. The goal of habituation is to extinguish responses to noxious stimuli through repeated exposure ‘do not respond’; rather than the processes above, which are assisting the CNS to ‘respond differently’ [42].
**it is acknowledged that due to new evidence, the concepts of adaptation and sensory substitution are now referred to in a more global sense as gaze stability [522].
Legend: ADL: activities of daily living; PA: physical activity; VRT: vestibular rehabilitation therapy.

The preceding section explored concepts underpinning the success of conventional VRT and hypothesised regarding possible transference to exergaming programmes. However, it is apparent that there may be more contributions to the success of exergaming in balance rehabilitation than simply improving physiological function, for example, vestibular gain. The following section explores the theory of flow and other responses which are possibly unique to the interactive exergame paradigm.

Psychological Contributions to the Efficacy of Exergames

Sinclair, Hingston, and Masek [(523)] were one of the first groups to discuss the theory of flow with reference to exergames. They defined flow as the “state of total engagement’ in an activity. It is the equivalent to what is called ‘being in the zone’ in the sporting world” [(523 p.292)]. The experience of flow is underpinned by nine key concepts:

- A balance between perceived skills and challenge.
- Merging of action and awareness.
- Clear and attainable goals (pertinent to the player’s skill and ability).
- Feedback regarding the activity is clear, to prompt an adjustment in play.
- High levels of concentration and focus is narrow (on the game).
- Control over the activity (player is ‘in charge’ of activity).
- Loss of self-consciousness or self-doubts, due to being absorbed in the task.
- Experience of time is altered.
- Activity is inherently rewarding (and thus the likelihood of playing for its own sake is increased) [(523)].

Thus, for exergames to be successful, acquiring a sense of flow during play will ensure better adherence and tolerance of stimulation [(524)] in a way that conventional therapy may not. In addition, an attractiveness-effectiveness balance, in which the game needs to intrigue to enhance the chances of play (attractiveness) and be an effective form of exercise in keeping with exercise recommendations, should be achieved [(525)]. Flow theory was furthered by Sweetser and co-workers and applied specifically to videogaming [(526)]. Their eight elements share many similarities with Sinclair et al., [(523)] but add concepts of immersion (deep engagement) and social interaction [(526)]. The resulting GameFlow theory was based on literature reviews concerning usability and user-experience and has been cited extensively in the research [(424)]. Indeed, GameFlow theory has been examined in the context of WBB. It is noted that GameFlow is not directly measurable nor validated [(424)]; although measures of flow exist, such as the Activity Flow State Scale used by Marston, Kroll, Fink, and Gschwind [(527)]. Questions regarding users' experience of flow and self-efficacy were included in a study comparing balance-related physical and psychological outcomes between WBB and conventional exercise [(528)]. Somewhat surprisingly, Kliem and Wiemeyer's [(528)] study suggested no change in self-efficacy levels, nor differences in flow between traditional and WBB exercises, leading them to question older adults' motivation to play digital games.

GameFlow theory adds the construct of social interaction to flow theory, but the proponents of GameFlow expressed reservations regarding its inclusion [(526)]. It is possible that social interaction playing with others may promote a feeling of competitiveness and thus, improve goal-setting and intention to play [(524)]. The quantitative component of this research touches on user experience of the WBB, while the qualitative aspect probes both experience and social ramifications.

Sweetser and colleagues [526] noted that not all eight criteria of GameFlow need to apply to every game and player, nor must all the prerequisites be met to enjoy a game. Furthermore, as noted above, exergames are influenced by the attractiveness of the game, which is dependent on the player's reflexes and physical capacity (effectiveness) [523]. Thus, a tension exists in finding an appropriate attractiveness-effectiveness balance, which might be particularly relevant in older adults.

Part Two

Evidence Supporting the Use of Exergames to Improve Balance and Prevent falls

Copious literature exists on the role of exergames in improving balance in older adults [473]. Several SR are discussed in this section, with a specific focus on WBB. However, the methodological issues which challenge many of the results should be noted. In general, studies employed small sample sizes, were pilot studies or lacked a control group or statistical power [493]. Interestingly, almost all intervention programmes failed to deliver the recommended exercise dosage suggested by Howe and colleagues' review [377]. This research planned to address many of these issues, as will be described in the Chapter VI. Methodology Chapter.

Older Adults' Adherence to Exercise-based Fall Prevention Programmes

Due to the feasibility design of the present thesis, older adults' adherence to exercise programmes will be discussed briefly. It should be noted that while some individuals may observe recommendations for aerobic exercise, adherence to balance and strength training programmes is significantly less [(513)]. A striking difference in adherence to PA recommendations occurs between those under 75 years of age (40 – 50% do aerobic exercise two or more times per week; while 18 – 20% perform strengthening exercises), and those who are older than 75 years of age (where the prevalence of people doing aerobic and/or strengthening exercises drops to 11 – 15%) [(529)]. As noted elsewhere, fall risk and injury severity increases with age; thus, when combined with the cessation of exercise, a potential public health calamity exists.

Overall adherence to exercise recommendations is extremely variable [(530)] and resistance to exercise common [(531)]. Evidence of attrition from population-based exercise programmes is patchy, and confounded by small sample sizes and short programme durations [(532)]. Total attrition is thought to be between 20 – 50% within three to six months of commencement of an exercise regimen [(458)]. Specifically, participation in fall prevention exercise programmes is low [(533)]. Relevant to the present thesis, evidence suggested that individuals with previous falls are reluctant to challenge balance in exercise [(513)]. However, no clear association is apparent regarding adherence to programmes and intervention efficacy in terms of fall prevention [(372)].

Methods of reporting adherence in cohort and RCT studies include calculating the proportion of participants completing the exercise programme, number of available sessions attended, number of home sessions completed per week, and the number of weeks in which the programme was undertaken [(534)]. Overall, study retention and adherence rates are sub-optimal [(460)]. Picorelli, Pereira, Pereira, Felício, and Sherrington's [(534)] SR highlighted that adherence was best during supervised phases of exercise programmes; and retention rates were most successful for populations with higher socio-economic status and education. In addition, better overall health and physical function, and lower body mass index were conducive to higher adherence [(460)]. Factors impacting poorer adherence included the use of psychotropic medication, depression, and a higher perceived risk of falling [(529)]. Furthermore, participant adherence is influenced by perceptions that the intervention in a trial will be effective (termed outcome expectancy) and that the participant is able to follow what is expected (efficacy expectancy) [(534)]. Self-efficacy is thought to relate to motivation and can affect adherence [(460)].

Features of exercise programmes aimed at reducing falls appear to contribute to adherence [(533)]. For example, home-based programmes are vulnerable to the idiosyncratic factors mentioned above, alongside concerns regarding costs of the interventions [(530)]. Moderate levels of home visit support, along with supervision of a physiotherapist are both positive factors encouraging adherence [(533)] and were adopted in this study. While such supervision is possible in an RCT, it may not be sustainable at population programme levels. Interestingly, a walking component (present in this research) may increase the chances of adherence [(459)]. Walking is a popular activity with older adults, but its contribution to reducing the risk of falls is controversial [(513)], as noted elsewhere. Specific to exercise programmes using technology, high, and even slightly better levels of adherence for exergaming when compared with conventional exercise (median 88.6% vs. 83.5% respectively) have been reported [535]. It is likely that high levels of supervision, short programme duration (<12 weeks), intensity (most commonly prescribed twice per week) and centralised rather than home settings contributed to the authors' [461] findings. The same group's [535] SR suggested a median attrition rate of 15% (range 0 – 36%) for technology-based interventions and median 13% (range 0 – 41%) for conventional exercise programmes.

Turning now to psycho-social factors affecting adherence, important barriers and facilitators for adherence have been identified. Fear of falling can both enable and discourage older adults from exercising [536]. For example, loss of independence due to an injurious fall is a significant concern for many older adults [537]. Yet, this fear of falling may contribute to a lack of confidence when exercising, and anxiety that PA may exacerbate the risk of injury [536]. Other predictors of attrition include subjective reports of poor memory, psychological distress including anxiety and depressive disorders, loss of interest in the intervention offered, and perceptions of a lack of time [532]. Attitude would appear to be a potent influential factor. A positive attitude towards PA influences behaviour and ultimately adherence [538]. Self-motivation and self-efficacy skills similarly contribute to adherence to home-based exercise programmes, as does the presence of social support and previous successful adherence to exercise regimens [530]. There is scant research on attitudes towards exergaming interventions [538]. One small study on a customised exergaming application demonstrated participants had a positive attitude towards the benefits of exergaming [464]. Motivations to play included feeling better, improving emotional status, and the enjoyable nature of the intervention [464].

CHAPTER VI. METHODOLOGY

Introduction

This chapter presents the mixed methods used in the present research. Quantitative feasibility methodology, using a cluster RCT design, was combined with qualitative methodology. A phenomenology paradigm was used to explore participants' lived experience of the interventions and adherence, facilitators, and barriers to participation. Within this qualitative tradition, focus group and content analysis design were adopted. The use of mixed methods, as presented in Figure 10, permitted a wider perspective [539] and added depth and breadth to the study [540]. Methodology is explored further in this introduction prior to detailed description.

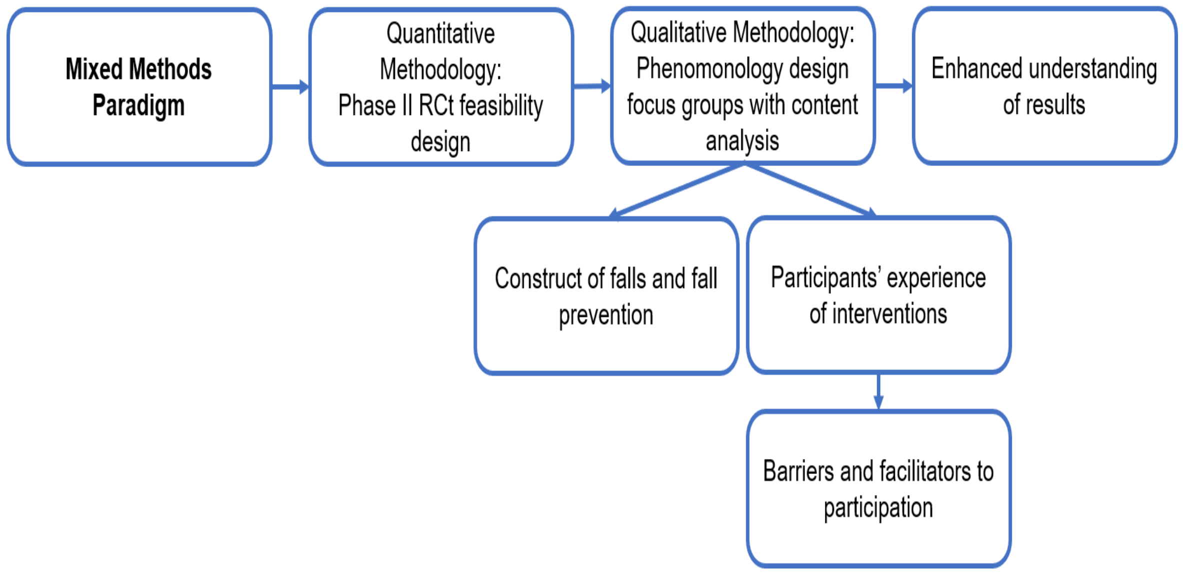


Figure 10. Schema of design and methodology.

An *RCT* (including feasibility RCT) is a quantitative approach with an experimental design, control and manipulation of variables, and use of objective endpoints [540]. Frequently, a positivist or post-positivist framework [540] is employed to drive question formation, data collection, and interpretation [541]. Positivist positions in RCTs have been criticised for failing to consider context [542]; thus, the adoption of mixed methods in this thesis.

Pathways from Phase I 'first in human' to large Phase IV trials are clear forpharmacological products, but less so for complex interventions [543]. Phase II designs may evaluate therapeutic endpoints against baseline measures, and precede broader application in Phase III therapeutic confirmatory trials [544]. Phase II trials feature in the Medical Research Council's (MRC) framework for developing and evaluating complex interventions [545]. The first stage develops the intervention for evaluation and implementation [545]. As discussed in Chapter I. Fall Risk Factors in Older Adulthood, the OEP is an established, evidence-based intervention successful in some countries, but with mixed and poor trial results in emerging regions. Theoretical underpinnings for how WBB could work to improve balance were described using a vestibular rehabilitation lens. Studies using the WBB have been plagued with methodological issues. Few studies have compared the two interventions; thus, equipoise is present. This, combined with a lack of clear recommendations for shaping future research in the Global North, makes a feasibility study in the South an appropriate endeavour.

RCTs strive for high internal validity; however, the cost may be compromised external validity, i.e., generalisability to real world settings [546]. Qualitative methodologies are neither replicable nor generalisable [547], but may provide context [548] not apparent from statistical analysis. In clinical research, qualitative inquiry may explore the acceptability and feasibility of interventions [549]. The use of qualitative methodology in feasibility studies is steadily increasing, particularly when interventions and settings are complex [550]. Exploring participants' experiences represents an important shift from paternalistic medical models to more person-centred care [551].

Historically, public health interventions have been implemented with a top-down approach, with the exclusion of end-users [(552)]. Considering that health is more than an absence of disease, self-management of chronic conditions is increasingly important with population ageing [(553)]. Equitable and collaborative models between healthcare professionals and patients are well-suited to facilitating coping with the social, physical, and emotional aspects of chronic care [(551)]. Thus, successful interventions such as fall prevention strategies must be responsive [(554)], and are more likely to be effective and promote adherence if end-users' views are solicited [(552)].

Phenomenology is a qualitative methodology, which explores individuals' lived experiences [(547, 555)]. Phenomenology embraces systematic, critical and rigorous interrogation of data [(547)]. Potential challenges are that skilled interviewers are required for data collection; and that the researcher may have an unintended impact on the collected data [(547)]. A post-positivist stance was adopted for the qualitative research component, demonstrated in the steps in data analysis [(556)]. Figure 11. Flow chart showing organisation of Chapter VI. depicts the organisational flow of the Chapter. For ease of reading, each methodology is described separately.

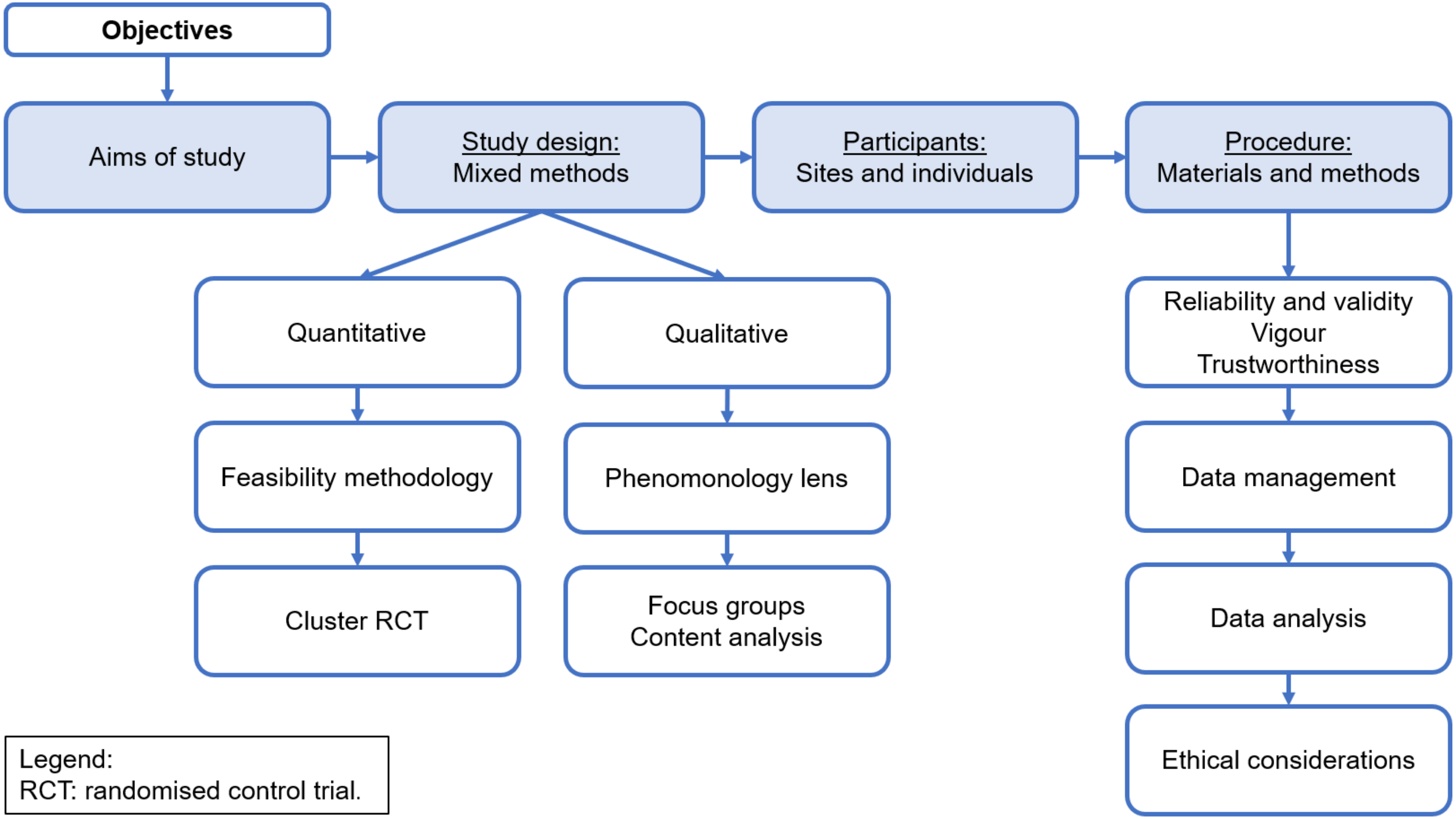


Figure 11. Flow chart showing organisation of Chapter VI.

Aim of the Study

The *aim of the study* was to examine the feasibility of conducting a future large-scale cluster RCT to compare the WBB with the OEP on balance and the risk of falls in independently-living older adults. To this end, a Phase II feasibility cluster RCT [557] assessed feasibility issues including recruitment, retention, sample size calculations for an appropriately powered RCT, safety and participant adherence. The construct of falls and their prevention, and participants' experience of the interventions, including facilitators and barriers, was the focus for qualitative exploration.

Objectives.

The objectives for the feasibility RCT, as informed by Bowen et al., Bugge et al., and Eldridge et al., [558-561] are presented in Table 5.

Table 5. Aims and objectives of the study.

Objectives	Questions related to objectives	Indicators/Endpoints indicating feasibility
Aim 1: To evaluate feasibility issues pertaining to the design of a future fully powered cluster Randomised Control Trial (RCT).		
Objective 1 To describe issues concerning recruitment of sites and participants.	Was recruitment of sites successful? Were managers of sites receptive to the research question? Were specific procedures (such as internal review) required to obtain site permission? • Did participants meet the desired fall risk profile? • What issues impacted enrolment of individual participants? • Were participant selection criteria appropriate?	• Description of site recruitment processes and suitability of sites. • Participant description. • Number needed to screen. • Additional inclusion or exclusion criteria.
Objective 2 To describe potential issues and sources of bias related to a future cluster design for randomisation of interventions.	• Did the design permit sample size calculations for a large future RCT? • Could sources of potential bias be detected using a cluster-randomisation design? • Were blinding procedures appropriate? • What were the safety issues pertaining to participation?	• Sample size calculation. • Presence/absence of possible selection bias. • Instances of unblinding and how these were managed. • Type, severity and nature of adverse events during the study. • Proposed changes for a future RCT.
Objective 3 To evaluate adherence to the interventions.	• Did the participants adhere to best practice guidelines for exercises? • Was retention successful?	• Mean dose, levels of adherence. • Factors impacting adherence. • Attrition from study.

Table 5 continued.

Objectives	Questions related to objectives	Indicators/Endpoints indicating feasibility
	Aim 1: To evaluate feasibility issues pertaining to the design of a future fully powered cluster RCT cont.	
Objective 4 To describe the costs associated with the feasibility study and to project these to a future fully-powered RCT.	• Was it possible to calculate the costs of the intervention, and the costs of a future fully powered trial?	• Costs analysis and projections.
Objective 5 To describe utility of the physical outcome measures and suitability for a future RCT.	• Which of the selected outcome measures were the most appropriate in this population? • What were the training requirements for research staff? Were permissions to use the intervention programmes easily granted?	• Identification of outcome measures capable of showing responsiveness. • Identification of floor and ceiling effects in tests. Identification of tests which were challenging for participants. • Are the training requirements reasonable in a resource-constrained setting?
	Aim 2: To seek preliminary evidence for the effect of the interventions, which may support a future RCT.	
Objective 6 To describe fall occurrence and changes in balance and fall risk in the participants.	• What is the rate of falls prior to and during the trial? • Can differences in self-assessment scales and physical endpoint of balance be demonstrated between WBB and OEP groups?	• Change in fall occurrence. • Identification of trends towards change in the outcome measures which might be useful to shape a future RCT.

Study Design

Feasibility cluster RCT.

Feasibility studies entail descriptive assessment [562] of the feasibility of a future large, well-funded RCT [543]. Practicality is a primary concern [562]. The piloting and feasibility stage of research explores if an intervention can be delivered as envisaged [562]; and if assumptions regarding effect sizes, rates of recruitment and retention are safe and suitable for any subsequent study [545].

Controversy exists concerning the use of feasibility trials to evaluate intervention efficacy [545]. Feasibility studies characteristically have small sample sizes and lack power, demanding caution when interpreting statistical results [562]. Despite these caveats, the value of the WBB intervention in its current form and its potential adoption in a large-scale RCT require exploration. Thus, short-term physiological outcomes were selected with a hope to detect within- and between-group differences.

Rationale for cluster randomisation.

Retirement facilities, rather than individuals, were randomised in clusters. Members of the cluster were individual residents at the facility. Each cluster was randomly allocated to one of the two intervention arms. Advantages of a cluster design include:

- Less threat of treatment contamination compared with randomisation of individual participants within the same residential setting [563]. However, a significant threat for unblinding of outcome assessors exists should the intervention allocation of the cluster be revealed [564].

- Economic, increased efficiency and possible improved adherence advantages [563]. WBB was placed at two sites rather than four, reducing operational costs.

Participants

Site selection criteria.

Selection criteria were:

- Location in the Southern suburbs of Cape Town, Western Cape, to minimise commuting time for visits to sites;
- Minimum of 40 – 60 residents living in independent accommodation, to maximise the concentration of potential participants in one location. The aim was to recruit 15 participants per cluster;
- Space for WBB equipment;
- Stable electricity supply (e.g. primary source to be formal electricity rather than generator/battery); and
- Email/telephone access to arrange appointments.

On-site medical facilities or nursing/rehabilitation staff were not required. Managers of the facilities provided information regarding the sites and their residents (Aim 1, objective 1) and thus, were regarded as participants and consented for ethical purposes. Knowledge of which residents were enrolled for the trial was not necessary, but should participants be uncontactable (e.g., if a participant died or moved) the manager was approached (See Appendix C Documents Pertaining to Site Recruitment for the documents completed with/by the site managers, including informed consent documents).

Sampling and randomisation of clusters.

Clusters were matched as closely as possible in terms of services, for example, existing exercise classes on site. Thus, purposive sampling was appropriate. Simple randomisation was employed after sites and individual participants had been recruited. An individual unrelated to the study's conduct drew a slip (WBB or OEP) from an envelope. Sites were designated A – D. The first slip pulled was allocated to Site A, the second to site B etc. Sites A and D were assigned OEP and Sites B and C were assigned WBB. Intervention allocation was revealed by the non-involved individual to the researcher and therapist immediately before the interventions commenced and sites informed. Data capturers and the statistician were aware of the study numbers, which were then linked back to sites prior to analysis.

Attempts were made to manage selection bias and allocation concealment. However, it was posited that with participants being in clusters, the disadvantages of simple randomisation would be somewhat mitigated; and participant attributes such as age, fitness, sex, and overall medical and physical condition reasonably well distributed [(565)].

Selection of individual participants within clusters.

The study population was older adults with a history of, or risk for falls. Non-probability purposive sampling was used [(566)]. Site requirements for independent living limited the variables of frailty and mobility of potential enrolees [(567)]. Ideal participants could not be "too fit or too frail" [(568 p.658)]. There was no exclusion on the grounds of sex[27], home language or ethnicity.

[27] The researcher acknowledges the debate regarding sex and gender and uses the term 'sex' referring to biologically-based differences between males and females 569. Hyde JS, Bigler RS, Joel D, Tate CC, van Anders SM. The future of sex and gender in psychology: Five challenges to the gender binary. Am Psychol. 2019;74(2):171-93..

Inclusion criteria: exercise-based intervention participants.

The following inclusion criteria applied:

a) ≥60 years of age.

b) Defined risk of falls i.e., ≥1 fall in the twelve months prior to enrolment, OR indication of fall risk on physical endpoints, OR ≥2 chronic illnesses, OR consume ≥3 prescription medications [570], OR have a combination of risk factors.

c) Living independently in selected cluster.

d) Able to stand and ambulate independently without assistive devices.

e) Not planning an absence from the trial site of ≥3 continuous weeks within the six months of enrolment, to ensure maximum possibility of adherence to the programme.

f) Prepared to exercise as prescribed in the intervention programmes for a minimum of three and maximum of six months.

g) Able to log exercise patterns, falls and injuries, plus any associated costs, for a period of six months.

h) Able to complete the physical endpoints and self-assessment questionnaires (see Table 6 at enrolment, three and six months).

i) Able to follow verbal and written instructions in any one of the three of the official languages of the Western Cape[28]. Grade 10 literacy was required so the programmes and logs could be managed by participants.

j) Contactable by telephone or electronic means for reminders and follow up.

[28] All participants proved to be fluent in English. The researcher, physiotherapist and research assistant are bilingual; and interpreters for isiXhosa would have been arranged if necessary.

Inclusion criteria: costs only participants.

Participants willing to log their falls, fall severity and related expenses only (i.e., not interested in the exercise-based interventions) were included in a non-intervention group (referred to as the 'costs' group) with the same assessments as for the intervention groups. The above inclusion criteria applied, except for item f.

Exclusion criteria.

Aim 1, objective 1 sought to refine eligibility criteria. Thus, exclusions were minimised to enhance generalisability [(571)]; rather, the focus was on cognitive and physical capacity of potential participants. Table 6 outlines the exclusion criteria and rationale.

Table 6. Participant exclusion criteria, method of detection and rationale for exclusion.

Exclusion criterion	Evaluation method	Rationale
Individuals vulnerable to potential harm:		
Cardiac pacemaker.	History.	WBB safety guidelines.
Epilepsy.	History.	WBB safety guidelines.
Waist circumference that precludes use of a gait belt.	Test.	Gait belt necessary for safety of the participant during assessments.
Active intervention is likely to be ineffective: (Individual has a disorder that makes him/her unsuitable or unlikely to respond to intervention; or is receiving treatment that is likely to interfere with the interventions)		
Orthopaedic (e.g. knee, hip or shoulder) surgery including replacement within last six months.	History.	Changes to proprioceptive cues, reduced mobility, possible de-conditioning, negative anatomical, physiological and psychological impact of hospitalisation [572]. Likely to be receiving active rehabilitation/ physiotherapeutic interventions.
Regular participation in rehabilitation programme.	History.	Will be receiving additional intervention, resulting in difficulty isolating the effects of the interventions.
Reduced likelihood to adhere to the interventions:		
Decreased cognitive function, defined as score of ≤2 on the Mini-Cog [573].	Test.	Need to be able to follow three step commands and to engage with interventions. Issues of autonomy regarding ethics.
Possible depression established by a score of ≥5 on the Geriatric Depression Scale short-form version [574].	Test.	Depression adversely affects exercise adherence recommendations [575].
Practical problems with participation in study:		
Mass >150kg.	Test.	Maximum load for WBB [576].
Severely restricted/absent upper limb mobility in dominant arm or hand.	History.	Need to be able to control WBB console.
Severely reduced visual acuity not correctable with spectacles or contact lenses.	History.	Need to fixate on target for stability exercises and to complete exercise log, self-assessment scales and read instructions.
Severely reduced auditory acuity so that conversational speech is inaudible even with assistive devices.	History.	Need to hear auditory feedback for both interventions.

Sample Size

Sample size estimations are usually informed by the expected benefits, risks and cost of the study; however, these are unknown in feasibility studies [577]. An audit of pilot and feasibility trials registered in the UK Clinical Research Network database found an average of 36 participants per arm in feasibility trials [577]. The audit was not confined to older adults, nor studies using cluster randomisation [577]. Considering the "captive audience" and likely stability of residence of participants in the sites, a sample size of 30 (approximately 15 per site) individuals per arm was targeted.

Recruitment and Enrolment

Recruitment of clusters.

Study information was sent to prospective sites. Sites were administered by stakeholder organisations, e.g., Cape Peninsula Organisation for the Aged (CPOA) and Evergreens, which offer a range of public/subsidised/private accommodation for older adults. Meetings with managers were scheduled to discuss consent, site facilities and logistic issues prior to negotiating community entry (see Appendix C Documents Pertaining to Site Recruitment for concept protocol documents and checklists).

Recruitment of individual participants.

Informational sessions introducing the study to possible participants at recruited sites were scheduled. All residents were invited to attend; and the event publicised by posters placed in communal areas at each site (see Appendix C Documents Pertaining to Site Recruitment). Trial recruitment and retention of older adults presents challenges ranging from community entry, to the sensitive nature of the study in terms of attitudes to falls (see Appendix C Documents Pertaining to Site Recruitment). After the presentation, refreshments were offered, and questions welcomed. Potential participants completed a slip with their contact details and deposited it a box at the back of the room (see Appendix C Documents Pertaining to Site Recruitment). Thereafter, appointments were made with potential participants for informed consent procedures (see Appendix D Informed Consent Documents for Individual Participants), followed by eligibility screening.

Equipment, Materials and Instruments

Equipment and materials.

- *Endpoint equipment:* Mini-BESTest: all materials complied with test specifications and included a box[29], foam balance pad, stop watch and an ankle incline board (see Appendix E MiniBESTest Balance Evaluation Systems Test). DGI: brightly coloured masking tape for marking distance, traffic cones, measuring rule, and a shoe box (see Appendix F Dynamic Gait Index). A gait belt was used to ensure participant safety.
- *OEP equipment:* weighted ankle cuffs.
- *WBB equipment:* television; batteries, console, balance board, remote control, and diary for booking sessions.
- *Informed consent and information sheet documents* (See Appendix D Informed Consent Documents for Individual Participants).
- *Participant pack* for recording endpoints (See Appendix G Monitoring Logs).
- *Site induction pack* for site evaluation (See Appendix C Documents Pertaining to Site Recruitment).
- *Exercise logs, programme instructions for participants* (See Appendix G Monitoring Logs).

[29] A piece of paper with the instructions "Step over box" in large font was pasted to the box.

- *Consumables:* clipboards, pens, tissues, hand disinfectant.

Instruments.

Pre-trial entry.

Self-assessment scales (SAS).

Mini-Cog™ [(578)] (see Appendix H Cognitive screening and Mini-Cog). The Mini-Cog was described as an effective screening tool for cognitive decline in older adults in various settings [(579)]; although later systematic review (SR) demonstrated insufficient evidence to recommend its use as a screen for dementia in primary care [(580)]. Nevertheless, this test was chosen for its brevity, lack of copyright. and relative resistance to linguistic and socio-economic factors compared with the Mini-Mental State Examination [(581)]. Three words are memorised, a clock drawing test is used as a distractor, and recall of the words checked [(582)]. Scores range between 0 – 5 (best score) [(583)]. The Mini-Cog's primary purpose was to safeguard potentially vulnerable individuals from exploitation by enrolling them in a trial, should there have been a suggestion their autonomy was impaired.

Geriatric Depression Scale [(584)] (see Appendix I Geriatric Depression Scale (short form)). The short form (GDS-SF) questions experiences of depression in the last week [(585)], and has been validated across different settings and populations [(586)]. A cut-off score of 5/15[30] was used to alert for the presence of possible depression [(587)].

Case History Questionnaire (see Appendix J Case History). Demographic, medical and falls data were captured on a customised document, which included the *Functional Comorbidities Index* [(588)]. The Index explores eighteen comorbidities with physical function rather than mortality as an outcome, and correlates well with the

[30] Sensitivity and specificity of this cut-off is discussed in the reference provided. The test was used as screen only.

Short Form 36 physical outcomes [588]. Scoring is simple with 0 representing no comorbidities and 18 the highest number of comorbidities [588]. A further section questioned symptoms of dizziness, imbalance, and vertigo [196].

Euro-QoL EQ-5D-3L health related quality of life questionnaire [589] (see Appendix K Euro-QoL EQ-5D-3L Health Questionnaire English version for South Africa). The EQ-5D-3L assesses physical, mental and social functions over three possible levels of responses, which range from no problem (with performing a task such as dressing, or experiencing a symptom such as pain), to some or extreme problems [590]. It is used frequently as a generic questionnaire to inform economic evaluations [591].

Self-efficacy for exercise scale (SEE) [592] (see Appendix L Self-efficacy for Exercise Scale [592]). Assessment of patients' self-efficacy is not routine for clinicians who prescribe home exercise programmes, despite the possible links between self-efficacy and adherence [593]. The SEE references theories of behavioural change and probes willingness to exercise [592]. Individuals estimate their confidence, ranging from not at all confident (0) to very confident (10), to keep to a specified exercise dose (three times per week for twenty minutes) [592]. Mean score for older adults is 5.5 (SD 3) out of a possible 0-10 [592].

Physical Activity Scale for the Elderly (PASE) (see Appendix M Physical Activity Scale for the Elderly (PASE)*)*. The PASE [594] was the first valid and reliable questionnaire aimed at assessing physical activity (PA) in older adults [595]. The questionnaire is commonly used in epidemiological studies and assesses short-term (preceding week) PA across home (including housework), occupational and recreational domains [596]. Scores from 12 questions are assigned in hours/week then multiplied by a PASE weighting, which is summed for all activities [596]. Higher scores signal higher levels of PA [597].

The EQ-5D-3L, SEE and PASE were conducted at base-line, three, and six months. Upon follow-up, the following were conducted:

Systems Usability Scale (SUS) (see Appendix N Systems Usability Scale) for WBB participants. The SUS [598] is a commonly used questionnaire to assess the usability of products or services [599, 600]. Participants use a five-point Likert scale to rate ten statements regarding the experience of using technology, and scores range from 0-100, with higher scores representing better usability [599]. The SUS was slightly modified by changing the wording from 'the product' to either WBB or exergaming. The SUS is resistant to minor changes in wording, and has excellent reliability and validity [600].

Borg Rating of Perceived Exertion Scale (RPE) (see Appendix O Borg Rating of Perceived Exertion Scale) [601]. The Borg RPE evaluates perceptions of the difficulty experienced during PA [602]. The higher the overall score on the Borg RPE (scored by numerical values and descriptors), the greater effort and exertion is perceived [602]. The Borg RPE has fair criterion and construct validity in older adults [603]. In the present thesis, the scale assisted understanding of participants' experience of the interventions.

Physical endpoints.

Mini Balance Evaluation Systems Test (Mini-BESTest©) [604] (see Appendix E MiniBESTest Balance Evaluation Systems Test). The Mini-BESTest's primary focus is dynamic balance and gait, including anticipatory and reactive postural control, making it applicable to daily living [605]. The Mini-BESTest has been included in a core set of outcome measures for balance [606] and is widely used. Scores range from 0-28 with higher scores indicating better balance [604]. The Mini-BESTest's sensitivity improves with each decade in life and new cut-off data have been published for older adults [607]. A score of ≤25 was used to indicate fall risk [608]. The Mini-BESTest has good to excellent psychometric properties [608].

Timed up and go (TUG) [609] (see Appendix E MiniBESTest Balance Evaluation Systems Test). TUG simple and cognitive is embedded in the Mini-BESTest. Cut-off points for TUG vary [2] and the utility of cut-offs is explored in the Results.

Five times sit to stand test (FTSST) [610] (see Appendix P Five Times Sit to Stand Test). The test was conducted with an armless chair as recommended in a recent SR [611]. Where the chair had arm rests, participants were instructed to fold their arms across their chests. Cut-off between 12s-16s suggest fall risk in the general older adult population [610] .

Dynamic Gait Index (DGI) [612] *and preferred walking speed* (see Appendix F Dynamic Gait Index). The DGI is a measure of dynamic balance during gait activities, used to predict fall risk [613]. Item 1 on the DGI serves as a baseline and examines self-paced (preferred) walking on a level surface [614]. Item 1 was timed over distance to produce preferred walking speed in m/s and analysed independently from the DGI. Ordinal scores are awarded using descriptors ranging from 0 (severe impairment) to 3 which is normal; a maximum of 24 is the best possible result [614]. Scores of ≤19 suggest fall risk and are used to monitor progress in therapy [3].

Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT-4) [615] (see Appendix Q Frailty and Injuries: Cooperative Studies of Intervention Technique (FICSIT-4)). The FICSIT-4 is a combination of commonly used tests of static balance, comprising standard, semi-tandem, and full tandem (sharpened) Romberg positions, with eyes open and closed[31], and Single Leg Stance (SLS). The test was adapted by asking participants to attempt to maintain each Romberg position for 30s and SLS

[31] See Glossary of Terms.

for 20s (embedded in the Mini-BESTest). The Jendrassik manoeuvre [616] was used to enhance the Romberg positions.

Research Procedures

Ethical clearance, trial registration, and permissions.

Permission to use the OEP and the WBB programme was granted by their developers (see Appendix A.2 Permission to use Otago Exercise Programme.). Permission for the research was granted from the University of Cape Town (UCT) Faculty of Health Sciences Human Research Ethics Committee (Reference HREC: 818/2015; renewal and qualitative protocol approval, 2017/2018). No-fault insurance was arranged with UCT. In keeping with the statutory requirements, the researcher completed a Good Clinical Practice qualification in 2015; renewed in 2018. Trial registration with the Pan African Clinical Trial Registry (PACTR201603001513802) and the South African Trial Registry (NHREC 4431 DOH-27-0916-5431) was completed and maintained. All trial documents referenced in this paragraph may be found in Appendix R Ethical Clearance and Trial Registration Documents.

Induction of participant into the study.

Potential participants received all information about the study, had an opportunity to ask questions and completed informed consent. Figure 12 shows assessments and where exclusion criteria were applied.

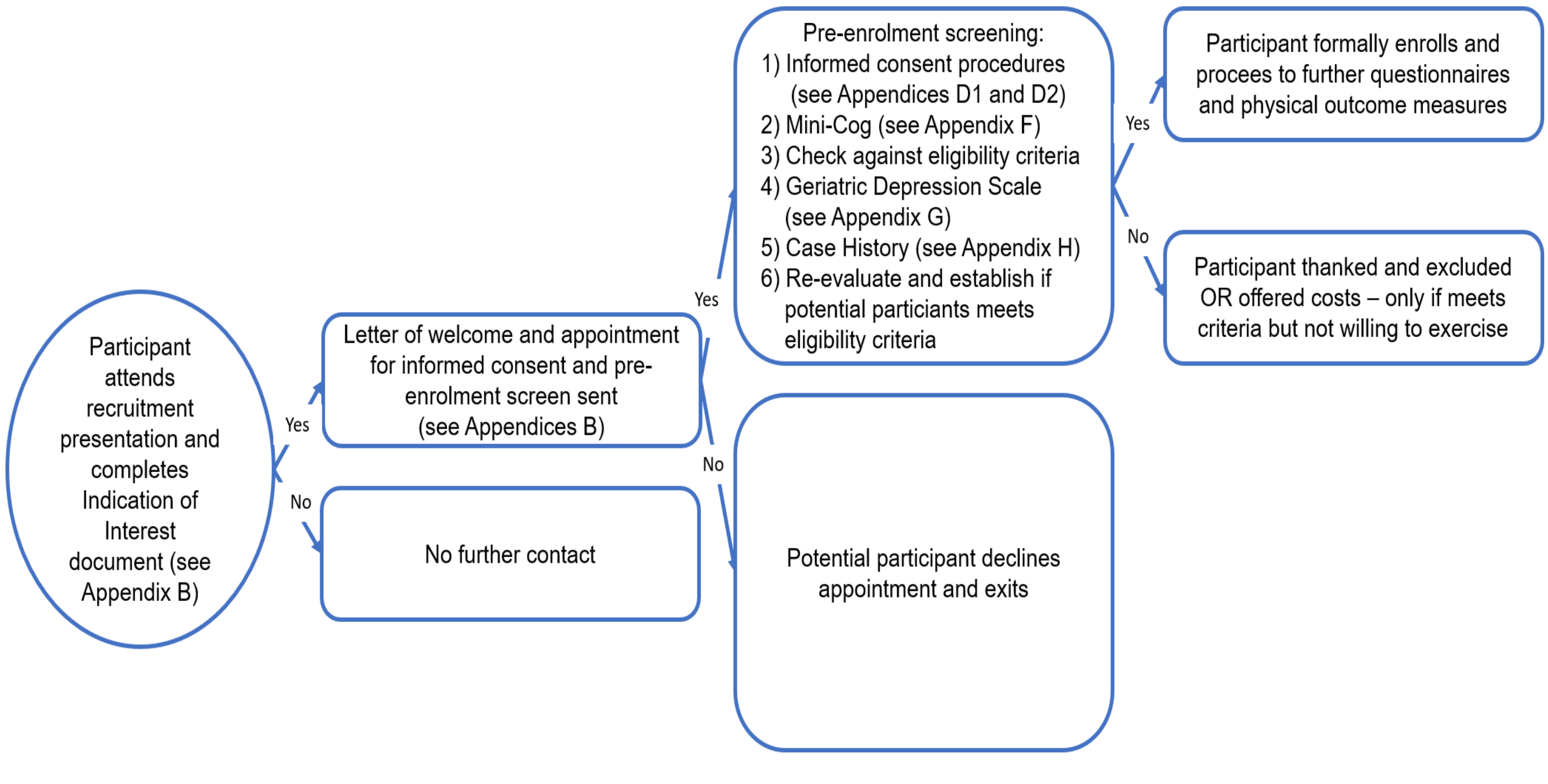


Figure 12. Decision tree for participant enrolment.

Baseline measures.

Baseline questionnaires and physical endpoints were administered. These are described in Equipment, Materials and Instruments and the Appendices. Tests were administered precisely as described. Any modifications are noted.

Eligible OEP and WBB participants receive interventions.

OEP participants received the programme as per Appendix A Exercise intervention programmes (OEP and WBB). Participants were required to complete 20-minute exercise periods at least three times per week, along with two walks of approximately 30 minutes per week, with an aimed overall target of two hours per week. Warm-up and cool down exercises were incorporated to ensure safety. Exercises were progressed by increasing the number of repetitions and complexity of the tasks. Participants received home visits and instruction in the OEP in weeks one (one hour), two, four, and eight (30 minutes each) and then at six months. Phone call follow ups were scheduled for months three, four, and five to enhance adherence. Aimed overall exposure was ≥50 hours.

WBB participants received the intervention outlined in Appendix A Exercise intervention programmes (OEP and WBB). Individual exercise sessions were 20 minutes, five times a week and walks commencing at ten minutes, five times per week, progressing over six weeks to 30 minutes five times per week. Assistance was provided while the participant mastered the technology and commenced the exercises. Interaction with the therapist and monitoring in terms of visits and phone calls was comparable to the OEP group. As the equipment was shared, it was thought that the WBB target may be ambitious, but aimed overall exposure was ≥50 hours.

Participants electing to enter the costs arm did not participate in either intervention. They were provided with fall logs. Follow-up visits, at which the same endpoints shown in Table 7 were scheduled, were planned for the end of the six-month period.

Repeated measures and monitoring.

Table 7 shows the frequency of endpoints in the trial. All participants were asked about health events since the last visit, with a focus on the risk factors outlined in the Case History Questionnaire and falls. Logs of exercise and falls, injurious falls, and costs were provided (see Appendix G Monitoring Logs).

Table 7. Schedule of endpoints.

Assessment	*Test*	*Appendix*	*Pre-enrolment*	*Trial entry*	*3 months*	*6 months*	*Contin-uous*
Cognitive screening	Mini-Cog	F	x				
Depression screening	GDS-SF	G	x				
Case History including Functional Comorbidities Index		H	x				
Health-related quality of life	Euro-QoL EQ-5D	I		x	x	x	
Attitude to exercise	SEE	J		x	x	x	
Physical activity levels	PASE	K		x	x	x	
Experience of WBB	SUS	L				x	
Perceived exertion for exercise	Borg RPE	M				x	
Tests of balance	Mini-BESTest	N		x	x	x	
	TUG (simple and cognitive)	Embedded in Appendix E		x	x	x	
	FTSST	O		x	x	x	
	DGI	P		x	x	x	
	FICSIT- 4	Q		x	x	x	
	Preferred walking speed	Embedded in Appendix F		x	x	x	
On-going exercise adherence Falls, injuries and incurred expenses	Log	R					x

Legend: Borg RPE: Borg Rating of Perceived Exertion; DGI: Dynamic Gait Index; FICSIT-4: Frailty and Injuries: Cooperative Studies of Intervention Techniques; FTSST: Five Times Sit to Stand Test; GDS-SF: Geriatric Depression Scale-Short Form; PASE: Physical Activity Scale for the Elderly; SEE: Self Efficacy for Exercise scale; SUS: Systems Usability Scale; TUG: Timed Up and Go.

Participants exit trial.

At the end of the trial, the participant was thanked for his/her participation, and invited to share his/her experiences in the focus group. All managers were thanked for permitting access to the sites. Ongoing support for staff and participants was offered after the trial was concluded.

Reliability and Validity

Reliability and validity of endpoints are presented with the description of each test used in the study in the Appendices, along with normative data.

Randomisation, allocation concealment and blinding.

Randomisation and blinding promote internal validity in RCTs [617]. Flaws in randomisation and allocation concealment in clinical trials may inflate treatment effects [618]. Armijo-Olivo and colleagues [619] explored these methodological issues in a large meta-epidemiological study (44 622 participants) of physiotherapeutic RCTs. Appropriate random sequence generation was found in a minority of studies (39.7%), and allocation concealment was acceptable in only 11.5% of reports [618]. Combined, even fewer (8.9%) trials had both adequate sequence generation and allocation concealment procedures [618]. Failure to adequately conceal treatment allocation tended to produce an over-estimate of treatment effects, but this was not statistically significant [618].

Blinding is an attempt to reduce bias [619], especially placebo and measurement biases [617] and increase the generalisability of the findings [620]. Blinding can be difficult to implement and maintain, particularly in trials that examine non-pharmacological interventions [381]. A meta-analysis (MA) of physiotherapeutic trials demonstrated that only 20% of trials were adequately blinded [621].

The investigator and physiotherapist were not blinded to site/intervention allocation. In this study, single blinding of the outcome assessor to the participants' intervention and the study hypothesis was attempted [(622)]. Blinding of outcome assessors is often more important than blinding those involved in the administration of treatment [(458)]. Instances of unblinding were managed by asking the assessor to complete Appendix S Record of Unmasking of Intervention Allocation Group. The research assistant was not involved in the initial enrolment of participants. WBB equipment at sites was located in a partitioned area so was not visible to her. At each follow-up, the participant was asked not to discuss the intervention and shown a brightly coloured piece of paper, left in front of the participant, to remind them. Even though three instances of unblinding occurred, as some participants were costs only, the research assistant could not be sure whether the participant had participated in an exercise intervention.

Training for physical endpoints.

Selecting outcome measures with established reliability and validity attempts to minimise bias [(620)]. Due to the complexity of the balance system and the issues with various endpoints already discussed, several tests were selected to find the most efficient. The researcher acknowledges the risk of redundancy.

Training was given on all tests and scoring (e.g. disagreements analysed and discussed) and repeated until a satisfactory level of agreement was found (seeChapter VII. Results). The researcher used models for the various outcome measures (e.g., preferred walking speed; FTSST). The outcome assessor observed the models and scored the tests along with the researcher. There was no discussion prior to the scores being awarded [(623)]. Reliability checks were embedded throughout the study and the researcher was present for every test with each participant at all follow-ups.

Sources of bias and efforts to manage them.

Table 8 tabulates possible sources of bias and strategies to manage them.

Table 8. Sources of bias and strategies to manage them.

Type of bias	Strategies to manage threat
Participant:	
Adherence	Exercise participants received regular follow-up with visits and telephone calls.
Hawthorne effect	Changes in behaviour linked to a motivational response prompted by the attention received during a clinical trial are possible (624). Care was taken that the encounter was similar for all participants.
Healthy volunteer	It is possible that only potential participants who felt capable of entering an exercise-based intervention volunteered. However, having a physiotherapist lead the interventions may have mitigated concerns regarding coping with the interventions.
Response bias	The stigma of falls was carefully managed to encourage full disclosure of falls and their severity.
Recall bias	Information was gathered prospectively during the trial. A daily calendar was provided for recording exercise sessions. A separate log for falls was provided. Participants were given stickers for the calendar, which had a reminder to complete the falls log if necessary. Participants were reminded to complete the log on an on-going basis.
Social desirability bias	Studies examining exercise frequency are prone to bias (623); however, it is likely that this was evenly distributed across the sample.
Small sample bias	Using small samples might result in an imbalance in factors influencing participants (565), but small sample sizes are common in feasibility designs (577).
Sample bias	Sample bias may result if recruited participants refuse to participate (565). Efforts to manage this were made by placing colourful advertisements that the interventions were ready to commence to remind potential participants. Participants received personal phone calls rather than text or other electronic reminders.
Zylen effect	Both intervention groups received the same contact time with the research team. This was an attempt to manage issues regarding the therapeutic alliance. Costs-only participants may have become resentful or demoralised (Zylen effect) due not being involved in an intervention, when others were (625). However, such participants could have opted into the intervention at any time.
Experimenter	Outcome assessors were blinded to intervention allocation and incidents of unmasking recorded.
Intervention	Participants were treated in the same manner irrespective of differences in their conditions.
Attrition	Exclusion of participants after recruitment may violate intention to treat (ITT) principles, leading to selection bias (626). ITT analysis was planned. Several participants had the initial outcomes conducted and withdrew before the intervention started.
Selection	Clusters were identified and recruited before randomisation. Treatment allocation was concealed from the managers providing permission/access until the day the trial commenced (627). Participants were recruited before the clusters were randomised.

Research personnel.

Intervention physiotherapist.

The therapist received training from several sources. She is an experienced neuro-rehabilitation physiotherapist who has worked extensively with balance-impaired and older patients. She is qualified in vestibular rehabilitation therapy. Programme delivery was well within her skills-set. For the OEP, on-line training was sourced from https://www.med.unc.edu/aging/cgec/exercise-program. A manual designed to equip physiotherapists with the skills to offer the programme (https://www.med.unc.edu/aging/cgec/exercise-program/tools-for-practice/ImplementationGuideforPT.pdf) underpinned the training.

Outcome assessor.

The outcome assessor was a Master's degree student studying vestibular interventions.

Participant Safety and Monitoring

Early stopping may be associated with an overestimation of treatment effects [628]. Due to the feasibility design, stopping rules were not applied.

Adverse events were tracked and reported to the UCT Human Research Ethics Committee (HREC) immediately (see Appendix T Reporting of Adverse Events). An independent trial steering committee was combined with a data safety management board. These committees were to determine adverse events' relationships to the study; however, the researcher only was informed about falls when she enquired at follow-up visits.

Data Management

Guidelines for good practice in the conduct of clinical trials with human participants in South Africa [629] require documents relating to a trial to be appropriately stored for a period of 15 years. These Guidelines will be observed.

A secure database was constructed using REDCap (www.project-redcap.org) software via the Clinical Research Centre at UCT. The researcher cleaned all the data prior to entry. Data capturers were trained and a meeting was held to manage any illegible entries to the case report forms, which could have resulted in transcription errors [630]. Omission errors were rectified by checking the source documents [631]. A random sample of 5% of data entered into the database (from source documents) was reviewed and the percentage error rate was calculated as follows [631]:

$$\frac{Absolute\ number\ of\ errors}{Total\ number\ of\ data\ points\ examined\ overall} \equiv \%$$

Error rates <1% are acceptable [630], and retraining would have occurred should this not have been achieved. Data were extracted from the database for statistical analysis using IBM® SPSS® Statistics software (Version 25).

All research staff with access to the database signed confidentiality agreements (see Appendix R Ethical Clearance and Trial Registration Documents) and used their staff/student numbers and University log-in procedures/passwords to access the database. UCT has appropriate anti-hacking and internet security protocols. Data were anonymised prior to entry with the removal of participants' names and the awarding of a study/site number. Site/intervention allocation was unmasked to the data capturers and statistician at this point.

Upon entering the demographic and medical data into the database an online Fall Risk Assessment Tool score calculator (FRAT-up) (http://ffrat.farseeingresearch.eu/runAssessment) was used to obtain a score indicating fall risk. The FRAT-up is a tool in which individual clinical variables are entered, along with defined fall risk criteria and a calculation of fall risk is generated [632]. The tool is quick and user-friendly. FRAT-up has been trialled in four large European cohorts [633] and MA found sensitivity for falls area under curve (AUC) of 0.646 [632]. While this figure is not particularly impressive, it is similar to findings for TUG and preferred walking speed [632]. The creators suggested the FRAT-up is a suitable tool to predict future falls [632]. See Appendix J Case History for a screenshot of the FRAT-up calculator.

Data Analysis

Aim 1 generated primarily descriptive information and statistics. All data were examined for normalcy of distribution using histograms and Q-Q tests, and either parametric or non-parametric statistics selected. Outliers were identified with box-and-whisker plots. Sample size calculations for a future study were computed using a presumed effect size of 0.8; assuming two groups of equal size and a 2-tailed significance threshold alpha of 0.05. The impact of a cluster design is explored in the Chapter VII. Results.

Participant data such as fall events, symptoms, the Functional Comorbidity Index and balance endpoints were compared between groups using t-tests, one-way ANOVA and chi square. Exercise exposure was calculated along with SD and range, and a box-and-whisker plot demonstrates these data. Adherence was explored using t-tests and in some instances Mann-Whitney U (non-parametric). Factors influencing adherence were explored using Fisher's Exact tests and Wilcoxon signed-rank tests for between group differences.

Aim 2 (preliminary data regarding effect of interventions) ideally required ITT and per protocol (PP) analysis [634, 635] but these were not possible due to extremely poor adherence and attrition, resulting in too few data for computation. Correlations between exercise regimen and falls were explored using tests such as Pearson's *r*. Between-groups comparisons for physical endpoints were analysed with t-tests, one-way ANOVA and chi-square. SUS data are reported using descriptive statistics and histograms.

Triangulation of results.

Triangulation of qualitative and quantitative data is increasingly used in RCTs and may augment evidence [636] by improving the accuracy and credibility of study of a phenomenon, in particular complex questions [637]. Triangulation approaches should be pragmatic [638]. When complex interventions are examined, as in this thesis, areas of convergence and dissonance are sought [639]. To give an example of triangulation in this work, focus group themes and views of interventions were contrasted with adherence data.

Ethical Considerations

This study was designed observing the Declaration of Helsinki (2013) [640]. The researcher signed the Singapore Statement on Research Integrity [641] (see Appendix R Ethical Clearance and Trial Registration Documents) and was aware of the Ottawa Statement for the design and conduct of cluster randomised clinical trials [642]. All ethical clearances, trial registration, and permissions were complete prior to commencing data collection.

Autonomy requires that decisions made by individuals are informed, and this necessitates provision of all information regarding a clinical trial [643]. *Veracity* is the obligation to tell the truth [644], and this was upheld in all communications regarding the trial. Older adults may be vulnerable [645] and have issues regarding capacity to give informed consent [646]. Details of screening individuals and proxy consent are given in Appendix U Capacity of Individuals to Participate in Decision-making; along with strategies for enhancement of the informed consent process. The concepts of *beneficence and non-maleficence* are similarly discussed in context in Appendix U Capacity of Individuals to Participate in Decision-making.

Confidentiality.

Participants were de-identified by allocating a study number to each participant. The key linking the coded identity of the participant was safeguarded by a password-protected file held by the researcher. All electronic devices and data storage were password protected and protected against hacking. Confidentiality agreements (see Appendix R Ethical Clearance and Trial Registration Documents) were signed by all staff involved with the research project. The researcher committed to not revealing confidential information to anyone who is not already in possession of it; and upheld her legal and ethical duty to observe confidentiality and privacy [647]. There were no breaches of confidentiality during the study. Should there have been, the UCT Faculty of Health Sciences HREC would have been informed immediately.

Risks and benefits for participants.

In South Africa, the risks of research interventions are compared with risks routinely encountered in everyday life [561]. As discussed, falls are frequent events when older individuals conduct ADL. Thus, it could not be guaranteed that falls would not occur during the trial, but these might be independent of the interventions. However, the potential risks of the interventions were evaluated.

Exercise-based interventions for improving balance in older adults can be regarded as safe, and for the OEP, benefits outweigh the risks [32]. There is sparse information on the types and frequency of injuries associated with the use of the WBB. Most literature consists of case reports, problems are mild and the prevalence of injury low [(648)]. Exposure was carefully monitored to avoid prolonged repetition of actions in games. In addition, the importance of warm-up exercises, moderation, and hydration was emphasised [(649)].

At the end of the trial, on-line training in both programmes was offered for staff members from each site. Research personnel remained available for additional support. WBB equipment was donated to the sites.

Justice.

Research in vulnerable populations or communities is only justified when it responds to the health needs of that community [(650)]. Falls and ageing are global problems, so there is a need to explore fall prevention strategies even in resource-constrained settings. The research is cognisant of social justice in that the research priorities are of concern to older adults [(651)].

Interventions need to be reasonably available to those who need them [(650)], and accessibility was a key motivation for this research. On-going support after the study has ended will ensure that those who have participated in the research continue to benefit from it [(651)]. Outcomes of a future large-scale study may be used to lobby for policy change and implementation, ensuring that the benefits will extend beyond the study population themselves, to the ageing population in general.

Justice demands that the selection of participants is fair, and that both the risks and benefits of participation are distributed equally [(644)]. Participants were

[32] See Chapter I. Fall Risk Factors in Older Adulthood.

selected as they related to the research question, that is, they were at risk for the disorder under investigation [(652)]. Gender, ethnic origin, socio-economic or linguistic background did not influence selection. Selected participants were likely to gain from the findings of the research [(644)].

Competence of researcher and staff.

The researcher is a clinician/researcher with over 30 years' experience in vestibular and balance assessment and management. She has directed national courses in vestibular assessment and rehabilitation therapy and taught alongside the international faculty that these courses have attracted. Development of this research was in conjunction with world authorities in vestibular rehabilitation, balance, and falls assessment and management. The supervisors are highly qualified academics (both with a physiotherapy background) with international reputations in clinical trial research at prestigious institutions, and healthy ageing/geriatrics, respectively.

The researcher attended Levels 1 and 2 of the Clinical Investigation Certification and Site Management (CLIC) Course (2015) and the required Good Clinical Practice certification training (2015; updated 2018). All research personnel, except for the statistician, were qualified and registered healthcare professionals bound by oaths and professional codes of conduct. Technical support was in place for the WBB. An otologist specialising in balance disorders was recruited to assess adverse events along with the rest of the management committee.

Referral.

The researcher facilitated written referrals (see Appendix V Example of Participant Referral for Further Services) for any conditions for which it was warranted. For example, those failing to meet the participant selection criteria due to screening test for depression or cognitive decline were referred to their health care practitioners for management. No condition resulting in exclusion was acute, and identified individuals were able to wait until his/her next routine visit to their health care practitioners. Routine follow-up avoided placing an additional burden on any participant due to showing interest in the study

Insurance for research-related injuries.

UCT sponsored the no-fault insurance for the study (see Appendix R Ethical Clearance and Trial Registration Documents). This information was disclosed to participants prior to study enrolment. The researcher has personal professional insurance and sites had pubic liability insurance. The following section describes the qualitative component of the research.

Qualitative Component

Aim

The aim was to explore participants' lived experiences of falls and the trial interventions.

Objectives.

The objectives were:

- To explore participants' attitudes towards falls and fall prevention strategies;
- To understand the participants' experience of the interventions; and
- To explore barriers and facilitators to participation in the exercise programmes.

Study Design

Using the phenomenology tradition, the design for the qualitative component of the research was a descriptive content analysis of data generated by focus groups [88, 653].

Framework for focus group design.

Focus group interviews and subsequent qualitative and quantitative content analysis (654) was conducted using an individualistic social psychology perspective (655). The latter is a common approach to explore patient satisfaction or the effects of programmes (655). Using the same paradigm, Ryan and colleagues highlighted the following constructs:

- Information is based on the ideas which individuals bring to the group.
- Assumptions that constructs raised are inherently stable.
- Interactions within the group should reveal a range of opinions regarding the topic of discussion.
- The group is structured and managed to stimulate thinking and interaction between group members.
- While still respecting qualitative methodology, there is a scientific orientation towards such issues as replication and objectivism. For example, questions may be directive.
- Protocols are standardised. Attempts to reduce bias are made (e.g., managing a participant's behaviour should s/he dominate the group; or individuals are reticent).
- The evidence that is generated is usually basic information and simple qualitative description.

A criticism of focus group methodology is that if the topic is intensely personal (e.g., living with stigmatising illness), fewer rich data may emerge (656) compared with individual interviews (657). Moreover, the group dynamic may reduce the range of issues discussed, and be limited by the intervention of the facilitator, while other approaches are less directive (655). Specific to the design, the primary focus was on speech content, thus non-verbal cues and other inferences were not considered [655]. Even though falls are described as stigmatising [241], the researcher noted participants' receptiveness and openness toward fall prevention. Therefore, a focus group was apposite to gather data in an efficient manner [658], and was compatible with a feasibility study. Furthermore, participants' acquaintance due to living at the same site facilitated a comfortable exchange of information [659]. Despite some disadvantages, focus groups permit collection of opinions about an intervention [655].

Sampling Plan

Sampling strategy and selection criteria.

Criterion sampling, used in phenomenology [660] identified willing participants. Intervention participants who attended their final endpoints were invited to participate. Ideal participants are data-rich, reflective, articulate, and diverse in opinion [661]. Participation was not linked to exercise adherence, as differences in experiences of the interventions were sought [661]. However, selection bias [662] is possible in that several participants did not attend the final outcome session and thus, their views were not sought.

Sample size.

The ideal sample size for each group is six to eight participants [657]. Restricting the size of the groups allows more time for discussion of each topic [660]. A group at the site of each intervention was planned. Multiple focus groups allow determination of data saturation [663]; but when using content analysis three to four groups are generally adequate [660].

Recruitment.

Willing individuals were contacted by the group facilitator and asked if they wished to participate. Using an assistant to contact the potential focus group participants likely reduced pressure to participate, as participants did not have a therapeutic relationship with that individual. Informed consent (see Appendix D Informed Consent Documents for Individual Participants) was sought prior to participation in the focus group.

Focus Group Setting

Each group was held at the respective site's common room. These rooms are private and routinely used for fun, social activities, so were unlikely to provoke anxiety in the participants [(659)].

Procedure

Permissions and consent.

Permission was granted from UCT's Faculty of Health Sciences HREC (see Appendix R Ethical Clearance and Trial Registration Documents for 2017 Protocol amendment for focus group permission).

Site access had already been granted. A thank you letter for continued access was sent to the managers, with a request for focus groups to be held at the site (see Appendix W Focus Groups). Individual consent for participation in the group (see Appendix D.3 Information sheet and Informed Consent Documents for Focus Groups.) was taken by the facilitator. The limitations to confidentiality (due to the nature of the group) were outlined. Participants were advised they were to be audio-taped, reminded of the assurance of anonymity, and requested to respect confidentiality. Participants who felt uncomfortable being audiotaped were free to withdraw.

Focus group procedure.

Groups commenced with refreshments and a relaxed, informal atmosphere was created. The facilitator re-introduced herself to the group (she had been a research assistant in the RCT) and highlighted the aims.

1) Individual task

Participants were asked to reflect on:

a) their construct of falls and fall management/prevention;

b) experiences of the intervention, and

c) their reasons for adherence or withdrawal.

Concept notes were made on colourful Post-it™ notes, which were placed on a flip chart and used to guide the discussion.

2) Focus group discussion

The facilitator used the interview schedule (see Appendix W Focus Groups) and flip chart to guide the discussion. She used pauses and probes when discussion flagged. Pauses ensured exhaustion of a topic prior to moving to the next; while probes (e.g., "tell me more", or "can you explain why you think this?") encouraged further discussion [664].

3) Close of focus group

Participants were thanked for their participation, given a token of appreciation and invited to partake of more refreshments.

4) Post-group activities

All groups audio recordings were transcribed verbatim. Transcriptions were verified against the audio recordings by the researcher.

Facilitator Preparation and Management of Group

Ground rules such as having only one person speaking at a time, signalling when a participant wished to speak, and switching off mobile phones were explained [(664)]. The facilitator indicated that she may need to progress the discussion at some points to complete the discussion on the three topics.

Participants were informed they could talk freely about their experiences of the interventions, whether positive or negative. The facilitator guided the discussion and was aware that she should not actively participate in it [(659)]. The facilitator recognised that views may have been critical of the interventions and strove to maintain an open and natural attitude. The facilitator avoided encouraging statements such as: “yes/I agree/OK”. Such comments may have indicated to the group areas where discussion may or may not be acceptable [(664)]. She strove to maintain neutral body language and facial expressions.

Shy participants were drawn into the group by directing a question to them. The facilitator stressed that she would like a range of views to be heard, in the hope that one person would not dominate the group [(659)]. Verbose participants were managed by requesting that they summarise their key point/s and then have further discussion after the group has been completed [(664)].

Assistant facilitator’s role.

The assistant facilitator was known to the participants, having assisted at the initial recruitment presentations. He had no active role in the discussion. His role was to ensure smooth recording of the session, greet anyone who arrived late, arrange seating, and ensure the refreshments were served.

Materials

- *Stationery:* flip chart, felt-tipped pens of different colours, brightly coloured Post-it™ notes.
- *Informed consent and information sheet documents* (see Appendix D.3 Information sheet and Informed Consent Documents for Focus Groups.).
- *Interview schedule* (see Appendix W.2 Interview schedule for focus group discussions.).
- *Name tags.*
- *Mobile phones* (one main, one back-up) with voice recording application.
- *Modest refreshments* (e.g., tea/coffee, muffins, biscuits, savouries).
- *Modest thank-you gifts* (UCT branded pens and plastic document storage folders, total value <R30 per gift).

Rigour and Trustworthiness

In qualitative research, the concept of trustworthiness is explained by the true value of the results, known as credibility, the applicability of the results, termed transferability, and dependability [665, 666]. Table 9 describes endeavours to promote trustworthiness.

Table 9. Endeavours to promote trustworthiness.

Credibility (The validity of conclusions drawn from data [667]).
• Careful selection of focus group participants [668]. • Verbatim transcription of audio recordings and verification of transcription [667]. Although video recording was not conducted, the facilitator did not note conflicting non-verbal cues or guarded behaviour. • Appropriate sample size [656]. However, increasing sample sizes does not necessarily result in richer data [656]. • Sufficient data ensure content analysis will highlight similarities and differences within the transcription [668]. • Debriefing with research supervisors [667]. • Member-checking was not utilised primarily due to participant fatigue. In addition, there was a risk of social desirability, recall and other participant-linked sources of bias.
Transferability (The applicability of the findings in other settings [667]).
• Assuring data saturation, where no new data, themes or codes arose [656].
Dependability (Consistency of results within and between studies [667]. Dependability also speaks to which codes or quotes to allocate to a specific category [668]).
Within study: • Checking for coding consistency at two points in time supports quality assurance [654]. A sample of the data was coded initially, and the coding repeated ten days later to evaluate and modify the coding frame. • Data-driven validity issues are revealed by examining the distribution of coding across the sub-categories [669]. If there were high frequency counts for residual categories, then more sub-categories were created [669].
Concept-driven validity (Comparing the results to what is already known to experts in the topic [654]).
• The researcher's supervisors are experienced qualitative and quantitative researchers and reviewed the coding frame. This method may be controversial [670].
Triangulation of results (Collation of evidence sourced by different research methods or types of data collection [671]).
• Triangulation allowed more holistic understanding of the participants' experience of the intervention and adherence.

Table 9 continued.

Confirmability (The objectivity of the research [667]).
• Efforts towards *reflexivity* were made by thorough description of the researcher's and facilitator's credentials, training and therapeutic alliance with the participants [667]. • The researcher was aware of her own stance regarding the research topic and the subjectivity of her interpretation.
Shaman effect (An individual's specialised knowledge and desire to provide feedback overshadows the data set's richness and thickness [656]).
• The facilitator was trained in appropriate focus group techniques.

Data Analysis

Data gathering and analysis occurred concurrently [670]. A qualitative content-orientated analysis [655] was used; acknowledged as method in its own right [654]. Qualitative data indicated what was said, while quantitative information highlighted the frequency of the codes counted [88]. The latter quasi-statistical data may provide an indication of the level of agreement on the issues discussed [663].

Deductive methods have a risk of bias, and the predetermined and thus inflexible framework are compelling reasons to avoid this approach [670]. In contrast, inductive reasoning makes few assumptions and allows the data to drive the analysis [665]. This commonly adopted approach is comprehensive, although time consuming [670] and was used in the analysis.

Phases in the analysis process.

Preparatory phase.

Focus group transcripts were read several times to familiarise the researcher and give an overall sense of the data.

Organising phase.

Units of text were coded into categories. A category is a description and reduction of text (which reflects the participants' opinions), while still maintaining the meaning of the content [88]. Categories are abstracted beyond the specifics of the transcribed data, and may apply to several passages of text [669]. Categories represent the main product of the analytical process, which contribute to the development of themes [88]. Suggestions for effective categories were informed by Schreier [654]:

- A concise name for the category.
- A description of, and indicators for the category, e.g., specific words.

- An example of text included in the category.
- Decision rules in cases of category overlap

Categories were clustered into themes. Themes require interpretation of the data and the implied meaning of the participants' words and experiences [88]. In content analysis, themes may be based on the frequency of occurrence in the text [653].

Reporting phase.

The final phase of analysis is reporting the data [653]. A summary of categories and themes is presented in the results. A quantitative count of contributions to categories is outlined [671]. Key pieces of text were selected, which illustrate the themes and assist with answering the research question [653].

Ethical Considerations

Having a research assistant make appointments for participants promoted *autonomy* and reduced the risk of coercion or social pressure to partake in the focus group. The small gift was unlikely to be construed as coercion, as it was not announced when recruiting. Moreover, the participants came from a background where a low-value gift would not be enticing.

Privacy: To protect their identity for the analysis and subsequent reporting, participants were asked if they wished to choose pseudonyms. None did so, thus, participants are simply referred to as Participant (P) 1, P2 etc. Groups are presented as WBB/OEP groups without reference to specific sites. There is no way to link individual identities to groups or sites, thus protecting privacy. However, participants were known to each other, and this was outlined in the informed consent document (see Appendix D Informed Consent Documents for Individual Participants). Participants were asked to preserve confidentiality by not discussing opinions voiced in the group outside the session.

Non-maleficence: It was not anticipated that any harm or emotional distress would result from participation in the group. However, provisions for support and feedback were made [(672)]. The researcher is qualified in psychological first aid and would have administered it if required, along with any further referrals. From earlier indications to the researcher, participants appeared to be eager to share their experiences of the interventions. Thus, the *risk/benefit ratio* appeared satisfactory.

CHAPTER VII. RESULTS

The results of this study are presented according to the Aims and Objectives[33].

Results of Aim 1

Aim 1 evaluated the feasibility issues pertaining to the design of a future fully-powered cluster RCT.

Objective 1. Site and Participant Recruitment

Three of six potential sites contacted directly by the researcher were enrolled. After successful enrolment of Site A, snowballing recruitment occurred to recruit Site Y. Site Y's manager was enthusiastic, however, the residents' committee indicated they were "past the point of interest in such projects." The manager suggested the average age of residents (≈90 years) likely contributed to their decision. Site D was successfully recruited using snowballing, as the researcher treated a patient from that site in her private practice. After the consultation, conversation turned to the research project, and the patient provided an introduction for her retirement village.

Overall, 36 hours were spent on site recruitment activities, including non-enrolled sites. Appendix X Additional Data for Results Chapter outlines the processes followed from first contact at the site to recruitment of individual participants at Site C. Similar processes were followed at all sites.

Failure to enrol sites.

The nurse manager of Site Z anticipated too few (6-8) residents would be interested in enrolling. The site was excluded, as an objective was ≥15 participants/site. Site X had a management structure which acted as a central hub for several other sites. Site X was eventually abandoned after repeated visits and

[33] Note that the researcher is aware of the convention not to cite references in Results. Those shown are to support formulae; or to inform the reader of contextual issues not commented upon elsewhere.

phone calls following up initial contact. Instability within Site X's nursing staff structure was reported as the reason for a decision not having been taken. The nursing staff were the pivotal decision-makers to assess the research proposal at Sites Z, X, A, and D.

Procedures linked to site initiation.

Results of the site inspections and site enrolment procedures are shown in Appendix C Documents Pertaining to Site Recruitment.

Description of sites.

All sites met the eligibility criteria. Complex negotiations regarding community entry were not required. The researcher is from a similar linguistic and ethno-cultural background to the residents of the sites.

The Southern suburbs of the Cape Town metropolitan area are predominantly English-speaking, and most suburbs' properties would require middle- and upward incomes to purchase homes[34]. All sites housed independent community-dwelling older adults[35]. Sites A and B are administered by the Cape Peninsula Organisation for the Aged (CPOA). This organisation sells properties on a life-rights basis. Income generated by the CPOA cross-subsidises residences in less affluent areas.

Site C offers both subsidised and non-subsidised apartments in the same complex for older adults who originate from the suburb in which it is located. Residents may have independent private incomes or are reliant on state pensions (thus low- income[36]). Site C is run by a board of trustees and does not aim to make

[34] Reference: *Understanding Cape Town property prices. Affordability of property prices in terms of household income*. Retrieved 6 December 2018 from https://ctproperty.weebly.com/property-prices-by-income-affordability.html.

[35] See Glossary of Terms.

[36] The current amount per month for a state old age pension is ZAR1 690, which equates to US$122.65 per month (exchange rate information correct as at 5.12.2018, retrieved 5 December 2018 from https://zar.mconvert.net/usd/1690). Reference: Kelly, G. (2017). *Social Grants. Everything you need to know about social grants.* Retrieved 6 December 2018 from https://www.groundup.org.za/article/everything-you-need-know-about-social-grants_820/.

a profit. Site D properties are sold on a life-rights basis and the estate is run by a board of trustees and professional management staff.

Site and protocol feasibility checklist.

A feasibility checklist was completed for each site and the results are shown in Table 10.

Table 10. Site and protocol feasibility checklist.

1. Population	**Result/finding**
Was there access to a suitable population?	Yes.
Was the proposed enrolment goal realistic?	Yes, although attrition problematic in costs group.
Was the proposed enrolment period realistic?	No. Recruitment was slow at all sites.
Did enrolment compete with other studies or rehabilitation programmes seeking similar participants?	No rehabilitation programmes/studies at any site. All sites had yoga/similar exercise classes available on a weekly basis. One session (Ageless Grace[37]) was observed and involved primarily seated exercises. Site B was participating in a memory study conducted by the University of Cape Town at the time of study enrolment.
Were the inclusion/exclusion criteria overly restrictive?	No.
Was a significant number of adverse events expected?	Fall risk as noted in Literature Review.
How ill was the population?	Post-hoc analysis showed participants at OEP sites (Sites A and D) were older and less well than WBB participants (Sites B and C).

2. Protocol	**Result/finding**
What changes were implemented to the protocol in terms of its design?	Several tests added. See below and Discussion.
Did the University's institutional review board have ethical concerns?	No major issues with ethical clearance.
Did the participants benefit from participation?	Yes. Focus group feedback was mostly positive regarding perceived benefit.
Were services (e.g., GP, physiotherapy) required, either screening for eligibility/during the study?	Referrals to independent physiotherapists were made pre- and during the trial for non-balance related issues.
Was necessary equipment and space available?	Yes. Site D participants preferred to be seen in their homes rather than the common area. As the homes were spacious, with moving some furniture, tests could still be completed.

[37] https://agelessgrace.com/ Retrieved 20 November 2018.

Table 10 continued.

2. Protocol Result/finding cont.	**Result/finding**
Were participant attrition/adherence problems foreseeable?	No. Due to unforeseen circumstances (waiting for equipment and a crisis in university education in South Africa – see below) there was a delay of up to four months for some participants between attending the recruitment presentation, enrolment and intervention entry. During this time several participants "cooled off" and then declined to join the intervention programme.
What modifications are needed to the case report forms?	Additional tests included, e.g., standard, sharpened and semi-tandem Romberg tests, FICSIT-4, and FTSST.
Were the data/case forms storage/accountability requirements complicated?	No
What problems were encountered with sustaining the programme, so that it could be available for participants at the end of the study?	No problems, all equipment left on site and with participants.

Table 10 continued.

3. Assessments	Result/finding
Were assessments frequent?	Assessments done at mid-point and end of study.
Were assessments difficult to conduct in the study population? E.g., were participants able to do more ambitious tests like the Mini-BESTest?	Participants were very apprehensive for the 30s stand on foam with eyes closed (embedded in Mini-BESTest). Participants expressed anxiety before the Mini-Cog, introduced as a memory test. Individuals were informed screening was necessary to prevent potentially vulnerable individuals being enrolled. The inclusion of the test to satisfy ethical requirements was discussed, yet potential participants still appeared apprehensive. Six individuals who failed the screen were offered a repeat test and were ultimately enrolled. All Mini-Cog excluded individuals were counselled appropriately by the researcher, who has extensive experience and training in addressing emotional issues and a psychology first-aid qualification. Permission/assent was sought from excluded individuals to inform nursing staff/site management of the failed screen, in order to observe duty of care.
Were the participants able to complete the exercise logs and report falls?	Although all participants had a minimum of secondary education, and English as their home language (with one exception who was mother-tongue Afrikaans, but proficient in English), assistance with the questionnaires was required. The negatively worded items in the GDS were particularly problematic. Few participants completed the PASE independently, leading to researcher-administration. Completion of exercise logs was sub-optimal. Participants failed to record falls on the log, and only revealed them when questioned at the follow-ups. No participant completed documentation of expenses related to falls.
Was the exercise schedule complex?	No.
4. Staff	**Result/finding**
Were qualified staff available to support participants and contact the research team if necessary?	Yes. The physiotherapist and site managers were able to contact the researcher at any time. The researcher's landline was diverted to her mobile telephone when she was data collecting in the field.

Table 10 continued.

If needed, was training available?	Training described in the Methodology Chapter. The researcher herself has a background in vestibular management including rehabilitation and conducted the initial assessments. She was present for follow-up in every participant. Training was provided for the research assistant. Training was provided for the data capturers.
Did the researcher have adequate time to devote to the study?	Very challenging as the researcher works and teaches full time. Unforeseen events, such as national student protest action[38] resulted in the University requiring staff to complete additional teaching and examinations at short-notice[39]. At times, data collection had to be delayed until university vacation periods, making precise timing of follow-up visits difficult.
Were additional staff required?	The use of a research assistant for follow-up assessments was necessary for blinding purposes. Her presence facilitated more efficient data collection. For example, she set up the tests while the researcher was engaging with the participant and assisting with questionnaire completion. A secretary was required to schedule initial and follow-up appointments due to the researcher's time constraints.
Were study visits complex, presenting possible scheduling difficulties, e.g., how many different study staff did participants encounter in a given visit?	Scheduling was comparatively straightforward. Participants encountered 1) the researcher on every visit and 2) the same research assistant on each follow-up assessment visit. The assistant's hours were flexible, which was helpful. The same physiotherapist did both interventions with all participants. Both the physiotherapist and research assistant were in equipoise.

[38] Makoni, M. & MacGregor, K. (2016). Violent protests at universities, including Cape Town. *University World News,* Issue 401, 20 February 2016. Retrieved 5 December 2018 from: Http://www.universityworldnews.com/article.php?story=20160219151407906.
[39] *Faculty of Health Sciences' suspension of classes in years 1-3 of undergraduate programmes and completion of teaching and examinations in Mini-semester in January 2017.* Retrieved 5 December 2018 from : Http://www.health.uct.ac.za/news/suspension-classes-years-1-3-undergraduate-programmes-and-completion-teaching-and-examinations.

Table 10 continued.

5. Budget	**Result/finding**
Did the preliminary budget appear adequate?	Yes. No unanticipated expenses.
6. Other	**Result/finding**
Were electronic or remote data retrieval systems used?	For the feasibility study, all data collection was completed manually into a source document. Data were captured to an electronic database (Redcap). For a future large-scale study, data could be entered directly on a tablet into the database.
Does the sponsor/PI expect this study to be audited by the regulatory bodies?	Possible, but unlikely as a non-pharmacological intervention.

Legend: FICSIT-4: Frailty and Injuries: Co-operative Studies of Intervention Techniques; FTSST: five times sit to stand test; GDS: Geriatric Depression Scale, GP: general practitioner; OEP: Otago Exercise Programme; PASE: Physical Activity for the Elderly Scale; PI: primary investigator; WBB: Wii Balance Board intervention.

Recruitment of participants.

The aim was to recruit a target sample size of 30 participants per intervention (in clusters, requiring four sites) over a four-month recruitment period. Upon site enrolment, one recruitment presentation was held per site between October 2016 and April 2017. Screening for eligibility of potential participants commenced in December 2016 until May 2017. Interventions were introduced from April 2017.

Participant screening and enrolment.

Eighty-eight potential participants attended eligibility appointments. Immediate exclusion prior to further assessment or consent occurred. Instances included use of mobility aids, and dementia reported by spouses. Table 11 accounts for the final number of participants. A total of 132 hours was spent on individual consent procedures and assessments. These hours represent contact time. Travel, venue/test set-up, gaps between appointments and individuals for whom time had been allocated and cancelled/ failed to attend is excluded. Interviews to obtain informed consent and conduct baseline measurements (questionnaires and physical endpoints) took one and a half hours per enrolled participant and were conducted by the researcher. Breaks during the assessment due to participant fatigue or dizziness were not necessary. Husband and wife participants were allocated a total of two hours as the questionnaires could be completed simultaneously.

Table 11. Recruitment of participants at each site.

Potential trial candidates	Site A (OEP)	Site B (WBB)	Site C (WBB)	Site D (OEP)
Total number of residents	79	83	92	90
Number estimated by manager to be independent	60	83	90	75
Completed indication of interest slip	23	28	40	18
Number of appointments made (note one appointment may have involved two potential participants if partners)	19	21	34	24
Number excluded by researcher prior to screening appointment (due to information revealed when contacted)	In frail care (1)	Orthopaedic injury (1)	Not well (2) Going away (1)	Orthopaedic issue (1)
Number declined to make appointment	No reason (2)	No reason (3) Too busy (1) No longer interested (1)	Too busy (2) Not well (3)	No reason (1)
Number of cancellations/no-shows	3	4	2	1
Number attended eligibility appointment N=88	14	20	34	20
Number who kept appointment and excluded prior to consent due to obvious exclusion criteria/individuals' reports	Too young/ intellectually challenged (1)	Walking stick (1) Knee replacement scheduled (1)	Dementia (2) Fractured pelvis (1) Walking stick (3) Recent hip replacement (1) Pre-surgery (2)	0

Number who kept appointment, consented but excluded from interventions due to not meeting eligibility criteria	Failed Mini-Cog (3)	Neurological disorder (1) (hydrocephalus, depression failed Geriatric Depression Scale) Sacral implant (1)	Failed Mini-Cog (3) Cardiac pacemaker (1)	Failed Mini-Cog (1) Acute dizziness (1)
Number who kept appointment but declined to enrol (i.e. eligible, refused)	Too irritable (2)	"Bitten off too much" (1) possible underlying anxiety	Too busy (3) Anxiety (1)	0
Total enrolment N=58	8	15	17	18

Note:

1) some individuals screened had ≥1 exclusion criterion; for some couples one response slip was completed for two individuals, hence the apparent disparity in the numbers.
2) The researcher is ideologically opposed to labelling/categorising individuals by their health condition [673] (e.g., the vestibular neuritis in bed 3), but the conditions are so listed in the Table for brevity.

Flow of participants through study.

Thirty participants commenced the interventions and 28 were enrolled in the cost-analysis only arm of the trial. The costs group included seven participants who withdrew immediately from the interventions. Reasons included already having an exercise regimen (3) and four cited loss of interest (they are not shown in the CONSORT diagram which follows). They were included in the costs group as they had baseline data and no follow-up (four WBB, three OEP).

shows participant follow-up throughout the study. For the costs group, only one participant completed full testing at baseline, three and six months.

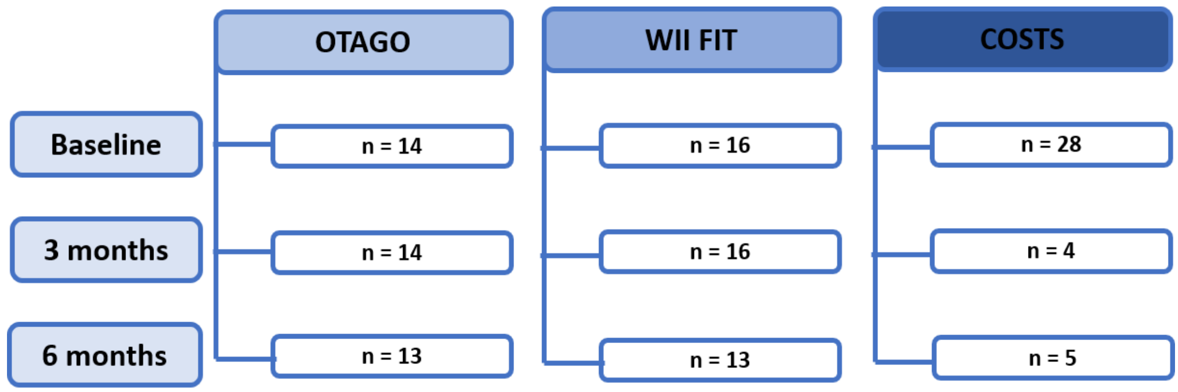


Figure 13. Numbers of participants available at follow-up points.

A CONSORT diagram of intervention participants' flow throughout the trial is shown in Figure 14. Several (seven WBB; six OEP) participants discontinued the interventions, despite this, most (81.2% WBB; 92.8%) presented for follow-up assessments.

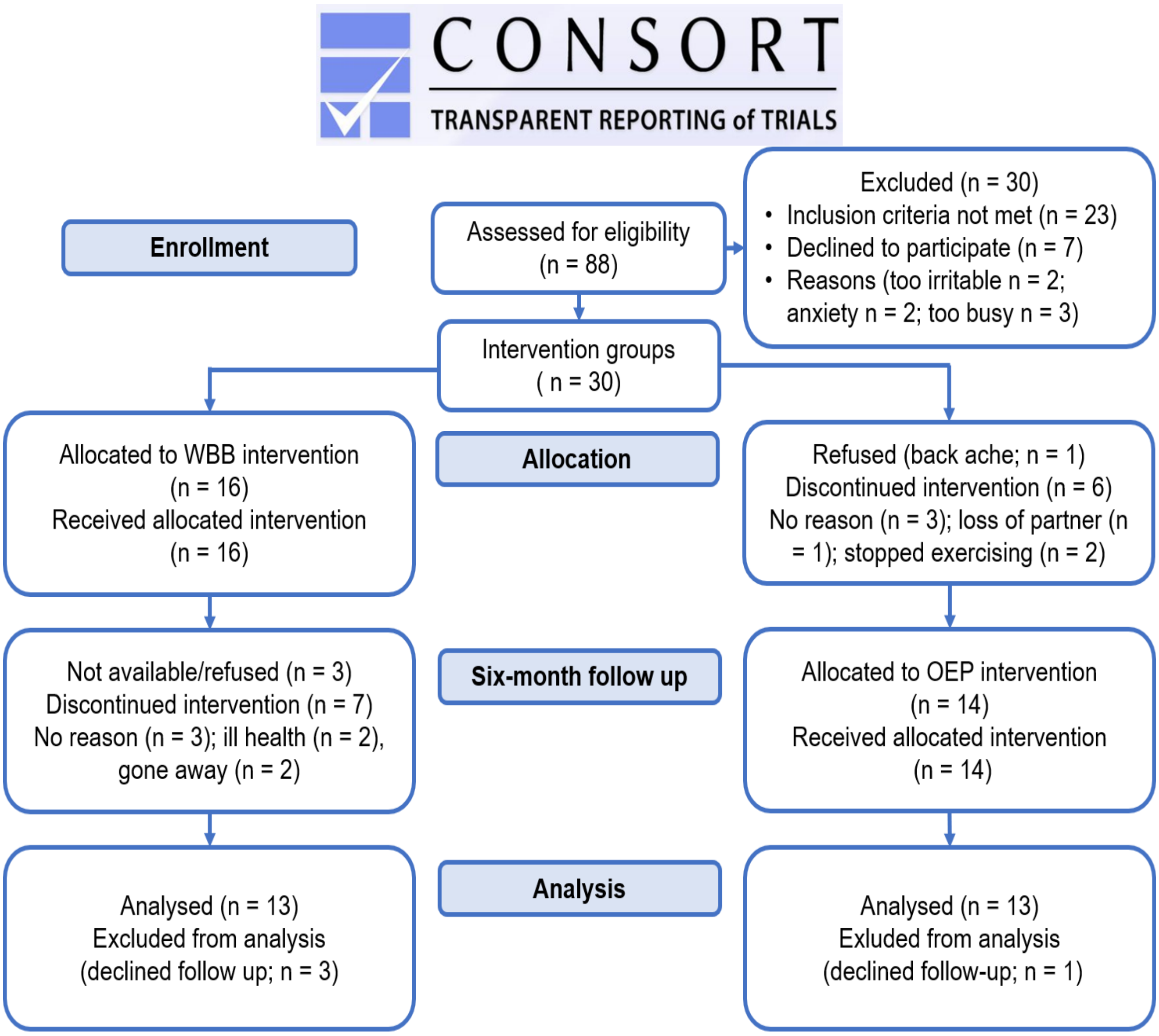


Figure 14. CONSORT flow diagram for intervention participants.

Profile of participants.

Table 12 presents participants’ demographic information including case history results, Functional Comorbidities Index and medication profile.

Demographic and case history information.

A female predominance was noted (≈ 2:1). Around half (48.9%) the participants had university or similar post-high school education. Combined, 50% of the sample had fallen in the year preceding enrolment. Symptoms of imbalance and dizziness were reported by all groups. Most common were vertigo, nausea, positionally- and posturally-induced symptoms.

Table 12. Participants' demographic data.

Variable	OEP *N* = 14	WBB *N* = 16	Costs *N* = 28
Sex			
Male	5 (35.7%)	3 (18.8%)	5 (17.9%)
Female	9 (64.3%)	13 (81.3%)	23 (82.1%)
Age (Years. Months ±SD) (range)	81.7±6.2 (72–92)	75.6±6.4 (67-87)	81.4±6.6 (70-97)
Mini-Cog score/5	4.5±0.9 (3–5)	4.6±0.7 (3–5)	3.9±1.3 (3–5)
Highest educational achievement			
< Matriculation [40]	0	2 (12.5%)	7 (25%)
Matriculation	6 (46.2%)	6 (37.5%)	9 (32.1%)
Tertiary education	7 (53.8%)	8 (50%)	12 (42.9%)
Marital status			
Single	2 (14.3%)	2 (12.5%)	5 (18.5%)
Married/ living with partner	6 (42.9%)	4 (25%)	10 (37%)
Divorced	1 (7.1%)	0	3 (11.1%)
Widowed	5 (35.7%)	10 (62.5%)	9 (33.3%)
Owns computer	12 (85.7%)	14 (87.5%)	16 (57.1%)
Basic computer literacy [a]	11 (78.6%)	13 (81.3%)	17 (60.7%)
Falls in year preceding enrolment (395)	6 (42.9%)	8 (50%)	16 (57.1%)
Single fall in last year	2 (33.3%)	6 (75%)	10 (62.5%)
Recurrent falls in last year	4 (66.6%)	2 (25%)	6 (37.5%)
Injurious falls category A	0	1	7
Injurious falls category B	2	3	2
Injurious falls category C	2	0	5

[40] Grade 12 school-leaving qualification also known as National Senior Certificate, typically undertaken at age 18 years. Reference: National Senior Certificate, retrieved 11 December 2018 from https://ncedu.ncape.gov.za/index.php/teacher/national-senior-certificate

Table 12 continued.

Variable	OEP N = 14	WBB N = 16	Costs N = 28
Injurious falls category D	3	2	5
Injurious falls category E	1	4	2
Indoor falls/outdoor falls	5/1	4/3[c]	7/9
Trip/slip	6/1	8/1	8/7
Symptoms of imbalance			
Vertigo (hallucination of movement of self or environment)	5 (35.7%)	3 (18.8%)	5 (17.9%)
Floating sensation	2 (14.3%)	2 (12.5%)	4 (14.3%)
Tendency to fall	1 (7.1%)	0	3 (10.7%)
Fainting	1 (7.1%)	2 (12.5%)	5 (17.9%)
Rotating or spinning of head	1 (7.1%)	2 (12.5%)	0
Nausea	3 (21.4%)	2 (12.5%)	7 (25%)
Sudden slips or trips	2 (14.3%)	2 (12.5%)	0
Positionally induced symptoms	5 (35.7%)	7 (43.8%)	4 (14.3%)
Posturally induced symptoms	5 (35.7%)	2 (12.5%)	8 (28.6%)
Physical strain	1 (7.1%)	0	1 (3.6%)
Transferring from seated in a chair	3 (21.4%)	1 (6.3%)	1 (3.6%)
Self-perceived memory score [b, c] /10	7.2±1 (5–9)	7.6±1 (6–10)	7.2±1.4 (4–10)
Functional Comorbidity Index score [d] /18	4.6±1.8 (2–8)	3±1.8 (1–7)	4±2.3 (1–10)
Number of prescription medications	4.9±3 (2–13)	3.5±2 (1–7)	4.3±2.2 (1–12)

Legend: SD = standard deviation; Category A: Serious injury: hospital/emergency services for fractured bones, head or internal injuries. Category B: Moderate injury: wounds, bruises, cuts requiring a medical/health professional examination. Category C: Minor injury: minor bruises or cuts not requiring health professional assistance, reduction in physical activities for at least three days. Category D – No physical injury detected. Category E: no injury but afraid of falling again [(395)].
[a] Able to Google and do emails. [b] Maximum score of 10. Higher score = better memory. [c] One participant did not answer the relevant question. [d] Higher scores = more medical conditions/comorbidities.
For continuous variables, means are presented ± SD, with range in parentheses. Categorical variables are presented as actual number of participants, with proportions in parentheses.

Baseline demographic/case history data between-groups comparison.

There was a significant difference between groups for age (F (2,57) = 4.9, p = .011); with the OEP and costs group significantly older than the WBB group (p = .035, and p = .017 respectively). A significantly higher proportion of participants in the OEP and WBB groups owned their own computer compared to participants in the costs group (*Fisher's test*, p = .05, V = 0.33). A significantly higher proportion of participants in the OEP and WBB groups fell due to tripping over an obstacle compared to participants in the costs group (*Fisher's test*, p = .005, V = 0.56). All other one-way ANOVAs and chi-square tests showed no significant difference between the WBB and OEP at baseline, or between either of the exercise-based intervention groups and the costs group.

Prescription medication use.

Thirteen (92.9%) of the OEP group, 14 (87.5%) of the WBB group, and 28 (100%) of the costs group were using prescription medication. However, there was no statistical significance between groups (p = 0.132). Half or more participants in each group (69% OEP; 50% WBB, and 61% costs) were taking ≥4 medications; although there were no statistically significant between-group differences (χ^2 = 1.05, p = .132, V = 0.24). Of those taking medication, the majority (76%) were taking cardiac/anti-hypertensive/respiratory treatment, and a large proportion (45%) were taking psychotropic drugs.

Functional Comorbidity Index.

Details of the Functional Comorbidity Index are shown in Table 13. The most common chronic health conditions reported were arthritis (>60% of participants in each group), osteoporosis and anxiety and panic disorders (≈30% in each group), cardiac conditions, and severe visual impairment (e.g., macular degeneration, history of glaucoma, cataract surgery. The latter could have inflated the prevalence of ocular pathologies). Note however, that vision and hearing had to meet inclusion criteria. Neurological disorders included a participant with a vestibular schwannoma and another with proprioceptive abnormalities. A significantly higher proportion of participants in the OEP and costs group had a degenerative disc disorder compared to those in the WBB group (p = .026). A higher proportion on participants in the OEP group had an upper gastro-intestinal tract disorder (e.g., reflux, ulcer) compared to those in the WBB and costs group (p = .051).

Table 13. Functional Comorbidity Index results.

Chronic health condition	OEP *N* = 14	WBB *N* = 16	Costs *N* = 28	χ^2	*p*	*V*
Arthritis [a]	11 (78.6%)	10 (62.5%)	17 (60.7%)	1.41	.495	0.16
Osteoporosis	4 (28.6%)	5 (31.3%)	8 (28.6%)	0.04	.980	0.03
Asthma/chronic obstructive pulmonary disease	2 (14.3%)	3 (18.8%)	4 (14.3%)	-	.588	0.06
Angina/congestive heart failure/myocardial infarct	6 (42.9%)	2 (12.5%)	9 (32.1%)	-	.188	0.25
Neurologic diseases [b]	0	0	3 (10.7%)	-	.320	0.24
Stroke/ Transient Ischaemic Attacks	0	1 (6.3%)	4 (14.3%)	-	.495	0.21
Peripheral vascular disease	3 (21.4%)	1 (6.3%)	1 (3.6%)	-	.135	0.26
Diabetes (Type I or II)	0	2 (12.5%)	3 (10.7%)	-	.581	0.18
Upper gastro-intestinal tract disorders [c]	7 (50%)	2 (12.5%)	5 (17.9%)	-	**.051**	0.35
Depression	4 (28.6%)	2 (12.5%)	6 (21.4%)	-	.584	0.14
Anxiety/panic disorder	4 (28.6%)	6 (37.5%)	7 (25%)	-	.702	0.12
Visual impairment/pathology	10 (71.4%)	7 (43.8%)	20 (71.4%)	3.84	.146	0.26
Hearing impairment	2 (14.3%)	3 (18.8%)	4 (14.3%)	-	.899	0.06
Degenerative disc disorders	9 (64.3%)	3 (18.8%)	15 (53.6%)	7.30	**.026***	0.36
Obesity	3 (21.4%)	1 (6.3%)	4 (14.3%)	-	.477	0.16

Notes: [a] Rheumatoid and osteoarthritis. [b] See text for examples. [c] E.g., reflux, ulcer.
Where no χ^2 statistic is reported, Fisher's exact tests were performed.

Issues Impacting Potential Enrolment

Eligibility and recruitment fractions.

The recruitment number is argued to be all the residents who completed indication of interest slips, which totals ≈109 potentially eligible candidates.

The *eligibility fraction* is:

$$Eligibility\ fraction\ \frac{Recruitment\ number\ (N{=}109)}{Number\ screened\ and\ found\ eligible\ (N{=}65)} = 1.67$$

The *enrolment fraction* is:

$$Enrolment\ fraction\ \frac{Number\ of\ individuals\ assessed\ (N{=}\ 88)}{Number\ eligible\ according\ to\ selection\ criteria\ (n{=}\ 65)} = 1.35$$

The *recruitment fraction* is the product of the eligibility and enrolment fractions, thus: 1.67x 1.35 = 2.25.

The *number needed to screen* to enrol/randomise one participant was:

$$Number\ needed\ to\ screen\ \frac{1}{recruitment\ fraction\ 2.25} = 0.44$$

Refinement of eligibility criteria.

Three exclusion criteria were implemented during the trial. Items 1 and 2 resulted in subsequent exclusion or limited physical endpoint assessment (items 2 and 3):

1) Sacral neuromodulation implants[41] (674) as they are contraindicated for WBB on the same basis as a pacemaker.
2) Acute vertigo/dizziness. One individual’s risk was assessed as so high (e.g., subjective imbalance resulting in furniture- and wall-crawling) she was immediately excluded and referred appropriately.
3) Use of vestibular sedatives. A second participant was unable to complete follow up assessments at three months, having taken a vestibular sedative

[41] Surgically implanted pacing device for incontinence management.

that morning. At six months, she was subjectively dizzy again and the outcome assessor elected not to evaluate physical endpoints due to fall risk.

Objective 2. Issues Related to Cluster Randomisation

Sources of potential bias.

Sources of bias are discussed here, although they are not specific to a cluster design. The recruitment strategy likely promoted *selection bias*. The presentations could have attracted individuals with concerns regarding falling, or those with injurious falls. Indeed, baseline data suggest 50% of the sample had fallen within the preceding year. Thus, fear of falling may have influenced participants. It is equally possible that those unconcerned about falls (but with/without fall risk), or with fatalist attitudes may not have attended. Possible *healthy volunteer bias* exists if participants joined for altruistic reasons. Results from the focus groups offer support for concerns regarding falls and altruism. A *Zylen effect* could have contributed to attrition in the cost group, where loss to follow-up was greatest.

Use of a cluster design.

The cluster design appears to have highlighted between-group differences at case history baseline, including an age imbalance, and computer literacy (see Table 14). Differences in baseline results for the questionnaires are discussed next. Participants' baseline physical endpoints are described later.

Baseline between-group differences for self-assessment scales.

Significant between-group differences on the EQ-5D-3L (p = .029) and EQ-5D-VAS (p = .005) were noted at enrolment. Post-hoc comparisons revealed that WBB participants had significantly lower EQ-5D-3L scores compared to those in the costs group (p = .012). WBB participants had significantly higher EQ-5D-VAS scores compared to costs and OEP groups (p = .003 and p = .015 respectively); suggesting the WBB group enjoyed significantly better self-perceived health-related quality of life than the other groups. There was no significant difference between groups regarding the presence of a positive screen for depression (GDS); nor differences in the exercise self-efficacy (SEE) and physical activity levels (PASE). Table 14 displays aggregated scores at baseline and follow-up, and between-group differences at baseline for the same SAS.

Blinding.

Blinding of the outcome assessor was partially successful. Three instances of unblinding occurred over two sites. However, the outcome assessor was unaware of the participants' allocation to an intervention/costs group, nor adherence data, limiting cross-contamination of the whole pool.

Table 14. Between group differences in self-assessment scales.

								Baseline between-group analysis		
Outcome measure	OEP baseline *n* = 14	OEP 3 months *n* = 14	OEP 6 months *n* = 13	WBB baseline *n* = 16	WBB 3 months *n* = 16	WBB 6 months *n* = 13	Costs baseline *n* = 8	*F*	*p*	η^2
SEE	6.79 (1.60)	6.79 (1.65)	6.38 (1.65) [b]	7.36 (1.81)	6.85 (1.47) [c]	6.24 (1.74)	7.26 (1.75)	0.45	.642	.03
EQ-5D-3L	1.23 (0.22)	1.20 (0.26)	1.17 (0.27) [b]	1.11 (0.13)	1.10 (0.18)	1.18 (0.21)	1.30 (0.11)	3.94	.029*	.18
EQ-5D VAS	77.79 (8.95)	77.71 (11.78)	81.83 (10.52) [b]	85.06 (6.66)	83.88 (10.59)	88.69 (10.71)	74.25 (7.67)	6.14	.005*	.26
GDS	1.31 (1.75) [a]	N/A	N/A	1.13 (1.85) [c]	N/A	N/A	1.50 (1.93)	0.97	.386	.04
PASE**	71.26 (28.12)	65.53 (35.44)	88.45 (39.54)	81.82 (40.04) [c]	70.85 (40.81)	78.43 (32.90)	51.65 (3.83)	2.46	.101	.13

Legend: EQ-5D-3L: EuroQol measure, EQ-5d VAS: EuroQol Visual Analogue Scale; GDS: Geriatric Depression Scale (measure only administered at baseline); N/A: not applicable; PASE: Physical Activity for Elderly Scale; SEE: Self-efficacy for Exercise scale.

[a] Data based on 13 participants. [b] Data based on 12 participants. [c] Data based on 15 participants. [d] Data based on 3 participants.
*p < .05. **One outlier (> 3 SD above the mean) was removed from the WBB baseline data.

Safety, Adverse Events[42] and Falls.

Table 15 depicts the number and severity of falls during the trial. No participant notified the researcher immediately after a fall. Falls were disclosed at follow-up visits. Falls in the costs group are likely under-represented due to a high level of attrition. Three OEP participants fell twice during the monitoring period. One WBB participant reported two falls. A total of 13 falls were recorded for a sample of 30 participants in exercise interventions. Thus, prevalence of falls was 16.6% for participants in the active interventions at a six month follow up, which compares favourably with a pre-intervention fall prevalence of 50% for all participants.

Table 15. Number and severity of falls during trial.

	OEP	WBB	Costs
Number of falls	8	5	2
Injurious falls category A: Serious injury: hospital/emergency services for fractured bones, head or internal injuries.	0	0	0
Injurious falls category B: Moderate injury: wounds, bruises, cuts requiring a medical/health professional examination.	3	1	0
Injurious falls category C: Minor injury: minor bruises or cuts not requiring health professional assistance, reduction in physical activities for at least three days.	1	1	1
Injurious falls category D: No physical injury detected	3	3	1
Injurious falls category E: No injury but afraid of falling again [(395)].	1	0	0
TOTAL falls: 15			

[42] See Glossary of Terms.

Other adverse events.

One OEP participant withdrew due to backache. This was a pre-existing condition, which she felt impaired her participation. No injuries directly related to active participation in the interventions were reported.

Sample size for future trials.

The feasibility study permitted computation of sample sizes for a future RCT. These are presented next.

Projected sample size for a future RCT using simple randomisation.

The 6-month SD and estimates of clinically significant minimal effect sizes (respective to specific tests) were used to calculate sample size for a future RCT assuming simple randomisation. The aim was to detect an effect size of 0.8, allowing for 20% attrition (referenced to published pilot study data [675]), based on two groups of equal size and a two-tailed significance threshold alpha of 0.05. For the pivot turn and stop test (number of steps, embedded in DGI), 15 participants/group would be required. For the FTSST, 46 individuals/group were estimated. Using the Mini-BESTest, 14 people/group were computed. A sample size of 55 per group for a future trial should be sufficient and allows for small levels of non-adherence. However, given the experience of this feasibility RCT, 40% incompletion rate is more likely; thus, the sample size would double to 110 per group.

Projected sample size for a future cluster-RCT.

Cluster randomisation may expose similarities between individuals within a cluster and promote Type 1 error [676]. Using data from the ICC (0.99) for the FTSST and a Minimal Clinically Important Difference (MCID) (2.3s), a Design Effect was calculated using:

$Design\ Effect = 1 + (n - 1)$x 0.99 = 3.97

Due to poor adherence, double the numbers of clusters (8) was thought necessary, to produce a total of 30 fully adherent participants, thus n = 4.

For a comparison of means, in a two-arm trial with equal allocation, the required number of individuals per group = m, is calculated [677] as

$$\mathrm{m} = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2\ 2\sigma^2}{\Delta^2}\left(1 + (n-1)\rho\right)$$

where Z_x is the xth percentage point of the standard normal distribution; Δ is the clinically important difference in treatment means and σ^2 the variance in the outcome. Average standard deviation = 3.97, variance = 15.6, $z_{1\text{-}\alpha\text{-}2\ =}$ 1.96

$z_{1\text{-}\beta\ =}$ -0.82.

Thus, $m = \frac{(1.96 - 0.82)^2 \times (2 \times 15.6)}{2.3^2} \times 3.97 = 30$ per group

Therefore, the total sample size would be 60. Noting poor adherence, 120 participants would be more realistic should a cluster design be employed.

Objective 3. Adherence

Adherence, exercise regimens and relationship to best practice guidelines.

Overall, a total of 30 participants completed the interventions. Exercise logs were lost in several cases, and incomplete in others. Of 14 OEP participants, three were missing all adherence data, and three were missing adherence data between 3- and 6-month appointments. Between enrolment and the 3-month visit, five (54.5%) were exercising ≥4 times/week, and five (45.5%) were exercising <4 times/ week. Between the 3- and 6-month visits, five (62.5%) were exercising ≥4 times/ week, and three (37.5%) were exercising <4 times/week.

Of 16 WBB participants, six provided no adherence data, and seven were missing adherence data between their 3- and 6-month appointment. Between enrolment and the 3-month visit, nine (90%) were exercising ≥4 times/week, and one (10%) was exercising <4 times/week. Between the 3- and 6-month visits, two (66.7%) were exercising ≥4 times/ week, and one (33.3%) was exercising <4 times/week.

Table 16 describes the 3- and 6-month adherence, overall rates of adherence, time spent exercising, and exercise sessions for both intervention groups. The overall rate of adherence to the exercise interventions was 25% for the OEP and 2% for the WBB ($p < .001$). Just over half (53%) of OEP participants exercised 100-minutes/week, whereas less than one third (31%) of WBB participants exercised for 130-minutes/week ($p = .131$). The overall rate of adherence based on >2 hours/week was 38% for the OEP and 41% for the WBB ($p = .832$); whereas the overall rate of adherence based on more than 150 minutes/week (gold standard) was 14% for the OEP and 20% for the WBB ($p = .558$).

Full adherence.

No participant in either group completed 100% of the prescribed exercises at the prescribed frequency, or 150 minutes of exercise/week. Furthermore, only one participant in the WBB group exceeded 2 hours/week. It could not be determined whether the total exposure of >50 hours over six months (best practice guideline) was met, because 12 participants had less than 6-months data (and nine had more than 6-months of data).

Partial adherence (using both a 40% and 50% threshold).

Based on the prescribed exercises at a set frequency.

One OEP participant (9%) and no participant in the WBB intervention partially adhered using a 50% threshold, whereas two participants (18%) in the OEP and none in the WBB intervention partially adhered using a 40% threshold.

Based on >2 hours per week.

Four OEP participants (36%) partially adhered using both a 40% and 50% threshold, where three WBB participants (30%) partially adhered using a 50% threshold and 40% (*n* = 4) partially adhered using a 40% threshold.

Table 16. Minutes and exercise sessions/week for both interventions.

Regimen and adherence	OEP			WBB			*p*-values				
	Time 1: 3-months *N* = 11	Time 2: 6-months *N* = 8	Overall *N* = 11	Time 1: 3-months *N* = 10	Time 2: 6-months *N* = 3	Overall *N* = 10	Otago 3 vs 6 month	WBB 3 vs 6 month	Otago vs WBB 3 months	Otago vs WBB 6 months	Otago vs WBB overall
Average minutes exercise/week	99 (36.3)	93.3 (38.9)	96 (34.9)	105.1 (31.5)	86.6 (34.0)	103.1 (33.5)	.048*	.256	.689	.798	.638
Average exercise sessions/week	4.8 (1.9)	4.7 (1.9)	4.6 (1.7)	5.9 (1.8)	4.9 (1.8)	5.8 (1.9)	.048*	.292	.193	.833	.134
Programme sessions/week	2.1 (0.7)	2 (0.7)	2.1 (0.6)	2.5 (1.1)	2.5 (0.3)	2.5 (1.1)	.095	.872	.415	.264	.400
Walk sessions/week	2.6 (1.4)	2.7 (1.7)	2.8 (1.5)	3.4 (1.0)	2.5 (1.6)	3.3 (1.1)	.105	.247	.175	.839	.362
Adherence											
> 2 hours/week	39.6% (36)	35.6% (38.7)	37.6% (35.9)	41.1% (27.1)	31.7% (25.7)	40.6% (27.7)	.089	.543	.920	.877	.832
> 150 minutes/week	15.3% (22)	10.9% (20.3)	13.5% (18.3)	20.6% (28.7)	13.3% (23.1)	19.7% (29)	.308	.552	.640	.869	.558
> 100 or 130/week	55.2% (32.2)	53% (38.4)	52.8% (33.8)	31.6% (28.6)	17.5% (20.5)	30.9% (29)	.074	.010*	.093	.171	.131
Based on intervention guidelines	32.1% (24)	21.6% (22.5)	24.9% (22.5)	1.8% (4.4)	0	1.7% (4.1)	.067	.423	<.001 [a]**	.085 [a]	.001 [a]*

Note: For average minutes exercise and average exercise session, means are presented with standard deviations in parentheses. For all adherence variables, mean proportions are presented with standard deviations in parentheses. [a] Mann-Whitney *U* test performed. **p* < .05. ***p* < .001.

Based on >150 minutes per week.

One OEP participant partially adhered using a 40% threshold, and one participant in the WBB intervention partially adhered using both the 40% and 50% threshold.

Adherence to best practice guidelines.

The mean exercise regimen for OEP participants was 96 minutes/week (*SD* = 34.9; range: 50.6 – 150.3), and for WBB participants was 103.1 minutes/week (*SD* = 33.5; range: 59.4 – 171.2). The mean exercise regimen in both groups falls short of best practice guidelines. See Figure 15 for a box and whisker plot of minutes spent exercising per week for each intervention.

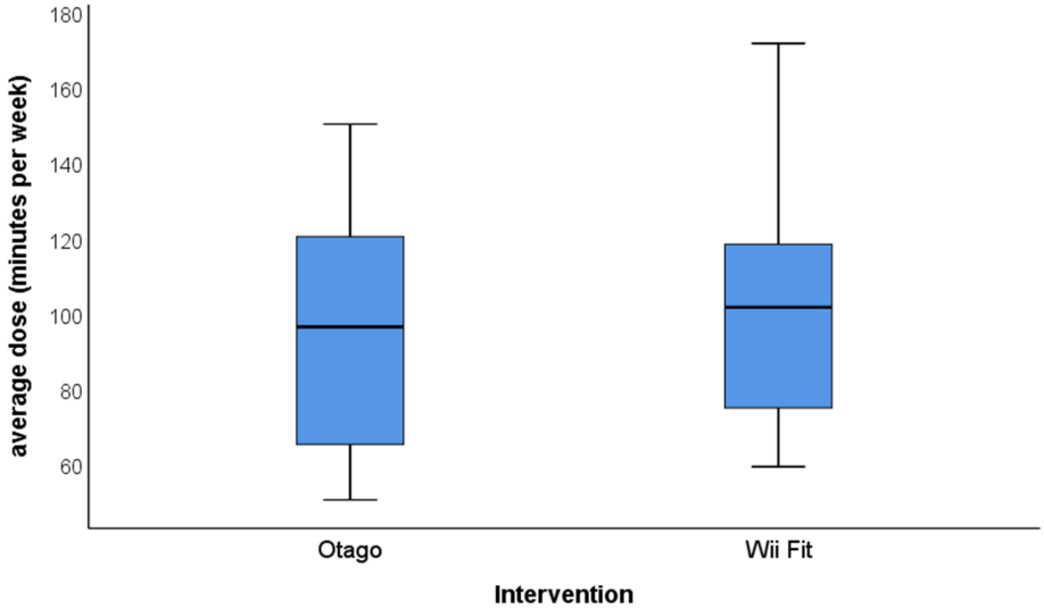


Figure 15. Intervention minutes spent exercising per week.

Relationship between adherence and intervention efficacy (i.e. falls).

There were no significant differences in intervention adherence rates between participants who had and had not fallen in the previous year (all *p* values < .145), or between participants who had and had not fallen during the study intervention period (all *p* values < .192).

Intrinsic factors influencing adherence.

Appendix X Additional Data for Results Chapter shows an analysis of demographic factors and scores from questionnaires with the potential to impact adherence. No intrinsic factors appeared to have influenced adherence in either intervention groups, including previous falls and fall risk. Partial adherence to >2 hours per week at a 50% threshold was used for the results shown in the Table, due to poor levels of full adherence. Calculations are shown for the three-month timeline. Attrition was more marked at six months, leaving too little data for computation.

Objective 4. Costs of the Feasibility Study and a Future RCT

Costs of feasibility RCT.

The breakdown of a total study cost of **R203 456.26** is shown in Appendix Y. Staff salary figures are 2018 rates applicable to contract staff.

Total cost per participant.

Costs per participant in an exercise intervention amount to R6 781.87 (given 30 participants). Expenses per participant including the costs group are R3 507.86. Costs participants required no contact with the physiotherapist, thus overall costs are reduced. Moreover, few costs participants were seen for follow-up, which reduced hours for data collection at three and six months.

Projected costs for a future RCT.

An overall sum of **R813 824.40** would be required for a two-armed trial including 120 participants. Adding a usual care group of 60 at R3 507.86 would increase the costs to **R1 024 296**. Should a future trial include sponsorship by international grant funders, additional costs for institutional ethics approval from UCT would be R14 980. Should industry fund the trial, this fee increases to R31 993.

Objective 5. Utility of Physical Outcome Measures

Results of inter-rater reliability tests are discussed first.

Intraclass correlation coefficients results.

Intraclass correlation coefficients (ICC) were calculated for several critical measures. Results may range from 0 (indicating no reliability) and 1, which represents perfect reliability with no measurement error [678]. Values between 0.75 – 0.9 are regarded as good reliability; while >0.90 is excellent [678]. Inter-rater reliability was high for all Romberg measures (ICC = 1.00, 95%CI: 0.99 – 1.00), FTSST (ICC = 0.99, 95%CI: 0.80 – 0.99), and preferred walking speed (ICC = 0.92, 95%CI: 0.66 – 0.98). The researcher and assistant scored items such as stepping over and around obstacles (DGI) identically.

Appropriateness of outcome measures.

All physical endpoints were attempted at least once by each participant. No participant refused outcome measures at the enrolment session, although a number mentioned apprehension for the eyes closed (EC) on foam (embedded in Mini-BESTest) at follow-up.

Proportion of participants meeting normative levels for physical end-points.

Varying degrees of challenge were apparent for balance endpoints. Most difficult was the sharpened Romberg EC, followed by 30s stand EC on foam, FTSST, and then sharpened Romberg eyes open (EO). Overall, the costs group performed more poorly than the exercise intervention groups. Standard Romberg with EO was achieved by all participants at every time point and is likely to have a ceiling effect. In contrast, sharpened Romberg EC was achieved by 12.7% of the baseline all-group sample and might be vulnerable to floor effects.

Table 17 presents the proportion of participants who were able to perform at or above normative levels for the tests of static and dynamic balance.

Table 17. Participants meeting/exceeding norms for physical endpoints.

Outcome measure	OEP baseline *n* = 14	OEP 3 months *n* = 14	OEP 6 months *n* = 13	WBB baseline *n* = 16	WBB 3 months *n* = 16	WBB 6 months *n* = 13	Costs baseline *n* = 8
Mini-BESTest	13 (92.9%)	13 (100%) [b]	10 (83.3%) [a]	14 (87.5%)	13 (81.3%)	11 (84.6%)	5 (62.5%)
Stand on foam EC	7 (50%)	6 (46.2%) [b]	3 (27.3%) [c]	12 (75%)	15 (93.8%)	12 (92.3%)	5 (62.5%)
Five times sit to stand	8 (66.7%) [a]	10 (76.9%) [b]	11 (100%) [c]	12 (75%)	13 (81.2%)	10 (76.9%)	5 (71.4%) [g]
Standard Romberg EO	14 (100%)	13 (100%) [b]	12 (100%) [a]	16 (100%)	16 (100%)	13 (100%)	8 (100%)
Sharpened Romberg EO	9 (69.2%) [b]	10 (90.9%) [c]	7 (70%) [d]	13 (86.7%) [f]	12 (75%)	9 (69.2%)	4 (57.1%) [g]
Sharpened Romberg EC	2 (18.2%) [c]	1 (9.1%) [c]	2 (25%) [e]	3 (20%) [f]	1 (6.7%) [f]	4 (36.4%) [c]	0 (0%) [g]

Legend: EC: eyes closed; EO: eyes open. All test outcomes except Mini-BESTest are measured in seconds.

[a] Data based on 12 participants. [b] Data based on 13 participants. [c] Data based on 11 participants. [d] Data based on 10 participants. [e] Data based on 8 participants. [f] Data based on 15 participants. [g] Data based on 7 participants.

Responsiveness.

Responsiveness[43] of tests is an important consideration when selecting endpoints for clinical trials. Table 18 depicts MCID for four balance endpoints and the proportion of participants who achieved MCID. Note the FTSST was particularly poor for the OEP group, while MCID changes in preferred walking speed were demonstrated, albeit in small proportions of participants.

Training and permissions for a trial in a resource-constrained setting.

Training was described in the Chapter VI. Methodology and was accomplished with ease. Outcome measures were accessible and permission to use the two interventions was granted quickly and easily. The only test incurring a once-off fee was the PASE.

[43] See Glossary of Terms.

Table 18. Participants achieving MCID on physical endpoints.

	OEP			WBB		
Outcome measure (MCID)	Time 1: Baseline - 3 months *n* = 14	Time 2: 3 - 6 months *n* = 14	Overall: Baseline -6 months *n* = 13	Time 1: Baseline - 3 months *n* = 16	Time 2: 3 - 6 months *n* = 13	Overall: Baseline - 6 months *n* = 13
Mini-BESTest (>4 points)	1 (7.7%) [a]	1 (9.1%) [d]	1 (8.3%) [b]	0	1 (7.7%)	2 (15.4%)
Preferred walking speed (>0.05m/s)	2 (15.4%) [a]	5 (41.7%) [b]	3 (27.3%) [d]	3 (18.8%)	2 (15.4%)	4 (30.8%)
FTSST (>2.3s)	0 [b]	0 [c]	0 [c]	0	6 (46.2%)	1 (7.7%)
Pivot turn and stop (>1.9 steps)	1(10%) [c]	2 (18.2%) [d]	0 [e]	1 (8.3%) [b]	1 (7.7%)	0 [f]

Legend: FTSST: five times sit to stand test.

[a] Data based on 13 participants. [b] Data based on 12 participants. [c] Data based on 10 participants. [d] Data based on 11 participants. [e] Data based on 8 participants. [f] Data based on 9 participants.

Results of Aim 2

Aim 2 sought preliminary evidence for the effect of the interventions on fall occurrence and changes in balance in exercise participants. This section describes the participants' physical endpoints at baseline, and then provides comparison with analysis at two further time points. Quantitative measures of the exercise participants' experience follow with Borg Rating of Perceived Exertion (RPE) and Systems Usability Scale results.

The statistical analysis was as follows:

- Three analyses of baseline measures (WBB vs costs; OEP vs costs and WBB vs OEP).
- Between-group analyses compared changes from baseline-3 months, 3-6 months, and baseline-6 months for both exercise interventions.
- Within-group analyses were conducted for within each of the WBB and OEP groups comparing baseline-3 months, and 3-6 months.
- The repeated analyses (eight in total) equates to a Bonferroni corrected p-value of 0.006.

Endpoints related to physical activity and balance.

Baseline static and dynamic balance.

At baseline, there were significant between-group differences for the FICSIT-4 score (p = .024) and Dynamic Gait Index (DGI) (p = .001). Post-hoc comparisons revealed that participants in the WBB group had a significantly higher FICSIT-4 score (p = .007) compared to those in the costs group. WBB participants also had a significantly higher DGI compared to those in the costs (p < .001) and OEP (p = .005) groups. These results suggest at the outset, WBB participants' baseline static

(FICSIT-4) balance was superior to the costs group; and DGI was better for the WBB participants than for either of the other groups.

Intervention group differences in change scores.

One-way ANOVAs revealed significant between-group difference for the TUG (F (5,77) = 2.51, p = .038), and Mini-BESTest (F (5,75) = 3.89, p = .004). TUG scores are discussed first. Post-hoc comparisons revealed that WBB participants showed a statistically significant difference between their baseline-3 months, and 3-6 month change in TUG scores (p = .001). From baseline-3 months, participants' scores in seconds decreased by 0.5±0.7, whereas from 3-6 months participants scores increased by 1.1±0.6. A decrease in the time taken to execute the TUG suggests a slight improvement in the short term, but this was not sustained.

While OEP participants showed an average decrease in Mini-BESTest scores of 0.8 ±16.2 from baseline to 6-months, participants in the WBB group showed an average increase of 3.7 ±7.8 over the same period (p = .004). Thus, OEP participants experienced negligible change in balance over a six-month period, while the WBB group improved in terms of both statistical and clinical significance, over the same time. Results of physical endpoints for balance are shown in Table 19.

Table 19. Between-group differences in physical endpoints over time.

								Between-group analysis		
Outcome measure	OEP baseline *n* = 14	OEP 3 months *n* = 14	OEP 6 months *n* = 13	WBB baseline *n* = 16	WBB 3 months *n* = 16	WBB 6 months *n* = 13	Costs baseline *n* = 8	*F*	*p*	η^2
Standard Romberg EO (s)	30 (0)	30 (0) [a]	30 (0) [d]	30 (0)	30 (0)	30 (0)	30 (0)	-	-	-
Standard Romberg EC (s)	27.1 (7.3)	30 (0) [a]	30 (0) [d]	30 (0)	29.5 (1.9)	30 (0)	26.9 (8.7)	1.15	.327	.06
Semi-tandem Romberg EO (s)	30 (0)	30 (0) [a]	30 (0) [d]	30 (0)	30 (0)	30 (0)	30 (0) [g]	-	-	-
Semi-tandem Romberg EC (s)	22.8 (11.8)	26.6 (6.8) [a]	24.2 (10.9) [d]	28.6 (5.5)	30 (0)	27.1 (7.3)	30 (0) [g]	2.58	.090	.13
Sharpened (full tandem) Romberg EO (s)	25.8 (7.6) [a]	27.8 (7.4) [b]	23.7 (11.1) [c]	27.5 (6.6) [f]	23.9 (11.0)	23.2 (11.5)	21.8 (11.1) [g]	1.22	.307	.07
Sharpened (full tandem) Romberg EC (s)	9.4 (10.8) [b]	9.2 (10.7) [b]	6.5 (4.8) [e]	13.2 (11.1) [f]	9.4 (9.9) [f]	6.9 (7.4) [b]	5.7 (10.7) [g]	1.18	.321	.07
SLS EO worst leg (s)	4.4 (3.8) [a]	5.4 (5.7) [a]	2.2 (1.6) [d]	8.5 (8.0)	7.4 (6.3)	5.7 (6.7)	3.9 (6.6)	1.96	.156	.10
FICSIT-4 Score	23.2 (3.4) [a]	24.3 (3.1) [d]	22.6 (4.3) [b]	25 (2.7)	24.6 (2.4)	23.7 (2.95)	20.5 (5.3)	4.18	.024*	.20
Mini-BESTest	20.4 (2.1)	20.2 (2.0) [a]	19.6 (3.9) [d]	22.5 (2)	21.6 (1.9)	22.6 (2.9)	19.6 (5.2)	3.09	.058	.15
Preferred walking speed (3m/s)	3.1 (0.8)	2.6 (0.6) [a]	3.0 (0.6) [d]	2.97 (0.46)	2.7 (0.4)	2.7 (0.6)	3.3 (0.7) [g]	0.67	.517	.04
Pivot turn and stop (steps)	5.2 (1.6) [c]	4.2 (1.5) [a]	4.7 (1.3) [d]	4.1 (1.7) [d]	3.5 (1.4)	3.46 (1.1)	5.9 (1.8)	2.95	.069	.18
Stand on foam EC (seconds)	17.3 (13.3)	16.6 (12.2) [a]	9.3 (10.7) [b]	22.9 (10.9)	28.4 (6.3)	28.6 (5.1)	18.7 (13.6)	0.84	.440	.05
FTSST	18.8 (5.2) [d]	17.5 (5.9) [a]	14.2 (1.6) [b]	16.0 (3.7)	14.8 (4.0)	14.9 (3.3)	20.1 (5.4) [g]	2.35	.111	.13
TUG-simple (s)	11.5 (3.2)	10.9 (1.0)	11.75 (2.8)	9.9 (1.2)	9.4 (1.2)	10.4 (1.3)	12.2 (1.9)	3.08	.058	.15
TUG-cognitive (s)	14.9 (3.6)	14.6 (2.3)	14.1 (2.9)	13.1 (3.4)	12.3 (2.2)	12.54 (2.3)	14.8 (3.2)	1.26	.298	.07
DGI total score	20.7 (3.0)	22.2 (0.9) [a]	20.1 (4.9) [d]	23.2 (0.8)	22.6 (1.3)	22.8 (1.0)	18.5 (4.6)	7.92	.001*	.31

Legend: EO: eye open; EC: eyes closed; DGI: Dynamic Gait Index; SLS: single leg stance, FICSIT-4: Frailty and Injuries: Cooperative Studies of Intervention Techniques Score, FTSST; five times sit to stand test; (s): seconds; TUG: Timed-up and Go.[a] Data based on 13 participants. [b] Data based on 11 participants. [c] Data based on 10 participants. [d] Data based on 12 participants. [e] Data based on 8 participants. [f] Data based on 15 participants. [g] Data based on 7 participants.

While the data showed negligible change on TUG between groups, and an improvement in the Mini-BESTest score for the WBB group over time, these statistical differences, while significant, require extrapolation into changes which might make a difference to participants' balance and related fall risk. Thus, MCID were analysed (Please refer to Table 18 in the previous section, which shows the proportion of participants reaching MCID for selected outcome measures). Preferred walking speed improved in some exercise participants (OEP: 27.3% and WBB: 30.8%). Endpoints like FTSST and pivot turn and stop were essentially unchanged at six months. The Mini-BESTest showed a very small proportion of participants reaching MCID levels.

Falls.

Direct medical costs related to falls.

No participant offered data related to direct or indirect expenses due to fall occurrence. However, both interventions were examined as to the occurrence of previous falls, falls during the trial, and fall severity. Feasibility of either intervention would be suggested if the rate of falls is reduced by 17% (which represents half the usual risk for older adults falling within one year, see Chapter I. Fall Risk Factors in Older Adulthood.

Association between outcome measures, fall risk and fall occurrence.

Association between previous falls and endpoints.

Participants' falls in the year prior to enrolment were not associated with any outcome measures at baseline, except the FRAT-up score. In the OEP (t (12) = -2.84, p = .015); WBB (t (14) = -4.31, p = .001) and costs (t (6) = -3.55, p = .012) groups, those who had fallen in the past year had significantly higher FRAT-up scores (indicating greater risk for falls) compared with those who had not fallen in the past year.

Having fallen in the past year was associated with some changes in outcome measures. In the OEP group from baseline to 3-months, those who had fallen in the past year had a significantly larger decrease in EQ-5D-3L overall scores ($U = 7.50$, $p = .029$). Unexpectedly, those who had fallen experienced a larger decrease in the pivot turn and stop scores ($U = 0.50$, $p = .017$) compared to those who had not fallen in the past year. The latter result is likely skewed by very fragile sample size for the calculation.

From 3- to 6-months, OEP participants who had fallen in the past year had a significantly larger decrease in Sharpened Romberg EC scores ($U < 0.01$, $p = .036$), and a larger decrease in DGI scores ($U = 3.00$, $p = .030$) compared to those who had not fallen in the past year. From baseline to 6-months, those who had fallen in the past year had a significantly larger decrease in FTSST scores ($U < 0.01$, $p = .008$), and a larger decrease in gait speed ($U = 5.50$, $p = .048$) compared to those who had not fallen in the past year. In the WBB group, from baseline to 6-months, those who had fallen in the past year had a significantly smaller decrease in FTSST scores ($U < 0.01$, $p = .001$) compared to those who had not fallen in the past year. Expressed simply, OEP participants with prior falls experienced a decline in balance, not experienced by WBB participants.

Association between falls during the study and endpoints.

Having fallen during the study was associated with several outcome measures. OEP participants who fell during the study had significantly lower GDS scores at baseline ($U = 6.50$, $p = .045$), lower EQ5D-3L scores at baseline ($U < .001$, $p = .001$), higher FICSIT-4 scores at 3-months ($U = 2.00$, $p = .016$), and higher EDQD-VAS scores at 3-months ($U = 6.00$, $p = .029$) compared to those who did not report falls during the study. Thus, those who fell presented a complex picture of less depression, but poorer QoL at study induction. Better balance and QoL could have prompted more activity and thus increased fall risk.

WBB participants who fell during the study had significantly higher FTSST scores at baseline (U = 5.00, p =.020), lower SEE scores at 3-months (U = 6.50 , p = .040), higher TUG simple scores at 3-months (U = 6.00, p = .030), higher TUG-cognitive scores at 3-months (U = 5.00, p = .020), and at 6-months (U = 2.00, p = .028), and higher FTSST at 6-months (U = 3.00, p = .049) compared to those who did not report falls during the study. Thus, in this instance deterioration in TUG simple, cognitive and FTSST appear to correlate with fall events.

Fall risk baseline data and falls in preceding year.

The following variables were explored to seek correlations between fall events in the preceding year and baseline data to examine if fall risk factors were predictive of falls:

- A >10% difference between TUG simple and TUG cognitive.
- TUG with cut-off points of 9s, 10s, >12 s, 12.47s, and 15s respectively.
- DGI <19.
- Pivot turn and stop requiring >4 steps.
- Presence of ≥4 medications.
- FTSST >15s.

There was no significant association between any of the above fall risk factors (measured at baseline) and having fallen during the past year in either the OEP, WBB, or cost groups (all p values >.107).

Fall risk baseline data and falls during study.

There was no significant association between any of the fall risk factors and having fallen during the study in either the OEP, WBB or cost groups (all p values >.126), with one exception. In the WBB group, those on ≥4 medications were significantly more likely to have fallen during the study compared to those on less than four medications (75% vs 25%, $p = .041$, $V = 0.65$).

The following section presents data related to the exercise regimen, falls, and changes in physical endpoints. The assumption that more exercise is better was made, resulting in 1-tailed correlational statistics.

Fall risk, fall events and changes in physical endpoints between intervention groups.

Outcome measures were evaluated against previous falls and fall events at three time points: study entry (baseline), three, and six months. The following endpoints were considered:

- A difference of >10% in the time in seconds between TUG simple and cognitive conditions, referred to here as Dual TUG (with cognitive being slower than simple).
- DGI <19.
- > four steps on pivot turn and stop.
- TUG simple scores with cut-off scores in seconds of 12, 9, 10, 15, and 12.47.
- FTSST score of >15 seconds.

Risk of falls.

Impact of Exercise Regimen on Physical Endpoints and Falls.

For the OEP group, from baseline-3 months, minutes of exercise was significantly negatively correlated with change in Romberg EC scores (r = -.671, p = .017), and significantly positively correlated with change in Dual TUG scores (r = .557, p = .047). From 3- to 6-months, minutes of exercise was significantly negatively correlated with change in TUG scores (r = -.634, p = .046), and significantly positively correlated with change in semi-tandem EC scores (r = .643, p = .043) and DGI (r = .637, p = .045). In the WBB group, similar results were observed from baseline-3 months. Minutes of exercise was significantly negatively correlated with change in Romberg EC scores (r = -.743, p = .007), and significantly positively correlated with change in Dual TUG scores (r = .653, p = .020). The negative correlation between minutes of exercise and changes in Romberg scores indicates that more minutes of exercise is related to less change in the Romberg outcomes.

There was no significant difference in exercise time per week between those who did and did not fall in the past year (OEP group: p = .436; WBB group: p = .310), or during the study (OEP group: p = .230; WBB group: p = .276).

Experience of the Interventions

Quantitative data.

Borg RPE.

Exercise intensity as measured by the Borg RPE was a mean of 11.3 (SD = 1.7) for OEP participants (range: 9 - 15) and 11.2 (SD = 1.9) for the WBB group (range: 9 - 15). Perceived intensity of exercise did not differ significantly between the two intervention groups (t (18) = 0.18, p = 857).

Experience of the WBB

WBB participants perceived the intervention as a user-friendly technology based on SUS results. Their opinions are shown in the pie chart in Figure 16. This is in marked contrast with the focus group responses, where participants voiced irritation with various aspects of the programme.

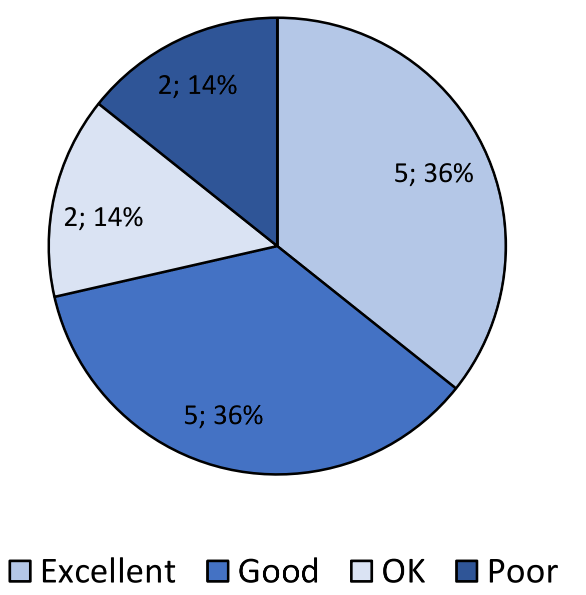


Figure 16. SUS results for user-friendliness of WBB (number, %).

Figure 17 and Figure 18 display histograms of responses to the SUS. Interestingly, there are several differences between opinion of the SUS and those voiced in the focus groups. For example, 13 participants disagreed with the statement that the games were difficult to use (Figure 17*).* Although this correlates with a similar SUS finding for the statement of the games' complexity, focus group data suggest frustration with the programme and a wish to circumvent aspects of it. The latter is at odds with most SUS participants finding the games well integrated (Figure 18).

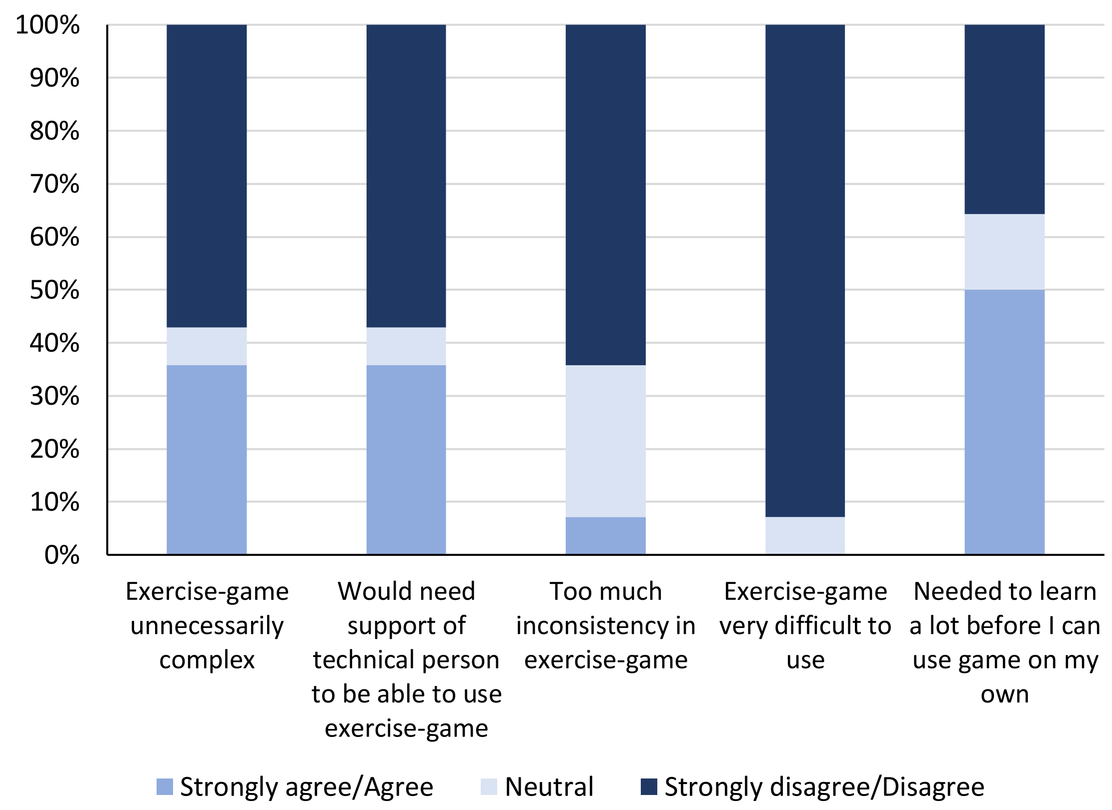


Figure 17. WBB participants' views of the intervention.

Figure 18 shows most participants disagreed with the statement that they would like to use the WBB frequently, which correlates with adherence data and the barriers to participation discussed by the focus groups. They expressed confidence using the WBB; and yet did not adhere to the prescribed frequency of sessions.

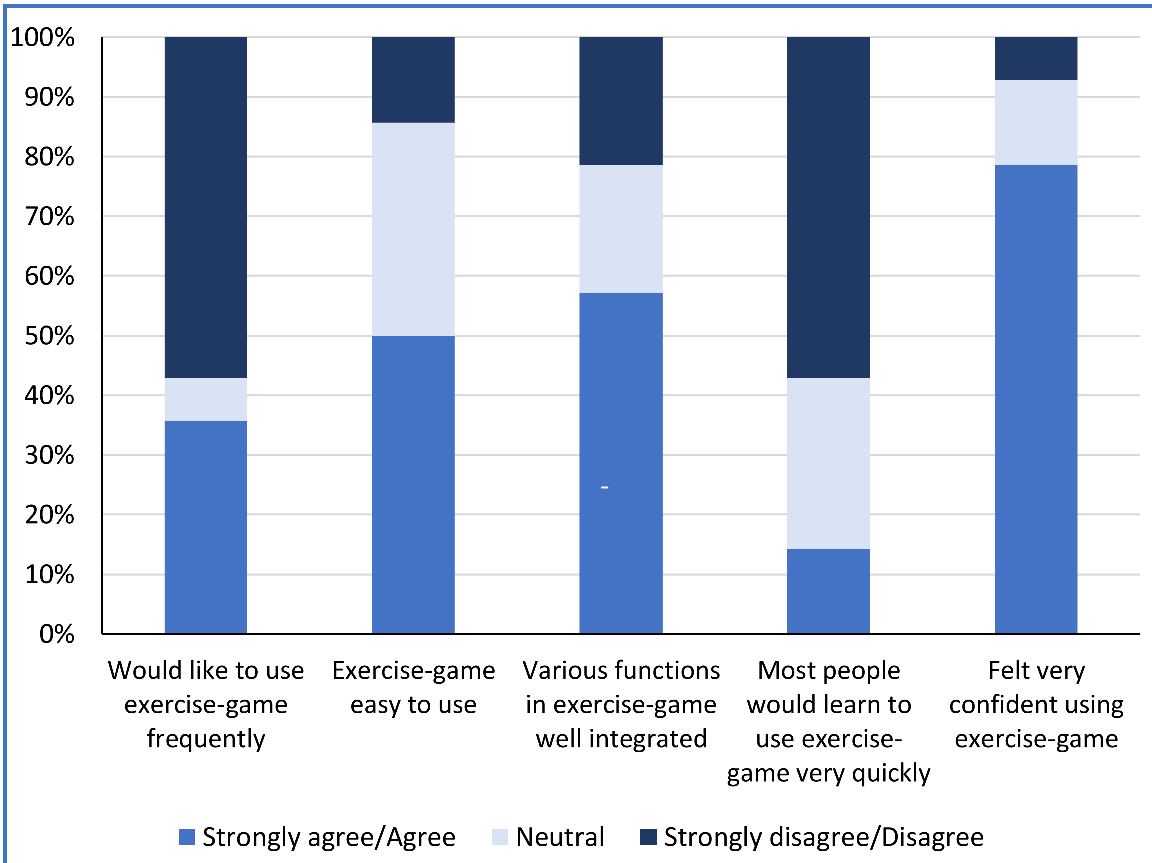


Figure 18. WBB participants' views on SUS (cont.).

Exercise participants' views of the interventions and falls are explored further in the following section, which presents the qualitative findings. The results from the qualitative component of this mixed method study are presented utilising the COREQ checklist [(5)].

Domain 1: Research Team and Reflexivity

Personal characteristics and facilitator's relationship with participants.

Focus group facilitator/s: the researcher made a conscious decision not to run the groups herself to encourage candid feedback regarding the interventions. The research assistant facilitated the focus groups and her qualifications are outlined in the Chapter VI. Methodology. While interested in falls and vestibular issues, her specific knowledge of either intervention was likely not detailed enough to significantly influence the focus groups' direction. It is possible a tacit impression of the benefit of the interventions may have resulted from endpoint assessments; however, she was uninformed regarding the overall results of the study.

The research assistant was cautioned to maintain neutral body language and show neither endorsement nor disfavour towards views expressed. The co-facilitator had a more logistical role in supporting the facilitator and did not actively participate other than ensuring participants were comfortable.

Domain 2: Study Design

Theoretical framework.

Steps describing content analysis are outlined in the Chapter VI. Methodology.

Participant selection, recruitment, and study settings.

Selection, recruitment, and eligibility criteria are described in the Chapter VI. Methodology.

Both WBB sites were used to host focus groups. Site D was used for an OEP group, as attrition was marked and interest in a focus group lacking at site A. One participant from Site A agreed to join the focus group at Site D (where he was acquainted with some participants) and then withdrew. One WBB participant at Site C forgot the appointment. The lounges at the three sites were booked for exclusive use during the focus groups thus, ensuring privacy. Overall six participants from Site B and four from Site C participated in WBB groups (collapsed into one set of results) and four participants comprised the OEP group. Of the ten WBB participants, one was male. One male participated in the OEP group.

Data collection and management.

Data were collected as previously described[44]. Groups lasted one and half hours as planned. Data saturation was not discussed at the time, as only one group per intervention per site was thought feasible due to participants' flagging interest. Transcripts were not returned to participants due to the additional burden with an already research-fatigued participant population. However, the resulting analysis was reviewed by the facilitator who agreed that the essence of the discussion had been captured appropriately.

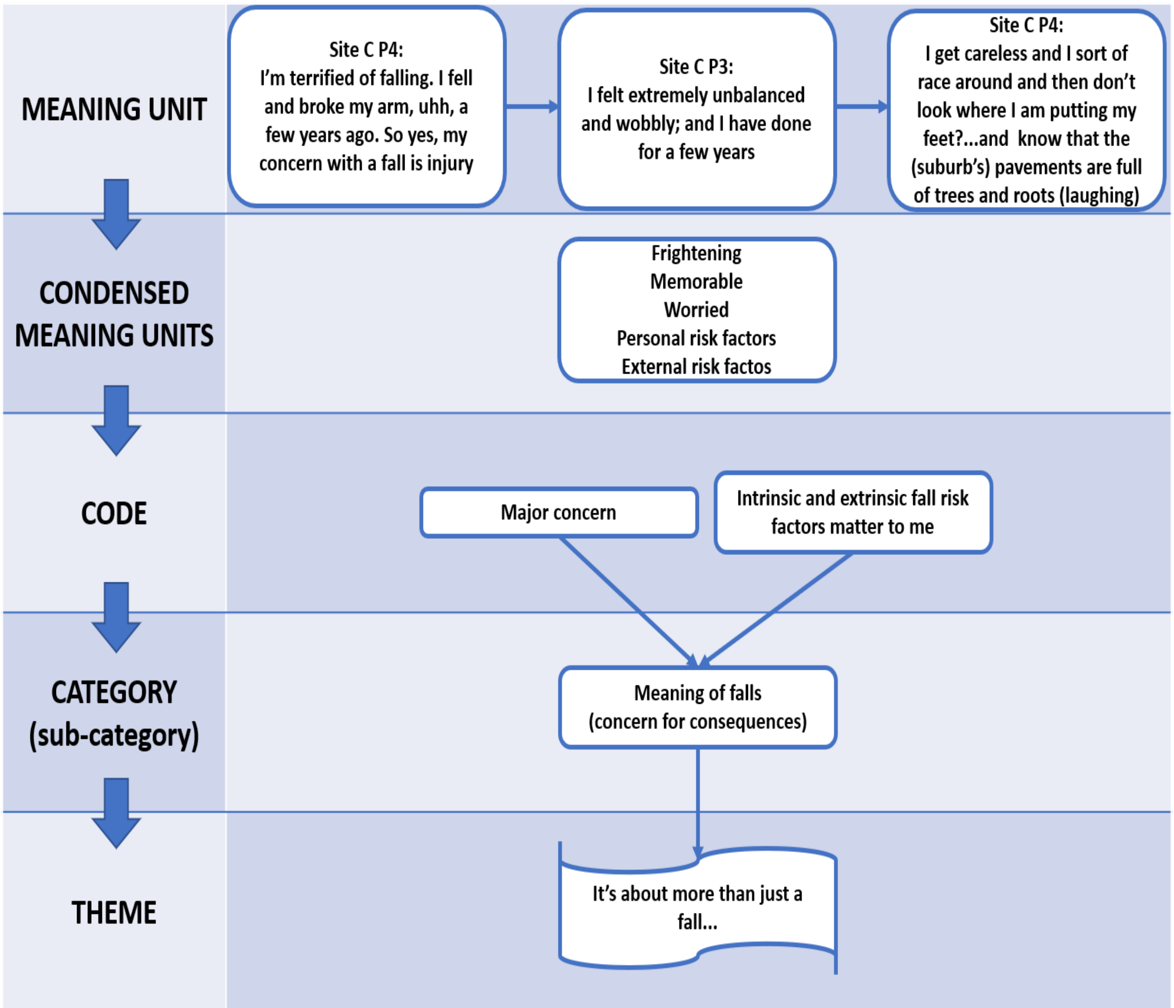
Domain 3: Analysis and Findings

Data coding.

Use of NVivo® software to assist with data analysis was envisaged. However, as expected with an individualistic social psychology perspective [(655)] the analysis required only standard word processing software[45]. Groups generated basic information and simple qualitative description. Thus, steps for data coding and creation of categories and themes are described in the Chapter VI. Methodology.

Figure 19 demonstrates the process of assigning a theme for the construct of falls. Similar processes were followed for development of all the themes but are not shown.

[44] See Chapter VI. Methodology.
[45] Microsoft Office 365.



Legend: P = participant

Figure 19. Steps towards abstracting data to a theme.

Participants' attitudes towards falls and fall prevention.

Theme: It's about more than just a fall…

This section relates to data from all focus groups[46]. Participants noted the inter-relationships of the constructs which emerged during the Post-it™ note individual activity used to initiate discussion. Key issues based on the frequency during discussion were:

[46] Site B and C were WBB groups, site D was the OEP group.

Fear of falling (19 mentions), and *previous injurious falls* (14 mentions), which subsequently enhanced fear of falling. Sticky notes for WBB posters included the words *incapacitated, terrified, fright, disaster, pain,* and *embarrassing* to symbolise the overall construct of falls*.* OEP participants' key words included *damage, fracture,* and *anxiety.*

Site C participant[47] (P)1's opinion that: "I think it's the incapacity…the injury and all that, that's why you're scared," demonstrates a strong association between fear of falling and injurious falls. Consequences of falls were discussed with reference to a potential loss of independence, a serious concern voiced across all groups. Site B P6's statement reflects the groups' overall discussion:

> I must say that the pain, the pain of it (*a fall*[48]) doesn't bother me at all. (*But*) the fear of a broken bone, and the long-term effects of it, which could, depending on how old you are, last for the rest of your life. That's what really concerns me. It might send me over to Site A (*reference to neighbouring facility with frail care facilities*)! Because of a broken bone, and I am no longer able to look after myself. …It's all the long-terms effects that concern me.

Site B P1 echoed with: "It (*a fall*) takes a second, it takes a minute, and you live with it for several weeks." Site B P5 added: "I think I am very independent. (*And*), the thought of having to be dependent on people just freaks me out totally!"

Figure 20 shows a word cloud of words used by participants to describe their construct of falls. The larger words were mentioned most frequently.

[47] No participant elected to assume a pseudonym. Due to the mixed methods design, assigning participants P1, P2 etc., was considered acceptable.
[48] Note: items in *italics* and parenthesised are insertions/changes by the researcher to aid with context or grammatical issues.

Figure 20. Word cloud of participants' constructs of falls.

Recognition of extrinsic risk factors contributing to falls. Extrinsic risk factors contributing to falls were mentioned frequently (20 times). The quotation from Site C P4 in Legend: **P = participant**

Figure 19 describes a combination of intrinsic and extrinsic risks (discussed below). She speaks of rushing around and not remaining focussed on foot position (intrinsic risk) and then stumbling over tree roots which have caused pavements to be very uneven (extrinsic risk).

Participants were preoccupied with negotiating the built environment. Site B P3 noted:

"I have, sure, used steps many a time. Going up is fine but going down! I feel more vulnerable than I used to be… I (*just*) can't, just like in the olden days, just go down."

The need for increased vigilance was a recurrent condensed meaning unit contributing to the theme. Site B P4 agreed and noted the need for adapting behaviour:

"Ah, I don't let anyone come behind me (*when negotiating steps*)! I must be the one at the back, so I am not panicky when I am going down the stairs, and I hold on very carefully."

Recognition of intrinsic risk factors contributing to falls (19 mentions). Participants showed some insight into intrinsic risks and management strategies developed during the intervention. Site C P3 described risk management:

> Well, I have to tell you, well yes, I do now (*implement fall prevention strategies*) because I've been made aware (*by the intervention*). I've also been made aware of my feet. What's happening to my feet. And it's umm, I am so aware of that now, and it (*WBB*) has definitely helped me! I umm, probably shouldn't say the next thing, but I am. The last few weeks almost, I can't tell you what a big change it's (*WBB*) made in my life! And my family noticed that! (*Facilitator uses a continuer to encourage more detail)*. They say I am walking better! (*Before the intervention*) I think I must have slowed down; and was looking at my feet and going on oddly.

Others expressed different views towards falls. Participants cited lack of concentration or confidence, inability to dual-task, rushing and carelessness contributing to fall events. Site B P2 noted: "I can trip over fresh air!". Increased awareness of intrinsic risk was noted by participants. Ageing was mentioned as a contributor to falls, particularly feeling younger than one's chronological age. Site B P2 quipped: "Just believing that I'm 35 (*years old*) instead of a lot more!" (Laughter in the room).

Participants acknowledged the impact of health on fall risk. Site B P2 and P5 recognised that balance is important for fall prevention, views echoed by participants at Site D. Perception of balance difficulty and the desire for help with medical issues was noted. For several, chronic imbalance was a key motivator to join the intervention programme. Site C P3 revealed:

"Wobbly, I felt wobbly. The first thing I did was race up to Christine when she addressed us here (*recruitment session*). And said, 'I am wobbly! Can I join the programme? Would it help me?'"

WBB participants'[49] experience of the intervention.

Theme: acceptance and commitment.

Key words from the Post-It™ note exercise regarding the experience of the WBB intervention were *motivation* and *benefit*. The theme of acceptance and commitment was developed. Acceptance commenced with realisation of the need for an intervention to improve balance. Both groups voiced sentiments of acceptance of being "older and wonkier" (Site C P1). The category of I am not as I was shaped the notion of acceptance of change, and that this change was not necessarily positive.

At times, curiosity prompted interest in enrolling. As Site C P4 noted: "Because I was curious about it, and thought I needed a few more challenges in my life." Site C P1 had been considering self-help strategies to manage her fear of falling and arrived with high hopes:

> I just thought it was going to be absolutely fantastic! I've been concerned about falling for a long time. And I have seen stuff on TV about doing things to help yourself. And that's why I (*actually*) came along, I thought it was going to be good!

[49] The findings from both WBB groups are combined in this section.

Participants discussed factors enhancing commitment to the intervention. Realisation that WBB promoted awareness of balance perturbations, and improved reaction times and balance was evident. Site C P3 commented:

"Umm, just realising how our reaction times vary, whether you're falling backwards, falling forwards, falling sideways (*body awareness created by WBB*). …We are more aware of our posture, of our body, and what we are doing at the time."

P1, 2, and 5 from Site B similarly mentioned the desire to improve their balance, or to prevent deterioration of balance. As P5 opined: "I do think that (*umm, eh*) having good balance is fantastic! And, I think at the end of it, that it's what (*actually*) prevents falls, really."

Altruistic reasons for enrolling were noted. One participant (Site B P4) enjoyed contributing to research projects and found the rationale for the study appealing. She thought the intervention might be helpful in rehabilitation settings and for fall education purposes. Site B P3 suggested that research into ageing concerns will make her and her children's generation "even better off at 70 (*years*) than I am."

Commitment was likely enhanced by a sense of mastery over balance-related tasks when playing. Both groups discussed specific games related to balance demands. Games had with increasing balance challenges, which were met. The following exchange is telling:

Site C P1: "So you're not hanging onto any support?"

Site C P4: "I'm not hanging onto stuff."

Group: "Oh, wow."

Participants appreciated the stimulating and "clever" aspects of the WBB and related improvement back to the construct of fall risk. Site C P2 noted:

"You can quite easily fall. So, you've got to be aware. (*And I*) I think, ahh the exercises you know, the whole discipline helps you to become more aware. You know, of what's going on around you. I think it's quite clever!"

Site B P5 concurred: "One of the things, I do think, that this (*WBB*) does, is makes one mindful. You know, like the water mindful[50]. You are mindful of exercise and doing things. And I think that is good!"

Commitment and motivation can be argued to be symbiotic. Motivation was a recurring category (26 condensed meaning units). Commitment wavered in both WBB groups. Site B P2 (who was poorly adherent) mentioned:

"Umm, I enjoyed it! I found the difficult bit was making up my mind to do it! Once you've started, you carry on, but I think my balance improved a little bit."

Similarly, Site B P4 added that she became annoyed with herself for not continuing with the intervention, especially as she was improving. Participants mentioned waning interest over time. Site C P3 summed succinctly:

> Umm, I stayed because it was fun! I ran out of steam at the end. I almost felt I needed motivating again. I was like: 'come on now, rally yourself again.' Umm, (*that was*), I sort of got *slap*[51] in the end.

[50] Reference to the worst drought in Cape Town in 100 years. At one point in 2018, the prospect of taps running dry was weeks away and strict rationing was/remains in place. Reference: retrieved 9 April 2019 from https://www.news.uct.ac.za/article/-2019-01-29-cape-towns-drought-under-the-microscope

[51] The term *'slap'* is an Afrikaans word meaning limp. The term is used commonly to describe flaccid, over-cooked, limp potato chips (French fries), which are popular in the Western Cape. Reference: Retrieved 8 January 2019 from https://theculturetrip.com/africa/south-africa/articles/18-south-african-slang-words-and-phrases-you-should-know/

Despite the poor adherence described in the quantitative results, some positive aspects relate to motivation. Particularly for Site B, the intervention promoted renewed interest in other forms of exercise and most continued with the walking programme. P3 walked and added aqua aerobics and Pilates to her training regimen. P6 continues to walk in his 91st year. P4 perceived improvements, which then facilitated group exercise, which she found more enjoyable, and started line-dancing and yoga classes.

Participants frequently described themselves as lacking in ‘discipline’ (15 mentions). Site B P1, whose adherence was very poor, noted:

> I went through the course with a permanent guilty conscience. You know, I never improved with the balance exercises on the TV, on the video (*WBB*). I just never improved, and I really did try. I don’t think I gave it my best shot because mainly, I didn’t have the discipline, and I didn’t have anyone to answer to.

Site B P4 agreed by noting her “laziness” and lack of self-discipline. At the same time, the importance of self-discipline was acknowledged by Site C P3: “I think there’s no benefit without the discipline.”

Barriers to the WBB are described next, but in this context, self-efficacy bears consideration. Mean SEE score for the WBB group at base-line was 7.36 (SD 1.81; maximum possible score meaning highest self-efficacy for exercise is 9). Scores declined with time to 6.85 (SD 1.47) at three months and 6.24 (SD 1.74) at six months. The trend towards a steady decline in self-efficacy triangulates well with the qualitative finding. PASE scores also did not change significantly for the WBB, rather remained somewhat low throughout.

The quantitative results suggest adherence was poor for both interventions. Nonetheless, WBB remained viewed in a positive light. While adherence data would suggest a lack of commitment, the focus on falls was appreciated. Furthermore, the WBB was successful in reducing fall prevalence. Changes in attitude were suggested by the intervention having promoted an increased vigilance of extrinsic and intrinsic fall risk factors. Site C P3 summed her experience up at the end of the focus group:

“But also, you know doing your bit when you (*researcher*) came with your tests (*physical endpoint evaluations*) and whatever. Umm, I think that’s also a real benefit from the whole program. So, all in all, very good programme.” (Everyone agrees).

Barriers and facilitators to participation in the WBB intervention.

This section has not been given a theme, rather barriers and facilitators will be discussed in turn.

Barriers.

Dislike and irritation in response to the coaching avatar was mentioned frequently (34 condensed meaning units) and strongly at Site C. Only one participant at Site B referred to a ‘gremlin’ in the WBB. Site C participants mentioned methods for circumventing the coaching avatar and suggested warming up at home and then doing the games using the WBB may have been preferable. The following passage from Site C P4 is typical of the discussion:

> What I didn’t like …is all the comments in-between. In my opinion they can be cut out. ‘Ahh hello, haven’t seen you for seven days’; or ‘you’ve been coming every day’, you’re like a good golden retriever!’ That sort of rubbish gets me… I want to get rid of all those

blurbs in-between. Just move with the actual exercise! ...That's the only thing I disliked about the programme - was the comments between the exercises. I can do without them! But just move on from breathing (*yoga style warm-up exercises focused on balance*) to doing whatever is required. But cut out all the blurb! That I found disturbing, it irritated me.

Site C P2 agreed:

"(*Umm, umm ja*[52]*)* I think that, that guy, he needs to keep quiet, I think." (Laughter from the other participants).

Co-facilitator: "Don't you have a mute button (laughing)?"

P2: "No, you don't for him!"

Waning interest and lack of active monitoring were cited as barriers to participation. However, some participants acknowledged that the exercise log was motivating, as the following passage demonstrates:

Site C P3: "I loved it! I thought it was fun! I hadn't done those sorts of exercises for years. …Umm, I got, ahh, slack at the end (clears throat). Almost, I felt somebody needed to galvanise me and say, 'where's your sticker?'… I'm just a lazy person, I think! But I loved it, it was fun!"

Site C P4: …I thoroughly enjoyed it! But I found over the longer term, you know, having Christmas and you get busy and you go away[53]. I found it hard to get back into routine. So, it's really just a

---

[52] Afrikaans for 'yes', frequently used in South African vernacular English

[53] Christmas falls in summer in South Africa and frequently long vacations are taken at this time. Older adults may join their children on holiday or host visitors during this period. For many industries (except service and tourism industries), annual breaks are scheduled from approximately 15 December to 10 January (Reference: https://www.safcec.org.za/page/Builders_Break, retrieved 6 December 2018).

lack of discipline. (But umm, I have enjoyed it). And yes, I do still do it, but not as regularly as was required in the beginning. Perhaps also because there's not someone sort of saying, 'have you done your exercises?' You know, (scoffs) almost like a school programme, where you need an exam at the end of two weeks (laughing)? Saying 'how far have you got, and what have you done?'. And that's where your follow up programme came in so well; because it makes you so aware and think – 'I must get back to it!' You know! So yes, I still do it, but not as regularly as I should.

Facilitator: "So what did you like about the whole programme? Everything from the games to the task that you had stickers for; and what did you dislike about it?"

> Site C P1: "The chart (*exercise log*) was very good. Because it made you, when you saw that there were no spots (*stickers signalling completion of WBB/walk*) you thought – 'you (*had*) better do something', you know! And that, but with that too I petered out towards the end."

Boredom with several exercises, specifically the yoga-style warm-up and cool-down exercises was reported. As with other barriers, some solutions were offered. Participants changed the type and intensity of games to maintain interest.

Facilitators.

The challenge of WBB facilitated play and increased practice. Site C P4 noted:

> I liked the challenge of trying to beat myself on those programmes! You know… some days you can hit the soccer ball, and

other days he (*interactive avatar*) sits and weeps on the grass (laughter)! But, (so) I enjoyed that! I enjoyed the challenge of got to do better, got to do better!"

A sense of competition was enjoyable and enhanced the fun aspect. Games such as skiing and those with scoring encouraged participation. Site C P2 commented:

> Well, I stayed because I just felt like I was getting somewhere! Except my scores weren't getting any better on those games! Yoh! Some days I'd say yoh, I'm gonna get 300 and I'd get 120. And the next day I'd get 80. And I thought 'no, this is crazy!', but I think it's the process (*that's*) that's more important that the scores.

It's a Wii bit of fun! Participants appreciated the imaginative aspects of WBB and the sense of playfulness. Benefits of participation were linked to a notion already discussed in terms of fall risk management, enhanced mindfulness of balance and balance challenges. Site C P2 continued:

> And I enjoyed the ramping, uhm, the going down the ramp and seeing how far I could. *Ja*, I was certain I was going to end up right on, in amongst the crowd! I end up just on… but anyway, *ja*, I think it's the whole process that's good. Because it makes you (*because you're*) aware of what's on, going on around you.

Interactive nature of games was at times helpful. Although interaction with the avatar was discussed as a barrier to participation, the usefulness of the interaction was acknowledged. Site C P3 noted:

"With that guy (*avatar*) and he would (*only*) say, 'your legs are shaking.' I think - I will smack you now (laughing)! Stop that! That's why I am here! My legs are shaking.''

The Results will be explored in the Chapter VIII. Discussion which follows.

CHAPTER VIII. DISCUSSION

"Until the great mass of the people shall be filled with the sense of responsibility for each other's welfare, social justice can never be attained."

Helen Keller

Introduction

The results are discussed with reference to the study's aims and objectives. The relevance and context of the research are described, and strengths and limitations are commented upon throughout the Discussion. The Chapter concludes with the implications of the study regarding clinical, professional and training perspectives, and recommendations for policy and future research.

Pursuant to previous Chapters, falls are associated with ageing, and a pressing public health crisis worldwide. Neither phenomenon will spare Africa. Here, communicable diseases are diminishing, as the continent faces a rise in non-communicable diseases (NCD) and a compression of disability-free years in an extended lifespan. There is irrefutable evidence to support the benefits of exercise for older adults, and this includes fall prevention. One evidence-based intervention is the OEP, used as the gold standard in this research. The OEP is the most widely prescribed exercise-based fall intervention globally, and has been proven to be effective, although not all studies have upheld the early, strong evidence [(679)]. Results for WBB programmes are less compelling, despite WBB's popularity. Undeniably, many studies have significant methodological challenges and inconsistent balance-related results, suggesting further interrogation is necessary [(680-682)]. Furthermore, little is known regarding older adults' experiences of exergaming (e.g. WBB) as a rehabilitation tool [(683)]. It was proposed that a stringently designed feasibility RCT would address a gap in knowledge and explore if a large, well-funded RCT is practical in a low-and-middle income country (LMIC) context. Feasibility study findings may inform future research extending into other communities in South Africa. Feasibility issues will be discussed first, followed by discussion of preliminary evidence in support of the interventions.

Feasibility of the Trial and Interventions

Site and participant recruitment.

The feasibility study highlighted partially successful site recruitment and high levels of participant enrolment resulting from eligibility screening. Furthermore, participants met eligibility criteria and were at risk of falls.

Site recruitment and implications for future RCT.

Site recruitment was supported by most of the managers approached, a positive finding. One site's enthusiasm extended to the purchase of a television to facilitate the WBB. Complex negotiations were unnecessary. However, entry into communities dissimilar to the researcher's background might present challenges; and thus, this study is limited by not having explored these aspects. The impact of diversity on facilitators and even on the analysis of focus groups has long been recognised. Significant differences in worldviews are likely [(565)], possibly impacting attitudes towards falls and even reporting of falls, although there is no direct evidence for this. For example, communities within South Africa may be health fatalistic[54], which could extend to falls and impair rehabilitative efforts, although little evidence exists. One small Egyptian study explored young, medium to high socio-economic status individuals' attitudes towards accidents and injury [(684)]. Interestingly, accidents including falls were perceived as being linked to destiny, out

[54] See Glossary of Terms.

of one's direct control and thus, not preventable [(684)]. Fatalism has been linked to reduced health-seeking behaviours and not accessing preventative interventions [(685)], so is relevant. In addition, older adults, and those with poorer socio-economic status tend to be more vulnerable to fatalistic beliefs [(686)]. Thus, efforts to manage cultural differences would be required, and these endeavours may test inherent assumptions and even biases, whether conscious or not [(565)].

Reports suggest research opportunism in exploiting vulnerable populations, particularly in LMIC [(687)]. Researchers are obliged to address societal issues and to improve lives and communities' well-being [(688)]. It can be argued that these duties are particularly pressing in South Africa, where many have underserved health needs [(689)]. Therefore, health innovations such as WBB should be explored in LMIC to ensure research is relevant [(690)]. Thus, a case to research fall prevention in different contexts within South Africa can be made.

Along with embracing the ideals of cultural competence[55], the style and design of a future RCT might have to be more person/patient- or community-centred; notions somewhat lacking in current RCTs [(691)]. For example, community-based participatory research designs might be more suitable, where the community is involved in all stages of the research process, from its design to dissemination and the implementation of findings [(691)]. Community-based research practices have proven successful with disempowered communities and in settings with health inequalities [(692)]. Such approaches also ensure that the research question is addressing the target population's needs [(691)], and meeting ethical imperatives, which are discussed later. However, in this report, issues of cultural differences were not

[55] See Glossary of Terms.

apparent. The use of classes, discussed elsewhere, might enhance a ‘community spirit’ which in turn may promote adherence.

Participants’ understanding of research designs, and effective communication is essential in clinical enquiry [693]. Protection of these rights is demanded by Institutional Review Boards [694]. When entering African communities, one might be required to work in the spirit of *Ubuntu*[56], which could affect how research ethics-related decisions are made. The individualistic approach of Western bioethics might be at odds with collectivist communities [695]. Furthermore, copious documentation, used in this study, might be intimidating [696]. For a future RCT, novel methods of explaining the research, which do not rely on high levels of literacy could be introduced. These might include videos of models undergoing assessments and interventions, slide shows or comics, which have been shown to be effective [697]. The latter methods are permitted by the University’s Human Research Ethics Committee [698].

Should a no-intervention control arm be adopted, the ethics of not offering an exercise-based intervention would require careful management. The notion that exercise is inherently successful in managing falls [699] would make a ‘usual care’ or no intervention group problematic to defend from an ethical standpoint. A stepped wedge design could be adopted. The design randomly allocates participants, in clusters, to interventions with varied starting times for interventions [700]. Thus, as the trial commences (point 1), all participants are in a control group, but at the final point of the trial all participants have received the intervention [701].

[56] See Glossary of Terms.

Participant recruitment.

Clinical trials may be fraught with recruitment and retention issues, with time, and expense implications [702]. In the present thesis, the number needed to screen (0.44) was favourable, and markedly less than rates cited in the literature, which ranged from 1.26 [429] – 5.88 [331]. Thus, attracting willing potential participants in this report's setting was uncomplicated. Focus group participants mentioned the potential for improving balance, fitness, having fun and enjoying contributing to research as motivators for enrolment. In contrast, a possible lack of intention to commit to an exercise programme was evident even at the outset of the research, with almost equal numbers entering the costs arm.

Participants may have found the recruitment presentation appealing. The presentation stressed maintaining independence and the potential positive economic impact of successful fall prevention. Many older adults have serious concerns regarding rising private medical costs [703], and using state hospital facilities, which are plagued with inequitable conditions and are poorly resourced [704-706]. Equally important to successful recruitment is that suitable participants are enrolled. Participants' fall risk profile is discussed next, prior to extrapolating the implications of fall risk in the South African context.

Suitability of participant eligibility criteria.

A priori eligibility criteria were not overly restrictive; a strength of the study in that participants demonstrated a range of medical conditions and co-morbidities, enhancing possible generalisability. Another positive finding was that only three exclusion criteria were added, and should be implemented in a future trial, viz., implants besides pacemakers (WBB group), acute dizziness and/or use of vestibular sedatives. Acute dizziness might yield outcome measures unsafe, while vestibular suppressants may impair performance on balance endpoints (707). Potential participants should be evaluated for common causes of dizziness prevalent in older adults, treated, then considered for inclusion after treatment.

Participants' fall risk profile.

Fall events in the year preceding enrolment.

The sample was predominantly female and ranged from young-old (67 years of age) to oldest-old (708) (97 years of age). Female sex and age are important risk factors for falls[57]. All participants were Caucasian; although ethnicity was not an eligibility criterion. An unexpected finding was that half (50%) the participants had fallen in the year preceding enrolment. This prevalence is considerably higher than that cited in the USA (28.7% (709)), but interestingly, compares with a small study from Grenada, which cited a rate of 51.6% for participants of African lineage (390). The reason for the similarity, despite the differences in ethnicity, could be the likelihood of greater extrinsic fall risks due to poor infrastructure in LMIC (710). Indeed, focus group participants noted links between environmental hazards and trips and slips. Moreover, this dissertation's prevalence is notably higher than previous South African studies, which considered ethnicity as a risk factor (240). Striking differences are apparent when compared with data from other LMIC like India (27.6% (711)), Iran (39.7% (712)), and China (18%, but up to 34% in some Sino-nations included in the review (264)). Despite likely variation underpinned by fall definitions and methodological differences, there is support for suggestions that falls are indeed an issue in LMIC.

[57] See Chapter I. Fall Risk Factors in Older Adulthood.

Participants' intrinsic risk factors.

The high prevalence of falls in the study sample is a risk factor for future falls [(713)]. Three important risk factors arose from the results and are presented next.

Presence of imbalance.

Symptoms of vertigo were noted by almost one in four participants (24.1%). In the combined intervention group, the relative risk (RR) was 1.54 (95%CI: 0.5 - 4.15). Positionally-induced symptoms were present in almost a third (31.2%); with an intervention group RR of 2.32 (95%CI: 0.93 – 5.76). Postural symptoms were reported by a quarter (25.6%) of the sample, leading to an RR of 0.81 (95%CI: 0.34-1.95) in the exercise participants. Thus, for some symptoms of imbalance at least, its presence increased the likelihood of a fall event. These results are relevant to audiologists. First, audiologists assess and manage dizzy individuals, so the high prevalence of symptoms of imbalance in the study sample is interesting. The finding of imbalance concurs with previously cited rates, which describe a third of adults >70 years of age having dizziness impacting activities of daily living (ADL) [(714)]. Second, positionally-induced symptoms might suggest Benign Paroxysmal Positional Vertigo (BPPV)[58], which is associated with ageing and has a lifetime incidence of around 10% [(14)]. BPPV is cost-effectively and easily treated with good resolution rates [(15)], and treatment falls within the remit of audiologists [(153)].

Posturally-induced symptoms of dizziness or vertigo might suggest the presence of orthostatic hypotension[59] [(708)]. A meta-analysis (MA) demonstrated that orthostatic hypotension is prevalent in older adults, and is associated with subjective and objective impairments of balance, difficulty with ADL and decreased motor

[58] See Glossary of Terms.
[59] See Glossary of Terms.

performance (51). Another MA (715) associated orthostatic hypotension with falls (OR 1.73. 95% CI 1.50 – 1.99). Thus, audiologists should be questioning older adults regarding postural and positional dizziness and referring the former as necessary. Further research is required to ascertain if successful management of orthostatic hypotension reduces fall risk (51). Interestingly, orthostatic hypotension has been thought to be associated with polypharmacy (716).

Apparent polypharmacy[60].

The results showed most participants (93.4%) used prescription medication/s. More than half (60%) consumed ≥4 medications, a higher rate than in high-income countries (≈40-50% (56)), but perhaps in keeping with national norms. Recent data from Nigeria and South Africa indicated that older adults attending clinics at tertiary/academic hospitals are prescribed a mean of 4.38 (SD 2.29, range 1-16 drugs) medications (717). Of 328 patients' prescriptions reviewed at the South African facility, polypharmacy was established in 40.2% (132) of cases (324). The national differences between rates of prescription may be attributed to the settings for the Nigerian/South African study. Tertiary hospitals might attract sicker and more complex patients than would be found in the general medical population. Nonetheless, most participants in this report were at elevating fall risk due to multiple medications.

Unexpectedly, polypharmacy was associated with a previous fall only in the WBB group. A possible explanation is that participants may have been newly prescribed, amplifying the risk (718). Contrary to this argument is that advanced years would be more likely to compromise pharmacokinetics and pharmacodynamics (719), thus increasing risk related to medication in the older costs and OEP groups.

[60] See Glossary of Terms.

Growing numbers of older adults are vulnerable to polypharmacy as individuals live longer with more chronic conditions [57]. Frailty and falls are associated with polypharmacy, prompting calls for deprescription [720]. Practitioners should evaluate risk/benefit ratios when adding medications to a regimen [720]. This protocol did not recommend medication review to any participant, and changes to medication profiles were not monitored. However, the results suggest that the criteria for polypharmacy were met by most of the study population, possibly impacting baseline measures and attenuating responses to the interventions; issues to be considered in a future trial.

Appropriate management of polypharmacy may be exacerbated by issues of disempowerment, marginalisation and individuals' reduced access to shared-decision making with his/her doctors [720]. Patient-centred care, a principle of which is negotiating treatment, is under-developed in sub-Saharan Africa [721]; and a Cape Town study has shown a lack of patient-focused care for older Capetonians [706]. Thus, it is possible that treatment plans are not optimally discussed, and that patients do not question their practitioners when new drugs are added [706]. Furthermore, linguistic and other differences between patient and provider, commonly encountered in South Africa, may exacerbate treatment negotiation and service delivery [722].

Use of fall-related drugs.

Not only is the quantity of medications germane, the drug type is important. Common fall-related drugs include psychotropic medications, like benzodiazepines and anti-depressants [723]. Almost half (45%) the participants consumed psychotropic medications. While the contribution of such drugs to fall risk is extensively described, there is less evidence to support medication review/withdrawal and reduction of fall risk [724], although some encouraging results have emerged [713]. Research findings that exercise-based interventions have a similar effect on mild-moderate depression compared with anti-depressants and psychotherapy [725] might apply to older populations. Evidence supporting exercise to manage anxiety has been relatively weak [726]; but more recent MA has found exercise interventions to be more effective for anxiety compared with controls [727]. Encouragement of exercise could well address the psychological issues faced by older adults, which currently result in prescription drugs.

Lack of physical activity (PA).

Low scores on the Physical Activity Scale for the Elderly (PASE) were noted across all groups (mean = 68.0), with the lowest in the costs group, although there were no statistically significant differences. Low scores suggest sedentary behaviour [385]. The maximum possible score for PASE is 361 [728]. In USA normative data, adults ≥65 years of age had an average score of 118.9 (SD 63.9) [594]. Validity and reliability of the PASE has not been well established in LMIC [729]. Comparison with either LMIC or post-Communist countries is difficult. For example, most (81.2%) participants in a Turkish study [730] were between 65-74 years of age, and the PASE mean score was 121.7 (±54.7). Czech citizens, with similar education levels to those in this study, were similarly notably younger (68 years of age SD 6.26) than this report's sample, and the mean PASE was 159 (SD 74.2) [728].

An unpublished South African study examining correlations between PASE results and falls in older adults (range, 65-89 years of age, median 76 years of age) adapted the PASE for the local context [242]. Mean scores of 110.64 (range 34.1-235) were found for participants with a history of falls; while slightly higher (122.7) scores were described for a no-falls group (range 25 – 269) [242]. Participants had varied socio-economic, cultural and ethnic backgrounds [242]. The higher scores in

Caine and colleagues' study likely relate to diversity, as most South Africans have to walk to access public transport, resulting in some light exercise [(731)]. This dissertation's more privileged participants would likely drive, take taxis or obtain lifts for transport. Their low PASE scores might partially explain the high levels of falls in the study sample, as high levels of activity are thought to have a protective effect regarding falls in older adults [(237)].

Indicators of frailty or pre-frailty.

Interestingly, although the participants resided in facilities for independent living, group averages for several physical endpoints suggested frailty or at least pre-frailty[61]. For example, healthy older adults should be able to accomplish TUG simple in seven seconds (s), with values of 7-10s predicting pre-frailty, while scores of >10s suggest frailty [(732)]. In this report, the costs group had the slowest score of 12.2s; followed by OEP participants with 11.5s and the younger WBB group achieved pre-frail status at 9.9s. Similarly, single leg stance scores of <10s suggest frailty [(732)]; and all groups met this criterion (OEP: 4.4s; WBB: 8.5s; costs 3.9s).

The overall levels of PA and predictors of frailty in this study are concerning. Frailty and pre-frailty are preventable and even treatable conditions, particularly if recognised early in their clinical course [(733)]. PA is capable of reducing the risk for frailty [(733)]. The participants' socio-economic status should have been favourable, as affluence in older adulthood increases the likelihood of health three-fold when compared with poverty [(732)]. Second, increased sedentary behaviour is associated with socio-economic deprivation [(734)]. Therefore, it is not unreasonable to suggest that poor neighbourhoods, where recreational facilities are lacking and safety is a concern [(735)], might be unsuited for encouraging PA. Thus, for the majority of South

[61] See Glossary of Terms.

Africans, facilitating behavioural change in favour of exercise requires a multi-faceted approach.

This section has discussed the participants' profile and considered falls, imbalance, polypharmacy, use of psychotropic drugs, and PA levels. A high prevalence of falls in the year prior to enrolment was noted, while low levels of PA and even frailty indicators were apparent. The overwhelming consensus of the scientific literature is that high levels of PA enhance well-being, mental health and protect against cognitive decline [(736)]. It is highly possible that intrinsic fall risks are similar or worse in other South African communities. A combination of intrinsic and extrinsic risks, such as poor infrastructure and built environments, makes for a potentially devasting future for an ageing population, discussed in the following section.

Implication of fall prevalence for planning and policy in South Africa.

South Africa is home to one of the most rapidly ageing populations on the continent, with the number of adults over 60 years of age expected to double as soon as 2020 [(737)]. By 2050, 80% of the world's older adults will reside in LMIC [(736)]. However, adding to the number of years lived does not imply years lived well. The loss of functional independence associated with ageing will see the number of older adults demanding either rehabilitation or long-term care quadruple by 2050 [(736)]. Many South Africans are disadvantaged in early life, enhancing the likelihood of requiring, or depending on long-term care in old age [(705)]. Evidence to support age-related vulnerability is that currently, one in four South Africans over 70 years of age have difficulties with self-care [(705)]. Moreover, the figure of 25% may be an under-estimation and context-dependent. Rural and impoverished districts could more closely resemble other African countries like Ghana. It is estimated that >50% of

Ghanaians between 65-75 years of age require assistance with ADL, and this figure rises to 65% for individuals over 75 years of age [738]. Some perspective is provided by contrasting these figures with Switzerland, a high income country with effective health and social services [739], where 5% and 20% of the respective age bands require support to cope with ADL [738]. Pertinent to falls, a large multi-national study using walking speed as a proxy for function described firm associations between poor socio-economic status and reduced physical function [740]. For example, by early old age (60 years of age), poor participants had already lost six years of good physical function; and the impact was more marked when major NCD were considered [740]. Thus, walking speed and issues managing the ADL present risk factors for frailty and falls [39]. Combined, socio-economic issues clearly impact upon successful ageing and herald increasingly pressing demands from an ageing South Africa.

The post-apartheid South African government has developed plans to improve its citizens' health and to raise life expectancy to ≥70 years of age by 2030. Policies and legislation concerning ageing should be appropriate for the diversity of older adults [741]. Acts like the Population Policy for South Africa, legislated in 1998, aim to enhance quality of life at population levels, including older adults [737]. To meet these goals, calls have been made to introduce programmes for active ageing and the prevention of age-related diseases through healthy living and exercise [742]. However, challenges arise when dysfunctional health care services combine negatively with poverty, increasing the possibility of ill-health in old age [743]. While spending on issues related to population ageing has not received priority, significant efforts will be required to address the fiscal risk of spiralling age-related deficits [743].

South African policies regarding older adults strive to ensure that families care for their elders, and are in line with African cultural values [738]. Indeed, for many Afro-centric communities, family responsibility and inter-generational care is regarded as a moral obligation [737]. China and other LMIC in Asia have a similar tradition of filial piety, but scholars are questioning an erosion of such values [744]. In Africa, the traditional fabric of family life has been impacted by migration and other socio-economic issues [737], while stigmatisation and ageism are on the rise [738]. Endeavours to improve services to older adults, such as state-funded old age pensions to those meeting means-test requirements, are laudable [737]. However, this support often translates to poverty-alleviation for an extended family [705], leaving less income for the recipient and on-going negative health consequences. Implications of responsiveness to health issues associated with ageing are considered next.

Effective national education initiatives may promote healthy living and successful ageing [743]. Healthcare professions concerned with rehabilitation, including audiology, occupational-, and physio-therapy, should extend activities beyond curative services to health promotion and disease promotion at a population level [745, 746]. Physiotherapists in particular are in an ideal position to function at a community or primary level [747]. However, there is a chronic shortage of physiotherapists across the continent [748]. More than 10 million South Africans have NCDs, which is predicted to rise by 28.7% between 2012 and 2025 [749]. At the beginning of the estimation period, the ratio of physiotherapist to NCD patient was 1:5,667, leaving the nation woefully underprepared to match the predicted NCD epidemic [749]. Moreover, primary care for older adults is not stressed in national physiotherapy curricula [750]; leaving an arguably underprepared workforce. In contrast, vestibular and balance assessment and management is a mandated outcome for graduating audiologists [751]. Many audiologists work at a primary or at least secondary level of care; making a case for these professionals to be part of, if not instrumental in, the team.

Not only are adequate numbers of staff and services required for delivery of community-based interventions, primary care services must function optimally [742]. However, local primary healthcare facilities have been shown not to meet the needs of older adults in communities [706]. NCDs are frequently poorly managed [752], resulting in more health-related dependency in old age, while staff are ill-equipped to care for the problems associated with ageing [705]. This is partly due to a lack of qualifications, for example, there is no gerontology nursing training in South Africa [705]; and nursing inputs for chronic disease management are also inadequate [752]. The demand for age-appropriate healthcare may be underestimated as health issues may be overlooked in many older adults. For instance, African South Africans are less likely use prescribed assistive devices (e.g., spectacles) or medications [705]. Negative and at times hostile attitudes from personnel experienced during clinical encounters [753] further discourage older South Africans from raising health concerns, leading to perceptions of poor service and care [706]. Even private health care for South African older adults suffers from a lack of patient-centeredness, and largely ignores issue of age and function [706]. Thus, at a national level, it is possible that reports of fall risk and falls might be trivialised, and their importance in terms of management overlooked.

The high rate of falls in this report suggests an urgent need to embrace the pillars of WHO Fall Action plans. These are: to improve awareness of falls and fall prevention, increase the assessment of fall risk factors, and to deliver culturally acceptable evidence-based interventions (754). However, concrete action to place falls on a public health agenda in South Africa is not apparent. For example, the National Department of Health guidelines for fall prevention have not been updated since 2000 (332). Thus, the plethora of evidence that exercise is effective, specifically to prevent falls, appears not be have been acted upon.

Issues Related to Use of a Cluster RCT Feasibility Design

Sample size calculations.

Sample sizes were calculated for a future RCT using both cluster and simple randomisation. When recruiting a small number of sites, it cannot be assumed that randomisation will result in balance between arms (755). Thus, the number of potential sites was doubled to eight. Using this assumption (and four fully adherent participants at each site), fewer participants (60) would be required for a cluster design than for simple randomisation (110 per group if using Five-times-sit-to-stand (FTSST) data; less participants [≈30 per group] would be required if using Mini-BESTest data and 40% attrition). This is a rather unexpected finding and likely linked to the design effect and other relevant data present for only one test (FTSST). Nevertheless, this cluster randomisation estimate is likely moot, as will be explored in the following section discussing issues with the cluster design.

Between-group differences at base-line.

Cluster designs are particularly susceptible to selection bias (662); although randomising whole institutions and applying an intervention at a cluster level (755) may have an attenuating effect. Both apply to this report and are limitations. Age imbalance is particularly problematic in cluster RCTs (756) and was demonstrated. OEP and costs participants were significantly older than the WBB group, suggesting either a selection (662) or a possible small sample bias (565). Older participants may have been resistant to a WBB intervention, although they were unaware of which intervention they would receive when they enrolled. A weakness of this study is that reasons for electing to join or cross over to the costs group were not probed.

Possible selection biases might be managed in a future trial by incentivising participants with clear goals and rewards when these are met. Monetary and gift incentives have been used in clinical trials in the United Kingdom, but there is little evidence that they improve recruitment and adherence [(757)]. Monetary incentives are ethically nuanced [(758)]. In addition, incentives should recognise participants' time and effort [(759)], a substantial expense in a future full-scale fall prevention exercise trial.

No baseline differences in propensity towards exercise were detected on the relevant scales, which is a favourable finding related to minimising possible bias. Similarly, no marked between-groups differences in falls and case history were found. However, potentially important between-group differences existed on static and dynamic balance endpoints. To illustrate, the WBB group had significantly better FICSIT-4 scores, suggesting better static balance than the costs group, and better dynamic balance (higher Dynamic Gait Index) than the costs and OEP groups. Thus, a possible quantitative variables limitation exists, where differences of age, possible fitness and balance exist between groups, and yet similar target doses of exercise were expected for both interventions [(565)].

Missing data.

Disadvantages of cluster randomisation include a tendency towards missing data [(760)]. Not all clusters may provide data at the end of a trial [(626)]. While costs participants were distributed across all the clusters, follow up in this group was the worst, leaving less data for comparison with the interventions, a study limitation. Missing data may negatively influence power and precision [(760)]. Further, bias arises if the missing endpoint is linked to the reason for participant's withdrawal [760], for instance, a fall. In this study, data could be regarded as missing at random [760], for example, a follow-up endpoint being overlooked, or declined by the assessor or participant. Several outcome measures were conducted, yielding a certain amount of redundancy and a strength of the design. Attrition from enrolment to the six-month point, most marked in the costs group, was a significant challenge impacting analysis.

Randomisation, allocation concealment, and blinding.

Randomisation promotes between-groups balance of variables and confounders [626]. Risk of bias or an over-estimation of effect sizes might result from inadequate randomisation, or failure to conceal allocation [618]. Trials of physiotherapeutic interventions tend to over-estimate the effect size [618]. Furthermore, allocation concealment was problematic in a large meta-epidemiological study of physiotherapeutic trials, with only 11.5% trials following appropriate procedures [621]. Adequate sequence generation for randomisation was better (39%); but less than one in ten (8.9%) trials managed both randomisation and concealment appropriately [621]. In this report, the researcher recruited all sites and participants prior to cluster randomisation procedures, a strength of the design. Selection bias is still possible due to the small number of clusters (four). That is, once the first three were known, there was a >50% probability of knowledge of the last site's allocation [662]. However, the allocation of interventions to sites was awarded at the last possible moment prior to the interventions commencing [61].

Blinding is problematic in clinical trials, particularly cluster designs [564]. OEP trials have either not detailed unblinding [330, 331, 409, 429], or reported no unmasking [162]. Blinding of outcome assessors is seldom evaluated or reported in physiotherapeutic trials [621]. Furthermore, blinding is challenging, with a review of physiotherapeutic RCTs finding only 20% of 80 included studies successfully masked [621]. Blinding recipients of physiotherapeutic interventions is at times impossible [621]. In this report, exercise participants were not informed which intervention was experimental. Outcome assessor blinding was attempted. Few instances of unblinding occurred. Costs and intervention participants were distributed across sites. Thus, one participant revealing the intervention would not necessarily lead to assumptions regarding other participants at the site. Furthermore, both the physiotherapist and outcome assessor were in equipoise; and finally, the outcome assessor was unaware of levels of adherence.

Safety issues.

No adverse events occurred during intervention/outcome measure sessions. Falls occurred during the intervention period but were not reported immediately to the researcher. Half the sample had fallen in the year preceding enrolment, and 15 falls occurred during the trial. As some participants fell repeatedly, the overall prevalence of falls in the combined intervention group was 16.6%, markedly less than in the year prior. Two falls occurred in the costs group, but this is likely to be an under-representation due to attrition.

The lack of reporting falls, despite reminders on the exercise logs, is problematic and weakens the study. First, it raises the possibility of recall bias, despite a prospective method of data collection. Second, the safety and monitoring committee were unable to assess each incident at the time of the event, an ethical concern. A future trial would require more stringent reminder systems for reporting of falls, such as weekly text messaging. In addition, efforts should be made to empower participants to report falls, without fear of consequences from site staff or loved ones. Changing the culture of falls reporting is an important step to ensure accurate data collection; and indeed, on a societal scale, to evaluate and manage falls in this population appropriately.

Statistical issues associated with a cluster design are discussed next, before commenting on use of a cluster design in a future study.

Statistical considerations.

Participants in clusters tend to be similar [(676)], so cannot be assumed to be independent in terms of variability [(760)]. Therefore, intra-cluster correlation or between-cluster variation may result, resulting in increased Type I errors and narrow confidence intervals [(760)]. In this study, clusters were collapsed into interventions and aggregated values were analysed, as suggested in literature [(760)]. This method has likely triggered an average treatment effects limitation [(565)], whereby an aggregated response to the interventions is reported. Average effects might be positive, influenced by a minority who enjoyed large effects; ignoring that some individuals may have had no or negative effects from the intervention [(565)]. Moreover, an assumption in RCT designs is that the background traits of participants remain constant [(565)], an unlikely scenario given the study population. However, attempts to mitigate the effects of ongoing ageing were made with comparatively short follow-up (six months) and questioning participants regarding any medical events between visits.

A SWOT analysis of the cluster design is presented in Figure 21, prior to proposing changes to the protocol.

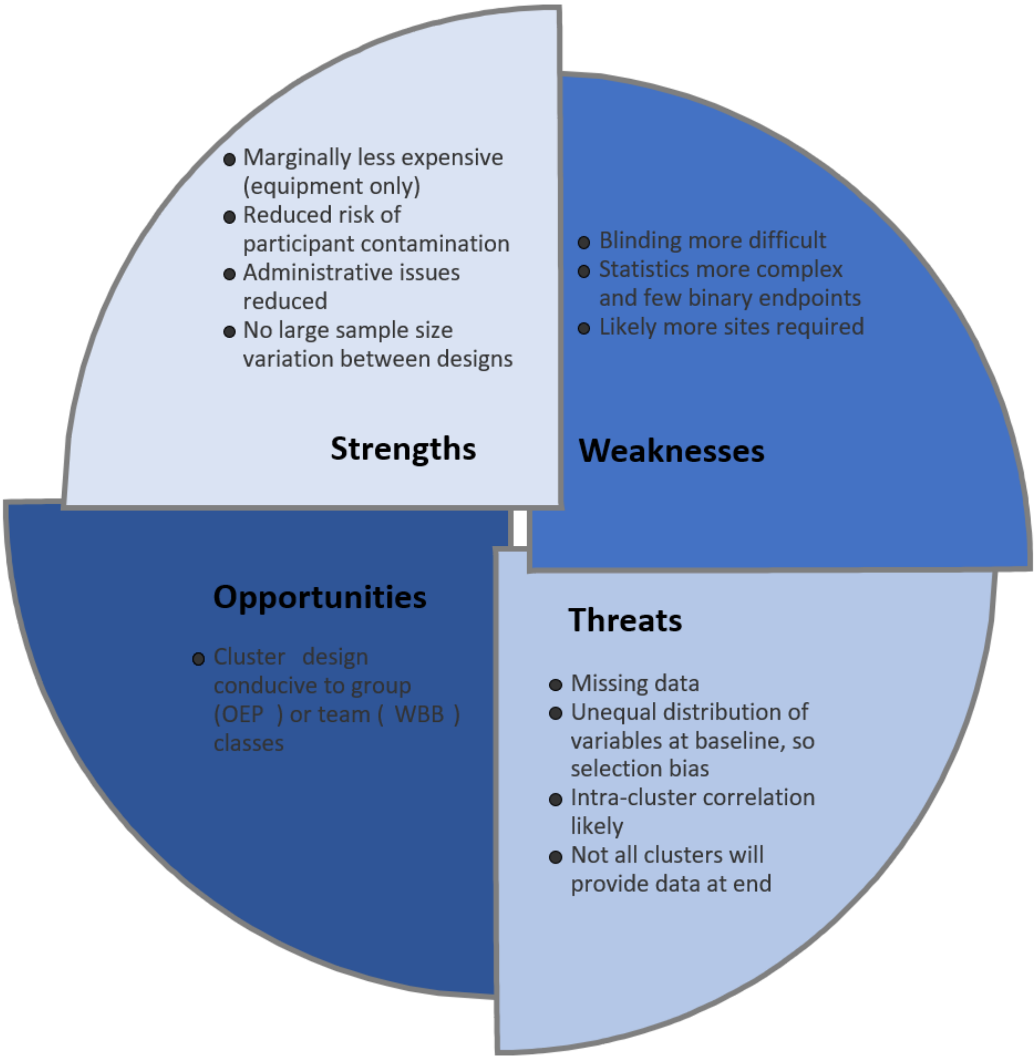


Figure 21. SWOT analysis of cluster design.

Proposed changes to protocol.

This study has shown that a future large RCT evaluating the two interventions would be possible, with modifications, and so has met its aims and objectives. Access to eligible participants was easy and barriers to future participation have been identified [562]. Assessment procedures and endpoints were successful, and those to be included in a future trial will be discussed. Acceptability of the interventions [562] was high and explored using quantitative and qualitative means, a strength of the design. Problems identified with adherence and attrition are surmountable, and solutions will be presented. Study-related processes were safe. However, some changes to a future protocol are recommended and detailed here.

Changes to randomisation/design.

Given the preponderance of negative items on the SWOT analysis (Figure 21), and issues regarding cluster-design, adoption of simple or stratified randomisation is recommended. OEP trials have employed stratified [409], permuted block [162, 330] or simple randomisation [429], and these methods would be suitable for a future trial. As noted, blinding of outcome assessors is more important than blinding of participants. If participants within the same site were receiving different or no interventions, instances of outcome assessor unblinding would not necessarily have a serious impact, unlike a classic cluster design. Second, the cost of WBB equipment was comparatively minor compared with overall costs, and duplication would not have substantial impact. Furthermore, changes to randomisation would ease the complexity of statistical analysis and permit a superiority or equivalence RCT design [761]. Based on the premise that some exercise is better than none [762], a non-inferiority design could also be considered [761].

Changes to statistical analysis.

The protocol anticipated per protocol (PP) and intention-to-treat (ITT) analysis; however, data sets were small, limiting the analysis. Both PP and ITT may yield biased estimates of treatment effects [763]. As found in this report, poor adherence is a common issue in clinical trials [764], and the statistical implications should not be underestimated [765]. ITT evaluates the effect of being offered an intervention, in contrast, more pertinent information concerns the effect of receiving it [764]. As some participants may not adhere to treatment, ITT tends to underestimate the efficacy of an intervention [766]. For exercise trials, small effect sizes could suggest that the intervention is ineffective, while poor adherence is in fact responsible [765]. An alternative strategy might be to continue with exercise regimens, while methods to improve adherence are introduced [765]. Similarly, PP may be less robust in studies characterised by poor adherence [764]. A recommendation for a future RCT would be to implement a complier[62] average causal effect (CACE) analysis.

CACE may be used as an adjunct to ITT, and estimates the effect of compliance, rather than assignation to an intervention [768]. CACE has only recently been adopted in physiotherapeutic trials [769] and sports and exercise psychology literature [768]; and the references cited are the first of their kind. *A priori* definitions for idealised compliance are required for CACE [768]. As guidelines exist for older adults' exercise requirements, CACE would be possible for a future RCT.

CACE may be more clinically relevant than ITT, as latent variables determining levels of compliance are randomised between control and intervention groups [764]. Compliers in the intervention group allow the proportion of would-be compliers in the control group to be estimated [769]. Non-adherent members of an intervention group should have mean scores resembling controls' [764]. Calculations are performed as per Knox:

> By representing the treatment difference observed through intention to treatment analysis as a product of the proportion of compliers and the complier averaged difference, and then re-

[62] Note: the researcher acknowledges the difference between compliance, which has negative connotations suggesting a lack of autonomy and patient passivity; and adherence, which is linked to self-efficacy, independence and self-determination. 767. Gardner CL. Adherence: A concept analysis. International Journal of Nursing Knowledge. 2015;26(2):96-101. In this instance, the term complier is used as it is the name of a statistical method.

organising the algebra, it is possible to estimate the complier averaged difference (CACE) [764p.3].

CACE estimates are flexible and allow important adherence data to be factored in when analysing treatment effects for clinical trials [765]. However, missing data are problematic with CACE calculations [764].

Changes to calculation of exercise regimen.

The overload principle dictates that individuals should do more than they are accustomed to [770]; and in terms of exercise, this implies working at or near the limits of capacity [771]. Thus, calculation of the intensity of exercise is important [772] and forms part of a commonly-used formula of frequency (how often), intensity (how hard), type (e.g., static or dynamic balance exercises), and time (how long) FITT framework [771, 773].

The Borg Rating of Perceived Exertion (RPE) was used in the present thesis, despite a general lack of interrogation of exercise intensity in RCTs of balance interventions [771, 772]. Although the Borg RPE showed no difference between perceived intensity of exertion between interventions (11.3 for OEP and 11.2 for WBB; range for both 9 – 15), it is acknowledged that the scale is not ideal to measure exercise intensity for balance-related tasks. Standardised instruments to gauge the intensity of balance exercises are in their infancy and require development and validation [772]. By including exercise intensity in dose calculations, evidence-based dose-response relationships may become clearer for balance interventions [774]. The exposure to balance training in this report complied with recommendations from expert opinion, that is ≥120 minutes per week, over several sessions per week [771]; but more precise prescription for a future trial would be preferable.

Changes to the delivery of the interventions.

Low levels of adherence were evident. While exploring adherence is integral to this feasibility study, the impact of poor adherence on statistical analysis represents a limitation of the study. Although initiated and supervised regularly by a physiotherapist, the interventions were home programmes, which are known to be associated with poor adherence (775). Adherence is even more challenging when participants have high levels of comorbidities and balance challenges (775), as in this report.

Group exercise.

Focus groups described a lack of motivation, and classes (OEP) or teams (WBB) were suggested as solutions. Participants noted that classes would oblige them to “be responsible” and “not let others down”, hinting at potentially powerful motivators for adherence. Peer-led and group OEP classes have been successful in populations with fall risk, with psychological and social benefits reported (191). Specifically, peer leaders are effective in promoting adherence to exercise (329) including in older adult populations (776). Improving adherence has produced conflicting results in terms of the benefit of exercise. For example, meta-analysis (MA) of participants’ timed-up-and-go (TUG) scores in peer-run classes was not favourable when compared with controls (329). In contrast, MA has demonstrated improved balance endpoints for group OEP, sustained for some months after trial cessation (679). The latter finding would also suggest that the loss of customisation, which could occur in group or video applications, may not be critical for OEP, and that generic programmes of OEP and WBB may work in a future large-scale RCT. Thus, classes may offer practical and logistic advantages, while enhancing adherence and possibly benefit. Certainly, in a resource-constrained setting, group application of interventions, led by lay individuals, would be more cost-effective than individualised programmes.

Furthermore, the social aspects of group exercise are important in older adults [777]. Playing exergames in teams could well enhance immersion, increase fun and improve confidence [778]. For example, peer-teaching and encouragement were valued by participants in a team bowling exergame tournament [778].

The benefit of flow experienced during exergaming was explored earlier. Wu and colleagues [779] proposed that enjoyment of exergaming would make it preferable to conventional exercise. Unexpectedly, researchers found the opposite, suggesting that exergaming might be difficult for older adults with little experience of interactive gaming [779]. Further, previous failure at managing interactive games could be demotivating. Previous challenges and a lack of customisation of exergames for older adults [779], might result in poorer adherence. Humour and mentoring, as in Zhang et al.'s work [778], might overcome such obstacles.

Team/group classes are suitable for sites like those in the present thesis, which had common areas for games to take place, and other participants close by. The researcher was struck by the sense of community at the sites, and this could be exploited by changing the nature of intervention delivery. These changes might positively impact adherence and should be considered for a future RCT.

Use of methods to enhance self-efficacy: motivational interviewing.

Along with not wishing to exercise alone, a common reason for not doing so [780], focus groups mentioned poor motivation as a barrier to participation in the intervention. Lack of motivation and poor health (suggested by the number of comorbidities and medications present in the sample) are frequently cited reasons to not adopt optimal physical activity levels [781]. Motivational interviewing uses a variety of person-centred tools to promote and support behavioural change [780]. Motivational interviewing is emerging in the audiology literature as a tool to encourage individuals to adopt and use amplification [782-784]. However, the technique is seldom used in physiotherapy or fall prevention programmes [785].

Participants' self-efficacy for exercise levels were not exceptionally low, even though PASE results suggested sedentary behaviour. Adherence was very poor for both interventions, suggesting that significant shift in behaviour would be necessary for a future trial to be successful. Arkkukangas et al., [785] evaluated motivational interviewing as component of an OEP intervention in an RCT. Several interesting findings emerged. First, activity levels at baseline were significantly associated with adherence over time, and second, motivational interviewing improved adherence [786]. Finally, although long term changes in balance and falls did not favour either the OEP or control group, the OEP group's activity levels over two years declined less than controls' [787]. It should be noted that participants required either an assistive device (cane) or some level of home support [788]. Both suggest some level of frailty or difficulty with the ADL, which may partially explain the lack of long-term benefit. In contrast, participants in the present thesis had to be fully independent, so caution should be used when extrapolating Arkkukangas' and colleagues' findings to a different population. Thus, adoption of more participant-centred techniques in a future trial might enhance exercise self-efficacy, and in turn, adherence.

More rigorous monitoring of exercise adherence.

More intense follow-up could result in better adherence, reduced attrition and less missing data, for example, exercise logs and reporting of falls. Weekly post-card drops reminding participants to complete falls and exercise logs and encouraging participation could work well. Cards would require hand-delivery as

South African postal services are poor[63] with frequent strikes, backlogs and non-delivery[64]. As not all participants had computers, and in less privileged settings this is highly likely, options such as automated email reminders are likely not feasible. However, many (≈80%) South Africans, including those from historically disadvantaged communities, now own smartphones[65], so SMS or interactive reminders and tracking could be attempted in a future trial. Logging of sessions could be achieved with an app or calendar on a smartphone. Despite high market penetration for smartphones, the competence of older adults using such technology would require prior exploration.

Many older adults prefer to use their smartphones for calls and texting, rather than accessing apps, email and the Internet [(789)]. For example, one Swiss study interrogating smartphones suggested young-old, male and active people were more likely to use technology to track physical activity [(790)]. This profile is almost exactly opposite to the participants in this report. Finally, advancing age, reduced socio-economic status and levels of education all impact negatively on the ability of individuals to use technology including the Internet; so possession of smartphones does not necessarily imply competence [(791)].

Adherence data could be obtained electronically for the WBB at least, given some modifications. At present, the WBB has a limited number of avatars, but more devices or some adaptation to the programme might allow researchers to track multiple participants' adherence.

---

[63] Reference retrieved 5.6.2019: https://businesstech.co.za/news/business/250373/how-south-africas-postal-service-compares-to-the-rest-of-the-world/

[64]Reference retrieved 5.6.2019: http://www.capetalk.co.za/articles/320757/it-s-time-for-sa-post-office-to-declare-its-incapacity-complaints-stream-in

[65] Refence retrieved 5.6.2019: https://www.itweb.co.za/content/GxwQDM1AYy8MlPVo

Changes to outcome measures.

Self-assessment scales (SAS).

Several SAS were utilised. They contributed considerably to the volume of paperwork and few participants, despite almost half (48.9%) having tertiary education, were able to complete them independently. For example, the PASE was chosen for its construct and criterion validity [(792)], and yet participants found it particularly difficult, resulting in researcher assistance. While SAS are inexpensive and putatively easy to complete, they are subject to recall bias and reporting errors, particularly prevalent in older adults [(792)]. These issues are pertinent to a future RCT, as health literacy is poor in LMIC [(793)], as well as in older adults, who may also have cognitive decline [(794)].

Use of patient/participant-orientated outcome measures is a growing trend in clinical trials, and ensure that interventions are thoroughly assessed [(795)]. Valid patient-related endpoints establish changes important to individuals, rather than statistical or methodological differences [(795)]. Thus, measures such as quality of life are important, but must be appropriately translated and validated [(796)], as is the case with the EuroQoL EQ-5D measures, available in six South African languages [(797)]. Robust translations and evidence of the cultural acceptability of instruments is important [(796)] if considering a large fully-funded trial in a South African context.

Physical endpoints.

Participants found the tests manageable. However, none incorporated environmental challenges encountered in real life, such as walking-while-talking, and managing moving people or objects in the environment. This deficiency results in difficulty testing all the constructs of balance, and might contribute to ceiling effects [(798)]. Ceiling effects are likely present in this report with moderate (costs group:

62.5%) to high (OEP group: 92.9%) numbers of participants achieving or exceeding normative levels at baseline for the Mini-BESTest. The Mini-BESTest has previously been described as resistant to floor and ceiling effects [605, 799]. Small numbers of participants demonstrated clinically significant differences the Mini-BESTest and preferred walking speed, implying responsiveness, but are too small to draw conclusions.

Standard Romberg eyes open (EO) was achieved by all participants throughout the trial and was probably too easy for high-functioning independent older adults. In contrast, the sharpened (full tandem) Romberg eyes closed (EC) was likely too challenging with very small numbers (costs: 0%; OEP: 18.2%, WBB: 20%) attaining normative levels at baseline, suggesting a floor effect. The difficulty participants had with sharpened Romberg EC upholds the suggestion that this condition is demanding and highly variable in older adults [60]. The Romberg results are difficult to compare with recent literature, where a sharpened Romberg was suggested as a screen for falls [62], as participants in the present thesis were required to hold the pose for 30s rather than the 60s previously described [62]. Nonetheless, the sharpened EO condition showed a range of responses, with the older costs group having less participants able to achieve normative levels (57.1%) than the OEP (69.2%) and WBB (86.7%). Notwithstanding, including Romberg tests as part of an overall FICSIT-4 test is likely worthwhile, as the latter identified statistically significant between-group differences in balance (between costs and WBB). Moreover, Romberg tests are included in outcome measures for the OEP, are simple to administer and do not require specialised equipment or intensive training.

The TUG was not correlated with a previous history of falls at various time cut-offs; nor using a difference of >10% between simple and cognitive modes. The lack of consensus on optimal time cut-offs for normative data for TUG makes the test unwieldy. The TUG was included in the protocol due to its common use in an older adult population (800); and as it assesses transfers and walking, two common scenarios in which falls occur (801). The dual-tasking nature of the TUG-cognitive might have more promise than TUG simple. Recent research examined counting the number of cognitive stops (pause of ≥2s between counting numbers backwards), number of cognitive errors, and number of motor stops (801). Results suggested that these modifications enhanced discriminative ability between participants who fell or not (801). While interesting, the necessity to videotape participants' performance for accuracy makes test administration and scoring more laborious. In addition, data provided were based on an instruction to walk as quickly and safely as possible (801), which is a variation on the standard method. Finally, counting backwards requires numeracy skills, which are challenging for disadvantaged South Africans, who experience poor levels of numeracy and basic education (802). More research is required to explore if these modifications to the TUG are useful and responsive.

Condition 4 m-CTSIB (30s stand on foam EC), included in the Mini-BESTest, was challenging for participants. Efforts were made to guard participants appropriately, and no safety issues occurred. Notwithstanding, the insecurity of standing with proprioceptive and visual cues reduced was unsettling for many of the participants. Recommended change would be to practice with an EO condition, followed by EC, which would allow the Mini-BESTest to be conducted as prescribed.

Future trials could explore tests like the Community Balance and Mobility Scale (803), which has been translated into other languages (804) and appears to be resistant to ceiling effects [804, 805], the Zur Balance Scale [806] and the newly developed X16 [734]. The X16 was implemented for large-scale population screening in China [734]. Unfortunately, preliminary reports suggest that the X16 is subject to floor and ceiling effects [734], likely partly attributable to the use of items from the Berg Balance Scale. However, the X16's simplicity, short test time and ability to be administered by volunteers with minimal training required are appealing [734].

Mini-Cog.

The Mini-Cog's purpose was to guard against including potentially vulnerable participants and ethical breach. The Mini-Cog generated notable anxiety and was failed by several potential participants. Another six appeared emotional having failed, and were offered a second opportunity by the researcher, and subsequently passed. This initial failure rate might imply the Mini-Cog is overly sensitive as a screening tool. For a future trial, validated tools to assess capacity to consent may be more appropriate [794] along with multi-media presentations to enhance understanding of the trial [807], which have proven effective.

Inclusion of FRAT-up.

The FRAT-up score was calculated upon data entry. The tool correctly predicted an increased risk of falls and falls in the year prior to trial entry in both the costs and OEP group. The ease and speed of the FRAT-up make it an attractive tool for use in future clinical research.

Retention, attrition and adherence.

> *"Physical activity is an elixir vita that promotes health and longevity better than any other lifestyle practice, but it is only effective if people do it. Exercise adherence is a difficult problem for people of any age, but it is challenging in older adults."*

(808p.3)

Retention and adherence were challenging issues. Methods to encourage adherence in a future trial have been discussed. For exercise participants, unanticipated delays between recruitment of three sites and commencement of the interventions could have contributed to a 'cooling off' period. The site recruited last (and closest to intervention introduction) experienced somewhat less attrition. Long delays between induction and the interventions may have contributed to participant apathy and loss to follow-up (809). WBB studies are vulnerable to loss during this time period, for example, 18% attrition has been cited (810). Postponements were unavoidable due to customs delays importing equipment. More importantly, the researcher had to teach a semester's work in three months, due to violent student protest action the preceding year[66]. Follow-up during the study will be discussed next.

The exercise groups had the best rates of throughput during the trial with 92.8% of OEP and 81.2% of WBB participants agreeing to follow-up at the six-month point. An extremely poor follow-up of costs participants (17.8%) was noted. The marked attrition in the costs group could be related to either a loss of interest, or the Zylen effect. Although participants were not 'bound' to their groups (i.e., a costs individual could join the intervention and vice versa), it is possible that the costs

[66] Referenced in the Chapter VII. Results.

participants had a similar experience to a control or non-intervention group. Hence, they could have been aggrieved, or lacked incentive due to not receiving the interventions [625]. These feelings may have been exacerbated by having a physiotherapist lead the interventions. Should a future trial occur in a different community, the desire for research participants to enjoy otherwise inaccessible health care and prevention [811], might result in improved retention in a no-intervention group. Once again, such a notion would raise delicate ethical concerns.

An MA of exercise interventions for falls cited attrition rates between 7.4% - 32.2% [378]. An SR of OEP research found data for key outcomes were available for >80% participants [53]. Studies of the OEP in LMIC had varying rates of attrition. An Iranian study described a loss of 41.9% OEP participants [331]; while a Thai study experienced 17.4% attrition in their OEP group [330]. Literature concerning attrition in WBB cited rates of between 0-33% in one MA [812]. Two studies had one in every three participants withdraw [813, 814]. A recent large (1016 participants) Spanish RCT of WBB had an overall rate of attrition rate of 36% at three months, and 46% of WBB had withdrawn by trial termination [815]. Compared with these data, attrition in this report's intervention groups (OEP: 7.2%; WBB: 18.8%) was manageable, although it is interesting that attrition was more marked in the younger WBB group compared with OEP participants.

The Results chapter suggested poor adherence and much missing adherence data. Continuous motivation and reminders may enhance commitment to exercise, particularly for older populations with multiple morbidity [808] and these should be implemented in a future trial, as discussed. Predictors of adherence are uncertain for fall prevention programmes [808]. Older individuals adherent to exercise programmes are likely to be from high socio-economic backgrounds, relatively active, healthy and fit [808]. The challenges to adherence, extracted from the participants' profile, are shown in the cause and effect diagram, Figure 22.

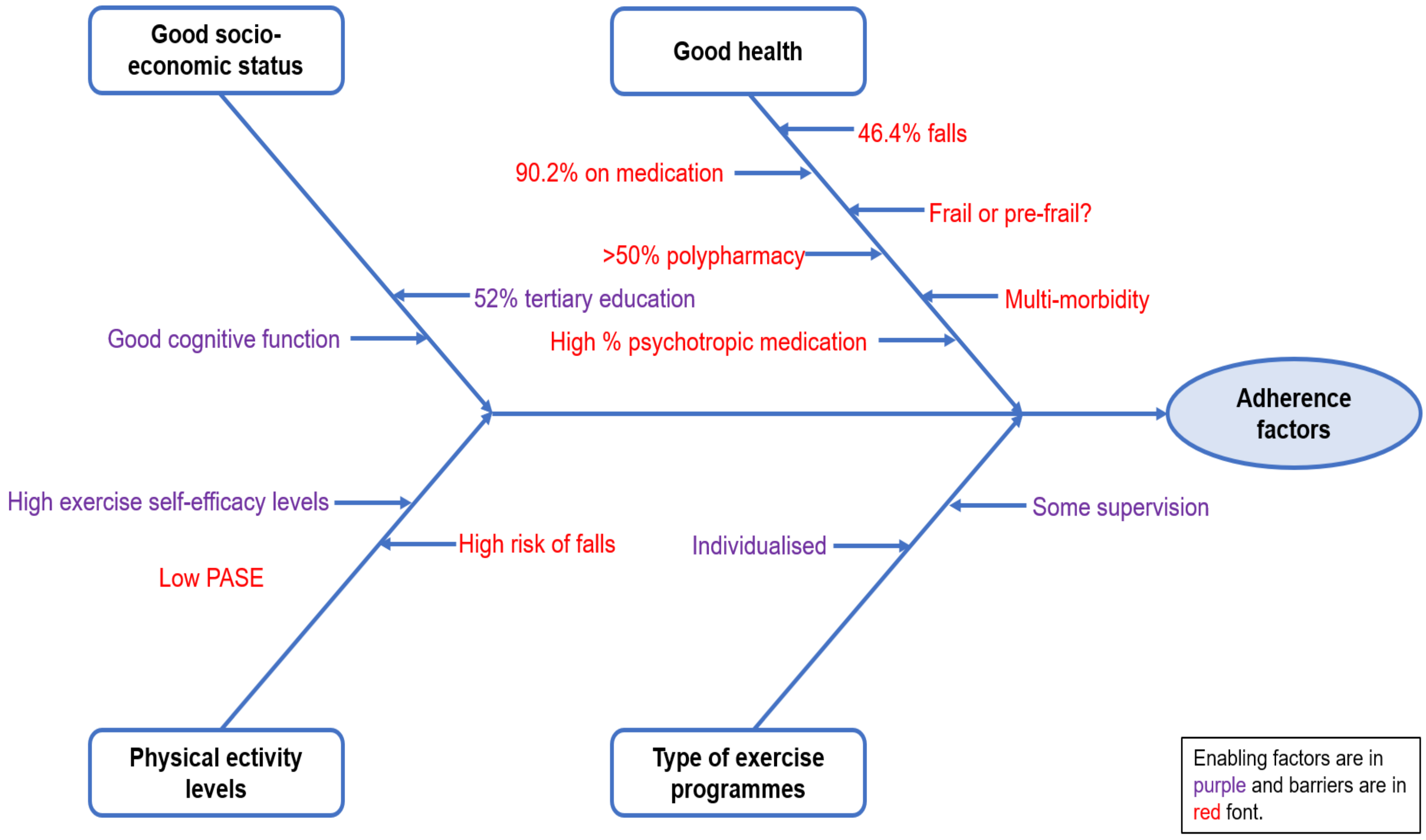


Figure 22. Root cause analysis of factors associated with good adherence.

This section compares adherence rates with published OEP and WBB rates. More WBB (90%) than OEP participants (54.5%) exercised ≥4 times per week in the initial three-month period; although rates were comparable at six months (WBB: 66.7% and OEP: 62.5%). However, only a small percentage of participants in either group reached adherence levels compatible with the gold standard of 150 minutes per week (WBB: 20% and OEP: 14%). Comparing adherence rates with literature is difficult as researchers set different standards for adherence. For example, adherence may be a proportion of prescribed sessions attended [(535)] rather than meeting an external criterion for exercise to be beneficial, as in this report.

Systematic reviews (e.g., Miller et al.) have not always confined their eligibility criteria to large home-based RCTs [(816)]. Adherence rates in a small case series or pre-test post-test design might be very different, due to issues such as therapeutic alliance, levels of supervision, or type of setting. Indeed, few exergaming interventions have been offered in a largely unsupervised manner or in home settings, resulting in outstanding questions regarding their effects [(817)]. Approximately a third (36.7%, ± 15.8%) of OEP participants in one MA met an exercise target of ≥3 times per week at 12 months after induction [(53)]. A Thai study of OEP set a target of 120 minutes per week, which was met by 29.6% of participants at three months [(330)]. Results in this thesis are somewhat comparable, with 38% of OEP and 41% of WBB participant meeting the 120 minutes per week target. Although not statistically significant, there was a trend towards better adherence in the WBB group, upholding suggestions that exergaming might encourage better adherence than conventional programmes [(535)].

Preliminary Evidence for the Interventions

Turning now to the secondary aim, this section will discuss physical endpoints with a focus on falls. Prior to discussion of these results, some consideration of strengths, and limitations of feasibility designs to assess efficacy is necessary. Strengths of this study include its stringency, adoption of RCT principles, choice of both questionnaires, and multiple endpoints for balance. The use of a phenomenological lens allowed exploration of participants' experiences and influenced recommendations for a future trial. Limitations are presented next.

First, while the effect of interventions may be part of feasibility outcomes, issues with small sample bias [565] are evident. An imbalance in background characteristics [565] was noted at baseline, with the WBB group being younger, and having better balance. WBB participants' static balance was superior to the costs group, and dynamic balance was better than both costs and OEP groups. Therefore, it might be argued that the inherent risk in the WBB participants was lower than for the other groups. Rather, caution should be adopted interpreting these data. While the respective outcome measures are commonly used in clinical and research settings [8, 386, 613, 818], gold standards are lacking [606]. Such deficiencies imply that measures are subject to floor and ceiling effects (already discussed) and lack sensitivity and specificity. Despite utilising a test battery, at the risk of redundancy, the endpoints still do not necessarily capture all the complex interactions between balance and self- or self- and environmental movement [613].

Second, small sample sizes necessitate caution [819]. While some improvements were noted on physical endpoints, these applied to very small numbers. Notwithstanding the small sample size, the fall risk factors including previous falls, multi-morbidities, polypharmacy, and even frailty indicate some level of generalisability to published data.

Sample bias [565] may have been operant, with several recruited participants requesting transfer to the costs group. Should this request have been motivated by a fall, bias would be further problematic. Although participants were questioned regarding falls at each follow-up, attrition in the costs group was marked and thus, information regarding falls in the costs group is limited.

Fourth, between-groups analysis may produce average treatment effects [565], where some participants had marked improvement, but the effect was attenuated by averaging. The statistical analysis also fails to capture participants' views of the interventions. Focus group members noted a subjective improvement in their balance, and in some participants, rekindled interest in other forms of exercise beneficial to balance, such as dancing [820]. Given that progressive ageing increases fall risk [821], small positive changes such as these might be helpful [675]. Thus, improved outcomes on physical endpoints of balance and mobility might be worthwhile to the individuals concerned [675]. For instance, the focus groups spoke of increased 'mindfulness' of their balance and gait and attributed such to the WBB. Such awareness might well reduce fear of falling, limit activity restriction and in turn, reduce fall events [822].

Reduction of falls in the exercise intervention groups.

The most interesting and clinically relevant finding regarding the impact of the interventions was the reduction in falls. Almost half (46.4%) the exercise group participants had fallen in the year preceding enrolment. During the six-month trial period, a total of 13 falls occurred across the 30 exercise participants, yielding a prevalence of 16.6%, a reduction of almost 30%. Given the participants' fall risk profile and pre-frailty status, this finding is encouraging. The reduction in fall events compares favourably with preliminary OEP findings, where a 30% reduction in falls was found for individuals between 65 and 79 years of age (394). The gain was evenly spread between exercise groups; suggesting that increasing physical activity with a focus on balance was helpful, but no clear advantage of WBB was evident for fall prevalence.

Putative mechanism for improvement in WBB group.

The improvement in the rate of falls in the WBB group bears further consideration. As explored in the Chapter I. Fall Risk Factors in Older Adulthood, the WBB can be argued to capture some of the essential tenets of vestibular rehabilitation therapy (VRT). However, the WBB is unlikely to address all the systems sub-serving balance. These limitations include the WBB's inability to simulate dynamic balance situations during gait, induce reactions to physical perturbations of balance, and that stepping activities are largely prevented by the use of a platform (823). Certain movements such as hopping and jumping are not possible when using the WBB (824). In addition, the WBB has been criticised for failing to foster use of sensory re-weighting strategies to maintain postural control (823), an important feature of VRT (825). The WBB limits exercise to within the bounds of an individual's stability and base of support (823). However, evidence suggests that VRT is more effective when individuals' limits of stability are reduced (826), so working within this constraint may not be crucial for improvement. In addition, it could be posited that gaze stability exercises, incorporated in the WBB, might improve static balance by triggering re-weighting processes (827). Recent research using a customised exergame for older adults suggested that gaze stability improved for the Dynamic Visual Acuity[67] test,

[67] See Glossary of Terms.

and further, that this translated to improvements in gait [521]. Therefore, while the precise mechanisms underpinning the results in the WBB group are unknown, it is likely some form of vestibular rehabilitation occurred and reduced fall risk.

The WBB has further advantages, which may have impacted this study. Dual-tasking, an essential quality of the WBB, has been described as helpful for balance improvements [823]. The fun nature of exergaming, enjoyed by participants, may encourage focus. The novelty of the task may stimulate neuroplastic processes [55] and have underpinned an improvement in the WBB group. The exposure and repetition of dual-tasks may have increased capacity to tolerate such challenges [55], and positively affected fall occurrence. Thus, even though the WBB does not offer a truly immersive virtual-reality type experience, aspects of having to negotiate complex visual stimuli and maintain balance may have a positive influence in daily life. In contrast, while VRT encourages patients to focus on the task in hand [828], dual tasking does not receive much attention in the OEP.

WBB and frailty.

Walking speed is the most widely used test conducted by doctors to predict frailty, and is simple and effective [829]. As discovered post-hoc and discussed, groups met some criteria for pre-frailty or frailty based on physical endpoints. Frailty itself is an important clinical issue, associated with increased morbidity, dependence, and mortality [830]. PA successfully addresses frailty, and improving balance and mobility is convincingly associated with improved health outcomes, including functional capacity and independence [830]. Several interesting findings arose from a recent review of PA interventions to address frailty. First, simple interventions were effective, and second, interventions with balance components were superior to others [830]. Finally, deterioration was attenuated for up to a year post-intervention [830].

Similar to the OEP, the WBB has demonstrated that lower limb strength can be enhanced [679, 823]. This improvement, along with increasing levels of PA, may translate into faster walking speeds, as found in both intervention groups in this study. Notwithstanding issues with adherence, a sizable minority of both groups (OEP: 41.7%; WBB: 30.8%) improved walking speed by a clinically significant margin. This change likely had a marked positive impact on fall risk. These findings are congruent with an SR, which suggested that WBB was effective for dynamic balance [460].

A Brazilian feasibility RCT [824] evaluated the WBB with frail or pre-frail adults. Physical endpoints like the Mini-BESTest, were similar to those used in this research, and demonstrated significant improvements [824]. The intervention was found to be acceptable, and there was a low incidence of adverse events [824]. Although there were methodological differences between the Brazilian work and the present thesis (e.g., the exercise target did not meet recommended guidelines, the setting was a tertiary hospital, and all exercise sessions were supervised [824]) the findings are positive and suggest further interrogation in the form of a large scale RCT is warranted. Moreover, the cited and current study have relevance to an emerging country setting. Both might suggest that the investment in public health exercise interventions is justified in view of an ageing population, arguably predisposed to falls and frailty issues.

Participants' experience of WBB.

The Results Chapter of necessity offers some interpretation of the qualitative data. Much of the focus group conversations were positive, although some individuals found various aspects of the WBB programme irritating. An SR cited a number of factors negatively influencing research participants' use of the WBB [460]. Several fears were expressed, and these included fear of falling and injury (when using the device), safety-related fears, a lack of confidence using the technology and increased anxiety [460]. As noted in the Results, several participants cited anxiety as a rationale for non-enrolment, but no-one mentioned anxiety as a reason for poor adherence. Similarly, no participant mentioned or experienced any safety issues or falls when using the system. The only congruence between the SR and this report relating to user experience is a loss of interest [460], in turn affecting adherence. Recommendations to address such decline, not already mentioned, include making the cognitive challenges more apparent (and thus, more rewarding), and closer monitoring of progression of acquired skills as an incentive [823].

The cited fear of technology, and anxiety linked to this [460], might not have been prevalent in this report due to a large majority (86.6%) of exercise participants owning a computer. Technological ability was not formally assessed, rather, being able to conduct email correspondence and internet searches was a proxy for basic skills. Older adults have been described as having challenges in terms of technical literacy [831]. Furthermore, digital inequality has been described, where individuals from higher socio-economic groups have better skills using the Internet than the disadvantaged, which in turn can translate into higher health literacy [832]. While older adults are an extremely diverse group, predictors of success with technology include previous employment, motivation, and knowledge of computers [832].

Pertinent to South Africa, numeracy skills also predict success in the adoption of new technology [833]. Older adults alive in 2020-2030 would have been schooled in the apartheid era; where mathematics was taught poorly, by largely unqualified teachers, to the majority of the population [834]. Thus, the ability to use WBB or similar devices would have to be considered for a future large RCT in a less affluent community. However, the value of technology in terms of health-related quality of life may mitigate the impact of numeracy and education levels [833]. A WBB study with older, underserved African Americans found that the perceived improvements in balance, recognition of the exercise benefits of the programme, and fun were highly prized [835] and could have overcome challenges with technology. Sentiments expressed by participants included feelings of both fun and frustration [835], similar to focus group participants in this work.

Fiscal Motivation for a Large Scale RCT

Costs of a future RCT.

This report has argued for the need to address falls as a problem associated with an ageing population in South Africa. Cost of the current feasibility study were extrapolated to estimates for a large RCT. Should three arms be envisaged, costs would be R1,024,296. Despite the controversy surrounding the efficacy of WBB for fall prevention, its potential for use in a LMIC behoves a future study. The context of South Africa, where qualified healthcare professionals are scarce and millions of South Africans are denied access to rehabilitation services [836], mandates judicious use of technology for rehabilitation purposes. The results suggest that with appropriate modifications, a future large trial might be justified as a next step prior to designing population-based interventions.

It has been suggested that a reduction in falls by at least 17% would yield a good return on the investment required to offer exercise-based fall prevention programmes at a population level [435]. This feasibility study met and exceeded this criterion. Not only were fall events reduced in the exercise groups, fall injuries were not serious. For both groups, minor or no injurious falls outweighed moderate injuries (requiring consultation with a health care practitioner [395]). Although fall occurrence was reduced during the trial, OEP participants had more moderate injuries than the WBB group (3:1). This is not surprising, given that the OEP group were older, and older adults are more likely to have severe fall injury when compared with younger counterparts [277]. Moreover, the OEP group had lower health status, and poor health in older adulthood is associated with a seven-fold increase in fall-related injury rate when compared with healthy cohorts [808]. The overall reduction in fall events, combined with their non-injurious nature, is notable.

As discussed, the South African government is increasingly recognising the needs of an ageing population. Planning for population- based interventions requires significant input, including economic predictions. A large RCT would permit estimation of QALYs and DALYs, along with projections for wide implementation of the programmes. The need for information regarding costs and efficacy of interventions for third party funders is essential [435], be they medical insurance or National Health Insurance.

Implications of the Study

Training implications.

All South African healthcare professions' curricula will require a shift towards management of chronic conditions such as NCD and to respond to issues of population ageing. However, it is challenging to summarise the status of gerontology studies and even research in Africa [737]. Calls to include geriatrics education and gerontology in undergraduate health science curricula in South Africa were made more than forty years ago [837]. They remain largely unanswered. As recently as 2015, a survey of medical curricula in Sub-Saharan Africa demonstrated that just one of 25 responding institutions offered a speciality in geriatric medicine [(367)]. Slightly less than half (40%) offered no consideration of gerontology at all [(367)]. Thus, there is a need to focus beyond simply training doctors appropriately, but to extend education in ageing to the rehabilitation professions, who are often at the front-line of management of the disability related to chronic disease and ageing [(736)]. Indeed, for the rehabilitation professions, practitioners should regard themselves as 'first responders' to the clinical issue of fall risk and fulfil their mandate towards health promotion and disease/disability prevention.

This study supports the notion that falls are indeed a problem in LMIC. Thus, embracing screening activities for falls should be mandated at all health care consultations for older adults, as has been the case in the USA for audiologists[68]. Moreover, the opportunities for inter-disciplinary practice should be fostered, and expanded across a variety of professions. Falls education should be targeted at nurses, social workers, health educators, and others in the public health system in order to achieve reductions in fall risk [(838)]. South Africa has commenced training community health care workers, who are at the forefront of primary services [(839)]. More recently, community rehabilitation workers have been introduced [(840)] ideally positioned to assess fall risk and implement interventions. Elsewhere, community care workers have been shown deliver exercise-based fall interventions safely and effectively [(841)]. Thus, utilising this cadre of staff could be cost-effective and efficient, and should be considered.

Clinical implications.

Besides training our professions to respond to ageing and falls, clinicians currently in practice should be actively engaged in managing falls. Nothing is known

---

[68] See Introduction.

concerning audiologists in Africa and their awareness of falls as a clinical problem in their patients. Results from Nigerian physiotherapists were encouraging, with high levels of physiotherapists being aware of fall risk factors, and most actively addressing them during treatment (842). Interestingly, half the respondents never or rarely referred patients with fall risk to any other professional (842).

The high occurrence of falls in this report suggest that health care professionals in this country should be vigilant and active partners in managing fall risk and promoting exercise-based interventions. However, changing clinical practice can be challenging and requires concerted, targeted education efforts for practitioners (843).

While evidence-based practice guidelines exist, and an abundance of evidence for exercise-based fall preventions strategies is available, uptake of guidelines has been described as sub-optimal in systematic reviews (844). Moreover, knowledge of guideline use in LMIC is likely under-represented in these reviews (845). For instance, although China has a unique dual system of traditional and Western medicine, low numbers of either type of practitioner utilised clinical guidelines (846). In Saudi Arabia, doctors cited a lack of institutional leadership, lack of awareness, and knowledge of guidelines as reasons for non-implementation (847). South African physiotherapists, particularly those working in state settings, indicated a lack of time to both research and implement guidelines was a barrier (845). Further obstacles were little confidence in finding and using evidence, and limited access to the literature (845). Thus, addressing attitudes towards the evidence base may be required, prior to focussing on falls.

In addition to encouraging practice of fall risk identification and management, referral pathways would have to be explicit (843). As the National Health Insurance system is currently being finalised [848], the timing is conducive to starting conversations regarding fall management pathways. The opportunity for all rehabilitations professions to unite in calling for better management of issues facing older adults, particularly those in poverty and disempowered, is now.

Policy implications.

While feasibility studies often lack firm evidence for the success of interventions, some results might signal the need for policy development and consolidation. For example, the high prevalence of falls in the year preceding participants' enrolment, and the marked reduction in fall events in the exercise groups, and acceptance of the WBB are of interest. South Africa has legislation protecting the rights of older adults and is attempting to turn the tide of age-related issues, as discussed earlier. The National Development Plan 2030 aims for transformation and correction of previous inequities [750]. With policies to increase all South Africans' life expectancy to 70 years by 2030 [747], there is scarcely a more pertinent time to focus national efforts towards care of older adults and fall prevention.

There is an urgent need to involve the public health system in planning for falls [838], and work should occur at a national and provincial level. To prevent disjointed planning and delivery across government departments (e.g. Health, Social Development, Human Settlements, Women, Youth, and Persons with Disability), a case could be made for a collaborative effort in the form of a coalition [849]. Alliances could unite stakeholders, be they older adult associations, government departments and non-government organisations in a common cause. Coalitions are in a powerful position to act as advocates for older adults, allowing their voices to be heard, promote their interests and lobby for action, and inform policy decisions [849].

Furthermore, coalitions raise the opportunity for transforming research efforts into policy through implementing multi- or trans-disciplinary approaches [850]. For example, the problem of falls could be approached from a health science and built environment perspective. Coalitions are likely to be able to use their combined influence to convince policy-makers regarding the cost-effectiveness of fall prevention strategies [849].

As discussed in the Chapter I. Fall Risk Factors in Older Adulthood, managing adverse consequences of falls is expensive, and many adults require care beyond simple acute injury treatment. National Health Insurance is becoming a reality in South Africa, but must be people-centred when health systems are constructed and reformed [851]. Second, universal health coverage has been criticised as an often over-medicalised model at the expense of health promotion and disease prevention, although efforts to address non-communicable diseases in Africa exist, for example, the Chronic Disease Initiative for Africa [851].

Failing to respond to the changing profile of South Africans in terms of age and chronic disease with targeted policy is potentially disastrous. The government is already considering the Sustainable Development Goals of wellness at every age, and so should seize the opportunity to implement proven interventions, and indeed technological innovations.

Recommendations for Future Research

Naturally, the first step towards future South African research is to conduct large scale epidemiological studies of fall risk, falls and their consequences in rural and urban settings across the country. These studies would permit issues of disability and the costs of injury to be calculated and direct the need for rehabilitative services. Principles of supply and demand should be observed for interventions [843], and there is scant knowledge of fall prevalence, nor attitudes towards falls and fall prevention strategies, implying these areas require further exploration.

Second, large scale, well-funded and adequately powered RCTs of exercise-based interventions should be conducted in different settings to explore efficacy. Additional research should explore the cultural appropriateness of various interventions including technological innovations, necessitating mixed methodologies.

Further research may explore preferences for the method of intervention delivery along with the professionals who offer such interventions, as well as the recipients. Costing of different models could be calculated in terms of the projected cost of programmes, and the costs saved by preventing DALYs.

This report raised several broader issues in the study population, which are not strictly linked to the rehabilitation professions, although the presence of such factors surely impacts upon them. These include polypharmacy, the high levels of participants taking psychotropic medications, and pre-frailty indicators in an older adult population living independently. The role of exercise might positively impact on these problems, and research is clearly required into these and other geriatric giants in South Africa.

The profile of participants suggests they have met only some of the criteria for successful ageing, which are: low probability of disease and disability, high cognitive and physical functioning, and active engagement in life [852]. Poor environmental conditions in South Africa have been described as barriers to successful ageing [853], so future research into successful ageing needs to be holistic and policies to address ageing concerns inclusive of both intrinsic and extrinsic factors.

Finally, self-efficacy for exercise levels were reasonable, so future research could focus on how to harness these into sustained action, and how exercise can contribute towards successful ageing programmes.

Conclusion

This report has demonstrated that with some adaptions, a large-scale RCT of the WBB to manage fall risk would be feasible. The mixed methods permitted exploration of participants' experiences as well as estimations of important constructs for a future trial, such as adherence, attrition, and retention. Valuable lessons have been learned which can be applied to future research.

The work has considered aspects of context in one community in a LMIC, preparing the way for adoption in other communities and future research. Furthermore, the interventions markedly reduced the occurrence of falls, suggesting further research is worthwhile. Finally, the report has offered a novel rationale for the mechanisms behind the possible success of the WBB, using a vestibular rehabilitation focus.

APPENDICES

Appendix A Exercise intervention programmes (OEP and WBB)

Appendix A.1 Summary of exergame systematic reviews

Table A.1. Summary of exergame systematic reviews.

Reference	Peng, Crouse and Lin [496]. (SR)
Objectives of reviewed studies	1) Laboratory studies evaluating the intensity of exergames (28 studies). 2) Intervention studies which use an exergame to increase PA (13 studies; eight of which were RCT).
Inclusion criteria for selected studies	• Off-the-shelf commercial home use games. • Games had to be used to increase PA or quantify intensity. • Studies had to have objective endpoints. • No restrictions for age of participants.
Endpoints/results	• Intensity studies had variable results ranging from vigorous PA when playing exergames and the majority suggesting light-moderate intensity PA. • Interventions studies showed exergames: Effective to increase amount of PA (three studies), and No difference between control and intervention (three studies). • Worse than comparator in influencing PA (one study). • Indeterminate results (six studies).
Comments	• English language literature searched. Purely qualitative studies excluded. Studies using the WBB were most common. • Small sample sizes (8-100 participants for laboratory studies; 12-60 for intervention studies). • Programme duration extremely variable ranging from 5 days to six months. Settings included schools, home and laboratory, making generalisability problematic. • Key issues such as randomisation (but not allocation concealment); adherence, missing data and power analysis were recorded. • Only one intervention study had older adult participants, limiting the relevance of this review. While this study used the Wii, many of the participants played while seated, likely enabling the lack of change in PA levels. • Risk of publication and language bias present.

Reference	**Larsen, Schou, Lund and Langberg [536]. (SR)**
Objectives of reviewed studies	1) Exergame interventions on physical health outcomes in healthy older adults (mean age between 73-86 years). 2) Rehabilitation of specific conditions (e.g. diseases, chronic conditions) studies were excluded.
Inclusion criteria for selected studies	• Included two studies with non-commercial exergames. • RCT with no or alternative intervention. • Of the four WBB studies, only one compared exergaming with a no exercise group. The other three studies were three-arm trials.
Endpoints/results	• Validated physical health outcomes had to be used and included BBS, SLS and TUG in the WBB studies. WBB studies: - No effect (one study). This study was the shortest duration and used the BBS, which could have been subject to floor and ceiling effects as noted in other Chapters. - -Improved static balance for the WBB but not dynamic balance (one study). - -Improved functional balance for WBB on TUG (one study) - -Improved balance for both WBB and Tai Chi groups (one study).
Comments	English language literature searched. Exergaming defined. • Cochrane Risk of bias tool used to interrogate allocation concealment, blinding, and attrition bias. Blinding and allocation concealment were either poorly managed or not reported. Studies were low to moderate methodological quality. • Only two studies implemented an intention-to-treat analysis (ITT). • Seven trials totalled 311 healthy older adults. Sample sizes ranged from 25-79 participants. • Programme duration for the WBB studies ranged from 3-20 weeks. For the WBB studies, attrition ranged from 0-33%. • Designs using exergaming plus additional exercise make it difficult to attribute improvement to the WBB. None of the WBB studies showed a superior effect of WBB to conventional exercise. • The use of PICOS criteria and inclusion of RCT with validated endpoints makes this review superior to that of Peng et al. [348]. • Risk of publication and language bias present.

Reference	**Booth, Masud, Connell and Bath-Hextall [468]. (MA)**
Objectives of reviewed studies	1) Virtual reality interventions for improving balance in adults with impaired balance. 2) Adverse effects, functional balance outcomes (e.g. walking speed) and QoL.
Inclusion criteria for selected studies	• All forms of virtual reality included, from commercial exergaming to bespoke systems. • Participants aged >16 years with impaired balance on an outcome measure (e.g. BBS) or falls/fall risk/ patients at a balance clinic. Hospitalised patients included.
Endpoints/ results	• Either validated measures such as BBS and TUG or incidence/number of falls. Six studies used WBB, most of which were combined with conventional physiotherapy/VRT rather than no intervention control groups • Improvement was noted in the WBB + physiotherapy and not WBB as a single intervention group. None of the improvements were statistically significant. Most frequent outcome measures were BBS (six studies) and TUG (five studies). Pooled analysis showed no significant difference in test (BBS, TUG) scores for exergaming groups compared with standard therapy, or no exercise groups. • The same finding applied to walking speed and 30 second repeated sit to stand test. No QoL measures were included Thus, while individual studies may have shown individual positive results favouring exergaming, the meta-analysis favoured standard physiotherapy interventions.
Comments	• Eight RCTs with 239 participants. Data from five trials were pooled for the MA. Sample size varied between 10-80. Diagnoses included stroke, brain injury and multiple sclerosis, making a heterogeneous sample. The wide age range is noted. WBB dose was variable. For example, one early study did not specify the minutes for each session but noted three weekly sessions over a total of four weeks [479]. • The 28 older adults exposed to WBB in Jorgensen and colleagues' [563] RCT had a total dose of 70 minutes/week over ten weeks, falling short of recommendations noted elsewhere, but nonetheless improved on TUG. No adverse effects were noted, and an ITT analysis was conducted, a strength in this study. Loss of participants from recruitment to commencement of the programme was 18%. Participants attended 76.7% of scheduled training session. • Methodological quality was deemed poor [468]. While randomisation was detailed in five of the eight studies, allocation concealment was not well described. Only half the studies blinded outcome assessors. Methods of collection fall-related data were not clearly specified. • The reviewers (468) highlighted the need for consistency in outcome measures between trials, adequately powered studies and methodological rigour.

Reference		**Schoene, Valenzuela, Lord and de Bruin [564]. (SR)**
Objectives of reviewed studies	1)	Evaluate the efficacy of interactive cognitive motor training on fall risk and fall events in older adults.
	2)	Compare interactive cognitive motor training (including exergames) with conventional interventions to reduce fall risk
Inclusion criteria for selected studies	•	Studies included true virtual reality training as well as commercial exergames (WBB=12).
	•	Participants had to be ≥ 60 years.
	•	Included studies had to have at least one physical, psychological or cognitive factor associated with falls or fall counts data as outcome endpoints.
Endpoints/results	•	Endpoints included BBS.
	•	Balance board training interventions showed improvement from baseline for BBS, strength and power. When combined with aerobic training, improvements were noted for static and dynamic balance and mobility.
	•	The reviewers noted some evidence to support improvements in physical and cognitive fall risk factors, but the impact of this improvement on fall events was not demonstrated.
Comments	•	Search included articles published in English, German and Dutch.
	•	Recognised fall definitions were used. Overall, 37 studies were included of which 16 used the WBB. Six trials focussed on either a history of falls or balance impairments in the participants.
	•	Similar to Booth et al., [468], the authors commented on issues with randomisation, allocation concealment and blinding, and lack of power [564].
	•	Only one study examined falls as an outcome measure, and none examined cost-effectiveness.
	•	Schoene et al., [564] posited that central processes triggered by engaging with interactive games plus motor activities might improve outcomes when compared with conventional exercise training.
	•	Furthermore, the potential of interactive games in terms of increasing adherence, ease of application and low cost was noted and thought to be important with older populations [429].

Reference		**Miller, Adair, Pearce, Said, Ozanne and Morris [475]. (SR)**
Objectives of reviewed studies	1) 2)	Effectiveness of exergaming to promote PA at home in adults >45 years of age. Safety, required supervision, cost and feasibility.
Inclusion criteria for selected studies	•	Unlike the SRs above, studies had to be in home settings.
Endpoints/results	• • • • •	SR examined feasibility issues (recruitment, adherence, retention). Fourteen studies were reviewed, two of which were RCT. WBB used in nine studies. Half were case studies [475]. Studies using the WBB found improvements on BBS and SLS in older adults. However, effect sizes and change scores were seldom described. The review was not restricted to RCT, comparative studies with or without a control arm and case series were included. Case series designs are low on the evidence hierarchy relative to RCTs and SR; although reservations about the categorisation of evidence are noted [565]. Sample sizes varied between 1-60 participants [475]. Doses ranged from 20-40 minutes, 2-3 times per week, over 6-10 weeks.
Comments	• • • • •	Feasibility was poorly described, and analysis of costs was lacking. Studies with available data described 37% of screened potential participants actually enrolled. Retention varied between 70 -100% (again the type of study plus small sample sizes is noted) and adherence ranged between 63- 100%. Minor pain was found in WBB participants but none so severe as to prompt withdrawal. Overall study quality was found to be weak and lacking in detail, particularly regarding feasibility matters. Due to similar design and feasibility issues noted in other SR already cited, the authors concluded that there was not enough evidence for recommendations for exergaming in clinical practice [475]. The authors noted the likelihood that high levels of functional capacity might be required for participants to manage exergaming in a home setting [328].

Reference	Molina, Ricci, de Moraes and Perracini [566]. (SR)
Objectives of reviewed studies	1) To investigate the effectiveness of exergames in improving physical function in adults >60 years of age. 2) Studies confined to specific patient populations such as stroke or dementia were excluded.
Inclusion criteria	• RCTs with either no intervention or conventional interventions (exercises, functional training, education) as comparators. • Physical function outcome measures related to mobility, including BBS and TUG. Eight papers had a WBB intervention.
Endpoints/results	• The reviewers concluded that there is 'no substantial evidence' [566] that exergames improved physical endpoints in older adults. This finding held for exergaming as a single intervention or when used in conjunction with other techniques [566]. • Overall the interventions were found to have few or no adverse events.
Comments	• Thirteen studies were included in the review. Issues were raised in terms of ceiling effects and responsiveness of selected measures in the included studies [566]. • WBB sample sizes were between 12 and 58 participants. • Note heterogeneous settings for the studies including falls/balance/orthopaedic clinic patients, and an in-patient geriatric unit. These locations challenge the generalisability of the findings for community-dwelling older adults. • Attrition in one small study was 33% [567]. The same research cited an improvement on BBS but for more challenging measures such as TUG change was not significant [432]. The BBS failed to meet Minimum Detectable Change in half the participants [432]; so the clinical applicability of such a finding is questioned. • Attrition in one study's [568] WBB group was also 33%, and no effect in favour of WBB was found. While sophisticated laboratory tests showed improvements in static and dynamic balance, functional balance tests including TUG and SLS did not change [568]. • Doses in the WBB studies ranged from 2- 3 x 30 minutes/week over three weeks [567] to 2 x 60 minutes over eight weeks [568]. The reviewers noted the lack of recommendations for the dosage of exergame intervention to prompt positive change in function [566]. • Concerns were raised regarding not only the small sample sizes but also stringent selection criteria which challenge studies' generalisability. ITT was rarely used. • Methodological issues were raised similar to previous reviews listed in this Table.

Reference		**Pietrzak, Cotea and Pullman [569]. (Scoping review)**
Objectives of reviewed studies	1)	Improvement of risk factors for falls in older adults. Factors investigated included fear of falling and balance.
Inclusion criteria for selected studies	•	Commercial off-the-shelf products.
	•	All designs apart from single-subject case studies were included. Designs included quasi-experimental design (eight), RCT (nine) and three comparative designs without randomisation. Group exercise interventions were included.
Endpoints/results	•	Varied endpoints including fall events, balance (BBS), and attitudes to exercise.
	•	Despite the caveats noted alongside, the reviewers found that overall, most (12) studies showed an improvement on balance and postural control. No improvement was found in seven studies. Three RCTs demonstrated that exergaming enhanced a physiotherapeutic regimen [569].
	•	Studies (three), which reported safety aspects had no adverse effects, but supervision of the sessions is noted.
Comments	•	Included 21 papers from high and one middle-high income country (Malaysia) and were all published in English. Two studies were not exclusively confined to older adults [569].
	•	Extremely small sample sizes for the RCT (varied between 5 and 21 participants per group). The heterogeneity of the included designs, settings and delivery of interventions (group, individual) makes analysis difficult and SR impossible.
	•	Three of the included studies [479] have been discussed elsewhere in this Table.
	•	One small study failed to demonstrate change on BBS or fear of falling after 12 weeks' exposure [484]. Of note is the direct supervision and non-home setting for this study. Despite this, 80% of participants attended ≥75% of sessions [336]. Qualitative interviews indicated the WBB was enjoyable and an acceptable alternative to usual care [366].
	•	Methodological issues included lack of power, short duration of intervention and follow up and frequent use of research settings [569].
	•	Pietrzak et al., [569] concluded that at the time of the review evidence to support exergaming in the prevention of falls is lacking. The ability of exergames to improve balance is more encouraging, but better designed studies in more diverse populations are required.
	•	The authors noted positive features of the WBB, which included portability, accessibility and availability as well as being far cheaper than true virtual reality systems [402].

Reference	**Bleakley, Charles, Porter-Armstrong, McNeill, McDonough and McCormack (537). (SR)**
Objectives of reviewed studies	1) Physical and cognitive effects of exergames in older population (>65 years). 2) Adherence, enjoyment and safety of users during exergaming.
Inclusion criteria for selected studies	• Exergames including virtual reality applications. • All study designs except case report or small case series with three or fewer participants. Designs included observation (five), RCT (five) and controlled trials (two). • Settings were community or retirement centres.
Endpoints/results	• One small study used WBB for a total of three hours in six participants and found an improvement on a falls efficacy scale [537]. • A second study demonstrated significantly improved quadriceps strength when compared with a control group; which would favour reduction of a key risk factor for falls [570]. • Several studies using the WBB reported favourable qualitative feedback regarding participant enjoyment and enhanced motivation [537]. • Twelve studies were selected. • Minor incidences of muscle pain were reported but none of the studies detailed serious adverse side effects [537].
Comments	• The reviewers made several important recommendations for future research which were adopted for this report. These include RCTs with a predetermined randomisation schedule and allocation concealment; blinding of outcome assessors, active tracking of participants to reduce attrition and the use of ITT analysis. • The reviewers noted a lack of reporting of adverse events and recommended better monitoring during trials [403]. Attrition was noted at between 10 and 15% of participants [403]. • Bleakley et al., [537 p.16] described 'clear trends' towards improvement in standing balance and balance confidence, as well as superiority over chair-based training. • However, it is argued that chair-based training is regarded as low-level exercise [571]. Chair-based training is often resorted to for older adults who are frail or unable to perform weight-bearing exercise; for which only inconsistent, poor quality evidence exists (572).

Reference		Laufer, Dar and Kodesh (573). (SR)
Objectives of reviewed studies	1)	Effects of WBB on balance in independent adults >55 years.
Inclusion criteria for selected studies	•	RCT with alternative intervention/ no exercise intervention
	•	Seven included trials had to have at least one measure of static/dynamic balance such as TUG, SLS.
	•	MA not possible due to differences in endpoints, control interventions and insufficient data.
Endpoints/results	•	None of the studies demonstrated an effect on fall frequency (but note, no long-term follow up).
	•	TUG improved in four studies compared with no or sham intervention; was unchanged in three, similar to control intervention in one and was less effective than an alternative intervention in one.
	•	Total of 285 participants (WBB n= 126). Participant groups were small ranging from 9-30 participants.
	•	Clinical rather than more realistic home-based settings were used and all except one were under supervision by an attending clinician.
	•	Exposure was widely varied between trials. Programme duration averaged 10 weeks (range 6-20 weeks). A mean of 19 sessions were provided (range 12-24 sessions) with a mean length of each session 57 minutes (range 35-90 minutes).
	•	Outcome measures were taken before and immediately after the intervention. Only one study included mid-point assessments.
Comments	•	While the outcomes are mixed, Laufer et al., (573) commented that due to the more complex nature of WBB than conventional exercises, a protective effect could exist. The dual-tasking common in balance-related activities such as walking and talking could well be enhanced with WBB practice.
	•	Only one study explored adverse effects and found none. All but one study had direct supervision, thus drawing conclusions regarding the effect of WBB in a home setting without supervision was not possible.
	•	Later reviewers like Donath, Rössler and Faudt (574) commented on an overall lack of data and quantitative analysis in Laufter et al.'s (573) review; and noted similar concerns regarding Molina et al.'s (566) review (above).

Reference	**Zhang and Kaufman [575]. (MA)**
Objectives of reviewed studies	1) Estimation of the effects of digital games (note, not confined to exergames) on physical and cognitive function of adults >55 years.
Inclusion criteria for selected studies	• Selected studies had to use commercially available games and single case studies were excluded. Fourteen studies focussed on balance. • Settings included nursing homes (where participants require assistance with ADL). • Papers included conference proceedings and dissertations, unlike all the other reviews cited above.
Endpoints/results	• Cohen's *d* was used for effect size estimates for studies with sample size, mean and standard deviations reported. Studies with small sample bias were corrected by converting *d* to the unbiased estimator Hedges' *g*. • Average effect size for WBB was $g = 0.70$ • Sample size of 299 participants in balance-related studies. • Digital games were found to improve older adults' physical balance with large effect sizes in community-dwelling samples.
Comments	• Processing speed was also shown to improve [576], which could be argued to have a possible protective effect for falls in terms of responding quickly to balance perturbations. • Interestingly, the reviewers demonstrated that neither age nor prior experience with technology were barriers to benefits. In addition, there was no clear advantage to greater levels of exposure. WBB had greater impact on balance in older adults than other digital games, although not statistically significant.

Reference	Donath, Rössler and Faudt [574]. (MA)
Objectives of reviewed studies	1) MA to establish the effects of exergaming on balance performance and functional mobility compared with alternative training or control in healthy adults >60 years. 2) To provide research recommendations regarding exergaming in older adults.
Inclusion criteria for selected studies	• RCT and non-randomised controlled interventions with pre-post testing. • Specialised populations such as those with neurological conditions were excluded, as were settings such as hospitals and institutions. Interestingly, studies with injurious fall participants were excluded.
Endpoints /results	• Endpoints included TUG, BBS, SLS, Romberg's with eyes open and closed conditions. • When compared with controls, exergaming produced medium overall effects (SMD = 0.70; 95% CI = 0.42-0.99) for standing balance and functional mobility (SMD = 0.54; 95% CI = 0.24-0.84). • When compared with alternative treatments which included Tai Chi, VRT and specific PA, a small overall effect was observed for both standing balance (SMD = -0.35; 95% CI = -1.03-0.32) and functional mobility (SMD = -0.44; 95% CI = -0.87-0.00) in favour of alternative treatments compared with exergaming. • Eighteen studies were included all published after 2011. Mean sample size was small at 32 (± 10). Exergames were given to 275 participants as a sole intervention. • Overall, the MA concluded that exergaming can be used to improve balance and functional mobility in healthy older adults. However, alternative (i.e. conventional) training/therapy was superior to exergaming for functional mobility outcomes and slightly better than exergaming for standing balance.
Comments	• Note the MA included three non-randomised trials and 17 did not employ blinding. Effect sizes referred to in the adjacent column were influenced by study quality. For example, the moderate effect for standing balance in favour of exergames was reduced after study quality was factored in; and the alternative treatment superior effect on balance performance disappeared.Donath et al., [574] commented on the quality both of trials and previous SR, which relied on papers with inadequate data. For several outcomes, better effect sizes were shown in methodologically weaker studies. High quality trials were scarce, particularly those which evaluated functional mobility. Reports with specific endpoints such as falls were lacking. • The reviewers concluded that many studies failed to advance evidence beyond preliminary status. For example, failure to report minimal clinically important differences; poor sample size estimations and unclear dosage and other methodological issue confounded many included studies. • Donath and colleagues [574], expressed particular concern regarding the lack of comparisons to other exercise modalities, and cautioned that more high-quality research is required. The need for research to thoroughly explore feasibility issues, fall outcomes, adherence and motivation was highlighted.

Reference	**Nawaz, Skjæret, Helbostad, Vereijken, Boulton and Svanaes [577]. (Scoping review)**
Objectives of reviewed studies	1) Theories used in research literature to evaluate exergames. 2) To describe which aspects of usability and acceptability are evaluated in exergaming literature and their outcomes.
Inclusion criteria for selected studies	• PubMed, Scopus and Engineering Village search engines used to cover computer and medical sciences. • Studies were confined to those with adults >55 years who could be either community-dwelling or in residential homes. • A wide range of technology was included in the selection criteria, but 12 studies used Wii. • Mixed methods studies were included. Nineteen studies were selected.
Endpoints/results	• Self-efficacy theories and Technology Acceptance Models were used to interpret the results of five studies. • Overall, there were few theoretical models underpinning studies which explored design and user experience of exergames. • Usability and acceptance were evaluated with several instruments including the Systems Usability Scale (SUS). Exergames were rated more user-friendly than website and mobile telephones. • The inclusion of studies with institutionalised participants could be influential on the results of the review in either a positive or negative direction. For example, if boredom is an issue, then the novelty of exergaming might impact experience positively. However, if assistance is needed in ADL, then participants may be unable to cope with technology.
Comments	• Only two studies were conducted in a home setting, thus, levels of supervision would be expected to be high and impact findings. • Positive aspects of exergaming included competition and feedback, challenge and opportunities for social interaction. Issues with speed and complexity of games, showing personal data such as body mass index and setup support were reported.

Reference	**Bonnechère, Jansen, Omelina and Van Sint [578] (Scoping review)**
Objectives of reviewed studies	1) Overview of exergames in physical rehabilitation to establish which clinical fields and what type of patients are using exergames. 2) Secondary aim was to establish clinical efficacy for various pathologies.
Inclusion criteria for selected studies	• Commercially available exergames included, and there were no restrictions on the types of pathology. • Designs included RCT, cohort and single-session studies. • Twenty-five studies (910 participants) concerned balance. Wii was used in the majority (79%) of all studies. • Outcome measures had to be relevant to PA before and after intervention.
Endpoints/results	• As with previous reviews, balance studies in ageing populations favoured improvements on static and dynamic balance endpoints compared with controls.
Comments	• Inclusion of single-session studies is questionable in terms of the hierarchy of evidence. Age groups were diverse. • Balance studies had an average sample size of 36 participants. Mean number of sessions for balance studies was18 (SD=9, range=8-48). Sessions were given three to four times per week over a total of four to six weeks. • The authors did not evaluate the quality of the studies or attempt an MA. In spite of this, Bonnechère et al., [578] recommended the inclusion of exergames in rehabilitation protocols. The need to explore adverse effects was noted.

Reference	**Tripette, Murakami, Ryan, Ohta and Miyachi [579]. (MA)**
Objectives of reviewed studies	Similar to Bonnechère et al., [578] the aims of this review were: 1) to identify the health-related domains (in health promotion and rehabilitation) in which the Wii is used. 2) to evaluate the effect of Wii (SR). 3) to quantify the effect (MA).
Inclusion criteria for selected studies	• Only RCT and two-arm trials were included in the MA. • Functional balance training studies included adults of all ages and residential settings for several RCTs in older adults. • MA outcomes included BBS, TUG over 3 metres and the Activities-specific Balance Confidence Scale (ABC). Low ABC scores are associated with falls and poor balance [580]. • Overall WBB had a positive effect on balance for at least some of the endpoints. • Improvements were similar, and in some cases better than conventional therapy. Three of the five studies which had poor results focused on healthy populations. • Adverse events were detailed by three research groups. Of the 393 community-dwelling healthy older adults exposed to WBB interventions there were three instances of back pain/strain, one fall and one hip strain.
Endpoints/results	• BBS showed significant improvements in healthy participants and patients. However, no superiority over conventional training was found. Reservations regarding the floor and ceiling effects of BBS (discussed elsewhere) and could account for this finding. • Of more interest, is that the TUG did not significantly reduce (time in seconds), which would indicate an improvement in dynamic balance. In healthy participants TUG change was -0.34s, 95% CI = -1.38 – 0.70. In patient groups there was no significant reduction in TUG times (-2.24s, 95% CI = -5.17 to 0.69). • When compared with conventional training, the Wii groups' pooled data suggested a more significant finding, more marked within patient populations (-1.76; 95% CI = -2.13 to -1.39).

Reference	**Tripette, Murakami, Ryan, Ohta and Miyachi [579]. (MA) cont.**
Comments	• The review was confined to Wii interventions. English, French and Japanese papers were included, an advantage over most of the other reviews in this Table. • Studies included in the MA had participants with a wide range of ages (childhood - older adulthood) and pathologies. • Overall, WBB interventions for balance were mainly successful in 50/55 studies. BBS improved for healthy and patient participant groups; while a positive trend for TUG was demonstrated in patient groups. Furthermore, when compared with conventional therapy, only the TUG showed improvements in the Wii groups. • The reviewers cautioned that these gains may not be relevant in daily living as the ABC failed to improve. The ABC is a patient-reported outcome measure that has been shown to independently predict future falls [580] and has been validated in adults >65 years [581]. However, ceiling effects have been found in adults >80 years and its responsiveness questioned [444]. • Controversy exists regarding balance confidence and actual performance. The ABC is influenced by several processes including health-related QoL, anxiety and depression, as well as balance deficits [195]. Thus, a mismatch in balance confidence and performance has been noted [582]. The lack of change in balance confidence could well be associated with the lack of strong findings of change in the TUG compared with the BBS. • Overall, the MA could not predict WBB-induced changes in specific patient populations [579]. • Tripette and colleagues [442] suggested further research to allow evidence-based decisions regarding incorporating Wii into therapy programmes. Caution was urged for unsupervised home-based programmes, as the quality of Wii-induced movements, while resembling those in rehabilitation programmes, may be orientated towards scores not movement execution [442].

Reference	Howes, Charles, Marley, Pedlow and McDonough (417). (MA)
Objectives of reviewed studies	1) Determine the effect of exergaming on physical health in adults >65 years, with a focus on balance and mobility. Cognitive improvements were also reviewed but not discussed here. 2) Detail adherence and feasibility aspects including dosage, research setting and levels of supervision. 3) Describe behaviour change techniques used to manage adherence in older adults.
Inclusion criteria for selected studies	• Only RCTs and quasi-RCTs were included. • Specific populations such as those with stroke or post-surgery were excluded.
Endpoints/results	• Adherence was computed by comparing the number of sessions completed by participants with the total number prescribed. • Exercise regimen was analysed according to recommendations for exercise for older adults and divided into studies which prescribed <120 minutes/week; ≥120 minutes/week and ≥150 minutes minutes/week. • Outcome measures included BBS; TUG, posturography, gait speed and fall events implies that improvements in balance on other measures do not necessarily translate into reduction of fall events. • The MA concluded that low-quality evidence existed for exergaming in terms of balance. After removing studies at risk of bias, SMD+0.55. 95% CI=0.19 – 0.91 (n=555). These findings suggest that exergaming at least 120 minutes/week may promote improvements in balance, but is no more effective than no treatment, or alternative interventions for functional mobility. As expected, the largest effect size was found when the regimen exceeded 150 minutes/week. • However, similar to Molina et al.'s (431) and Tripette and colleagues' (442) work, TUG failed to demonstrate a significant effect (SMD=-0.13, 95%CI=-0.36 – 0.09). As TUG measures functional mobility and is linked to fall risk, failure to establish a meaningful effect size implies improvements in balance on other measures do not necessarily translate into a reduction of fall events. • Howe and colleagues noted that participants in four of the 16 balance studies had TUG scores of >13.5s and postulated that the functional status of participants at base line could have masked change. • TUG is postulated to be insensitive to early detection of impairment (442). In addition, deficits might affect either the balance or gait components of the TUG (293). Lower (i.e. faster) cut-off scores for TUG are discussed in relation to fall risk elsewhere in this thesis.

Reference	**Howes, Charles, Marley, Pedlow and McDonough (417). (MA) cont.**
Comments	• Most studies were situated in a clinical or research facility (14/25 studies which disclosed the setting) and only three studies were unsupervised. • Adherence data were available or calculated for 17 studies and the mean rate was 78.8%. A similar rate (77.9%) was found in studies reporting adherence in comparison groups (nine reports). • A total of 17 balance-related trials, with 743 participants, were included. A variety of interventions were used, including WBB and bespoke programmes. • Not all study populations were healthy, and included residents in nursing homes, balance-impaired and frail participant groups. The diversity of settings and range of comorbidities may well have contributed to the results of the review. • Adverse events (AE) were inconsistently reported in over two thirds of the included studies (25/35). The mean size of groups of participants was 53. Similar rates of AE (from 1-13 participants) were reported for control and intervention groups. • Only nine studies included in the MA focus on older adults with balance impairments. Thus, further research is required to establish efficacy and safety with any degree of certainty [301]. • Reports of exergaming at home; and with no or limited supervision does not appear in the literature at the time of the review [301]. It is possible that with less supervision, adherence may differ from formal research or rehabilitation settings. • The reviewers highlighted that feasibility issues were only partially or poorly explored. Methodological flaws affecting internal validity were noted. Howe and colleagues [301] noted inadequate evidence to recommend exergaming over conventional exercise paradigms for older adults. Specifically, evidence to support improving mobility in the population was found to be lacking. Further research with a focus on feasibility issues and rigorous design was recommended [301].

Reference	**Tăut, Pintea, Roover, Mañanas and Băban [583]. (MA)**
Objectives of reviewed studies	1) To identify the effectiveness of exergames on improvements of upper arm mobility and balance/movement functions. 2) To describe study characteristics and game features which may contribute to the success of exergames in motor rehabilitation.
Inclusion criteria for selected studies	• A variety of designs were included. Almost two-thirds (62%) were RCTs. Other methodologies included case series and one group pre-test post-test paradigms. • Of 61, only five were in home settings.
Endpoints/results	• Mean age of participants was 61 years (range 32-86 years). Nine studies evaluated falls in older adults. • Interestingly, the MA demonstrated that regardless of rehabilitation type, longer duration of training did not promote better outcomes. Age did not appear to significantly interfere with outcome efficacy.
Comments	• Relevance of this MA is limited concerning this thesis. Selection criteria were focused on upper limb mobility or mobility following stroke. Designs and the age of participants were heterogeneous. • The review highlighted the importance of social involvement, with games in which there could be team involvement having greater effect sizes than individual activities.

Reference	**Zeng, Pope, Lee and Gao [584]. (SR/MA)**
Objectives of reviewed studies	1) To describe the effectiveness of exergames in adults >60 years with chronic illnesses and/or physical impairments. 2) To explore future directions for exergaming in research and rehabilitation.
Inclusion criteria for selected studies	• Nineteen studies including eight RCTs and four case studies. • All used commercial exergaming systems, with Wii predominating. • Participants included those with stroke, Parkinson's diseases, frailty and post knee replacement or amputation. • Retention was at least 70% across studies.
Endpoints/results	• Outcomes were categorised into physical, cognitive and psychological groups. The two latter included outcomes like depression, balance confidence/fear of falling and pain. Physical balance-related outcomes included BBS, DGI, SLS, TUG and sharpened Romberg. • Eleven studies evaluated static and dynamic balance with ten reporting balance improvements (note that four of six low-quality studies did not prove statistical significance). • Attenuating these results further, only three RCT improved overall balance; and one design incorporated conventional therapy as well as exergaming. Thus, it is difficult to evaluate effectiveness.
Comments	• The high number of pre- or non-experimental designs included is noted [584]. Due to the low quality of the designs, MA was not possible. • Power calculations were outlined in ten of the nineteen reports. Overall power to demonstrate significant effects is weakened by the multiple designs, diverse interventions and outcome measures [447]. Findings were similarly challenged by a lack of control groups in some studies. • Sample sizes ranged from 1-58 (median 20). Interventions lasted 1 - 58 weeks (median six weeks). • Overall, the authors [584] suggested that exergaming had a null or positive effect on balance abilities in older adults. The authors suggested a more cohesive approach to exergame research, with a focus on exposure; evaluation of exergames as a stand-alone treatment option, and identification of which games are most helpful for remediation of specified diseases or impairments (ibid.). • Due to the possibility of either under- or over-estimation of the effectiveness of exergaming, further well-designed research remains necessary [447]

Reference	**Nguyen, Ishmatiova, Tapanainen, Liukkonen, Katajapuu, Malika et al.** [450]. **(SR)**
Objectives of reviewed studies	1) To describe the impact and effect of serious games (note, review was not confined to exergames) on health and well-being associated with successful ageing. 2) To describe the research methods used in included papers.
Inclusion criteria for selected studies	• Selection criteria included adults >50y which could be argued to be 'young' for older adults. • Ten of the 13 papers using commercial consoles used Wii. • Specialised populations such as individuals with stroke, Parkinson's and Alzheimer's were included.
Endpoints/results	• Similar to Zeng et al. [584] , physical, cognitive and social domains were explored. • Studies were categorised as qualitative, quantitative or mixed, and designs (e.g. RCT, survey and comparator groups) tabulated. • Balance-related outcome measures included TUG and BBS. • Eight of ten included papers on balance and postural control outcomes indicated improvements. However, only four of the ten had a no-intervention control group.
Comments	• The reviewers noted previous reservations regarding weak research designs, even within RCT. They called for economic analyses in order to establish cost-effectiveness of serious games in older adults [303]. • Nguyen et al. [303] suggested research with high levels of validity and better-quality evidence will impact policy decisions regarding implementation of serious games to extend or preserve well-being important to successful ageing.

Reference	**Choi, Guo, Kang and Xiong [585]. (SR)**
Objectives of reviewed studies	1) To review research concerning exergaming and interactive interventions for fall prevention in older adults.
Inclusion criteria for selected studies	• Older adults ≥60 years enrolled in pre-post training or intervention designs. • Sample sizes varied between 2-95 participants across control and intervention groups. • Not all studies (six) had control groups; while others used no intervention (10) or conventional exercises (nine). • The average number of participants per paper was 30 (SD = 22). Comparator groups received no intervention, conventional exercise or were young adults. Interestingly, this review differs from many others in the Table by having a large number (88%) set in the community or retirement centres. • Each session varied between 15 – 60 minutes (average 34.8 minutes; SD = 11.1 minutes), with between two and five sessions per week. Duration of the programmes varied from three to 20 weeks (average 7 weeks SD = 4 weeks).
Endpoints/results	• Like other reviews in this Table, the Wii was most commonly used (14/25 papers). • Physical outcome measures included BBS and TUG. QOL and fear of falling were also measured in some studies. • Overall the reviewers agreed that balance may improve due to exergaming interventions, and that exergaming is more effective than no intervention. When compared with conventional therapy/exercise, the results are more diverse and at times contradictory. • Note some studies examined cognitive outcomes.
Comments	• Concerns were expressed regarding the use of clinical tests, which are largely unable to focus on which aspects of balance improve due to exergaming interventions. Clinical tests lack precision when compared to objective measures such as computerised dynamic posturography; a standardised and well accepted method to measure balance and perturbation to balance [586]. • Disagreement persists regarding exercise exposure. Regimen issues, sample size variation, study design and patient versus population differences, makes firm conclusions elusive [585]. Choi and colleagues [448] recommended researchers find consensus on a protocol blueprint. This blueprint could promote standardisation, lending to refinement of dose and other issues [448]. The authors' [585] recommendations are prudent, as numerous research groups outlined in this Table have commented on the difficulty of SR and MA due to either poor or diverse methodologies.

Reference	**Pope and Gao [453]. (MA)**
Objectives	1) To establish the effectiveness of exergaming rehabilitation protocols for physical and psychological deficits in young, middle-aged and older (≥ 65 years) age groups. 2) To establish which diseases/disabilities are best suited for exergaming rehabilitation.
Inclusion criteria for selected studies	• Designs were restricted to RCT and had a minimum of ten participants. • Comparison groups included non-exergame interventions, and control groups were either conventional therapy or no intervention. • Fourteen studies were included in the MA (six of these concerned older adults). The median number of enrolled participants was 31 (range 17 – 84). • For the studies confined to older adults, mean sample size was 36 (range 23-54). The median intervention duration was 6.5 weeks (range 4-26 weeks).
Endpoints/ results	• Balance control measures included BBS, TUG and FTSST. • A small, marginally positive effect was noted when compared with control interventions for balance control rehabilitation (Hedge's g = 0.16, p= 0.27; 95% CI = -0.13 – 0.46).
Comments	• In contrast to other SR noted above, included studies in Pope et al.'s [306] MA described randomisation procedures appropriately. Of the six studies focussed on older adults, one study [568] recorded attrition of >30%. • Groups were shown to be comparable in terms of outcome variables at baseline. • The studies were not consistent in management of missing data, and only half used ITT analysis. Similarly, the use of a power analysis to estimate sample size was only used in 50% of the studies. • Interestingly, when compared with young adults, the effect size of older adults' outcomes in terms of balance rehabilitation was strikingly diminished. Pope and Gao [306] postulated that capacity for neuroplastic adaptation may be greatest when younger, and a decline with ageing could have been responsible for reduced efficacy. However, short intervention periods and a possible lack of intensity of training per session could also have contributed to the small effect in older adults. • Finally, included studies did not use exergaming exclusively and general physical function rehabilitation was frequently included in treatment regimens. • Despite marginal effects having been shown, Pope and Gao [306] noted several positive features of exergaming. These included convenience and home applications, and remote monitoring by health care professionals. Online gaming communities for patients with similar issues could enhance motivation and adherence. • Recommendations for future research included using home settings rather than clinical environments, and to explore the effects of exergaming on psychological outcomes.

Reference		**Neri, Cardoso, Cruz, Lima, de Oliveira, Iverson et al. [587]. (MA)**
Objectives of reviewed studies	1)	To establish to effectiveness of exergames compared with conventional therapy/no intervention for fall prevention in older adults.
Inclusion criteria for selected studies	•	RCT designs were selected. While 28 were included in the SR, only six were analysed in the MA.
	•	Combined, 1121 participants enrolled in the studies, with sample sizes varying between 8-136 older adults.
	•	Programme duration ranged from 2-20 weeks, with between one to five sessions per week. Sessions lasted between 15-60 minutes.
	•	Interventions included WBB and true virtual reality systems.
Endpoints/results	•	Endpoints included postural balance, fear of falling and risk of falls. Outcome measures included clinical tests (e.g. BBS, FTSST, functional reach, TUG) and more objective tests such as computerised dynamic posturography.
	•	TUG outcomes were combined from three studies (36 experimental recipients and 34 no treatment controls). A significant improvement in TUG scores was noted in the virtual reality groups (MD: -1.20; 95% CI = -1.62, -0.77; þ <0.01) after three to six weeks' exposure. This improvement, compared with no treatment groups was sustained, but less marked (reduction of 0.87 seconds) at eight to 12 weeks.
	•	Overall, the reviewers [450] found that evidence to support the use of exergaming remained inconclusive.
Comments	•	Varied settings and populations including individuals in nursing homes. Less than half (46%) the studies used a random sequence generator, and fewer still (18%) described allocation concealment, resulting in methodological challenges. Single blinding was achieved in 54% of the studies.
	•	Most papers (86%) either did not use ITT or failed to describe the analysis in enough detail.
	•	High risk of bias was evident in most of the studies, which Neri and colleagues [450] suggested might have promoted an over-estimation of the effect.
	•	The authors [450] suggested the TUG findings were important by extrapolating that every additional second taken (to complete the TUG task) may be associated with an increase in the risk of falls between 2 -9%; thus, reducing TUG times should result amelioration of fall risk.

Reference	**Neri, Cardoso, Cruz, Lima, de Oliveira, Iverson et al. [587]. (MA) cont.**
Comments	• Although statistically significant, the reduction in TUG times does not necessarily translate into clinically meaningful changes and reduction of fall risk. Indeed, the responsiveness of TUG has been poorly described in the few studies in which it has been examined [2]. • TUG scores may be reduced due to faster transitioning time or gait time (or both), making conclusions about reduction in fall risk more nebulous. Finally, TUG in its simple form may not be helpful for high-functioning adults, and it is suggested that TUG with dual-tasking (e.g. manual, cognitive) better resembles the more complex tasks required to assess fall risk in such a population [588]. Indeed, the time difference relationship between TUG and TUG with dual tasking is important for fall prediction [452] and is part of the Mini-BESTest used in this thesis. • Neri et al., [587] suggested further research, particularly focused on effectiveness and cost analysis of exergaming interventions and noted the high risk of bias in many of the studies reviewed.

Reference	Taylor, Kerse, Frakking and Maddison [425]. (MA)
Objectives of reviewed studies	1) To evaluate RCTs using exergaming to improve physical function in adults >65 years. 2) To evaluate safety, game appeal and usability of such games for older adults.
Inclusion criteria for selected studies	• Eighteen RCTs comparing exergaming with no intervention (seven studies)/ placebo/ traditional therapy (five RCTs) and had endpoints measuring physical performance or SAS. Three studies recruited participants with balance deficits or fall risk. • Gaming systems were commercial, modified commercial products or purpose-built systems. Eleven studies used WBB. • Settings included assisted living, acute hospitals and nursing homes. • Programme duration for community-dwelling participants ranged from three to 20 weeks (most were eight weeks) with 2-3 sessions of approximately 40 minutes per week.
Endpoints/results	• Endpoints included ABC, BBS and TUG (mean TUG baseline was 10.3 [SD 4.1] seconds. This falls well within normal limits [589, 590]. Thus, it is hardly surprising that exergaming when compared with conventional therapy or no intervention failed to reach significance for TUG measures). • However, 30s chair stand scores demonstrated a statistically significant effect in favour of exergaming.
Comments	• The mixed settings make the MA results less generalisable. In addition, only one study focussed on a home environment, the rest were set in gymnasia or research facilities. • Only 22% of the RCTs were awarded a low risk of bias rating. • Trial completion (number of participants who completed the trial) was a median of 89%. • Programme adherence was 77-100% in the exergaming group and 87-100% in control groups. These values were noted to be somewhat higher than previous adherence data for exercise RCTs [425]. The short period of interventions is noted and likely influential. • Participants found the games appealing, with reports of the enjoyable nature, enhanced motivation and ability to use the games noted [272]. • The authors [272] noted improvements in favour of exergaming on BBS and sit-to-stand measures. While meeting criteria for meaningful clinical change on the BBS, this measure was posited to be subject to ceiling effects. In addition, no conclusion could be drawn regarding outcomes in populations with balance or mobility issues [272].

Legend: ABC: Activities-specific Balance Confidence Scale; ADL: activities of daily living; AE: Adverse events[69]; BBS: Berg Balance Scale; CI: confidence interval; FTSST: Five times sit to stand test; ITT: intention-to-treat; MA: meta-analysis; MD: mean difference; PA: physical activity; PICOS: participants, interventions, comparisons, outcomes, study design; RCT/s: randomised control trial/s; SAS: self-assessment scales; SD: standard deviation; SLS: single leg stance; SMD: standardised mean differences; SR: systematic review; SUS: Systems Usability Scale; TUG: timed up and go; VRT: vestibular rehabilitation therapy; WBB: Wii Balance Board.

[69] See Glossary of Terms.

Appendix A.2 Permission to use Otago Exercise Programme.

Christine Rogers

From:	Clare Robertson <clare.robertson@otago.ac.nz>
Sent:	01 August 2012 12:08 AM
To:	Christine Rogers
Subject:	Re: training to use Otago Exercise Programme as intervention in RCT at the University of Cape Town
Attachments:	ACC1162.pdf; Falls_research Aug 2011.doc

Dear Christine

Thank you for your interest in our research.

There are no copyright issues involved in using the Otago Exercise Programme. Unfortunately the online training you mention is no longer available. However, an experienced physiotherapist can prescribe the Programme using the information provided in the instructor manual (attached).

I would urge you to take great care that the Otago Exercise Programme is delivered in your planned trial exactly as described in the instructor manual (i.e. as tested in our research) as this worked in reducing falls. For example, home visits at baseline, 2, 4, 8 weeks and 6 months, with a phone call in the months with no home visit to maintain motivation. A diary to record the days exercised or walking also promotes adherence. Exercises start light and are progressed. Provide each participant with a folder with clear pockets containing photocopies of the exercise sheets for each exercise prescribed (change as level of difficulty increases). The only equipment needed are ankle cuff weights.

As for your study design - the Programme is most effective in reducing falls in those 80 years and older and those with a previous fall. The most common reason given for agreeing to participate in our trials was that their doctor had invited them (had endorsed the Programme). I have attached a list of publications relating to the Otago Exercise Programme as providing copies of our BMJ articles would help to engage GPs.

When planning your study it is also important to become familiar with the CONSORT statement so that you will be able to report a high quality RCT.

Very best wishes for your research,
Clare

--
Associate Professor M. Clare Robertson, PhD
Research Associate Professor
Department of Medicine
Dunedin School of Medicine
University of Otago
P.O. Box 913
Dunedin 9054
New Zealand
Tel: +64 3 474 7007 extension 8508
FAX: +64 3 474 7641

On 18/07/12 7:41 PM, "Christine Rogers" <Christine.Rogers@uct.ac.za> wrote:

Dear Dr Robertson

I am a staff member and PhD candidate at the University of Cape Town,

1

South Africa. I am investigating the use of a novel intervention to reduce fall risk and would like to compare this, using an RCT design, with a gold standard. I have read about the Otago Exercise Programme and would like some input regarding its use. While I am an audiologist I specialise in dizziness, vertigo and rehabilitation for this. I would be employing a physiotherapist to do the interventions as I would like to maintain some sort of blinding if at all possible. I saw on the Internet that the School of Physiotherapy at the Auckland University of Technology used to offer a distance learning programme regarding use of the Otago Exercise Programme; but could not find up to date information. Distance training in the application of the programme would be ideal as funding for the project is extremely limited and, for example, flying to the UK to do a course over some weeks would be out of the question.

Please would you be kind enough to advise me if there are any distance training programme which I and the physiotherapist could do? With deep respect, I would also like to ask for permission to use the Otago Exercise Programme as the control intervention in my study. Please could you advise me if there would be any costs involved or copyright issues of which I should be aware?

Please forgive my approaching you via email; and I hope to hear from you soon,

Yours faithfully,

Christine

###

UNIVERSITY OF CAPE TOWN

###

Appendix A.3 Otago Exercise Programme.

OtagoExercises.pdf

Please left double click on the link above to open the Otago Exercise Programme PDF. Highlights from the training resources cited below are included in this Appendix. See below for an example of the main features of the OEP and how the exercises were progressed.

Main features of the Otago Exercise Programme.

The chart below describes the assessments, activities, intensity, progressions, frequency, length of exercise sessions, and duration of the strengthening and balance exercises and walking programme.

Otago Main Features			
	Strengthening	Balance Retraining	Walking
Assessment	30 Second Chair Stand Test	Four-Stage Balance Test Balance	Timed Up & Go
Activity	Five leg muscle strength exercises Four levels of difficulty	Twelve balance retraining exercises Four levels of difficulty Not all exercises may be prescribed	Advice about walking
Intensity	Moderate Challenge 8-10 repetitions before fatigue	Moderate Challenge Each exercise at a level that the patient can safely perform unsupervised	Usual pace with usual walking aid
Progressions	Increase from one to two sets Increase amount of ankle weight after 2 sets of 10	Supported exercise to unsupported exercise	Walk indoors Advance to walking outdoors when strength and balance have improved
Length of Exercise Sessions	Approximately thirty minutes total for exercises; Exercises can be divided up over the day		Thirty minutes; can be split into three ten- minute walks throughout the day
Frequency	Three times a week with rest day between	At least three times a week	At least twice a week

Progression of Exercises at Follow-up Visits	
Strengthening	**Balance Retraining**
▪ Increase ankle weights or the number of sets performed, according to the *Levels and Repetitions for the Exercises* chart. – Participants should complete two sets of 10 repetitions before progressing to the next level – Increasing weights should not produce adverse side effects (e.g., pain, injury, cardiovascular events, non-compliance) if prescribed and done correctly.	▪ Progress from holding onto a stable structure to performing the exercise without support. ▪ Progress through the levels of exercise according to the *Levels and Repetitions for the Exercises* chart.

Reference: downloaded 12.2.2016 from:
http://www.med.unc.edu/aging/cgec/exercise-program/tools-for-practice/ImplementationGuideforPT.pdf/view

Levels and number of repetitions for the exercises.

The chart below provides information about the Otago Exercise Programme exercises, including how many repetitions and which exercises can be done at each level. This information will be useful for physical therapists when meeting with a patient. It details the number of repetitions per exercise based on the patient's starting abilities. Remember that not everyone will start at the first level or be prescribed all of the balance exercises. Some balance exercises may have to be modified due to pain or safety. All strength exercises are prescribed throughout the duration of the program, although not all may be prescribed at the first home visit.

Otago Exercise Levels and Repetitions			
WARM-UP (FLEXIBILITY) EXERCISES			
Head Movements	Stand tall, 5 times on each side	Trunk Movements	Stand tall, 5 times each side
Neck	Stand tall, 5 times	Ankle Movements	Stand or sit, 10 times
Back Extension	Stand tall, 5 times		
STRENGTHENING EXERCISES			
Knee Extensor Knee Flexor Hip Abductor	**ALL 4 LEVELS** Ankle weights are used to provide resistance; perform 10 repetitions of each exercise, when able to do 2 sets of 10		
	LEVEL C	**LEVEL D**	
Calf Raises	10 repetitions, hold support,	10 repetitions, no support, repeat	
Toe Raises	10 repetitions, hold support,	10 repetitions, no support, repeat	

Otago Exercise Levels and Repetitions				
BALANCE RETRAINING EXERCISES				
	LEVEL A	**LEVEL B**	**LEVEL C**	**LEVEL D**
Knee Bends	10 repetitions Hold support	10 repetitions No support *or* 10 repetitions Hold support, repeat	10 repetitions No support, repeat	10 repetitions, 3 times No support
Backwards Walking		10 steps, 4 times Hold		10 steps, 4 times No
Walking and Turning Around		Walk and turn around (do a figure 8) twice Use walking aid	Walk and turn around (do a figure 8) twice	
Sideways Walking		10 steps, 4 times Use walking aid	10 steps, 4 times No support	
Tandem Stance (Heel Toe Stand)	10 seconds Hold support	10 seconds No support		
Tandem Walk (Heel Toe Walk)			Walk 10 steps Hold support, repeat	Walk 10 steps No support, repeat

One Leg Stand		10 seconds, hold support	10 seconds, No hold	30 seconds,
Heel Walking			10 steps, 4 times Hold support	10 steps, 4 times No support
Toe Walk			10 steps, 4 times Hold support	10 steps, 4 times No support
Heel Toe Walking Backwards				Walk 10 steps No support, repeat
Sit to Stand	5 stands, 2 hands for support	5 stands, 1 hand *or* 10 stands, 2 hands for support	10 stands, no support *or* 10 stands, 1 hand for support, repeat	10 stands No support, repeat
Stair Walking	As instructed	As instructed	As instructed	As instructed repeat

Reference: https://www.med.unc.edu/aging/cgec/exercise-program/tools-for-practice/ImplementationGuideforPT.pdf

The chart below shows how the exercise prescriptions and visits were recorded.

Participant ID				
Visit Number	1	2	3	4
Date (mm/dd/yy) Note if Cancellation (C) or No Show (NS)				
Therapist ID				
Meeting Type Face-to-Face(F) or Phone (P)				
# of Falls since last visit				
Warm-up Yes (Y) or No (N)				
Strength Exercises				
Front Knee Record as Weight/Reps				
Back Knee Record as Weight/Reps				
Side Hip Record as Weight/Reps				
Calf Raises Record as Weight/Reps Note Support: 1 Hand (1H), 2 hands (2H), No Support (NS)				

Toe Raises Record as Weight/Reps Note Support: 1 Hand (1H), 2 hands (2H), No Support (NS)				
Balance Exercises Note Support: 1 Hand (1H), 2 hands (2H), No Support (NS)				
Knee Bends Record as Support/Time or Steps/Reps				
Backwards Walk Record as Support/Time or Steps/Reps				
Walk and Turn Record as Support/Time or Steps/Reps				
Heel Toe Stand Record as Support/Time or Steps/Reps				
Heel Toe Walk Record as Support/Time or Steps/Reps				
One Leg Stand Record as Support/Time or Steps/Reps				
Heel Walking Record as Support/Time or Steps/Reps				
Toe Walking Record as Support/Time or Steps/Reps				

Heel Toe Walk Backwards Record as Support/Time or Steps/Reps				
Sit To Stand Record as Support/Time or Steps/Reps				
Walking				
Stair Walking Record as # of Steps				
Walking Record average minutes walked, # of times/day, and # times/week				

Reference: https://www.med.unc.edu/aging/cgec/exercise-program/tools-for-practice/ImplementationGuideforPT.pdf

Training resources to equip the physiotherapist who delivered the intervention were sourced from https://www.med.unc.edu/aging/cgec/exercise-program/tools-for-practice/ImplementationGuideforPT.pdf. Note this was the original reference used, but the link is no longer active. The reference below is very similar to the material from the University of North Carolina:

http://www.hret-hiin.org/Resources/falls/16/OtagoExerciseProgramTrainingManualFall2013.pdf

Reference:

Video resources:

https://www.med.unc.edu/aging/cgec/exercise-program

Choose from the Videos to download.

Appendix A.4 Permission to use WBB exercise programme.

Dear Christine
Here you go, my thesis is on the e-repository of the institution if you need any further information. This is the link

http://library.rcsi.ie/F/?func=find-b&local_base=RCSMAIN01&request=meldrum&find_code=WRD

A few comments that might help- One of our interesting findings was in relation to the ABC, whilst not significant, it showed that the Wii group had less confidence than the conventional group after treatment….could be random but I'll be interested to know what you find. We found no evidence for superiority of the Wii, except perhaps in the overall enjoyment, tiredness after and difficulty with balance exercises. The Wii seemed to be superior in these. Also usability was less with elderly, not un-expected but 3 elderly randomised to the Wii had to cross to the conventional group. We screened them pretty carefully for ability to use a wii, asked them if they were comfortable with the tv remote, was there someone who could help them etc. Finally, consider using some form of rocker for the Wii board or foam on it, an unstable surface I think crucial if you are trying to upscale vestibular function in particular. The criticism levelled at the Wii Fit Plus is that it is mostly static balance…which is why I put in the stepping aerobics programme…to get them starting, stopping and changing direction…all require vestibular input.

with best wishes for your thesis, I really enjoyed my PhD years despite the ups and downs!
Dara

From: Christine Rogers [mailto:christine.rogers@uct.ac.za]
Sent: 23 June 2015 10:37
To: Dara Meldrum
Subject: RE: researcher at University of Cape Town doing Wii Fit study on fall risk reduction requests guidance

Dear Dara

Many thanks for your very quick response. I would love to have a pre-print version if at all possible, and that would be very gracious of you.

Best wishes

Christine

From: Dara Meldrum [mailto:dmeldrum@rcsi.ie]
Sent: 23 June 2015 11:29 AM
To: Christine Rogers
Subject: Re: researcher at University of Cape Town doing Wii Fit study on fall risk reduction requests guidance

Christine
Thanks for your mail and interest in my research. Your project sounds very interesting. Our study will be fully published next month in APMR and the exact exercises and the exercises booklets will be in the supplemental material. Have you access to archives of phys med rehab? I will prob be able to send you a pre print version so if you would like that I can email on?
All the best
Dara

Sent from my iPhone

Dr. Dara Meldrum BSc, MSc, PhD (NUI, RCSI), MISCP
Lecturer

RCSI

RCSI School of Physiotherapy
Royal College of Surgeons in Ireland
123 St. Stephen's Green, Dublin 2, Ireland
T: 2368
E: dmeldrum@rcsi.ie **W:** www.rcsi.ie

RCSI DEVELOPING HEALTHCARE LEADERS
WHO MAKE A DIFFERENCE WORLDWIDE

On 23 Jun 2015, at 10:21, Christine Rogers <christine.rogers@uct.ac.za> wrote:

Dear Dr Meldrum

Many thanks for taking the time to read this email. I am a Ph.D. student at the University of Cape Town and am at the proposal stage of my dissertation. I am doing a cluster randomised superiority RCT looking at Wii vs. the Otago Exercise Programme for reducing falls and using secondary outcomes of balance and gait measures. I would appreciate, if you wouldn't mind sharing it, information about exactly which exercises you chose for your intervention for vestibular rehab. If you could also tell me if you did warm up and cool down exercises, and the nature of these, I would be most grateful.

Thank you so much for your assistance,

Warm regards from Cape Town,

Christine

Christine Rogers

Senior Audiology Lecturer
University of Cape Town

Division of Communication Sciences and Disorders
Department of Health and Rehabilitation Sciences
F45, F Floor, Old Main Building
Groote Schuur Hospital
Observatory
Cape Town, 7925

Tel: +27 21 406 6315
Fax: + 27 (0) 86 611 0725
Christine.Rogers@uct.ac.za
www.uct.ac.za

Appendix A.5 Wii Fit Balance Board Programme.

Week 1 Exercises

Safety Instructions for Balance Exercises- PLEASE READ CAREFULLY

To improve balance, you have to challenge it. This means you will be unsteady when doing the exercises in this booklet and there is a risk you might fall. This risk must be minimized to ensure your safety.

So, this week when performing the exercises, your therapist recommends

Having someone beside you that is able to steady you

Having a chair(s)/couch/counter beside you to hold/lightly touch

When using the Wii Fit Plus you will be concentrating on the screen *as well as your* balance so be careful to make sure you are not losing your balance.

Only do the exercises in the way your therapist has taught you. If at any time you feel unsteady, please make *sure* you have a firm support such as suggested above to help you regain your balance. The aim is to decrease your reliance on the support while remaining SAFE.

I confirm I have read the safety instructions before doing these exercises

Week 1 Wii: Your session on the Wii should last **20 minutes** 5 days per week. Please do not exceed this.

Please have a high-backed chair or other support surfaced nearby to use as needed.

Go through your exercise programme on the Wii Fit Plus as set up by your therapist.

My Wii Fit Plus → My Routine

1. **Warm-up exercises** – Wii 1 (yoga deep breathing) to Wii 6 (yoga deep breathing)

Wii 1 –Yoga Deep Breathing- Do this exercise as instructed by the Wii trainer. Try and keep your balance steady keeping the red dot in the yellow circle.

Wii 2 – Deep Breathing- This time practice shifting your weight onto your toes, to the right foot, back onto your heels, to the left foot as if draw a circle with the red dot around the yellow circle.

Wii 3 – Standing knee. If you cannot bring your foot right up to your chest just try and get it off the ground, lightly touch the chair with your hands for support and then aim to decrease your dependence on the chair. You are aiming to try and stay on one leg with no support, but this will take time.

Wii 4 – Single leg extension. You may not be able to do the arm movements in this exercise, Try and do the leg movements. Only do small leg movements this week. Lightly touch the chair with your hands for support and then aim to decrease your dependence on the chair.

Place the chair ***in front of you*** for the remaining exercises.

Wii 5 – Sideways Leg Lift. You may not be able to do the arm movements in this exercise. Try and do the leg movements but put your foot down if you need to. Only do small leg movements this week. Lightly touch the chair with your hands for support and then aim to decrease your dependence on the chair.

Wii 6 – Yoga Deep Breathing –Do this exercise as instructed by the Wii trainer. Try and keep your balance steady keeping the red dot in the yellow circle. This exercise is for relaxation.

2. **Wii Exergames** – Heading game – Free stepping

- Go to Wii Fit Balance Games and play the **Heading Game** once. Try to move your head **as fast as you can. This is game 1.**

Scores________________________

- Go to Wii Fit Balance Games and play the **Table tilt game** once. **This is game 2.**

Scores________________________

- Go to Wii Fit Balance Games and play **Penguin slide** once. **This is game 3.**

Scores_________________________

- Go to the Wii Fit Aerobics and select **Free Stepping**. Step for 2 minutes (i.e. from 10 minutes down to 8 minutes, keep in rhythm with the Wii. Keep your eyes on the screen at all times, and make sure the screen is in focus. If this exercise becomes very easy during the week, practice turning your head slowly from side to side during the exercise while looking at the screen. Press “+” to remote controller to quit. **This is game 4.**

3. **Week 1 Walking**

Walk outside 5 out of 7 days for 10 minutes. Have someone with you if instructed by your therapist.

4. **Please complete the log of your exercises below**.

Exercise set	1	2	3
	Warm up (breathing, Standing knee, leg extension And lift)	Wii Exergames Please write the game number of the game you have played here (games 1-4)	Number of minutes walked
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			

Week 1 Log of exercises. Please tick each box. In box 2 detail then, actual games played by their number. In box three enter the number of minutes walked each day.

If you have any concerns or questions about your exercises, please call (therapist’s name) ___________________

on_________________________

Week 2 Exercises

PLEASE RE-READ THE SAFTEY INSTRUCTIONS ON PAGE 1 CAREFULLY

Wii Week 2: your session on the Wii should last **20 minutes** 5 days a week. Please do not exceed this. Please have a high-backed chair or other support surface nearby.

Go through your exercise programme on the Wii Fit plus as set up by your therapist in the clinic.

Week 2 Wii

My Wii Fit Plus →My Routine.

1. Warm –up exercises Wii 1 (yoga deep breathing) to Wii 6 (yoga deep breathing)

Wii 1-Yoga Deep breathing- Do this exercise as instructed by the Wii trainer. Try and keep your balance steady keeping the red dot in the yellow circle.

Wii 2- Yoga Deep breathing.

This time practice trying to shift your weight from front to right to back and draw a circle with the red dot around the yellow circle. Try closing your eyes for short periods.

Wii 3- Standing Knee

If you cannot bring your foot right up to your chest just try and get it off the ground, lightly touch the chair with your hands for support and then aim to decrease your dependence on the chair. **Try and improve the length of time on one leg this week.**

Wii 4 - Single Leg Extension may not be able to do the arm movements in this exercise. Try and do the leg movements. Only do small leg movements this week. Lightly touch the chair with your hands for support. **Try to decrease your dependence on chair this week.**

Place the chair *in front of you* for the remaining exercises.

Wii 5- Sideways leg Lift. Place the chair in front of you for this exercise. You may not be able to do the arm movements in this exercise. Try and do the leg movements. Only do small leg movements this week. Lightly touch the chair with your hands for support and then aim to **decrease your dependence on the chair.**

Wii 6- Yoga Deep breathing – Do this exercise as instructed by the Wii trainer. Try and keep your balance steady keeping the red dot in the yellow circle.

2.Wii Exergames – Heading game - aerobics

- Go to Wii Fit Balance games and play the **Heading** once. (**Try and move your head faster this week**). **This is game 1.**

Scores______________________

1. Go to the Wii Fit Balance Games and play **Table tilt** game once. **This is game 2.**

Scores_______________________

2. Go to Wii Fit Balance Games and play **Penguin slide** once. **This is game 3.**

Scores__________________________

5. Go to the Wii Fit **Aerobics** and select **Step Basics**. This has more difficult patterns than last week. Keep your eyes on the screen at all times, and make sure the screen is in focus. **This is game 4.**

Scores____________________________

3. Week 2 Walking programme.

Try and walk outside daily for **15 minutes**. Have someone with you if instructed by your therapist.

4. **Please complete the log of your exercises below**.

Exercise set	1	2	3
	Warm up (breathing, Standing knee, leg extension And lift)	Wii Exergames Please write the game number of the game you have played here (games 1-4)	Number of minutes walked
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			

Week 2 Log of exercises. Please tick each box. In box 2 detail the actual games played by their number. In box three enter the number of minutes walked each day.

If you have any concerns or questions about your exercises, please call_________________

Week 3 Exercises

PLEASE RE-READ THE SAFTEY INSTRUCTIONS ON PAGE 1 CAREFULLY

Wii Week 3; your session on the Wii should last **20 minutes** 5 days a week. Please do not exceed this. Please have a high-backed chair or other support surface nearby.

Go through your exercise programme on the Wii Fit plus as set up by your therapist in the clinic.

My Wii Fit Plus →My Routine.

1. Warm –up exercises Wii 1 (yoga deep breathing) to Wii 6 (yoga deep breathing)

Wii 1-Yoga Deep breathing- Do this exercise as instructed by the Wii trainer. Try and keep your balance steady keeping the red dot in the yellow circle.

Try and close your eyes this week for the count of 10.

Wii 2- Yoga Deep breathing.

This time practice trying to shift your weight from front to right to back and draw a circle with the red dot around the yellow circle.

This week try and close your eyes for the count of 10.

Wii 3- Standing Knee

If you cannot bring your foot right up to your chest, just try and get it off the ground. Continue to try and improve your ability on this exercise.

Wii 4 - Single Leg Extension. You may be able to do the arm movements in this exercise this week. Lightly touch the chair with your other hand for support and then aim to decrease your dependence on the chair.

Place the chair *in front of you* for the remaining exercises.

Wii 5- Sideways leg Lift. Place the chair in front of you for this exercise. You may be able to add in the arm movements as well as the leg movements this week. Lightly touch the chair with your other arm for support and then aim to **decrease your dependence on the chair.**

Wii 6- Yoga Deep breathing – Do this exercise as instructed by the Wii trainer. Try and keep your balance steady keeping the red dot in the yellow circle.

2. Wii Exergames – **Heading game - aerobics**

- Go to Wii Fit Balance games and play the **Heading** twice. (**Try and improve your score this week**). **This is game 1.**

- Go to the **Training Plus** and play the **Table Tilt plus** game twice. **This is game 2.**

- Go to the **Wii Fit Aerobics** and select **Step Basics**. If you are able to do the routine no problem this week try and move your head from side to side slightly during the programme, whilst keeping your eyes on the screen. At all times make sure the screen is in focus. **This is game 3.**

3. **Week 3 Walking programme.**

Try and walk outside 5 out of 7 days for 20 minutes. Have someone with you if instructed by your therapist.

4. **Please complete the log of your exercises below**.

Exercise set	1	2	3
	Warm up (breathing, Standing knee, leg extension And lift)	Wii Exergames Please write the game number of the game you have played here (games 1-4)	Number of minutes walked
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			

Week 3 Log of exercises. Please tick each box. In box 2 detail the actual games played by their number. In box three enter the number of minutes walked each day.

If you have any concerns or questions about your exercises, please call_________________

Week 4 Exercises

PLEASE RE-READ THE SAFTEY INSTRUCTIONS ON PAGE 1 CAREFULLY

Wii Week 4: your session on the Wii should last **20 minutes** 5 days a week. Please do not exceed this. Please have a high-backed chair or other support surface nearby.

Go through your exercise programme on the Wii Fit plus as set up by your therapist in the clinic.

My Wii Fit Plus →My Routine.

1. Warm –up exercises Wii 1 (yoga deep breathing) to Wii 6 (yoga deep breathing)

Wii 1-Yoga Deep breathing- Do this exercise as instructed by the Wii trainer. Try and keep your balance steady keeping the red dot in the yellow circle.

Try and close your eyes during this exercise.

Wii 2- Yoga Deep breathing.

This time practice trying to shift your weight from front to right to back and draw a circle with the red dot around the yellow circle. Close your eyes while doing this. **See if you can increase the speed this week.**

Wii 3- Standing Knee

See if you can start bringing your leg up higher this time**. Try not to touch the chair, this week put your other foot down if you lose your balance.**

Wii 4 - Single Leg Extension. Do the arm movements in this exercise this week. Lightly touch the chair with your hands for support and then aim to **decrease your dependence on the chair.**

Place the chair *in front of you* for the remaining exercises.

Wii 5- Sideways leg Lift. Lift place the chair in front of you for this exercise. Try to do the full exercise this week.

Wii 6- Yoga Deep breathing – Do this exercise as instructed by the Wii trainer. Try and keep your balance steady keeping the red dot in the yellow circle.

2. Wii Exergames – Heading game - aerobics

- Go to Wii Fit Balance games and play the **Heading** twice. (**Try and improve your score this week**). **This is game 1.**

- Go to the **Training Plus** and play the **Table Tilt plus** game twice. **This is game 2.**

- Go to the **Wii Fit Aerobics** and select **Step Basics**. Try and move your head from side to side slightly as well as up and down during the programme, whilst keeping your eyes on the screen. At all times make sure the screen is in focus. **This is game 3.**

3. Week 4 Walking programme.

Try and walk outside 5 out of 7 days for 20 minutes. Have someone with you if instructed by your therapist.

4. Please complete the log of your exercises below.

Exercise set	1	2	3
	Warm up (breathing, Standing knee, leg extension And lift)	Wii Exergames Please write the game number of the game you have played here (games 1-4)	Number of minutes walked
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			

Week 4 Log of exercises. Please tick each box. In box 2 detail the actual games played by their number. In box three enter the number of minutes walked each day.

If you have any concerns or questions about your exercises, please call us.

Week 5 Exercises

PLEASE RE-READ THE SAFTEY INSTRUCTIONS ON PAGE 1 CAREFULLY

Wii Week 5; your session on the Wii should last **20 minutes** 5 - 7 days a week. Please have a high-backed chair or other support surface nearby.

Go through your exercise programme on the Wii Fit plus as set up by your therapist in the clinic.

My Wii Fit Plus →My Routine.

Place the chair *in front of you.*

1. Warm –up exercises Wii 1 (yoga deep breathing) to Wii 6 (yoga deep breathing)

Wii 1-Yoga Deep breathing- Do this exercise as instructed by the Wii trainer. Try and keep your balance steady keeping the red dot in the yellow circle.

Throw a ball in the air when doing this.

Wii 2- Yoga Deep breathing.

This time practice try to shift your weight from front to left to right to back and draw a circle with the red dot around the yellow circle.

Wii 3- Yoga Deep breathing- Do this exercise as instructed by the Wii trainer. Try and keep your balance steady keeping the red dot in the yellow circle. **Move your head from side to side and up and down.**

Wii4- Palm Tree. Do as instructed by Wii trainer.

Wii 5- Tree Pose. See if you can start getting into this pose, if you find it hard just place one foot on the other but see if you can do the arm movements. Try not to touch the chair, this week put your other foot down if you lose your balance**.**

2. Wii Exergames – step to heading game

- Go to the **Training Plus** and select **Step Plus. This is game 1.**

Scores.____

- Go to **Training Plus** and select **Snowball** fight and play twice. **This is game 2.**

Scores____________________________________

- Go to **Training Plus** and play the **Balance Plus** game once. **This is game 3.**

Scores__________________________________

- Go to Wii Fit Balance Games and play the **Heading game** once. **This is game 4.**

Scores_____________________________________

3. Week 5 walking programme.

Try and walk outside 5 out of 7 days for 30 minutes. Have someone with you if instructed by your therapist.

4. **Please complete the log of your exercises below**.

Exercise set	1	2	3
	Warm up (breathing, Standing knee, leg extension And lift)	Wii Exergames Please write the game number of the game you have played here (games 1-4)	Number of minutes walked
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			

Week 5 Log of exercises. Please tick each box. In box 2 detail the actual games played by their number. In box three enter the number of minutes walked each day.

If you have any concerns or questions about your exercises, please call us.

Week 6 and onwards Exercises

PLEASE RE-READ THE SAFTEY INSTRUCTIONS ON PAGE 1 CAREFULLY

Wii Week 6: your session on the Wii should last **20 minutes** 5 - 7 days a week. Please have a high-backed chair or other support surface nearby.

Go through your exercise programme on the Wii Fit plus as set up by your therapist in the clinic.

My Wii Fit Plus →My Routine.

Place the chair *in front of you.*

1. Warm –up exercises Wii 1 (yoga deep breathing) to Wii 6 (yoga deep breathing)

Wii 1-Yoga Deep breathing- Do this exercise as instructed by the Wii trainer. Try and keep your balance steady while moving **your head from side to side and then up and down** keeping the red dot in the yellow circle. Try closing your eyes for short periods.

Wii 2- Yoga Standing knee pose

Do this exercise as instructed by the Wii trainer.

Wii 3- Yoga Deep breathing- This time practice trying to shift your weight from front to left to right to back and draw a circle with the red dot around the yellow circle.

Wii4- Yoga Deep breathing. Do as instructed by Wii trainer. Try and keep your balance stead keeping the red dot in the yellow circle.

Wii 5- Yoga Tree Pose. Continue to try and improve this pose.

2. Wii Fit Exergames

- Go to the **Training Plus** and select **Step Plus. This is game 1**.

Scores.____

- Go to **Training Plus** and select **Snowball** fight and play once. **This is game 2.**

Scores___________________________________

- Go to **Training Plus** and play the **skateboarding** once (this will be difficult, do not try unless you are instructed by your therapist. If you cannot do the skateboard, try **skiing** or **Balance Bubble**. Then try to master skateboarding in the remaining week of the programme. **This is game 3.**

Scores_________________________________

- Go to **Training Plus** and play the **Balance Plus** game once. **This is game 4.**

Scores____________________________________

3. Week 6 and beyond walking programme.
Try and walk outside five times a week for 30 minutes. Have someone with you if instructed by your therapist.

4. **Please complete the log of your exercises below**.

Exercise set	1	2	3
	Warm up (breathing, Standing knee, leg extension And lift)	Wii Exergames Please write the game number of the game you have played here (games 1-4)	Number of minutes walked
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			

Week 6 Log of exercises. Please tick each box. In box 2 detail the actual games played by their number. In box three enter the number of minutes walked each day. More logs appear on the following pages

If you have any concerns or questions about your exercises, please call us.

Week 7-12 logs were provided as shown below

Please complete the log of your exercises below.

Exercise set	1	2	3
	Warm up (breathing, Standing knee, leg extension And lift)	Wii Exergames Please write the game number of the game you have played here (games 1-4)	Number of minutes walked
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			

Week 7 Log of exercises. Please tick each box. In box 2 detail the actual games played by their number. In box three enter the number of minutes walked each day.

Week 8

Please complete the log of your exercises below.

Exercise set	1	2	3
	Warm up (breathing, Standing knee, leg extension And lift)	Wii Exergames Please write the game number of the game you have played here (games 1-4)	Number of minutes walked
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			

Week 8 Log of exercises. Please tick each box. In box 2 detail the actual games played by their number. In box three enter the number of minutes walked each day.

Appendix B Supplementary Tables to Support Literature Review

Appendix B.1 Fall prevalence in LMIC referenced to USA data.

Table B.1. Fall prevalence in LMIC referenced to USA data.

Region and country	Design	Sample size and description	Fall occurrence %/year	Comments
Africa				• Paucity of fall prevalence data from Africa [238].
South Africa (urban) [240].	Cross-sectional household survey with follow up at one year	837 adults >65y	Overall 26.4% Caucasians: 42.9% Mixed ancestry: 34.4% Black African: 6.4%	• Retrospective data collection, so vulnerable to recall bias. • Hauer et al.'s fall definition used [854]. • Not stated if the questionnaires regarding falls and risk factors were researcher- or self-administered, which could raise concerns regarding bias, given the level of education of sub-sections of the sample. • Marked variance in prevalence based on ethnicity.
North America **USA [262]** **Note studies discussed throughout text, which cite higher prevalence in the USA population**	On-going survey, but cross- sectional analysis used	12 669 Medicare recipients >65y	22.1% national annual incidence, which represents 6.86 million adults falling per year	• Questionnaire asked about having 'fallen down' rather than using a standardised definition of falls. • National sample using systematic randomised sampling of clustered ZIP (postal) codes ensured good distribution of population, so likely to be generalizable. • Focus was on community-dwelling older adults. • Similar to Kalula et al., above, a 12-month recall may have promoted under-estimation of falls due to recall bias.

South America				
Argentina, Brazil, Barbados, Chile, Cuba, Uruguay,	Cross-sectional study in seven cities	H-EPESE 1483 adults >71y	21-34% depending on location of city.	• Phrasing of the question regarding falls varied slightly between the two studies. Participants were asked either if they had 'fallen down' or fallen to the ground or floor.
Mexico, South Western USA (Mexican-American) [263]**.**	Essentially two studies: H-EPESE in South Western USA and SABE in the rest of the cities.	SABE 9 765 adults >60y		• Urban cities were selected, so the diversity of regions and settings was not captured [263].
Ecuador (rural and urban) [855]**.**	Cross-sectional household survey	5 227 adults >60y	37.4%	• Question was simply 'have you fallen in the last year' so subject to varied interpretation and recall bias. • Highest rates of falls were in rural Andes mountainous regions.
Brazil (urban) [856]**.**	Cross-sectional survey	2 209 adults > 60y	27.1%	• Large sample selected by a cluster-randomisation of municipalities. • Fall definition not specified. • Likely recall bias due to twelve-month recall period.
Brazil [857]**.**	National cross-sectional survey in urban areas	6 616 adults >60y	Northern regions:18.6% South East regions: 30% National average: 27.6%	• The low rate in the North was attributed to a younger group of participants. Two studies are referenced later in the Chapter II (Martins et al.; Teixeira et al.).

Asia				Falls literature from the ASEAN states is limited and difficult to access [1]. Papers from six of the 11 nations in the group were included in a scoping review of falls-related literature [1]. Articles had to be in English and participants community-dwelling adults >60 years. All studies were retrospective and cited fall prevalence at lower levels than Western countries [1]. The authors suggested filial piety could be a major cultural difference contributing to lower fall occurrence [1].
China [264].	SR of 21 studies from five regions in Asia, majority of studies in urban centres.	Community-dwelling older adults >60 years	Retrospective studies: 11 – 34% Prospective studies: 15 – 26% Median: 18%	• SR with what appear to be very limited MeSH search terms. • Both prospective and retrospective studies included with follow-up periods of up to one year. • English and Chinese literature searched. • Selected studies used differing definitions for falls. • Risk factors for falls resemble high-income countries but fall events consistently lower. • Due to the heterogeneity of the studies, a meta-was not possible.
India [858].	Review of 16 articles and three unpublished studies	Adults >60 years	14 – 53%	• MeSH search terms appropriate but limited by selected search engines. • Used accepted fall definition. • Studies included are mostly cross-sectional surveys with very small sample sizes. • Authors suggest that the occurrence of falls in the sub-Continent is under-reported. • Selection criteria for included studies unclear and not conducted using SR methodology. Bias not evaluated. • Severe lack of epidemiological information related to falls and fall risk in the Asia region.
India (rural) [859].	Cross-sectional survey	561 adults >60 years	13% overall Females: 17% Males: 8%	• Fall definition not standardised simply: ‘Have you fallen?’

Sri Lanka (rural) **[860].**	Cross -sectional household survey	300 adults >65 years	34.3% falls	• Primary aim was to assess knowledge of falls and fall prevention strategies. • Definition of fall not given.
Thailand (urban) **[861].**	Cross-sectional survey	1043 adults >65y	19.8%	• Used a standardised definition of falls. • Participants were attending a health fair at local hospitals so possible healthy volunteer bias. • Homogenous sample regarding ethnicity. • Authors noted weight below normal and obesity both associated with fall risk.
Near and Middle East				Authors from the Middle East agree that there is sparse literature regarding fall prevalence emanating from the region [267, 268, 862].
Iran [863].	Cross-sectional community survey	400 adults >60y	24.8%	• Study situated in a town in a predominately agricultural region of Iran. • Further interrogation not possible due to abstract only available in English and the article itself is in Farsi.
Egypt [864].	Survey of patients at primary health care centres	340 adults >60y	60.3%	• Systematic selection bias may exist in that patients attending a general practice could well have more chronic illness, a known contributor to falls than the general population. • Fall description not given. • Generalisability of this study is questioned. • Interestingly, over half the sample of the older adults surveyed were young-old at 60 – 64 years of age. • In addition, 64.4% if the respondents were categorised as being at nutritional risk and two-thirds of them had fallen.

Egypt [233]**.**	Cross-sectional household survey, urban and rural settings	1034 participants >60 years	33.3% overall Ages 80 -89 years: 52.4% >90 years: 73.4%	• Specifically excluded falls due to major intrinsic events.
Saudi Arabia [862]**.**	Cross-sectional digital survey	1182 indirect participants	49.9%	• Digital survey in which adults >18 years of age with a relative >60 years of age collected data from the older adults and entered it on digital link. • Definition of fall not disclosed.
Turkey (mixed urban and rural) [865] **.**	Cross-sectional survey	2 322 adults >65y	28.5%	• Sample drawn from outpatients attending a specialised geriatric service in a major centre, therefore previous issues with selection bias noted. • Almost 10% of the participants came from a nursing home which is likely to have elevated the rate of falls in this sample.

Legend: H-EPESE: Hispanic Established Populations for Epidemiological Studies of the Elderly; SABE: Health Wellbeing and Aging study, SR: systematic review.

Appendix B.2 OEP eligibility, enrolment, recruitment and attrition data from trials in high and LMIC.

Table B.2. OEP eligibility, enrolment, recruitment and attrition data from trials in high and LMIC.

Study/ country/ reference	Target population	Eligibility fraction	Enrolment fraction	Recruitment fraction	NNS	Number assessed at baseline	Number completed follow up/period.	Attrition from randomisation to final physical endpoint measure/group
OEP and executive function. Canada [409].	308 patients at a falls clinic.	0.58	0.41	0.23	4.34	31 OEP 28 controls	28 OEP at six months 24 controls at six months	Attrition OEP: 9.68% Attrition controls: 14.2%
Modified OEP + balance exercises or OEP and stretch exercises. United Kingdom [162].	29 patients at a falls clinic.	1.00 (only eligible participants invited to join trial)	0.72	0.72	1.38	10 OEP+ balance 11 OEP + stretch	7 OEP + balance 8 OEP + stretch	Attrition OEP + balance: 30% Attrition OEP + stretch: 27.8%
OEP and control. Iran [331].	12,315 attendees district health services.	0.24	0.71	0.17	5.88	275 OEP 276 controls	160 OEP 157 controls	Attrition OEP: 41.9% Attrition controls: 43.2%

Study/ country/ reference	Target population	Eligibility fraction	Enrolment fraction	Recruitment fraction	NNS	Number assessed at baseline	Number completed follow up/period.	Attrition from randomisation to final physical endpoint measure/group
Modified OEP and control. Thailand (330).	670 attendees at primary care clinics.	0.93	0.65	0.60	1.66	219 OEP 220 controls	181 OEP 176 controls	Attrition OEP: 17.4% Attrition controls: 20%
Multi-factorial study including modified OEP and control. Thailand (429).	311 recruited from previous study.	0.89	0.89	0.79	1.26	131 OEP 146 controls	118 OEP 111 controls	Attrition OEP: 10% Attrition controls: 24%

Legend: NNS= number of patients needed to be screened.

Appendix B.3 Trials of OEP: adherence, safety and outcome measures.

Table B.3. Trials of OEP: adherence, safety and outcome measures.

Study/country/reference	Required dose/week/ duration	Adherence	Safety/adverse events	Outcome measures (those included in this research are in blue)	Comments
OEP and executive function. Canada [409].	3 OEP, 2 walks x 6 months.	25%: ≥3/week 57%: ≥2/week 68%: at least 1/week.	2 low back pain. One discontinued.	GDS, PASE, Functional Comorbidities Index, TUG, Tests of central executive function, Physiological Profile Assessment.	Small sample (N=59), dose (150 minutes/week) meets recommended guidelines [866].
Modified OEP + balance exercises or OEP and stretch exercises. United Kingdom [162].	2 OEP group classes/week, supervised home session (number not specified) x 2 months.	Adherence not measured.	No serious adverse effects. Two adverse effects, neither related to intervention (one unrelated foot injury; one acute hospitalisation).	Functional Gait Assessment, Physiological Profile Assessment, SAS of balance confidence, vertigo symptoms severity and anxiety/depression.	Very small sample (N=15), total dose (32 hours over 8 weeks). Dose (240 minutes/week) exceeds recommended guidelines but short duration longitudinally.
OEP and control. Iran [331].	3 OEP/week x 6 months.	Adherence not measured.	No details.	BBS, TUG, 30s chair stand, self-assessment scales of balance confidence and falls risk.	If done 3x/week then meets recommended guidelines.
Modified OEP and control. Thailand [330].	120 OEP minutes/week x 12 months but physical endpoints only	29.6% at 3 months achieved 'good'	Knee pain: two cases in each of the experimental and control groups.	TUG, FTSST, EQ-5D, BBS.	Participants were assessed as having mild balance dysfunction on entry. Dose falls short of recommended guidelines.

	measured at baseline, 3 and 6 months.	adherence (met dose) 32.4% at 6 months and 56.8% at 12 months were 'exercising regularly'.	Of 219 participants in the experimental group, there were 51 falls. Of 218 participants in the control group, there were 61 falls.		
Multi-factorial study including modified OEP and control. Thailand [429].	4 OEP/week x 4 months.	Overall 90% adherence at 4 months. Of 118 participants, 51 had 100% adherence and 90 achieved >80%.	Mild pain and discomfort, settled on continuation of exercises, number of participants not specified.	Functional reach, TUG (simple, cognitive, manual), PASE, FTSST.	Dose meets recommended guidelines. Extremely high adherence. It is noted that the participants were drawn from a previous study on falls, which may have contributed to the high adherence.

Legend: GDS: Geriatric Depression Scale. PASE: Physical Activity Scale for the Elderly. SAS: self-assessment scales; TUG: Timed-up-and-go. FTSST: Five times sit to stand test

Appendix C Documents Pertaining to Site Recruitment

Appendix C.1 Information sheet provided to site managers after initial meeting.

Department of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Tel: +27 (0) 21 406 6315

E-mail: Christine.Rogers@uct.ac.za

Internet: www.uct.ac.za

../../2016

The Manager

Communicare/Evergreens/CPOA

Via email

Dear Mr/s …

Re: invitation for residents living at your facilities to join a research study to reduce fall risk

I am Ph.D. student at the University of Cape Town and seeking your permission to conduct a research study at your facilities. This letter serves as confirmation of our meeting today and will outline the study again prior to asking you to indicate your consent for your facility to be used as a site for the trial.

Brief outline of the study

Older adults are at risk of falls and this risk increases with every year of age. We know that falls can have disastrous consequences for those who have fallen and their families, and challenges older adults' ability to live independently and age-in-place. We also know that exercise programmes can successfully address and reduce falls and fall risk. One such programme, the Otago Exercise Programme was developed in New Zealand. Newer interventions that require research to see if they are possibly effective include the Wii Fit Balance Board. Much of the research that has already been done on the latter is flawed and the question of 'can it work?'

needs to be answered before questions of 'how well does it work?' The purpose of this study is to evaluate the steps needed for a larger scale clinical trial (called a randomised control trial) to be feasible – and answer the 'can it work' question. A secondary aim of the study is to see if there is early evidence to support the use of the Wii Fit exercise programme. We understand that some people may be interested in helping with the research but not willing to commit to an exercise-based intervention programme. We will ask all the participants, including the latter, to help us with collecting information about their falls, their injuries and resulting costs from any injuries over a six-month period.

What kind of people are we looking for to enter the study?

The study wishes to enrol participants older than 60 years, with Grade 10 (old Standard 8) or higher education, who are currently living independently in retirement facilities such as those offered by your organisation. They need to be neither too fit nor too frail and we will assess this with a series of simple tests. No tests will be done unless the individuals have been fully informed and signed all the consent documents. This study has been subjected to a rigorous review process and has received ethical clearance from the University of Cape Town, Faculty of Health Sciences Human Research Ethics Committee (Reference number HREC 818/2015). All participants' information regarding study entry, test results, progress through the trial and closure is of course completely confidential to protect the identity of the participants. Participants are free to withdraw from the trial at any time without having to give reasons.

What we need from you as a manager

We would like to negotiate the opportunity for us to access people living in your organisation's facilities. You should be aware that your consent is being sought for us to approach individual participants and to make your facility available for the exercise programme and its research aspect to run.

What will happen at the facility?

I will visit the facility to meet the key stakeholders, introduce myself and set up a date to give a fun, interactive presentation introducing the study. Interested people will drop a slip with their contact details in a box at the back of the room. Thereafter I will contact individuals, send them study information and informed consent documents and make an appointment to see them. Once all questions have been answered, informed consent will be taken. Then participants will be assessed for their risk of falls with simple tests and questionnaires. Once participants at four sites have been recruited a date for the exercise programme to commence will be set. On the day of commencement, it will be revealed which site will be receiving which intervention. This means that the site has a 50:50 chance of receiving either the 'gold standard' exercise programme, namely the Otago Exercise Programme, OR the novel intervention, which is the Wii Fit programme.

Appropriately trained, qualified and registered staff will conduct the exercise programmes. Participants will receive instruction in the programmes as well as telephonic and home visit follow-ups during the trial. They will be asked to keep a log of exercises done and any adverse side effects including falls. The study is sponsored by the University of Cape Town and has the protection of no-fault insurance, which is explained to each participant in detail. There is no direct benefit for the participants in terms of payment; however, evidence suggests that exercise is very beneficial and thus, could be helpful for individuals enrolled in the study. The risks are no more than those living in the community and both interventions have been shown to be safe. Every effort will be made to ensure participants' safety throughout.

At the end of the study, we will offer your staff an opportunity to receive training in falls prevention and fall management, to ensure on-going support. In addition, we will offer to train a nominated member of staff in either of the exercise programmes used during the study. We will leave all the necessary equipment for your facility. On-going contact with the research team will be available.

To summarise, I am approaching you for permission to use your facility as a research site. Residents within your facility will be informed regarding possible participation in the study. Everyone at located at one site will receive the same programme. The decision as to which site gets which intervention is made with random allocation.

I will be contacting you again in the near future to answer any further questions you may have before asking you to sign the attached consent documents. I conclude this letter by providing you with my supervisors' contact details as well as the details of the Chair Person of the Faculty of Health Sciences Human Research Ethics Committee.

Yours sincerely,

Christine Rogers
Student: Christine Rogers, Telephone 021 406 6315. Email: Christine.Rogers@uct.ac.za

Supervisors' contact details:

Prof Dele Amosun: Telephone 021 406 6628 Email: Seyi.Amosun@uct.ac.za

Dr Delva Shamley: Telephone 021 650 1975 Email: Delva.Shamley@uct.ac.za

If you have any ethical queries or concerns, in particular regarding individual rights or the welfare of any research participant, please contact the Faculty of Health Sciences Human Research Ethics Committee at the numbers below:

Faculty of Health Sciences Human Research Ethics Committee

Telephone: 021 406 6492 Email: sumayah.ariefdien@uct.ac.za

Appendix C.2 Consent Form granting permission for use of facility to recruit participants.

I have read this consent form and the Information Sheet and had the opportunity to ask any questions I may have.	
I agree to the facilities for which I am responsible to participate in this study. I know that this does NOT oblige anyone living in such a facility to participate in this study, nor will there be any pressure for anyone to do so. The decision I have made is completely my own. I agree for the results to be used for research purposes and that the results may be published.	
I know that I can withdraw the facilities from the study at any time without having to give a reason why.	
During the write up of the study, and any subsequent publication, I understand that the facilities and participants within them will not be identifiable.	
I am willing to allow the researchers access to the site for a period of up to one year, even though the exercise programme is for a shorter time than this. During this time initial and follow up visits and phone calls will be made to individuals enrolled in the study.	
I understand that the risks involved in this study are minimal and similar to those encountered in daily living.	
I have been informed that individual participants may possibly benefit from doing the exercise programmes by improving their balance and strength. They do not have to pay for the exercise programmes nor will I receive payment for my granting of permission to use the facility.	

Signed:………………………………………..

Name: ………………………………………..

On behalf of (Organisation):…………………………………………………

Date: ………………………………………..

Appendix C.3 Information letter to invite site managers to be participants.

Department of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Tel: +27 (0) 21 406 6315 Fax: +086 611 0725

E-mail: Christine.Rogers@uct.ac.za

Internet: www.uct.ac.za

../../2016

The Manager

Communicare/Evergreens/CPOA

Via email

Dear Mr/s …

Re: invitation for your participation as site manager in a research study

I am Ph.D. student conducting research for degree purposes at the University of Cape Town and seeking your possible participation in a research study. This is quite separate from your agreeing to allow us to approach the residents of your facility. *This letter serves as confirmation of our meeting today and will outline your personal role in the possible research prior to asking you to indicate your consent your personal participation as a manager of the facility*. [70]

Brief outline of the study

Older adults are at risk of falls and this risk increases with every year of age. We know that falls can have disastrous consequences for those who have fallen and their families; and challenges older adults' abilities to live independently and age-in-place. We also know that exercise programmes can successfully address and reduce falls and fall risk. One such programme is the Otago Exercise Programme, which was developed in New Zealand. Newer interventions that require research to

[70] Blue text indicates changes/contextual factors which differentiate this information sheet from others.

see if they are possibly effective include the Wii Fit Balance Board. Much of the research that has been done on the latter is flawed and the question of 'can it work?' needs to be answered before questions of 'how well does it work?' The purpose of this study is to evaluate the steps needed for a larger scale clinical trial (called a randomised control trial) to be feasible – and answer the 'can it work' question. A secondary aim of the study is to see if there is early evidence to support the use of the Wii Fit exercise programme. We understand that some people may be interested in helping with the research but not willing to commit to an exercise-based intervention programme. We will ask all the participants, including the latter, to help us with collecting information about their falls, their injuries and resulting costs from any injuries over six months.

Finally, and this is where you come in, we would like to explore the practical issues which may arise during the study and how participation in the study is regarded by the site managers. We need to record issues such as site assessment/feasibility forms, study initiation checklists, and site visit forms (we have attached examples to this information sheet). We will be logging the amount of support the facility needs to help the programme run – for instance, if there are any human or data management problems incurred because of the trial being run at the facility.

This study has been subjected to a rigorous review process and has received ethical clearance from the University of Cape Town, Faculty of Health Sciences Human Research Ethics Committee (Reference number HREC 818/2015).

What we need from you as a manager and possible participant in the research study

We would like some of your time as we initiate the study in your facility. We will discuss the concept of the study with you and then ask you to describe it back to us. We will ask for your help in completing forms similar to those we have attached. We will ask you to let us know of any problems the exercise participants experience with access, space and function as a result of the study. We will also ask you, in case of us not being able to contact an exercise participant, to inform us of their status (for example, moved away, in hospital). Your overall involvement will probably take a total of one hour per month. We anticipate that your total involvement once you have agreed to be approximately five hours.

What are the risks and benefits of my participating in the study?

There are no direct benefits from your participation in the study. However, information gathered will give indications as to the feasibility of a large-scale study which could occur in settings such as yours. In addition, should the Wii Fit show possible benefit, the application of using it in developing countries could be of value where resources are scarce. The risks are of course your time in meetings with the research team. Unfortunately, there is no payment for your participation in the study. You are under no obligation to participate in the study and you may, of course, change your mind about participating at any time without having to offer an explanation.

What about my privacy?

We will take every effort to make the site unidentifiable in the research report and any subsequent publications, thus protecting your identity as well as that of the site. Only the researchers will know your identity. Once you have joined the study you will be given a research number so your name will never be revealed. All documents will be kept as confidential and safeguarded in both physical and electronic forms. Steps have been taken to make sure they are secure from tampering and hacking. All the individuals you will meet in the course of this study are qualified and registered health care practitioners (e.g. physiotherapists, audiologists) and are bound by their professional codes of ethics. All study personnel have signed a confidentiality agreement. Any breaches of confidentiality will be dealt with immediately.

Where do I find further information?

Please feel free to discuss any concerns with any of the research team. The names and contact details of the student and her supervisors are at the end of this letter. In addition, the contact details for the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee, who granted approval for this study to be conducted, have been provided.

What do I do next?

I will be contacting you again in the near future to answer any further questions you may have before asking you to sign the attached consent documents. I conclude this letter by providing you with my supervisors' contact details as well as the details of the Chair Person of the Faculty of Health Sciences Human Research Ethics Committee. Please feel free to contact me or my supervisors at the numbers given below should you have any questions.

Yours sincerely,

Christine Rogers
Student: Christine Rogers, Telephone 021 406 6315. Email: Christine.Rogers@uct.ac.za

Supervisors' contact details:
Prof Dele Amosun: Telephone 021 406 6628 Email: Seyi.Amosun@uct.ac.za
Dr Delva Shamley: Telephone 021 650 1975 Email: Delva.Shamley@uct.ac.za
If you have any queries or concerns about the ethical conduct of this study, in particular regarding issues of individual rights or the welfare of a research participant, please contact the Faculty of Health Sciences Human Research Ethics Committee at the number below:

Faculty of Health Sciences Human Research Ethics Committee

Telephone: 021 406 6492 Email: sumayah.ariefdien@uct.ac.za

Appendix C.4 Concept Protocol used with site managers who agreed to participate.

Explanation to manager: Concept Protocol

This is a seed document for a concept Protocol, used to begin discussion on a proposed protocol to introduce it to collaborators, sponsors and funders.

Study Title	The feasibility and potential effectiveness of a conventional and video exercise-based intervention to alter balance related outcomes including fall risk: a cluster randomised phase II clinical trial.		
Presenter	C Rogers	Investigators	D Shamley, C Rogers
Period & Duration	2016/7/8/9	Site(s) - Location	Sites A, B, C, D. Cape Town Metropole.
Study Objectives	Process, resources, management, scientific assessment of feasibility of large-scale RCT.		
Population & sample size	Approximately 15-25 per site	Estimated Budget & funding source	Student's own funds
Potential risks			
Falls (participants will be at risk for falls as inclusion criterion). In the case of Wii Fit participants, possible repetitive strain injury. Risks will be ameliorated by careful selection of participants. Those at high risk (e.g. mobility issues) will be excluded. Warm-up and cool down exercises will be prescribed for both exercise groups. Hydration and moderation will be emphasised.			

Potential benefits
Exercise programmes to improve balance are generally safe and there is proven evidence for their efficacy to reduce falls. Less is known about Wii Fit. Equipment will be left at sites, in-house staff trained, and on-going support offered.
State strategic implications of the research
The outcomes of the research will inform decisions regarding the feasibility of a large-scale randomised control trial. Should the Wii Fit programme show preliminary evidence of effect, then it has potential to be applied in resource-constrained setting such as some of those in South Africa.
Additional comments
After the meeting we will ask you to jot down the key points of what we have discussed.

Reference: adapted from template freely available from: *www.theglobalhealthnetwork.org*.

(Retrieved 4.2.2016)

Appendix C.5 Protocol Feasibility Checklist (see Results).

Factors to consider**:**

1. Population	
Was there access to the right patient population?	
What was the attendance figure at the introductory meetings where the study's aims were presented?	
Was the proposed enrolment goal realistic?	
Was the proposed enrolment period realistic?	
Did enrolment compete with other studies or rehabilitation programmes seeking the same patients?	
Were the inclusion/exclusion criteria overly restrictive? (Consider the likely	
Did you expect a significant number of adverse events? (How ill was this	
2. Protocol	
What changes were or should have been implemented to the protocol in terms of its design?	
Was the protocol ethical? Did the HREC have problems with it?	
Did the participants benefit from participating in the study?	
Was the need for other services (e.g., GP, physiotherapy) apparent when either screening for eligibility or during the study?	
Was necessary equipment and space available?	
Were participant compliance problems foreseeable? What was the yield from phone calls and reminders?	
What modifications are needed to the case report forms?	
Were the data/case forms storage/accountability requirements	
What problems were encountered with sustaining the programme so that it could be available for participants at the end of the study? (This can impact on patient satisfaction.)	
3. Assessments	
Were assessments frequent?	
Were assessments difficult, e.g., participants able to do more ambitious tests such as MiniBESTest?	
Were the participants able to complete the exercise logs and report	
What was the completion rate of logs of falls at 12 months?	
Was the exercise schedule complex?	

4. Staff	
Were qualified staff available to support participants and contract the research team if necessary?	
If needed, was training available?	
Did the PI have adequate time to devote to the protocol?	
Were additional specialists needed?	
Were study visits complex, presenting possible scheduling difficulties, e.g., how many different study staff did participants encounter in a given visit?	
5. Budgets	
Did the preliminary budget appear adequate?	
Will sponsor pay for an adequate number of screen failures (Especially important for complex protocols)?	
Any other protocol required equipment or procedure etc?	
6. Other	
Is adequate space available?	
Will electronic or remote data retrieval systems be used?	
Does the sponsor/PI expect this study to be audited by the regulatory bodies?	

Reference: adapted from template freely available from: www.theglobalhealthnetwork.org.

(Retrieved 4.2.2016)

Appendix C.6 Pre-study site selection visit checklist.

Name of the staff member at site: ___________________________

Designation: ____________________

Date of Visit: ___________________________

Attendance of the Site Personnel during visit:		
Site No.	**Name of the staff member**	**Designation**

Note: yellow fill in cells denotes results/pertinence to current research study/findings

Activity	**Yes**	**No**	**NA**
Is Principal Investigator willing to sign Confidentiality agreement?			
Discussed about financial agreement?			
Discussed investigator responsibilities under ICH or applicable regulatory guideline?			
Discussed study design, site and participant inclusion and exclusion criteria, randomization & unbinding, adverse and serious adverse effects reporting?			
Discussed possibility of monitoring and auditing visits?			
Are investigator qualifications and updated CV available?			
Does the investigator have the necessary qualifications, expertise, facilities, and time and support staff, to carry out the proposed research?			
Are the sub-investigator qualifications and updated CV available?			
Are the investigators aware of ICH-GCP guidelines?			
Are study staff qualifications and experience adequate to carry out clinical trial?			

Time-line for target patient enrollment?			
Discussed the recruitment strategy?			
Is there space for programmes to take place (common area for meetings, location of WiiFit equipment)			
Are there any competing programmes (e.g. in-house exercise classes, physiotherapy visits) that could impact recruitment?	all sites		
Is adequate participant in house facilities available (stable electricity supply, TVs)? TV required and purchased for one site (funded by CR) and was provided by second site at their expense			
Is there internet facility available at trial site?			
Is a fax machine available at trial site?			
Is machine available for photo copying and scanning of necessary documents?			
Are there adequate facilities to handle patient safety procedures?			
Are adequate archives /record keeping room available at trial site?			
Are adequate safety and physical security systems maintained at the trial site?			
Access to source documents?			
Access to study and medical records?			
Record keeping and retention			

Emergency Procedures and Precautions [adapted from [867]]

Is there support available at trial site, to handle SAE/medical emergencies? No permanent full-time nursing staff at three of the four sites. Researcher qualified in CPR.			
Is there a telephone? Should have at least one phone that remains in a designated location. Instructions should give the exact location (street address) and instructions on which door to enter or other specifics about the building (e.g. security arrangements).			
Is there a first aid kit? How often is it checked and items replaced when expired? 6 Months			

Is anyone on site qualified in CPR? See above			
Is there 24-hour cover for CPR and first aid?			
Are there facilities for diabetic emergencies (e.g. provision of juice/biscuits)?			

Reference: adapted from template freely available from: *www.theglobalhealthnetwork.org*. (Retrieved 4.2.2016)

Appendix C.7 Site assessment and feasibility questionnaire.

Residence name	
Type of residence	Retirement facility: fully independent only (e.g. no meals) ◻ Retirement facility: some support (e.g. some meals provided) ◻ Retirement facility: mixed fully independent and assisted living ◻ Sick bay/nursing care available on-site ◻
Address	
City	Cape Town
Country	South Africa
Telephone	(021)
Mobile	
Facsimile/Fax	(021)
Website	www.
Email	
Management structure: Directors Manager Residents' Committee Chair Person to contact Preferable time to contact	
Number of nurses and other support staff	
Resident physiotherapist?	
In-house exercise facilities?	Pool ◻ Exercise equipment (e.g. treadmill, stationary bike) ◻ Tennis court ◻ Other: Specify

How many residents in facility?	
Of these, how many are estimated to be fully independent and possible candidates for recruitment?	
How many clinical research studies are currently active at your site?	

Agreements

Is there any legal person necessary to review the Clinical Trial Agreement (CTA)?	Yes □ No □
If 'Yes', what are the timelines of this review (in terms of days)?	
Is there an authorized signatory from your site? If 'Yes' please provide the details: Name of the Authorized signatory? Designation? Contact Number?	Yes □ No □

Financial:

Is there any special site cost? If 'Yes' what is the amount?	Yes □ No □
Any other (please specify):	

Ethics Committee:

Does the Institute have any Ethics committee?	Yes □ No □
Contact Person: name and contact details	
Is the committee constituted as per the ICH-GCP guidelines?	

Does it have a written Standard Operating Procedure? Please provide a copy	
Is there a list of IRB members and their professions? If 'Yes' kindly provide the details	
Do you have a checklist for submission of the documents? If 'Yes' please provide If 'No' please check the list of documents required for submission	• Protocol and amendments • Case Report Forms • Investigator's Brochure • ICF and ICF updates • Translation of ICF and • Translation certificate • Safety information and • Compensation to participants • Participant recruitment procedures (Advertisements) • Investigators' current CV • Investigator undertaking • If there are any other documents required for submission, please mention here.
Fee for review of trial proposal? Any additional fee for amendment approvals during the conduct of study?	
How many copies of each document are required for the submission?	
Is there any format for applying for an Ethics Committee review for a clinical trial? If 'Yes' kindly provide	Yes □ No □

How many days prior to the meeting should the study documents be submitted?	
How many days after the meetings will the approval letter is issued?	
Do you maintain a written record/MOU of the activities of the meeting?	
Do you make the documents available upon request from the regulatory authorities and Auditors?	
How are Ethics committee meetings (in weeks); what is the next date?	
Do you have any policies/procedures in place to call for any emergency meetings on demand for your IEC or IRB	

Space and Equipment:

Does the site have dedicated separate room for clinical research?	Yes □	No □
Does the site have space for storage of study related materials?	Yes □	No □
Does the site have a space for monitoring?	Yes □	No □
Does the site have dedicated cupboard for study document storage?	Yes □	No □

Name:

Signature& Date

Designation:

Reference: adapted from template freely available from: *www.theglobalhealthnetwork.org*. (Retrieved 4.2.2016)

Appendix C.8 Study initiation checklist.

Name of the study centre and Site ID:	
Date:	

Document /Activity	Yes	No	N/A	Comments
Ensure signed and dated curriculum vitae are available for study site staff.				
Familiarize staff with the protocol.				
Familiarize staff with the two programmes				
Ensure that a trial agreement has been signed and agreed with site.				
Ensure indemnity/insurance is available for trial site.				
Ensure HREC approval has been granted for the study, contact details of HREC and reference number provided to site				
Ensure adequate study staff is available.				
Discuss and determine the particular responsibilities of the staff in the clinical trial team.				
Familiarize staff with GCP requirements				
Check that facilities that are required are available and functional.				
Locate a suitable place to store the equipment.				
Ensure materials and documents for the trial have				

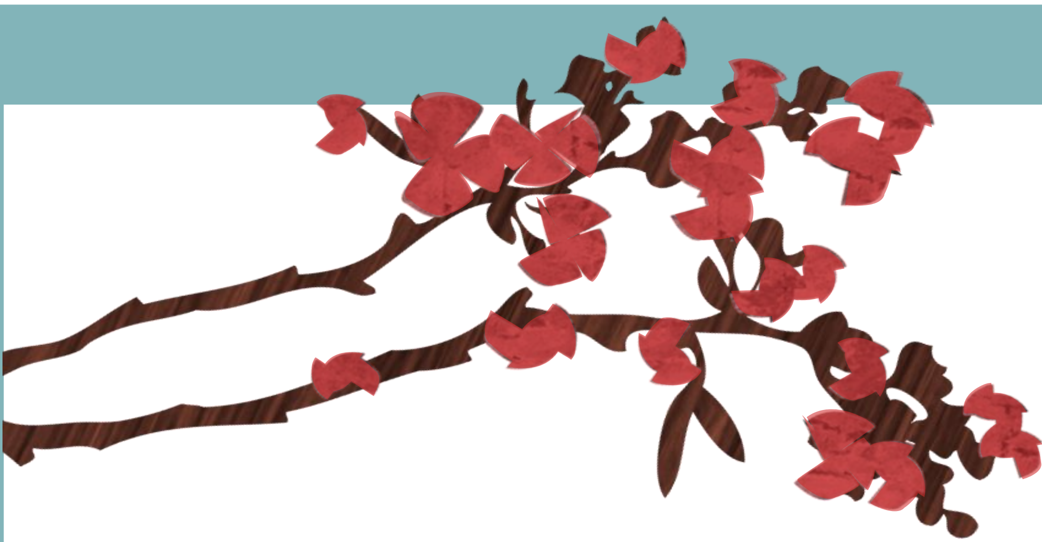
been received and securely stored.				
Prepare and maintain investigator's file.				

Principal Investigator ___________________

Signature and date

Reference: adapted from template freely available from: *www.theglobalhealthnetwork.org*. (Retrieved 4.2.2016)

Appendix C.9 Invitation to recruitment presentation to attract potential participants to study.



MAINTAIN INDEPENDENCE!

UCT PRESENTATION

<u>Wednesday 5 April 2018, 4.45pm</u>

Come and hear Christine Rogers, senior staffer and doctoral student at the University of Cape Town, talk about factors which contribute to older adults' risk of falls. Falls are one of the so-called 'geriatric giants' – events that can challenge one's independence and well-being. However, falls are not accidents! Rather, they are predictable and can be reduced by identifying and improving your personal risk factors.

Christine will talk about an exciting customized exercise- based research project which may improve balance and strength and allow you to maintain your independent living lifestyle!

If you are interested in taking part in her study of measures to improve balance and reduce falls, and cannot attend the presentation, please leave a message on **021 406 6315**, or email Christine.Rogers@uct.ac.za

Site D Clubhouse, snacks will be served!

Appendix C.10 Indication of interest and response slip.*

Department of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Tel: +27 (0) 21 406 6315

E-mail: Christine.Rogers@uct.ac.za

Internet: www.uct.ac.za

Date: / /2016/7/8

Good day

Re: Indication of interest to participate in clinical research study

This form is to let us know if you are interested in the information provided at the presentation today. If you think you would like to find out more about the study, please complete the slip attached and place it in the box provided at the back of the room. We will contact you to make an appointment to see you. We will explain the study in more detail, and you can ask any questions you wish. If you agree to join the trial, we will do some screening activities to see if you are the kind of participant we are looking for. If so, we will discuss the study again and ask if you would like to join. You are under no obligation to complete this form or to join the study, this is simply to see if you may be interested in hearing more about the study.

Thank you

Christine Rogers

Ph.D student

Response slip for potential participant to complete.

Dear Christine

Yes, I think I may be interested in finding out more about your research study.

I am contactable in the following ways (tick which you would prefer):

□ via email and my email address is: ……………………………………………..

□ via telephone and my land-line number is:
……………………………………………

□ via mobile telephone and my number is:
………………………………………………

The best time to contact me is:

□ early in the morning (before 8am)

□ between 8 and 4pm

□ in the evenings before 8.30pm

I would like to be addressed by my:

□ first name, which is ……………………….

□ surname, which is ………………………… and

□ title which is: Prof, Dr, Mr, Mrs, Ms (please circle which is appropriate)

*note the font size and type face will be appropriate for an older audience

Appendix C.11 Letter of welcome to study and eligibility screening appointment.*

Department of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital, Observatory 7925

Tel: +27 (0) 21 406 6315

E-mail: Christine.Rogers@uct.ac.za

Internet: www.uct.ac.za

Date: / /2015

Dear …………………………………

Re: Letter of welcome to clinical research study

Thank you for returning your details. This letter is to welcome you to your first appointment, so we can talk about the research study and see if you would be suitable to join it.

Your appointment is on……………………………………… at …………am/pm. If this appointment is inconvenient, please do let me know at the above contact telephone number or email address. We will meet at ………… (venue).

We have attached some forms which give more information about the study and what you will be expected to do to participate in it. Please read all the forms carefully and feel free to make a note of any questions you may have so you can ask them when we meet. You will see we have added the informed consent form, which is very important as you will be asked to sign this to say you would like to join the study. We have given this to you now, so you have plenty of time to think about your participation before we meet; and to talk to your family and friends about it if you so wish. You are able to change your mind about joining the study at any time, including if you have already joined up.

We look forward to meeting you next time,

Best wishes
Christine Rogers, Ph. D student

*note the font size and type face will be appropriate for an older audience

Appendix C.12 Matters Pertaining to Recruitment of Older Adults

Recruitment from a sample of older adults can be challenging [567] . Care was taken to ensure recruitment strategies were sensitive to older people's concerns regarding falls, fall prevention and fall risk. Marketing of the study emphasised the health benefits of a fitness programme and improving strength and balance to promote prolonged independence.

Participants who enrol for a study and fail to complete it may undermine both the internal and external validity of a trial [868] . The following strategies were implemented to enhance recruitment and retention:

Removal of barriers to recruitment [869].

Transport and care-giver burden are among the reasons older adults decline to enrol in research [870]. Onsite assessments avoided transport difficulties. The research team encouraged adherence by supporting both the participant plus any significant others.

Effective contact with the potential study population [869].

Effective contact is one of the first steps of an active recruitment strategy [620]. Care was taken to maintain good relationships between the stakeholders, including potential participants, and research personnel [620]. Materials, including information sheets, were shared with all the interested parties and feedback sought. Jargon-free, clear and fun presentations were prepared to promote wellness and maintenance of independence through better balance, then second, to introduce the study [869].

Management of initial and follow up appointments [869].

Interested individuals were contacted by telephone/email. Every effort was made to put the person at ease, for example, asking how s/he wishes to be addressed [869]. Culturally appropriate pleasantries were made before study information was given. An information pack, including a letter of welcome on University letterhead, with full contact details, information sheet and consent form were sent with the appointment for the initial baseline data collection session. Prior information allowed the recipient to peruse the consent form at home reducing the risk of coercion [869]. The appointment was confirmed telephonically two days prior. Regular reminders of appointments are important steps to encourage participant retention and were implemented via telephone, text messaging or emails [620].

Responsiveness to issues of vulnerability [869].

Efforts was made to ensure potential and enrolled participants were comfortable. The precise nature of the study, requirements for eligibility and participation, and risks/benefit ratios were explained in detail. The physical surroundings were familiar and secure, as the venue was within the older adults' residence or communal areas on the site. Outcome measures were referred to as activities rather than tests to reduce anxiety about performance [869].

Continuation of care during and after study period.

Periodic reminders were made (as per OEP protocol) via phone to enhance participation. Exercise programmes were offered after the trial terminated.

Appendix D Informed Consent Documents for Individual Participants

Appendix D.1 Information sheet and Informed Consent document for the Otago Exercise Programme.*

Department of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Tel: +27 (0) 21 406 6315

E-mail: Christine.Rogers@uct.ac.za

Internet: www.uct.ac.za

../../2016

Good day

Re: Invitation to participate in research clinical trial with an exercise-based intervention: Otago exercise programme

This letter explains the purpose of the research study and gives details of what your involvement will be, should you decide to participate. The study is towards a Ph.D. degree and the candidate is Christine Rogers.

What is the study about? Why is it important?

Falls and near-falls (slips and trips) are very common in older adults. In fact, over the age of 65 years, one in three adults fall each year. Of those who fall, more than half will fall repeatedly. Falls are a serious issue for both the person who has fallen and their families. For example, injuries, ranging from cuts and bruises to broken bones may result. These injuries may challenge independence as well as lead to more falls or a fear of falling. There are also a number of costs, besides physical and psychological ones, when falls occur. These include hospitalisation, the need to take time off work or other activities (or have loved ones do the same), and sometimes even costs which can be incurred if a change in physical living conditions is required (e.g. move from living alone to living in an assisted environment). In many countries around the world, these costs are a concern to planners in public health and efforts are being made to prevent and manage falls better.

What many people do not realise is that falls are not an 'automatic' part of ageing. Often, they are thought of as accidents and as such cannot be prevented. This is really not so. In fact, there are many ways to reduce the risk of falling. For example, in regions such as North America and Europe, at routine doctor's visits, older adults are usually asked about falling and screened for their risk of falls. In addition to identifying who is at risk, programmes are also being put in place to reduce individuals' risk of falling. These range from improving vision by having cataract surgery happen as soon as possible; vitamin D supplementation if necessary, managing medication profiles (reducing the number of medications and focusing on certain types known to add to the risk of falling) and so on. A lot of research is happening in the area and the way is being led by teams in the USA and Europe. So, we know what works in terms of preventing falls.

One of the most successful ways to reduce the risk of falls in a person is to improve his or her sense of balance, as well as their strength, especially in the legs. There is really good proof that exercises can help reduce the risk of falls. For example, the famous Centers for Disease Control in the USA is currently rolling out exercise classes aimed at older adults in order to reduce their fall occurrence in many parts of America. They have chosen one particular type of programme called the Otago Exercise Programme, which is what we will be studying in this research.

What is the Otago Exercise Programme?

The Otago Exercise Programme (OEP) was developed in New Zealand in the 1990s. Since then, it has spread across Australia, North America and Europe as a fall prevention exercise programme. Good quality research has been done on the OEP and we know it works in these settings. As mentioned, the programme has been ear-marked by a very renowned institution in the USA as the programme-of-choice for their fall prevention efforts.

The Otago Exercise Programme which will be explained to you verbally and in writing but will be described here too. The programme works on improving your balance and strength through a series of exercises. The three key activities are: <u>improving your strength, improving your balance and improving your walking.</u> Here we will describe the type of activities you can expect to do in the programme:

- Each session starts with a five-minute <u>gentle warm-up</u> session. Examples of exercises done now are: standing and moving your head in different directions, for example, left and right; arching the back gently while standing, moving the body from the waist to the left and right.
- After the warm up we will work on <u>improving your strength</u>. Often these are done using weighted cuffs around the limb you are lifting. If you are not ready for this at the start of the programme, we will guide you as to when this is safe for you to try. Examples of these exercises are: sitting watching TV with the

back well supported, strapping the cuff to your ankle and straightening and lowering the leg, then repeating with the other leg. Another would be standing tall against a bench (holding on) and then lifting the exercise leg, with the cuff, out to the side and returning it. Other activities include standing tall and raising your toes by coming back onto your heels, first holding on to the counter and then not.

- Improving your balance. Balance is important for everyday activities. Examples of exercises include: knee bends; backwards walking with and then without support, walking in a figure-of-eight, and standing on one leg (with and without support). We will also work on moving to standing from a seated position.
- Finally, there is a walking programme. We will assess your walking ability and suggest when, where and for how long to walk each time. Ideally, we would like the walk to be thirty minutes, but this can be broken up into ten-minute sessions and is not every day. You should realise the Otago Exercise Programme is designed scientifically to work as a whole – it is not designed as a 'pick and mix'. For example, if you only do the walking this is not ideal.

The programme will be done by you, in your home (either alone or with friends, it's up to you) at a time convenient to you. We will show you what to do. You will be doing some form of exercise for about 20 minutes most days of the week (this includes the time when you are taking a walk). Your overall commitment to exercise would be two hours per week, which is what has been recommended to help balance and prevent falls in older adults. We explain below about the rest of your time commitment if you join the programme.

Great, if the Otago Exercise Programme works, why do the research?

We know that certain forms of exercise help improve balance, but these programmes often need highly trained staff and special settings, so it can be difficult offering such services in a country like South Africa. We are trying to see if a different programme, with video game-based exercises, can work in the same way that other recommended exercise programmes (like the Otago) do. There are some studies which have been done on both the videogame exercises and other fall intervention programmes; but none have been done in South Africa, so we do not know if a large-scale study could work here. The current study plans to answer a 'can it work' question for both the Otago and the alternative programme to give information how to proceed.

We also have no idea how falls, injuries and associated costs of those injuries affect people in South Africa. Therefore, as a part of the study, we will be asking everyone involved to keep track of any falls, injuries and costs related to the falls for a one-year period. In fact, if the exercise programme is not for you, but you are interested in the research itself, you can join the study and simply furnish us with information about these matters.

What do I have to do?

Once you have agreed and signed that you want to join the study:

- First you will be asked about your history of falls in the last year. We will also ask about your exercise habits and medical history, for example, if you have any illnesses (such as diabetes and hypertension) and if you take any medication.
- We will also check if your mood is normal as being depressed can make a difference to the results. This check involves answering a short questionnaire. In order to protect you, we will also ask you to do a simple memory task to check your thinking is clear.
- You will have screening activities to see what your balance is like standing and walking. All the activities are very simple and easy to do and will be explained to you in detail. They are used across the world and are reliable and safe.
- We will also be asking you to fill in some questionnaires about your quality of life and current levels of exercise. We estimate that you will need literacy at Standard 8 level or higher.

You are welcome to ask questions at any time and we will make sure you are safe and comfortable throughout the study. We expect that some people may have to leave the study at this stage if they are not suitable. This meeting will take about one hour of your time. The Table below gives you an idea of what to expect and when things will occur.

The exercise programme:

The exercise intervention runs over 6 months and you will keep in close touch with the study staff during this time. Of course, there is nothing to stop you from continuing with the programme for as long as you wish. You will do the exercises and make a note in a diary each day about what you have done and any problems you have experienced, such as falling or feeling dizzy. We'd like you to keep these notes even if you stop exercising. We will show you what to do and how to do it. We will come back and see you at regular intervals and also keep in touch with you by phone. The exercises will be shown to you by an experienced therapist. Exercises take about 15 - 20 minutes per session and you will have sessions or walks most days of the week. We will lend you all the things you need to be able to do the exercise programme. We encourage you to join up either on your own or with some friends.

When you enter the study	Re-assessment at three and six months
• Simple screening tests for depression and memory • Questionnaires about quality of life, attitude to exercise, current levels of exercise • Four activities to assess your current levels of balance and walking ability • You start keeping an exercise log. records of any falls plus associated costs	• Questionnaires about depression, quality of life, attitude to exercise, current levels of exercise • You will have kept records of all your exercise activity and any falls plus associated costs • Four activities to assess your current levels of balance and walking ability • At six months this is the end of the formal exercise programme but you are welcome to continue the exercises and let us know about falls.

Table: What to expect at different time points in the study

At the mid-way point and end of the study:

You will have balance activities repeated to see if your results have changed. We will do the activities at three and six months after you started the programme. We will also check how you enjoyed the programme and if your quality of life has changed in any way. At the end of the study, an opportunity to continue with the programmes will be offered and staff at your facility trained in how to run them.

What is my risk?

Overall the risks are very low and no more than what is faced in everyday living. The Otago Exercise Programme is well researched and used across the world to help older adults maintain their health, strength, balance and independence. It has been used by thousands of people and there have been very few problems, all of which have been very minor, for example, muscle aches and pains when using different muscle groups. In order to protect you as much as possible against risks, we will exclude you from the study if you are very frail or have conditions in which exercise could be harmful – e.g. acute heart failure. Please feel free to discuss any concerns about the risks with the research team. We will be monitoring you and recording any problems during the trial and they will be managed appropriately.

What if something goes wrong?

The University of Cape Town (UCT) has insurance cover for the event that research-related injury or harm results from your participation in the trial. The insurer will pay all reasonable medical expenses in accordance with the South African Good Clinical Practice Guidelines (Department of Health, 2006), based on the Association of the British Pharmaceutical Industry Guidelines in the event of an injury or side effect resulting directly from your participation in the trial. You will not be required to prove fault on the part of the University.

The University **will not be liable** for any loss, injuries and/or harm that you may sustain where the loss is caused by:

- The use of an unauthorised medicine or substances during the study.
- Any injury that results from you not following the protocol requirements or the instructions that the study personnel may give you.
- Any injury that arises from inadequate action or lack of action to deal adequately with a side effect or reaction to the study intervention.
- An injury that results from negligence on your part.

By agreeing to participate in this study, you do not give up your right to claim compensation for injury where you can prove negligence, in separate litigation. In particular, your right to pursue such a claim in a South African court in terms of South African law must be ensured. Note, however, that you will usually be requested to accept that payment made by the University under the SA GCP guideline 4.11 is in full settlement of the claim relating to medical expenses.

An injury is considered to be trial-related if, and to the extent that, it is caused by study activities. You must notify the study personnel immediately of any side effects and/or injuries during the trial, whether they are research-related or other related complications.

UCT reserves the right not to provide compensation if, and to the extent that, your injury came about because you chose not to follow the instructions that you were given while you were taking part in the study. Your right in law to claim compensation for injury where you prove negligence is not affected. Copies of these guidelines are available on request.

What can I gain from the joining?

There is very little knowledge about how falls and their related injuries affect South Africans. In particular, planning for ageing in developing countries has been lacking and yet as a nation we are getting older! Information gathered in this research will answer several questions, which include if a large-scale study is possible in a developing country; what it would take to accomplish such a study; and if there is a future for new technology such as the Wii-Fit balance board to play a role in fall prevention programmes. So, you will be able to help provide important information on all these questions. In addition, you will have an opportunity to have your risk of falls assessed (which will be discussed with you after the activities) by a qualified health care professional and see how and if this changes as a result of being in an exercise programme.

Even if you just agree to give us information about falls and the costs, you will have access to important information regarding the risk of falls and what you can do to prevent them.

If I don’t join is there anything else I can do?

If you decide not to join the trial, we will provide you with pamphlets containing important information about falls and fall prevention. These will be left at reception or with the manager of your facility for you to collect when convenient. We will recommend websites which detail check-lists for you to do at home to make sure your environment is as safe as possible in terms of fall risk. You can of course talk to your own doctor and physiotherapist if you have concerns or ask the research team for a referral. We will also give the manager a list of exercise classes aimed at older adults in your area should you think joining one would be a good idea.

Payment and expenses

You do not have to pay to join the study, nor will you incur any expenses as we will come to you and supply all the necessary equipment. Unfortunately, there is no payment to you for your participation.

What if I change my mind?

You do not have to join the study, it is strictly on a voluntary basis. As it involves a commitment of your time over a six-month period, please take your time to consider if this is the right thing for you. You can withdraw from the study at any time without having to explain your reasons.

What about my privacy?

Only the researchers will know your identity. Once you have joined the study you will be given a research number so your name will never be revealed. All documents will be kept as confidential and safeguarded in both physical and electronic forms. Steps have been taken to make sure they are secure from tampering and hacking. All the individuals you will meet during this study are qualified and registered health care practitioners (e.g. physiotherapists, audiologists) and are bound by their professional codes of ethics. All study personnel have signed a confidentiality agreement. Any breaches of confidentiality will be dealt with immediately.

Where do I find further information?

Please feel free to discuss any concerns with any of the research team. The names and contact details of the primary researcher and her supervisors are at the end of this letter. In addition, the contact details for the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee, who granted approval for this study to be conducted, have been provided.

What do I do next?

Please take a look at this information sheet and the consent form attached. Please have them ready at your appointment to meet the researchers. Please feel free to contact me or my supervisors at the numbers given below should you have any questions.

Primary investigator: Christine Rogers, Telephone 021 406 6315. Email: Christine.Rogers@uct.ac.za

Supervisors:

Prof Dele Amosun: Telephone 021 406 6628 Email: Seyi.Amosun@uct.ac.za

Dr Delva Shamley: Telephone 021 650 1975 Email: Delva.Shamley@uct.ac.za

If you have any ethical queries or concerns, in particular regarding individual rights or the welfare of any research participant, please contact the Faculty of Health Sciences Human Research Ethics Committee

Faculty of Health Sciences Human Research Ethics Committee

Telephone: 021 406 6492

Email: sumayah.ariefdien@uct.ac.za

*****Note: font and format were suitable for an older adult

Consent Form

I have read/had read to me this consent form and the Information Sheet and had the opportunity to ask any questions I may have.	
I agree to participate in this research study. The decision I have made is completely my own. I agree for my results to be used for research purposes and that the results may be published.	
I know that I can withdraw from the study at any time.	
I know all the details about me, including medical information, will be kept private. Even if the results of the study are published, I understand that I will not be identifiable.	
I understand what I am required to do in terms of the tests and the exercise programmes and am willing to join the study for a period six months. During this time, I will receive follow up visits and phone calls to monitor my progress.	
I understand that the risks involved in this study are minimal and similar to those encountered in daily living.	
I have been informed that I may possibly benefit from doing the exercise programmes by improving my balance and strength. I do not have to pay for the exercise programmes nor will I receive payment for my participation.	

Study number:

Signature of Participant: ____________________Date: ______________________

Appendix D.2 Information sheet and Informed Consent Document for Wii Fit programme*.

Department of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Tel: +27 (0) 21 406 6315

E-mail: Christine.Rogers@uct.ac.za

Internet: www.uct.ac.za

Date: .../../2016

Good day

Re: Invitation to participate in research clinical trial with an exercise-based intervention: Wii Fit balance board

This letter explains the purpose of the research study and gives details of what your involvement would be should you decide to participate. The study is towards a Ph.D. degree and the candidate is Christine Rogers.

What is the study about? Why is it important?

Falls and near-falls (slips and trips) are very common in older adults. In fact, over the age of 65 years, one in three adults fall each year. Of those who fall, more than half will fall repeatedly. Falls are a serious issue for both the person who has fallen and their families. For example, injuries, ranging from cuts and bruises to broken bones may result. These injuries may challenge independence as well as lead to more falls or a fear of falling. There are also a number of costs, besides physical and psychological ones, when falls occur. These include hospitalisation, the need to take time off work or other activities (or have loved ones do the same), and sometimes even costs which can be incurred if a change in physical living conditions is required (e.g. move from living alone to living in an assisted environment). In many countries around the world, these costs are a concern to planners in public health and efforts are being made to prevent and manage falls better.

What many people do not realise is that falls are not an 'automatic' part of ageing. Often, they are thought of as accidents and as such cannot be prevented. This is really not so. In fact, there are many ways to reduce the risk of falling. For example, in regions such as North America and Europe, at routine doctor's visits, older adults are usually asked about falling and screened for their risk of falls. In addition to identifying who is at risk, programmes are also being put in place to reduce individuals' risk of falling. These range from improving vision by having cataract surgery happen as soon as possible; vitamin D supplementation if necessary, managing medication profiles (reducing the number of medications and focusing on certain types known to add to the risk of falling) and so on. A lot of research is happening in the area and the way is being led by teams in the USA and Europe. So, we know what works in terms of preventing falls.

One of the most successful ways to reduce the risk of falls in a person is to improve his or her sense of balance, as well as their strength, especially in the legs. There is really good proof that exercises can help reduce the risk of falls.

What is the study about?

We know that certain forms of exercise help improve balance, but these programmes often need highly trained staff and special settings, so it can be difficult offering such services in a country like South Africa. We are trying to see if a different programme, with video game-based exercises, can work in the same way that other recommended exercise programmes do. There are some studies which have been done on both the videogame exercises and other fall intervention programmes; but none have been done in South Africa, so we do not know if a large-scale study could work here. The current study plans to answer a 'can it work' question to give information how to proceed. We will do activities looking at your balance when standing and walking and these give us an idea of your ability to manage everyday life. By repeating the activities at the end of the trial period, during which you will have received an intervention of video-based exercises, we can see if you have improved or stayed the same. You will also be asked to complete questionnaires about your physical activity levels, quality of life and attitude to exercise at different times during the trial; and to keep a log of your exercise patterns and any falls and related costs for a year.

What is the intervention?

The intervention is a video game-based exercise programme using equipment called the Wii Fit and a balance board. This will also have a walking programme included, so you will be doing some form of exercise for 20 minutes most days of the week. Your overall commitment to exercise would be two hours per week, which is what has been recommended to help balance and prevent falls in older adults. The programme has been designed by a physiotherapist and includes warm-up and cool-down exercises. The games are fun and inter-active and concentrate on your balance and co-ordination. To give you an idea of what to expect, in the first week, you will need someone beside you to ensure you keep your balance and a chair for support, if needed. You will stand on the balance board, look at the screen in front and keep your weight evenly distributed. The Wii trainer will give you instructions to do some yoga deep breathing. Improving your balance: you will try standing on one leg, extending your leg and some leg lifts. Improving your fitness: you will progress to playing games such as slides; stepping and aerobics and even, as you become better with the programme, more ambitious activities such as skiing. Finally, there is a walking programme. We will assess your walking ability and suggest when, where and for how long to walk each time.

The programme will be done by you, in your home (either alone or with friends, it's up to you) at a time convenient to you. We will show you what to do. We explain below about the rest of your time commitment if you join the programme.

Why do the research?

We know that certain forms of exercise help improve balance, but these programmes often need highly trained staff and special settings, so it can be difficult offering such services in a country like South Africa. We are trying to see if a different programme, with video game-based exercises, can work in the same way that other recommended exercise programmes (for example, the Otago Exercise Programme) do. There are some studies which have been done on both the videogame exercises and other fall intervention programmes; but none have been done in South Africa, so we do not know if a large-scale study could work here. The current study plans to answer a 'can it work' question for both the Otago and the alternative programme to give information how to proceed.

We also have no idea how falls, injuries and associated costs of those injuries affect people in South Africa. Therefore, as a part of the study, we will be asking everyone involved to keep track of any falls, injuries and costs related to the falls for six months. In fact, if the exercise programme is not for you, but you are interested in the research itself, you can join the study and simply furnish us with information about these matters.

What do I have to do?

Once you have agreed and signed that you want to join the study:

- First you will be asked about your history of falls in the last year. We will also ask about your exercise habits and medical history, for example, if you have any illnesses (such as diabetes and hypertension) and if you take any medication.
- We will also check if your mood is normal as being depressed can make a difference to the results. This check involves answering a short questionnaire.

In order to protect you we will also ask you to do a simple memory task to check your thinking is clear.

- You will have screening activities to see what your balance is like standing and walking. All the activities are very simple and easy to do and will be explained to you in detail. They are used across the world and are reliable and safe.
- We will also be asking you to fill in some questionnaires about your quality of life and current levels of exercise. We estimate that you will need literacy at Standard 8 level or higher.

You are welcome to ask questions at any time and we will make sure you are safe and comfortable throughout the study. We expect that some people may have to leave the study at this stage if they are not suitable. This meeting will take about one hour of your time. The Table below gives you an idea of what to expect and when things will occur.

The exercise programme:

You will be asked complete treatment over 6 months and to keep in touch with the study staff during this time. You will do the exercises and make a note in a diary each day about what you have done and any problems you have experienced, such as falling or feeling dizzy. We will show you what to do and how to do it. We will come back and see you at regular intervals and also keep in touch with you by phone. The exercises will be shown to you by an experienced therapist. Exercises take about 15 - 20 minutes per session and you will have sessions or walks (up to another 20 minutes) most days of the week. We will lend you all the things you need to be able to do the exercise programmes. We encourage you to join up either on your own or with some friends. In particular, if you do the Wii exercises we would like you to have someone close by to help you if necessary, especially when getting on and off the board.

At the mid-way point and end of the study:

You will have balance activities repeated to see if your results have changed. We will do the activities at three and six months after you started the programme. We will ask you to continue with the log of exercises and any falls during this time. We will also check how you enjoyed the programme and if your quality of life has changed in any way. At the end of the study, an opportunity to continue with the programmes will be offered and staff at your facility trained in how to run them.

When you enter the study	Re-assessment at three and six months
• Simple screening tests for depression and memory • Questionnaires about quality of life, attitude to exercise, current levels of exercise • Four activities to assess your current levels of balance and walking ability • You start keeping an exercise log. records of any falls plus associated costs	• Questionnaires about depression, quality of life, attitude to exercise, current levels of exercise, and how you found using the Wii Fit programme • You will have kept records of all your exercise activity and any falls plus associated costs • Four activities to assess your current levels of balance and walking ability • At six months this is the end of the formal exercise programme but you are welcome to carry on recording information about exercise levels, falls and their costs

Table: What to expect at different time points in the study

What is my risk?

Overall the risks are very low and no more than what is faced in everyday living. The Wii Fit and balance board is an experimental intervention. There have been a few cases of injuries such as sprains and strains caused by people playing with the games for abnormally prolonged periods of time, but these have been minor. In order to protect you as much as possible against risks, we will exclude you from the study if you are very frail or have conditions in which exercise could be harmful – e.g. acute heart failure. Please feel free to discuss any concerns about the risks with the research team. We will be monitoring you and recording any problems during the trial and they will be managed appropriately.

What if something goes wrong?

The University of Cape Town (UCT) has insurance cover for the event that research-related injury or harm results from your participation in the trial. The insurer will pay all reasonable medical expenses in accordance with the South African Good Clinical Practice Guidelines (Department of Health, 2006), based on the Association of the British Pharmaceutical Industry Guidelines in the event of an injury or side effect resulting directly from your participation in the trial. You will not be required to prove fault on the part of the University.

The University **will not be liable** for any loss, injuries and/or harm that you may sustain where the loss is caused by:

- The use of an unauthorised medicine or substances during the study.
- Any injury that results from you not following the protocol requirements or the instructions that the study personnel may give you.
- Any injury that arises from inadequate action or lack of action to deal adequately with a side effect or reaction to the study intervention.
- An injury that results from negligence on your part.

By agreeing to participate in this study, you do not give up your right to claim compensation for injury where you can prove negligence, in separate litigation. In particular, your right to pursue such a claim in a South African court in terms of South African law must be ensured. Note, however, that you will usually be requested to accept that payment made by the University under the SA GCP guideline 4.11 is in full settlement of the claim relating to medical expenses.

An injury is considered to be trial-related if, and to the extent that, it is caused by study activities. You must notify the study personnel immediately of any side effects and/or injuries during the trial, whether they are research-related or other related complications.

UCT reserves the right not to provide compensation if, and to the extent that, your injury came about because you chose not to follow the instructions that you were given while you were taking part in the study. Your right in law to claim compensation for injury where you prove negligence is not affected. Copies of these guidelines are available on request.

What can I gain from the joining?

There is very little knowledge about how falls and their related injuries affect South Africans. In particular, planning for ageing in developing countries has been lacking and yet as a nation we are getting older! Information gathered in this research will answer several questions, which include if a large-scale study is possible in a developing country; what it would take to accomplish such a study; and if there is a future for new technology such as the Wii-Fit balance board to play a role in fall prevention programmes. So, you will be able to help provide important information on all these questions.

In addition, you will have an opportunity to have your risk of falls assessed (which will be discussed with you after the activities) by a qualified health care professional and see how and if this changes as a result of being in an exercise programme. Even if you just agree to give us information about falls and the costs, you will have access to important information regarding the risk of falls and what you can do to prevent them.

If I don’t join is there anything else I can do?

If you decide not to join the trial, we will provide you with pamphlets containing important information about falls and fall prevention. These will be left at reception or with the manager of your facility for you to collect when convenient. We will recommend websites which detail check-lists for you to do at home to make sure your environment is as safe as possible in terms of fall risk. You can of course talk to your own doctor and physiotherapist if you have concerns or ask the research team for a referral. We will also give the manager a list of exercise classes aimed at older adults in your area should you think joining one would be a good idea.

Payment and expenses

You do not have to pay to join the study, nor will you incur any expenses as we will come to you and supply all the necessary equipment. Unfortunately, there is no payment to you for your participation.

What if I change my mind?

You do not have to join the study, it is strictly on a voluntary basis. As it involves a commitment of your time over a six-month period, please take your time to consider if this is the right thing for you. You can withdraw from the study at any time without having to explain your reasons.

What about my privacy?

Only the researchers will know your identity. Once you have joined the study you will be given a research number so your name will never be revealed. All documents will be kept as confidential and safeguarded in both physical and electronic forms. Steps have been taken to make sure they are secure from tampering and hacking. All the individuals you will meet during this study are qualified and registered health care practitioners (e.g. physiotherapists, audiologists) and are bound by their professional codes of ethics. All study personnel have signed a confidentiality agreement. Any breaches of confidentiality will be dealt with immediately.

Where do I find further information?

Please feel free to discuss any concerns with any of the research team. The names and contact details of the primary researcher and her supervisors are at the end of this letter. In addition, the contact details for the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee, who granted approval for this study to be conducted, have been provided.

What do I do next?

Please take a look at this information sheet and the consent form attached. Please have them ready at your appointment to meet the researchers. If you have any questions related to the study, please contact:

Primary investigator: Christine Rogers, Telephone 021 406 6315. Email: Christine.Rogers@uct.ac.za

Supervisors:

Prof Dele Amosun: Telephone 021 406 6628 Email: Seyi.Amosun@uct.ac.za

Dr Delva Shamley: Telephone 021 650 1975 Email: Delva.Shamley@uct.ac.za

If you have any ethical queries or concerns, in particular regarding individual rights or the welfare of any research participant, please contact the Faculty of Health Sciences Human Research Ethics Committee

Faculty of Health Sciences Human Research Ethics Committee

Telephone: 021 406 6492

Email: sumayah.ariefdien@uct.ac.za

*Note font and format were suitable for an older adult reader.

Consent Form

I have read/had read to me this consent form and the Information Sheet and had the opportunity to ask any questions I may have.	
I agree to participate in this research study. The decision I have made is completely my own. I agree for my results to be used for research purposes and that the results may be published.	
I know that I can withdraw from the study at any time.	
I know all the details about me, including medical information, will be kept private. Even if the results of the study are published, I understand that I will not be identifiable.	
I understand what I am required to do in terms of the tests and the exercise programmes and am willing to join the study for a period of six months. During this time, I will receive follow up visits and phone calls to monitor my progress.	
I understand that the risks involved in this study are minimal and similar to those encountered in daily living.	
I have been informed that I may possibly benefit from doing the exercise programmes by improving my balance and strength. I do not have to pay for the exercise programmes nor will I receive payment for my participation.	

Study number: ☐

Signature of Participant: ____________________Date: ______________________

Appendix D.3 Information sheet and Informed Consent Documents for Focus Groups.

Department of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Tel: +27 (0) 21 406 6315

E-mail: Christine.Rogers@uct.ac.za

Internet: www.uct.ac.za

29.7.2017

Dear …………………………….

Re: your experiences in the fall prevention clinical trial

Thank you so much for your interest in the trial so far. Just to remind you, my name is Christine Rogers, I am a doctoral degree student at UCT and the purpose of this study is for research. I understand that you may have started the exercise programme, and either continued with it; or for some reason decided it was not for you. Some of you have already given very valuable feedback about your experience and I am interested to learn more about this.

I would like to host something called a focus group and believe you could make a valuable contribution to my understanding of the research I am doing. This letter explains what is requested in more detail. It is followed by an informed consent form.

What is this part of the research about?

I will be running a small group of between six and eight people at a time that suits you. All the participants in the group will come from your residence, and we will meet in the communal area, which I will book so we have some privacy. We will start by having some refreshments and settling in. Then we will do some activities which are described in more detail below.

What do I have to do?

Once you have agreed to join the group and signed the consent

You will be asked to think about three things:

- Your attitude to falls and any thoughts about fall prevention
- Your experience of the exercise intervention (whether good or bad – I'd like to know!)
- What if anything, made you leave the programme OR continue with it

Then you will put your thoughts or the most important ideas on sticky notes.

After that we will discuss as a small group. Everyone is encouraged to participate and have his or her say. I will chair the group to make sure we cover all the areas in the time we have. To finish, we will look at the sticky notes again and arrange them on a big sheet of paper in order of the most important to the least important.

What else do I need to know?

- As always, your participation is entirely voluntary. You do not have to agree to join the group. Even if you do say yes and arrive, you may leave at any time without having to explain why.
- Unfortunately, we cannot pay you for your participation, but you will be given refreshments and a small token of my appreciation for your time.
- I expect the discussion to take about 90 minutes plus time for tea, so you need to allow about two hours of your time overall.
- The discussion session will be audio-recorded. The conversation will be written out in full and then analysed. Your name will not be used in the write up, rather you will be given a pseudonym. If you would like to choose your own pseudonym, please let me know; otherwise I will allocate one to you.
- Unlike the other parts of the research programme so far, you will know who the other members of the group are. This means that while I can protect your identity and privacy in any write-up of the results, the other participants will know who you are and what you think. I will ask everyone to keep the session confidential to "outsiders" but cannot do more than this. Thus, I can keep your results anonymous and confidential to me, but not within the group.

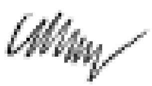
What about risks and benefits?

- While there is no direct benefit for you, your experience will give us valuable feedback about the study and the design of any future studies.
- It is unlikely that much personal or distressing information will be revealed in the group. However, should you become emotional or upset you will receive immediate psychological first aid after the session and a referral if you request it.
- There is a potential risk in terms of a breach of confidentiality in the group. I will ask everyone present to keep the group's confidence but cannot guarantee they do so.
- Your name will never be entered into the report; and the site will not be identifiable, so it will not be possible for anyone reading the report to trace your thoughts and comments back to you.
- These precautions, plus the voluntary nature of the study, make the risk/benefit ratio acceptable

Please do feel free to ask any questions you might have. As you know, the overall project has approval from our Human Research Ethics Committee (reference number HREC 818/2015) and permission to conduct this part of the trial has been granted.

Should you have any questions please don't hesitate to ask. My supervisors' names and contact details appear below; as do the details of the Chair of the Ethics Committee.

Thank you again for your time



Christine Rogers

Contact details of supervisors:

Student: Christine Rogers, Telephone 021 406 6315. Email: Christine.Rogers@uct.ac.za

Supervisors:

Prof Dele Amosun: Telephone 021 406 6628 Email: Seyi.Amosun@uct.ac.za

Dr Delva Shamley: Telephone 021 650 1975 Email: Delva.Shamley@uct.ac.za

If you have any ethical queries or concerns, in particular regarding individual rights or the welfare of any research participant, please contact

Faculty of Health Sciences Human Research Ethics Committee

Telephone: 021 406 6492 Email: sumayah.ariefdien@uct.ac.za

Consent Form

I have read this consent form and the Information Sheet and had the opportunity to ask any questions I may have.	
I agree to participate in this focus group. The decision I have made is completely my own. I agree for my results to be used for research purposes and that the results may be published.	
I know that I can leave the group at any time. Changing my mind about being in the group will not make any difference to my participation in the overall programme.	
I know that this session will be audio-recorded, and the results written up. I will be given (or may choose) a pseudonym to protect my identity. The identity of the site is protected.	
I understand that the nature of this group is that the others in it will know who I am and what I think.	
I understand that there are minimal risks involved participating in the group. If I become distressed or emotional, I may ask the researcher to refer me appropriately or counsel me after the group.	
I understand that I will not receive any payment for my participation in the group.	

Study number: [ ]

Signature of Participant: ____________________Date: ______________________

Pseudonym: _______________________________

Appendix E MiniBESTest Balance Evaluation Systems Test

Appendix E.1 Introduction.

The MiniBESTest was adapted from the original BESTest which examines all the sub-systems supporting balance and postural control [871]. Research suggests the original BESTest is rarely used by clinicians (<1%) to examine balance and related fall risk, although elements of the test are used more commonly, such as SLS (79.1% of a poll of physiotherapists in Canada) and TUG (27.6%) [872].

Anson and colleagues[873] evaluated psychometric data for the MiniBESTest in a population of older adults with non-specific balance deficits. They found excellent test-retest reliability (ICC[71] 0.84; 95%CI 0.73 – 0.90); and standard error of mean (SEM) = 1.4. The MiniBESTest's responsiveness was examined and calculated as MDC[72]$_{95}$ = 4.0[873]. A recent Thai study found the MiniBESTest (AUC[73] 0.71) superior to the BBS (AUC 0.59) and TUG (AUC 0.41) in correctly predicting falls [875]. The feasibility study was designed prior to the research cited above, and the MiniBESTest included due to the uncertainty of which outcome measures would be helpful in a large-scale RCT. Recent research has examined the role of the MiniBESTest and fall risk in older adults and justifies the choice of test in the current design [210, 607].

---

[71] Intra-class coefficient.
[72] Minimum Detectable Change.
[73] Area Under Curve (calculated in a Receiver Operating Characteristic (ROC) statistical test). ROC tests assess the accuracy of a diagnostic test or prediction models 874. Obuchowski NA, Bullen JA. Receiver operating characteristic (ROC) curves: review of methods with applications in diagnostic medicine. Phys Med Biol. 2018;63(7):07TR1..

Appendix E.2 MiniBESTest procedure instructions and score sheet [(604)].

ANTICIPATORY SUBSCORE (ITEMS 1-3) SUBTOTAL: ……./6

1. SIT TO STAND

Instruction: ***"****Cross your arms across your chest. Try not to use your hands unless you must. Do not let your legs lean against the back of the chair when you stand. Please stand up now.****"***

(2) Normal: Comes to stand without use of hands and stabilizes independently.

(1) Moderate: Comes to stand WITH use of hands on first attempt.

(0) Severe: Unable to stand up from chair without assistance OR needs several attempts with use of hands.

2. RISE TO TOES

Instruction: *"Place your feet shoulder width apart. Place your hands on your hips. Try to rise as high as you can onto your toes. I will count out loud to 3 seconds. Try to hold this pose for at least 3 seconds. Look straight ahead. Rise now."*

(2) Normal: Stable for 3 s with maximum height.

(1) Moderate: Heels up, but not full range (smaller than when holding hands), OR noticeable instability for 3 s.

(0) Severe: < 3 s.

3. STAND ON ONE LEG

Instruction: "Look straight ahead. Keep your hands on your hips. Lift your leg off of the ground behind you without touching or resting your raised leg upon your other standing leg. Stay standing on one leg as long as you can. Look straight ahead. Lift now."

Left: *Time in Seconds Trial 1: _____Trial 2: _____*

(2) Normal: 20 s.

(1) Moderate: < 20 s.

(0) Severe: Unable.

Right: *Time in Seconds Trial 1: _____Trial 2: _____*

(2) Normal: 20 s.

(1) Moderate: < 20 s.

(0) Severe: Unable

To score each side separately use the trial with the longest time.

To calculate the sub-score and total score use the side [left or right] with the lowest numerical score [i.e. the worse side].

REACTIVE POSTURAL CONTROL (ITEMS 4 – 6) SUBTOTAL …../6

4. COMPENSATORY STEPPING CORRECTION- FORWARD

Instruction: "Stand with your feet shoulder width apart, arms at your sides. Lean forward against my hands beyond your forward limits. When I let go, do whatever is necessary, including taking a step, to avoid a fall."

(2) Normal: Recovers independently with a single, large step (second realignment step is allowed).

(1) Moderate: More than one step used to recover equilibrium.

(0) Severe: No step, OR would fall if not caught, OR falls spontaneously.

5. COMPENSATORY STEPPING CORRECTION- BACKWARD

Instruction: "Stand with your feet shoulder width apart, arms at your sides. Lean backward against my hands beyond your backward limits. When I let go, do whatever is necessary, including taking a step, to avoid a fall."

(2) Normal: Recovers independently with a single, large step.

(1) Moderate: More than one step used to recover equilibrium.

(0) Severe: No step, OR would fall if not caught, OR falls spontaneously.

6. COMPENSATORY STEPPING CORRECTION- LATERAL

Instruction: "Stand with your feet together, arms down at your sides. Lean into my hand beyond your sideways limit. When I let go, do whatever is necessary, including taking a step, to avoid a fall."

Left

(2) Normal: Recovers independently with 1 step (crossover or lateral OK).

(1) Moderate: Several steps to recover equilibrium.

(0) Severe: Falls or cannot step.

Right

(2) Normal: Recovers independently with 1 step (crossover or lateral OK).

(1) Moderate: Several steps to recover equilibrium.

(0) Severe: Falls or cannot step.

Use the side with the lowest score to calculate sub-score and total score.

SENSORY ORIENTATION (ITEMS 7 – 9) SUBSCORE …../6

7. STANCE (FEET TOGETHER); EYES OPEN, FIRM SURFACE

Instruction: "Place your hands on your hips. Place your feet together until almost touching. Look straight ahead. Be as stable and still as possible, until I say stop."

Time in seconds: ________

(2) Normal: 30 s.

(1) Moderate: < 30 s.

(0) Severe: Unable.

8. STANCE (FEET TOGETHER); EYES CLOSED, FOAM SURFACE

Instruction: "Step onto the foam. Place your hands on your hips. Place your feet together until almost touching. Be as stable and still as possible, until I say stop. I will start timing when you close your eyes."

Time in seconds: ________

(2) Normal: 30 s.

(1) Moderate: < 30 s.

(0) Severe: Unable.

9. INCLINE- EYES CLOSED

Instruction: "Step onto the incline ramp. Please stand on the incline ramp with your toes toward the top. Place your feet shoulder width apart and have your arms down at your sides. I will start timing when you close your eyes."

Time in seconds: ________

(2) Normal: Stands independently 30 s and aligns with gravity.

(1) Moderate: Stands independently <30 s OR aligns with surface.

(0) Severe: Unable.

DYNAMIC GAIT (ITEMS 10 -14) SUBTOTAL ……/10

10. CHANGE IN GAIT SPEED

Instruction: “Begin walking at your normal speed, when I tell you ‘fast’, walk as fast as you can. When I say ‘slow’, walk very slowly.”

(2) Normal: Significantly changes walking speed without imbalance.

(1) Moderate: Unable to change walking speed or signs of imbalance.

(0) Severe: Unable to achieve significant change in walking speed AND signs of imbalance.

11. WALK WITH HEAD TURNS – HORIZONTAL

Instruction: “Begin walking at your normal speed, when I say “right”, turn your head and look to the right. When I say “left” turn your head and look to the left. Try to keep yourself walking in a straight line.”

(2) Normal: performs head turns with no change in gait speed and good balance.

(1) Moderate: performs head turns with reduction in gait speed.

(0) Severe: performs head turns with imbalance.

12. WALK WITH PIVOT TURNS

Instruction: “Begin walking at your normal speed. When I tell you to ‘turn and stop’, turn as quickly as you can, face the opposite direction, and stop. After the turn, your feet should be close together.”

(2) Normal: Turns with feet close FAST (< 3 steps) with good balance.

(1) Moderate: Turns with feet close SLOW (>4 steps) with good balance.

(0) Severe: Cannot turn with feet close at any speed without imbalance.

13. STEP OVER OBSTACLES

Instruction: “Begin walking at your normal speed. When you get to the box, step over it, not around it and keep walking.”

(2) Normal: Able to step over box with minimal change of gait speed and with good balance.

(1) Moderate: Steps over box but touches box OR displays cautious behaviour by slowing gait.

(0) Severe: Unable to step over box OR steps around box.

14. TIMED UP & GO WITH DUAL TASK *[3 METER WALK]*

Instruction TUG: "When I say 'Go', stand up from chair, walk at your normal speed across the tape on the floor, turn around, and come back to sit in the chair."

Instruction TUG with Dual Task: "Count backwards by threes starting at ___. When I say 'Go', stand up from chair, walk at your normal speed across the tape on the floor, turn around, and come back to sit in the chair. Continue counting backwards the entire time."

TUG: ________seconds; Dual Task TUG: ________seconds

(2) Normal: No noticeable change in sitting, standing or walking while backward counting when compared to TUG without Dual Task.

(1) Moderate: Dual Task affects either counting OR walking (>10%) when compared to the TUG without Dual Task.

(0) Severe: Stops counting while walking OR stops walking while counting.

When scoring item 14, if subject's gait speed slows more than 10% between the TUG without and with a Dual Task the score should be decreased by a point.

TOTAL SCORE: ……/28

Appendix E.3 MiniBESTest Equipment and scoring descriptors.

Subject Conditions: Subject should be tested with flat-heeled shoes OR shoes and socks off.

Equipment:

- Temper® foam (also called T-foam 10cm thick, medium density T41 firmness rating)
- chair without arm rests or wheels
- incline ramp
- stopwatch
- a box (23cm height)
- 3 meter distance measured out and marked on the floor with tape [from chair].

Scoring: The test has a maximum score of **28** points from **14 items** that are each scored from 0-2.

“0” indicates the lowest level of function and “2” the highest level of function.

If a subject must use an assistive device for an item, score that item one category lower. If a subject requires physical assistance to perform an item, score “0” for that item.

For **Item 3** (stand on one leg) and **Item 6** (compensatory stepping-lateral) only include the score for one side (the worse score).

For **Item 3** (stand on one leg) select the best time of the 2 trials [from a given side] for the score.

For **Item 14** (timed up & go with dual task) if a person’s gait slows greater than 10% between the TUG without and with a dual task then the score should be decreased by a point.

1. Sit to stand	Note the initiation of the movement, and the use of the subject’s hands on the seat of the chair, the thighs, or the thrusting of the arms forward.
2. Rise to toes	Allow the subject two attempts. Score the best attempt. (If you suspect that subject is using less than full height, ask the subject to rise up while holding the examiners’ hands.) Make sure the subject looks at a non-moving target 4-12 feet away.

3. Stand on one leg	Allow the subject two attempts and record the times. Record the number of seconds the subject can hold up to a maximum of 20 seconds. Stop timing when the subject moves hands off of hips or puts a foot down. Make sure the subject looks at a non-moving target 4-12 feet ahead. Repeat on other side.
4. Compensatory stepping correction-forward	Stand in front of the subject with one hand on each shoulder and ask the subject to lean forward (Make sure there is room for them to step forward). Require the subject to lean until the subject's shoulders and hips are in front of toes. After you feel the subject's body weight in your hands, very suddenly release your support. The test must elicit a step. NOTE: Be prepared to catch subject.
5. Compensatory stepping correction – backward	Stand behind the subject with one hand on each scapula and ask the subject to lean backward (Make sure there is room for the subject to step backward.) Require the subject to lean until their shoulders and hips are in back of their heels. After you feel the subject's body weight in your hands, very suddenly release your support. Test must elicit a step. NOTE: Be prepared to catch subject.
6. Compensatory stepping correction - lateral	Stand to the side of the subject, place one hand on the side of the subject's pelvis, and have the subject lean their whole body into your hands. Require the subject to lean until the midline of the pelvis is over the right (or left) foot and then suddenly release your hold. NOTE: Be prepared to catch subject.
7. Stance (feet together): eyes open, firm surface	Record the time the subject was able to stand with feet together up to a maximum of 30 seconds. Make sure subject looks at a non-moving target 1.2 – 3.6m away.
8. Stance (feet together): eyes closed, foam	Use medium density Temper® foam, 10cm thick. Assist subject in stepping onto foam. Record the time the subject was able to stand in each condition to a maximum of 30 seconds. Have the subject step off the foam between trials. Flip the foam over between each trial to ensure the foam has retained its shape.
9. Incline – eyes closed	Aid the subject onto the ramp. Once the subject closes eyes, begin timing and record time up to 30s maximum. Note if there is excessive sway.

10. Change in gait speed	Allow the subject to take 3-5 steps at normal speed, and then say “fast”. After 3-5 fast steps, say “slow”. Allow 3-5 slow steps before the subject stops walking.
11. Walk with horizontal head turns	Allow the subject to reach normal speed, and give the commands “right, left” every 3-5 steps. Score if you see a problem in either direction. If subject has severe cervical restrictions allow combined head and trunk movements.
12. Walk with pivot turns	Demonstrate a pivot turn. Once the subject is walking at normal speed, say “turn and stop.” Count the number of steps from “turn” until the subject is stable. Imbalance may be indicated by wide stance, extra stepping or trunk motion.
13. Step over obstacles	Place the box (23 cm height) 3m away from where the subject will begin walking. Two shoeboxes taped together works well to create this apparatus.
14. Timed Up and Go with dual task (see Appendix N.4 for more information)	Use the TUG time to determine the effects of dual tasking. The subject should walk a 3 meter distance. TUG: Have the subject sitting with the subject’s back against the chair. The subject will be timed from the moment you say “Go” until the subject returns to sitting. Stop timing when the subject’s buttocks hit the chair bottom and the subject’s back is against the chair. The chair should be firm without arms. TUG with Dual Task (also referred to as TUG-COG): While sitting determine how fast and accurately the subject can count backwards by threes starting from a number between 100-90. Then, ask the subject to count from a different number and after a few numbers say “Go”. Time the subject from the moment you say “Go” until the subject returns to the sitting position. Score dual task as affecting counting or walking if speed slows (>10%) from TUG and or new signs of imbalance.

Retrieved 9 April 2014 from
http://www.bestest.us/files/7413/6380/7277/MiniBEST_revised_final_3_8_13.pdf

Normative data for the MiniBESTest are as follows: Mean (SD) scores: ages 60-69: 24.7/28 (2.2); ages 70-79: 21.0/28 (SD3.1) and ages 80-89: 19.6/28 (4.2) [876]. The impact of increasing age is marked.

Appendix E.4 Timed-up-and-Go.

TUG procedure was conducted as above and was evaluated as an independent test as well as a component of the MiniBESTest. An MA [(19)] revealed that a cut-off point of ≥13.5 seconds limits the diagnostic accuracy of the TUG; and cautioned regarding its use for identification of community-dwelling adults at high risk of falling in clinical practice. However, it is commonly used in both research and clinical practice [(386, 818)] and is recommended by the professional societies and in clinical guidelines[74]. The Centers for Disease Control's recommendation of a 12s cut-off [(348)] was implemented.

Rydwik and colleagues' [(2)] SR revealed an ICC of 0.91 and suggested the TUG was able to discriminate between individuals with falls or no falls; but not fall risk. The same review demonstrated known-groups validity and concluded the test was reliable and valid, but that responsiveness data was lacking [(2)]. More recently, TUG-cognitive was reported to have significant correlation with fall events [(877)]. In addition, strong correlations between TUG and objective measures of gait have been noted [(878)]. Normative data [(879)] for TUG are shown in Appendix Table N.4; which clearly demonstrates the impact of sex and increasing age.

Table E.1. Normative data for TUG by age and sex.

	Age (M) 65-69 years	(M) 70-74 years	(M) 75-79 years	(M) 80-84 years	Age (F) 65-69 years	(F) 70-74 years	(F) 75-79 years	(F) 80-84 years
N	418	348	205	73	475	326	172	67
Mean TUG score (seconds)	10.4	10.9	12.2	13.3	11.4	12.0	13.1	14.3
Standard Error	0.1	0.1	0.2	0.3	0.1	0.1	0.2	0.3
95%CI	10.2 – 10.7	10.6 – 11.1	11.9 – 12.6	12.6 – 13.7	11.2 – 11.7	11.7 – 12.2	12.7 – 13.4	13.7 – 14.8

Legend: (M): males (F): females.

[74] See discussion in Literature Review.

Appendix F Dynamic Gait Index

The DGI [880] is a widely used measure of dynamic balance during gait activities, yielding information regarding functional stability useful for fall risk prediction [881]. Item 1 on the DGI serves as a baseline and examines self-paced (preferred) walking on a level surface [614]. In this study, Item 1 was timed to produce preferred walking speed in m/s; and items embedded in the MiniBESTest were not repeated.

Challenges to dynamic balance are added by changes in speed or direction, head turns (horizontal and vertical); avoiding obstacles and climbing stairs [614]. Ordinal scores are awarded using descriptors ranging from 0 (severe impairment) to 3 which is normal [614]. Total score is 24, which is the best possible result [614]. Scores of ≤19 suggest fall risk and are used to monitor progress in therapy [3].

While concurrent validity with TUG has been established along with ICC between 0.84 – 0.96 [614]; ceiling effects in high functioning older adults limit the DGI's responsiveness [881]. Romero and colleagues [3] established an MDC_{95} of 2.9 DGI points. Table F.1 shows normative values per decade for DGI [616]. Note the widening range with ageing.

Table F.1. DGI scores per decade of life.

Decade of life	Mean DGI score	SD	Inter-quartile range
6th	23.9	0.4	22 - 24
7th	23.2	0.9	21 - 24
8th	22.0	2.0	13 - 24

Preferred walking speed.

Item 1 of the DGI was time to calculate preferred walking speed in m/s. Preferred walking speed is a valid, reliable and sensitive test of functional status and overall health and is widely used clinically and in research [882]. There are strong correlations between reduced preferred walking speed and adverse events in older adults, including falls, morbidity, and mortality even in healthy older populations [883]. Moreover, this 'sixth vital sign' [882] may allow responses to rehabilitation and fall risk reduction to be estimated [882]. Individuals with a walking speed of <1.0m/s are at higher risk for falls [883].

Preferred walking speed is a responsive measure with clinically meaningful changes ranging from small (0.05m/s) to substantial (0.1m/s) over 4 or 10m courses [882]. Table F.1 presents results from a MA [884] pooling preferred walking speeds and the slowing with age is most apparent.

Table F.2. Results from meta-analysis demonstrating impact of age and sex on preferred walking speed.

Sex/age	Number of participants pooled	Gait speed in cm/s (range)	Grand mean 95%CI range (cm/s)
M 60-69 years	941	133.9 (126 – 141.2)	103.3 – 159.0
M 70 – 79 years	3, 671	126.2 (121.0 – 132.2)	95.7 – 141.5
M 80 – 99 years	1, 091	96.8 (83.4 – 110.1)	66.38 – 122.1
F 60 – 69 years	5, 013	124.1 (118.3 – 130.0)	97.0 – 145.0
F 70 – 79 years	8, 591	113.2 (107.2 – 119.2)	83.0 – 150.0
F 80 – 99 years	2, 152	94.3 (85.2 – 103.4)	55.7 – 117.0

Legend: (M): male; (F): female; cm/s: centimetres per second.

Number of steps for 360° pivot turn and stop.

DGI item 5 requires a pivot 360° turn and stop. The number of steps to complete the turn were counted and analysed separately. Researchers have known for decades the greater the number of steps required to complete the action, the higher the risk of falls (885). The DGI instrument and method follows.

Dynamic Gait Index method and instructions

1. Gait level surface* _____

Instructions: Walk at your normal speed from here to the next mark (6.1m)

Grading: Mark the lowest category that applies.

(3) Normal: Walks 6.1m, no assistive devices, good speed, no evidence for imbalance, normal gait pattern

(2) Mild Impairment: Walks 6.1m, uses assistive devices, slower speed, mild gait deviations.

(1) Moderate Impairment: Walks 6.1m, slow speed, abnormal gait pattern, evidence for imbalance.

(0) Severe Impairment: Cannot walk 6.1m without assistance, severe gait deviations or imbalance.

*Note: preferred walking speed was embedded here and recorded as metres per second. The participant was at his/her preferred speed when timing commenced (i.e. dynamic start), and the end of the timing period/distance was not announced to prevent slowing. Timing was initiated when the first foot stepped over the first marker and ended when the first foot passed over the second marker. The participant was asked to “do a normal walk”.

2. Change in gait speed _____

Instructions: Begin walking at your normal pace (for 1.5m), when I tell you “go,” walk as fast as you can (for 1.5m). When I tell you “slow,” walk as slowly as you can (for 1.5m).

Grading: Mark the lowest category that applies.

(3) Normal: Able to smoothly change walking speed without loss of balance or gait deviation. Shows a significant difference in walking speeds between normal, fast and slow speeds.

(2) Mild Impairment: Is able to change speed but demonstrates mild gait deviations, or not gait deviations but unable to achieve a significant change in velocity or uses an assistive device.

(1) Moderate Impairment: Makes only minor adjustments to walking speed or accomplishes a change in speed with significant gait deviations, or changes speed but has significant gait deviations, or changes speed but loses balance but is able to recover and continue walking.

(0) Severe Impairment: Cannot change speed or loses balance and has to reach for wall or be caught.

3. Gait with horizontal head turns _____

Instructions: Begin walking at your normal pace. When I tell you to "look right," keep walking straight, but turn your head to the right. Keep looking to the right until I tell you, "look left," then keep walking straight and turn your head to the left. Keep your head to the left until I tell you "look straight", then keep walking straight, but return your head to the centre.

Grading: Mark the lowest category that applies.

(3) Normal: Performs head turns smoothly with no change in gait.

(2) Mild Impairment: Performs head turns smoothly with slight change in gait velocity, i.e., minor disruption to smooth gait path or uses walking aid.

(1) Moderate Impairment: Performs head turns with moderate change in gait velocity, slows down, staggers but recovers, can continue to walk.

(0) Severe Impairment: Performs task with severe disruption of gait, i.e., staggers outside 38cm path, loses balance, stops, reaches for wall.

4. Gait with vertical head turns _____

Instructions: Begin walking at your normal pace. When I tell you to "look up," keep walking straight, but tip your head up. Keep looking up until I tell you, "look down," then keep walking straight and tip your head down. Keep your head down until I tell you "look straight" then keep walking straight, but return your head to the centre.

Grading: Mark the lowest category that applies.

(3) Normal: Performs head turns smoothly with no change in gait.

(2) Mild Impairment: Performs head turns smoothly with slight change in gait velocity, i.e., minor disruption to smooth gait path or uses walking aid.

(1) Moderate Impairment: Performs head turns with moderate change in gait velocity, slows down, staggers but recovers, can continue to walk.

(0) Severe Impairment: Performs task with severe disruption of gait, i.e., staggers outside 38cm path, loses balance, stops, reaches for wall.

5. Gait and pivot turn _____

Instructions: Begin walking at your normal pace. When I tell you, “turn and stop,” turn as quickly as you can to face the opposite direction and stop.

Grading: Mark the lowest category that applies.

(3) Normal: Pivot turns safely within 3 seconds and stops quickly with no loss of balance.

(2) Mild Impairment: Pivot turns safely in > 3 seconds and stops with no loss of balance.

(1) Moderate Impairment: Turns slowly, requires verbal cueing, requires several small steps to catch balance following turn and stop.

(0) Severe Impairment: Cannot turn safely, requires assistance to turn and stop.

Number of steps noted here.

6. Step over obstacle ____

Instructions: Begin walking at your normal speed. When you come to the shoebox, step over it, not around it, and keep walking.

Grading: Mark the lowest category that applies.

(3) Normal: Is able to step over the box without changing gait speed, no evidence of imbalance.

(2) Mild Impairment: Is able to step over box but must slow down and adjust steps to clear box safely.

(1) Moderate Impairment: Is able to step over box but must stop, then step over. May require verbal cueing.

(0) Severe Impairment: Cannot perform without assistance.

7. Step around obstacles _____

Instructions: Begin walking at normal speed. When you come to the first cone (about 3m away), walk around the right side of it. When you come to the second cone (3m past first cone), walk around it to the left.

Grading: Mark the lowest category that applies.

(3) Normal: Is able to walk around cones safely without changing gait speed; no evidence of imbalance.

(2) Mild Impairment: Is able to step around both cones but must slow down and adjust steps to clear cones.

(1) Moderate Impairment: Is able to clear cones but must significantly slow, speed to accomplish task, or requires verbal cueing.

(0) Severe Impairment: Unable to clear cones, walks into one or both cones, or requires physical assistance.

8. Steps _____

Instructions: Walk up these stairs as you would at home**, i.e., using the railing if necessary. At the top, turn around and walk down.

Grading: Mark the lowest category that applies.

(3) Normal: Alternating feet, no rail.

(2) Mild Impairment: Alternating feet, must use rail.

(1) Moderate Impairment: Two feet to a stair, must use rail.

(0) Severe Impairment: Cannot do safely.

**note due to many South African homes not having steps, the words “as you normally would” will be substituted for “as you would at home”. In facilities where steps were not readily available, participants were asked how they normally negotiated steps.

TOTAL SCORE: ___ / 24

Appendix G Monitoring Logs

Appendix G.1 Exercise Log.

Study number: **Dec 20..**

	MONDAY	TUESDAY	WED	THURSDAY	FRIDAY	SAT/SUN
WEEK 1	1 Exercised: Y/N Duration: Walk: Y/N Duration:	2 Exercised: Y/N Duration: Walk: Y/N Duration:	3 Exercised: Y/N Duration: Walk: Y/N Duration:	4 Exercised: Y/N Duration: Walk: Y/N Duration:	5 Exercised: Y/N Duration: Walk: Y/N Duration:	6/7 Exercised: Y/N Duration: Walk: Y/N Duration:
WEEK 2	8 Exercised: Y/N Duration: Walk: Y/N Duration:	9 Exercised: Y/N Duration: Walk: Y/N Duration:	10 Exercised: Y/N Duration: Walk: Y/N Duration:	11 Exercised: Y/N Duration: Walk: Y/N Duration:	12 Exercised: Y/N Duration: Walk: Y/N Duration:	13/14 Exercised: Y/N Duration: Walk: Y/N Duration:

WEEK 3	15 Exercised: Y/N Duration: Walk: Y/N Duration:	16 Exercised: Y/N Duration: Walk: Y/N Duration:	17 Exercised: Y/N Duration: Walk: Y/N Duration:	18 Exercised: Y/N Duration: Walk: Y/N Duration:	19 Exercised: Y/N Duration: Walk: Y/N Duration:	20/21 Exercised: Y/N Duration: Walk: Y/N Duration:

Appendix G.2 Log of falls, injuries and expenses incurred.

Participant number:

Please complete the following each month (we will send you a reminder!):

(Please note, we also want to know about trips, slips and near-misses)

2017/8	Date/s of fall, slip or trip	What happened?	Injury sustained (see note below table): A, B, C, D, E
January			
February			
March			
April			
May			

June

July

August

September

October

November

December

Note:

If you have fallen at any time, please indicate the type of injury you sustained by entering A, B, C, D, or E in the “Injury sustained” column using the descriptions of types of injuries below (please ask if you are not sure):

Consequences of falls – fill in A, B, C, D or E in the appropriate column

□ A – Serious injury: needed to be admitted to hospital or to the accident and emergency unit with fractured bones, head or internal injuries

□ B – Moderate injury: wounds, bruises, cuts requiring a medical/health professional examination such as physical examination, X-ray, sutures (stiches)

□ C – Minor injury: minor bruises or cuts not requiring health professional assistance, reduction in physical activities for at least three days

□ D – No injury: no physical injury detected

□ E – no injury but afraid of falling again

Please complete the next page as well!

Please complete this log regarding the costs incurred due to your fall. Complete for each and every fall, even if you had no injuries or costs you can think of. See the examples below for guidance

Date and time	Injury category A-E – see above	Action taken	Treatment	Tests	Hospitalisation Days/cost per day	Surgery Type/cost	Physiotherapy (post-op or not). Visits/cost of visit	Medication, type and cost	Equipment	Other
4.2.2016 11.30 pm	A, fractured hip	GP (house-call, R600), ambulance to hospital (R2 500)	Admission	X-Rays (R1000) Blood tests (R1000) Lung-function tests (R2000)	10 days at R4 500 per day	Hip replacement, R80 000 including theatre fees and anaesthetist	In-patient 10 visits at R400 Out-patient 15 visits at R400	Panado, (R100); Voltaren, (R500)	Crutch hire (R500)	Step-down facility 10 days at R4 500 per day; carer once home, 10 days at R500 per day
5.5.2016, 8am	C, minor cuts and bruises	No doctor required	Self-medicated with Brufen and Arnica gel	None	None	None	None	Brufen, (R30); Arnica gel (R80)	None	Needed to send washing to laundromat instead of doing it myself, (R50)

Appendix H Cognitive screening and Mini-Cog

Appendix H.1 Introduction.

Various tests exist to screen for cognitive change in older people, the most common of which is the Mini-Mental State Examination [(581)]. However, there is evidence that the Mini-Mental State Examination (MMSE) may not be widely applicable, and its validity has been challenged by differences in the educational, cultural and linguistic backgrounds of those being tested [(886)]. Due to these constraints, other instruments such as the Mini-Cog have been shown to be as good [(581)], or even better than the MMSE with less bias [(887)], suggesting it is an effective screening tool for older adults in various settings [(573, 579, 583)].

The Mini-Cog is a simple, evidence-based test which is easy to administer and score and uses only minimal equipment [(579, 888)]. The test requires memorisation of three words and a clock drawing test, thereafter memory of the three assigned words is tested [(582)]. The clock drawing test evaluates different facets of cognitive integrity including auditory and visual comprehension, knowledge and executive function [(889)] and serves as a distraction between the memory tasks [(582)]. The Mini- Cog's sensitivity is 74% and specificity for dementia is 89% [(890)]. Administration time is under three minutes and it is easy for non-English speakers [(890)] making it suitable in the South African context.

Scoring is between 0 and 5; one point is given for each word correctly recalled [(582)]. If the clock is correctly drawn (as indicated by the instructions) two points are awarded, and no points if it is abnormal [(582)]. Scores of 0-2 suggest probable impairment [(582)] and resulted in exclusion from the research, while scores between 3 and 5 suggest low likelihood of cognitive impairment [(573)].

Appendix H.2 Permission to use Mini-Cog.

Christine Rogers

From:	soob <soob@uw.edu>
Sent:	15 June 2015 09:55 PM
To:	Christine Rogers
Subject:	Re: Request for permission to use Mini-Cog in research study at the University of Cape Town

Ok. Thanks for providing these important details. And I appreciate the subtleties you highlight. Just so you know - no cognitive screen is proven to be a generally valid means of excluding participants - depends on the study goals and protocol.
Please use the Alz.org version of the mini/cog with the original cut score (0-2 high likelihood of dementia, 3-5 lower likelihood).
Good luck with your study!
Best,
Soo

Sent from my iPhone

On Jun 15, 2015, at 3:46 AM, Christine Rogers <christine.rogers@uct.ac.za> wrote:

Dear Dr Borson

Thank you so much for your response. In essence the study is a clinical trial (cluster randomised, single-blinded) of older adults at risk for falls. Risk will be assessed by previous fall history; number of illnesses and prescription medications and scores on a variety of balance tests. Interventions will be the Otago Exercise Programme as the gold standard and then a computer-based intervention aimed to improve balance and strength and thus reduce the risk of falls. Endpoints include occurrence and time to fall, injurious falls and then improvements on the measures of balance.

As you will know, sadly South Africa has a history of gross human rights abuses and there is still evidence that human/patient rights abuses continue in clinical practice. The University of Cape Town has a proud record of opposition to such violations which also continues today. Our Human Research Ethics Committees and other regulatory authorities for clinical research are very thorough in terms of attention to fairness and human rights protection and rightly so. In this country older adults would be regarded as a vulnerable group upon which to do research (even if cognitively intact). My reasoning for screening for cognitive issues is to ensure that there is every chance that the informed consent procedure is fair and that potential participants are able to make an autonomous decision. The law in South Africa is that proxy consent can only be granted through a court order for each and every individual and so it would be very difficult to achieve this in order to do research on cognitively impaired participants. It is also unlikely that such court orders would be granted in order to conduct research, rather they would be reserved for decisions regarding implementing proven treatments where a person is not able to make the decision as to accept or reject such treatment themselves. So while I agree we need more studies regarding fall prevention in cognitively impaired individuals, it is not part of my current study nor is it likely that such a study could be conducted in South Africa given the legal constraints.

Furthermore, the research I have accessed on the Mini-Cog suggests that is relatively resistant to the effects of language, culture and socio-economic status

1

which are important considerations in South Africa; and thus my request to use this test rather than another such as the MMSE. Should you be gracious enough to grant permission, given the constraints of my study, I would request that you recommended the precise scale that you would approve. I have seen the one on the Alzheimer's website as well as the one in your original work.

Thank you once again,

Best wishes

Christine

From: soob [mailto:soob@uw.edu]
Sent: 12 June 2015 03:45 PM
To: Christine Rogers
Subject: Re: Request for permission to use Mini-Cog in research study at the University of Cape Town

Dear Ms. Rogers,
Thank you for your interest in the Mini-Cog, and I wish you every success in your research. I have a couple of questions.
May I learn more about the study? (I am hoping that you don't plan to use the Mini-Cog to exclude individuals from preventive interventions - we need more studies that address fall prevention in cognitively impaired seniors.)
Which Mini-Cog form do you plan to use? I have seen various 'versions' on the internet that aren't always correct.
Best,
Soo Borson MD

From: Christine Rogers <christine.rogers@uct.ac.za>
Sent: Friday, June 12, 2015 2:14 AM
To: soob
Subject: Request for permission to use Mini-Cog in research study at the University of Cape Town

Dear Professor Borson

I am a staff member and Ph.D. student at the University of Cape Town. My doctoral study is examining the clinical and cost-effectiveness of two interventions to reduce fall risk in older adults. As part of assessing potential participants, I need a mental capacity screening test and would like to use the Mini-Cog. I am thus writing to you for permission to use the instrument and hope that you will grant it.

Yours faithfully

Christine

Christine Rogers

Senior Audiology Lecturer
University of Cape Town

Division of Communication Sciences and Disorders

2

Appendix H.3 Mini-Cog™.

MINI-COG™

Instructions

ADMINISTRATION	SPECIAL INSTRUCTIONS
1. Get patient's attention and ask him or her to remember three unrelated words. Ask patient to repeat the words to ensure the learning was correct.	• Allow patient three tries, then go to next item. • The following word lists have been validated in a clinical study:[1-3] **Version 1**: • Banana • Sunrise • Chair **Version 2**: • Daughter • Heaven • Mountain **Version 3**: • Village • Kitchen • Baby **Version 4**: • River • Nation • Finger **Version 5**: • Captain • Garden • Picture **Version 6**: • Leader • Season • Table
2. Ask patient to draw the face of a clock. After numbers are on the face, ask patient to draw hands to read 10 minutes after 11:00 (or 20 minutes after 8:00).	• Either a blank piece of paper or a preprinted circle (other side) may be used. • A correct response is all numbers placed in approximately the correct positions AND the hands pointing to the 11 and 2 (or the 4 and 8). • These two specific times are more sensitive than others. • A clock should not be visible to the patient during this task. • Refusal to draw a clock is scored abnormal. • Move to next step if clock not complete within three minutes.
3. Ask the patient to recall the three words from Step 1.	Ask the patient to recall the three words you stated in Step 1.

Scoring

3 recalled words	Negative for cognitive impairment
1-2 recalled words + normal CDT	Negative for cognitive impairment
1-2 recalled words + abnormal CDT	Positive for cognitive impairment
0 recalled words	Positive for cognitive impairment

References

1. Borson S, Scanlan J, Brush M, Vitaliano P, Dokmak A. The mini-cog: a cognitive "vital signs" measure for dementia screening in multi-lingual elderly. Int J Geriatr Psychiatry. 2000;15(11):1021-1027.
2. Borson S, Scanlan JM, Chen P, Ganguli M. The Mini-Cog as a screen for dementia: validation in a population-based sample. J Am Geriatr Soc. 2003;51(10):1451-1454.
3. McCarten JR, Anderson P, Kuskowski MA et al. Finding dementia in primary care: the results of a clinical demonstration project. J Am Geriatr Soc. 2012;60(2):210-217.

CLOCK DRAWING TEST

Patient Name: ____________________________ **Date:** __________

800.272.3900 | alz.org®

alzheimer's association®

Appendix I Geriatric Depression Scale (short form)

Appendix I.1 Introduction.

The Geriatric Depression Scale (GDS) was developed as a self-report measure to screen for depression in older adults [891]. The GDS has been widely used [892] and correlates well with clinical diagnoses of depression [893]. The GDS is in the public domain and available free of charge [586]. The short form (GDS-SF) reduced 30 questions to 15 forced choice questions regarding subjective experiences of depression in the last week [585], and has been validated across different settings and populations [586]. The short form version has good psychometric properties [894]. Recent meta-analysis (MA) of the GDS-15 using a cut-off score of 5/15 demonstrated sensitivity of 0.89 (95%CI 0.80 – 0.94) and specificity of 0.77 (95% CI 0.65 – 0.86) [587]. The GDS-15 was used to screen participants for depression. The short form takes between five and seven minutes to complete [895]. The brevity and simplicity of the GDS may reduce older adults' anxiety about having to complete what could be perceived as a psychological test and enhance the completion rate (891).

Of the fifteen questions, ten indicate depression when answered affirmatively, and the remaining five when answered negatively [895]. Answers are totalled to give a score out of 15, while incomplete answers were subjected to a prorated score [896]. For example, if the answers are provided for 12/15 questions and four are highlighted, the score would be 4. Three answers were omitted, so one third of the omitted answers are added to the original score e.g. 4 + 1 = 5 [896]. A cut-off score of ≥5 suggests a positive screen for depression [894] and resulted in exclusion of the participant.

Appendix I.2 Geriatric Depression Scale (short form, 15 item).

Instructions:

Circle the answer that best describes how you felt over the past week.

1. Are you basically satisfied with your life?	Yes	No
2. Have you dropped many of your activities and interests?	Yes	No
3. Do you feel that your life is empty?	Yes	No
4. Do you often get bored?	Yes	No
5. Are you in good spirits most of the time?	Yes	No
6. Are you afraid that something bad is going to happen to you?	Yes	No
7. Do you feel happy most of the time?	Yes	No
8. Do you often feel helpless?	Yes	No
9. Do you prefer to stay at home, rather than going out and doing things?	Yes	No
10. Do you feel that you have more problems with memory than most?	Yes	No
11. Do you think it is wonderful to be alive now?	Yes	No
12. Do you feel worthless the way you are now?	Yes	No
13. Do you feel full of energy?	Yes	No
14. Do you feel that your situation is hopeless?	Yes	No
15. Do you think that most people are better off than you are?	Yes	No

Total Score: …….

Appendix I.3 Geriatric Depression Scale (short form, 15 items) Scoring Instructions.

Instructions:

Score 1 point for each **highlighted** answer.

1. Are you basically satisfied with your life?	Yes	**No**
2. Have you dropped many of your activities and interests?	**Yes**	No
3. Do you feel that your life is empty?	**Yes**	No
4. Do you often get bored?	**Yes**	No
5. Are you in good spirits most of the time?	Yes	**No**
6. Are you afraid that something bad is going to happen to you?	**Yes**	No
7. Do you feel happy most of the time?	Yes	**No**
8. Do you often feel helpless?	**Yes**	No
9. Do you prefer to stay at home, rather than going out and doing things?	**Yes**	No
10. Do you feel that you have more problems with memory than most?	**Yes**	No
11. Do you think it is wonderful to be alive now?	Yes	**No**
12. Do you feel worthless the way you are now?	**Yes**	No
13. Do you feel full of energy?	Yes	**No**
14. Do you feel that your situation is hopeless?	**Yes**	No
15. Do you think that most people are better off than you are?	**Yes**	No

Total Score:

Geriatric Depression Scale (may be copied without permission) downloaded 30 April 2013 from: http://chcr.brown.edu/GDS_SHORT_FORM.pdf

Appendix J Case History

Appendix J.1 Case history questionnaire including Functional Comorbidities Index.

Good day

I would like to know some basic information about your health to assess if you may be suitable to join the trial. Please answer all the questions below. Thank you!

Name: …………………………………………………………………………………….

Date of birth: ……………………………………………………………………….

Male/ Female (please circle one)

Contact telephone number landline: …………………………………..

Cellular telephone:…………………………………………………………………

Email address: ……………………………………………………………………..

Highest educational achievement (e.g. grade at which left school, university degree):…………………….

Marital status: Single □ Living with life-partner □ Divorced □ Widowed □

Do you live in assisted living or frail care? Yes □ No □

Are you computer literate? Yes □ No □

Do you own your own computer? Yes □ No □

Are you planning to be in Cape Town for the next six months with no long absence (e.g. more than three weeks), for example holidays, planned? Yes □ No □

Are you already enrolled in a regular rehabilitation programme (e.g. on-going physiotherapy, cardiac rehabilitation at gym)? Yes □ No □

The questions below ask about if you have fallen and any medical conditions you may have

1. Have you fallen in the last year? This includes falls that are accidents like falling after slips and trips. Yes □ No □

2. How many times have you fallen in the last year?.................... (Number of times)

Below is a list of consequences of falls. In question 3 you will be asked the cause and settings of the falls. Please use either A, B, C, D or E to describe the results of the fall for each and every fall you have had in the last year.

Consequences of falls – fill in A, B, C, D or E in the appropriate column below (Question 3)

□ A – Serious injury: needed to be admitted to hospital or to the accident and emergency unit with fractured bones, head or internal injuries

□ B – Moderate injury: wounds, bruises, cuts requiring a medical/health professional examination such as physical examination, X-ray, sutures (stiches)

□ C – Minor injury: minor bruises or cuts not requiring health professional assistance, reduction in physical activities for at least three days

□ D – No injury: no physical injury detected

□ E – no injury but afraid of falling again

3. Regarding your falls **<u>in the last year</u>**, please fill in the following:

Number of falls outdoors……….. Number of falls indoors (e.g. at home):…………..

	Yes/No	Number of fall/s	Consequences
Cause of falls Tripping (over an obstacle)			Circle: A, B, C, D, E Using the descriptions above
Slipping (slippery surface)			Circle: A, B, C, D, E Using the descriptions above
Fall when standing up			A, B, C, D, E
Falling from bed			A, B, C, D, E

4. Below is a list of symptoms commonly experienced by people concerning dizziness and balance[75]. Please tick **all** that apply to you:

Symptom/sensation	Tick if **YES**
Rotation or spinning of surroundings	
Floating sensation	
Tendency to fall	
Fainting or almost fainting sensations	
Rotation or spinning of head/self	
Nausea	
Sudden slips or trips	
Sensation provoked by changing positions (e.g. turning head, rolling over in bed)	
Sensation provoked by changing between lying/sitting/standing	
Sensation provoked by physical strain	
Sensation provoked by arising from chair	

5. Please tick any chronic illnesses you may have (Functional Comorbidities Index)

Arthritis (rheumatoid and osteoarthritis) □
Osteoporosis □
Asthma □
Chronic Obstructive Pulmonary (Airways) Disease, Acute respiratory distress syndrome, or emphysema □
Angina □
Congestive heart failure (or heart disease) □
Heart attack (myocardial infarct) □
Neurological disease (such as multiple sclerosis or Parkinson's) □
Stroke or TIA □
Peripheral vascular disease □
Diabetes (types I and II) □
Upper gastrointestinal disease (ulcer, hernia, reflux) □
Depression □
Anxiety or panic disorders □
Visual impairment (such as cataracts, glaucoma, macular degeneration) □
Hearing Impairment (very hard of hearing, even with hearing aids) □
Degenerative disc disease (back disease, spinal stenosis, or severe chronic back pain) □

[75] Tuunainen, E., Rasku, J., Jäntti, P., & Pyykkö, I. (2014). Risk factors of falls in community-dwelling active elderly. *Auris, Nasis, Larynx, 41*, 10 – 16.

Obesity and/or BMI >30 □

6. Please list all prescription medications here (the dose does not matter, just the name of the drug or even just what it is for, e.g. thyroid, blood pressure). If you take more than one drug for blood pressure, please mention how many medicines you take for it (see the example):

Example: blood pressure (Pharmapress + 2 others)	

7. Are you able to stand and walk without assistance including devices such as walking sticks/canes? Yes □ No □

8. Do you have a pace-maker (cardiac pacer)? Yes □ No □

9. Do you have epilepsy? Yes □ No □

10. Is your body weight over 150 kg? Yes □ No □

11. Do you have any problem with either arm/hand that would stop you from using a remote control? Yes □ No □

12. Do you have any problem with either hip/leg/foot that would stop you from doing exercises standing or a walking programme? Yes □ No □

13. Is your eyesight (with corrected vision e.g. spectacles or lenses, if necessary) good enough to see a TV screen and to read instructions? Yes □ No □

14. Is your hearing (with a hearing aid, if necessary) good enough to hear instructions? Yes □ No □

15. How would you rate your memory in terms of the kinds of problems that you have? 1 = major problems and 10 = no problems. Please put a mark on the scale below to indicate what you think[76].

1	2	3	4	5	6	7	8	9	10

[76] Mullen, S. P., Wójcicki, T. R., Mailey, E. L., Szabo, A. N., Gothe, N. P., Olson, E. A., ... & McAuley, E. (2013). A profile for predicting attrition from exercise in older adults. *Prevention Science*, *14*(5), 489-496.

16. Do you have any neurological disorders like Parkinson's disease, damage from a stroke etc. that might prevent you from participating? If so, please give details here:

    ………………………………………………………………………………………… ………………………………………

17. Have you had recent (within the last year) hip or knee surgery including replacements? Yes □ No □

18. Do you have any severe or life-threatening illness (e.g. cancer, end-stage disease of organs such as kidney, lung or heart; even if you are not on treatment)?

    Yes □ No □

Thank you!

Appendix J.2 FRAT-up webpage screenshot.

Retrieved 29.3.2019 from http://ffrat.farseeingresearch.eu/runAssessment

Current risk of the subject: Unknown

Health profile of the subject:

Does the subject suffer rheumatic disease?	Yes	No	Use prevalence
Does the subject suffer Parkinson?	Yes	No	Use prevalence
Does the subject use sedatives?	Yes	No	Use prevalence
Does the subject live alone?	Yes	No	Use prevalence
Does the subject suffer any pain?	Yes	No	Use prevalence
Does the subject use a walking aid?	Yes	No	Use prevalence
Dizziness or unsteadiness last year?	Yes	No	Use prevalence
Urinary incontinence last year?	Yes	No	Use prevalence
Does the subject use antiepileptics?	Yes	No	Use prevalence
History of previous falls?	Yes	No	Use prevalence
Fear of falling (Deshpande)?	Yes	No	Use prevalence
History of previous strokes?	Yes	No	Use prevalence
Is the subject female?	Yes	No	Use prevalence
Does the subject use antihypertensives?	Yes	No	Use prevalence
Diabetes blood glucose 126?	Yes	No	Use prevalence
Visual acuity (3 meter):	Use prevalence		
Hearing impairment?:	Use prevalence		
Contrast sensitivity?:	Use prevalence		
Age:			

	☑ Use prevalence
Revised Walking Subscore:	☑ Use prevalence
Subject's number of IADL:	☑ Use prevalence
Number of drugs used by the subject:	☑ Use prevalence
How does the subject feel:	☑ Use prevalence
Number of ADL disabilities (0-6):	☑ Use prevalence
Physical activity level:	☑ Use prevalence
MMSE score:	☑ Use prevalence
Visual stereognosis:	☑ Use prevalence
CESD:	☑ Use prevalence

Run the assessment! Generate a report (.pdf)

Appendix K Euro-QoL EQ-5D-3L Health Questionnaire English version for South Africa

Introduction

The EQ-5D-3L measures health status and outcome of healthcare programmes across a myriad of settings and applications [(897)]. The EQ-5D-3L has been validated in South Africa [(898)] in different communities where the three level instrument performed well [(899)]. It is a simple, generic instrument, which has been stable since its development in 1990, apart from more levels added for each of the domains of mobility, self-are, usual activity, pain/discomfort and anxiety/depression [(899)].

Appendix K.1 Permission to use Euro-QoL EQ-5D-3L.

Christine Rogers

From:	Mandy van Reenen <vanreenen@euroqol.org>
Sent:	21 May 2015 02:43 PM
To:	Christine Rogers
Subject:	RE: New registration
Attachments:	Effective_South Africa (Afrikaans) EQ-5D-3L Paper Self complete v1.0 (ID 24012).docx; Effective_South Africa (English) EQ-5D-3L Paper Self complete v1.0 (ID 23955).docx; Effective_South Africa (Xhosa) EQ-5D-3L Paper Self complete v1.0 (ID 24146).docx

Dear Ms/Mr. Rogers,

Thank you for registering your research at the EuroQol Group Foundation's website.

As the study you registered involves low patient numbers (150) you may use the EQ-5D-3L instrument (Paper version) free of charge. Please note that separate permission is required if any of the following is applicable:

- Funded by a pharmaceutical company, medical device manufacturer or other profit-making stakeholder;
- Number of respondents ≥ 5000
- Routine Outcome Measurement;
- Developing or maintaining a Registry;
- Digital representations (e.g. PDA, Tablet or Web)

Please find attached the EQ-5D-3L version for South Africa (word format). A brief user guide is downloadable from the EuroQol website (www.euroqol.org).

Best regards,

Mandy van Reenen (Oemar)
Communications Officer
EuroQol Research Foundation

EQ-5D

T: + 31 88 4400190
E: vanreenen@euroqol.org
W: www.euroqol.org

From: Christine Rogers [mailto:Christine.Rogers@uct.ac.za]
Sent: Sunday, May 17, 2015 9:53 AM
To: userinformationservice
Subject: New registration

1

ID: 8975

Job title:	Academic
First name:	Christine
Surname:	Rogers
Organization:	University of Cape Town
Postal address:	13a Windsor Avenue Diep River
Postal/Zip code:	7800
City:	Cape Town
Country:	ZA
Telephone:	27214066315
E-mail:	Christine.Rogers@uct.ac.za
Work environment:	Academia
Other work environment:	Hospital/ clinical practice
Title / Description of your study, trial, project or other:	The clinical and cost effectiveness of the Wii Fit Balance Board versus a conventional exercise programme to reduce fall risk. A Phase II cluster randomised clinical trial.
Objective:	To explore the cost and clinical benefit of an exergaming programme versus convention programme to reduce fall risk
Design: (when in doubt, we will ask for study protocol or Ethics Committee approval letter)	Intervention study (randomized or non-randomized trial)
Clinical area:	Rehabilitation (effects of)
Source of funding:	Self-funded at present
Number of patients / respondents:	150
Starting date (year only):	2015
Finishing date (year only):	2016
Which version of the EQ-5D would you like to use?:	EQ-5D-3L Paper
Countries:	South Africa
Languages:	Afrikaans (South Africa),English (South Africa),Xhosa (South Africa)
Which other generic health measures will you use?:	None
Which other disease / condition specific health measures will you use?:	None
Journal articles or other published reports:	None
Are you prepared to have this information published in any EuroQol reports/surveys regarding usage of EQ-5D?:	Yes
Are you prepared to have your details made available to colleagues who are involved in research in a similar area?:	Yes
Terms of use:	I agree with the Terms of use

2

Appendix K.2 Euro-QoL EQ-5D-3L Health Questionnaire English version for South Africa.

By placing a tick in one box in each group below, please indicate which statements best describe your own state of health TODAY.

Mobility
I have no problems in walking about ❑
I have some problems in walking about ❑
I am confined to bed ❑

Self-Care
I have no problems with self-care ❑
I have some problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

Usual Activities *(e.g. work, study, housework, family or leisure activities)*
I have no problems with performing my usual activities ❑
I have some problems with performing my usual activities ❑
I am unable to perform my usual activities ❑

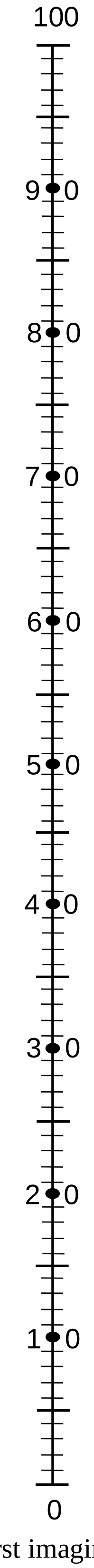
Pain / Discomfort
I have no pain or discomfort ❑
I have moderate pain or discomfort ❑
I have extreme pain or discomfort ❑

Anxiety / Depression
I am not anxious or depressed ❑
I am moderately anxious or depressed ❑
I am extremely anxious or depressed ❑

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale, in your opinion, how good or bad your own health is today. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.

Best imaginable
state of health



Your own state of health today

Worst imaginable
state of health

Appendix L Self-efficacy for Exercise Scale [592]

Please circle the number that corresponds to the following statements:

How confident are you right now that you could exercise three times per week for 20 minutes if:

(A score of 0 represents not confident and a score of 10 represents very confident)

1. The weather was bothering you

Not confident	1	2	3	4	5	6	7	8	9	10	Very confident

2. You were bored by the programme or activity

Not confident	1	2	3	4	5	6	7	8	9	10	Very confident

3. You felt pain when exercising

Not confident	1	2	3	4	5	6	7	8	9	10	Very confident

4. You had to exercise alone

Not confident	1	2	3	4	5	6	7	8	9	10	Very confident

5. You did not enjoy it

Not confident	1	2	3	4	5	6	7	8	9	10	Very confident

6. You were too busy with other activities

Not confident	1	2	3	4	5	6	7	8	9	10	Very confident

7. You felt tired

Not confident	1	2	3	4	5	6	7	8	9	10	Very confident

8. You felt stressed

Not confident	1	2	3	4	5	6	7	8	9	10	Very confident

9. You felt depressed

Not confident	1	2	3	4	5	6	7	8	9	10	Very confident

Appendix L.1 Reliability and validity of the SEE.

The SEE was developed for older sedentary adults enrolling in exercise programmes, to predict future adherence based on qualities of self-efficacy for managing barriers to exercise.

Construct and criterion validity of the SEE has been established, and correlations between efficacy for exercise expectations and actual adherence to regular exercise demonstrated (r=.42; p=<0.05). Validity was tested with a structural equation model. Correlations between the latent variable (SEE) and each item were explored using a lambda X. Scores of >0.5 are desirable. Estimates for lambda X were ≥0.81.

Reliability: the SEE has internal consistency, with a desirable target of a=>0.70 and the SEE having a=0.92 [592].

Appendix M Physical Activity Scale for the Elderly (PASE)

Appendix M.1 Permission to use the PASE.

Christine Rogers

From:	eCommerce@neriscience.com
Sent:	07 October 2014 02:46 PM
To:	Christine Rogers
Subject:	PASE Order Payment Confirmation

Thank you for your recent purchase of the Physical Activity Scale for the Elderly (PASE). This e-mail is confirmation that we have received your payment. You can download a master copy PDF of the instrument and the associated administration and scoring manual at the links below.

Instrument: Download
Administration and Scoring Manual: Download

If you have any questions regarding your recent purchase, please contact media@neriscience.com

1

Appendix M.2 Physical Activity Scale for the Elderly©.

LEISURE TIME ACTIVITY

1. Over the past 7 days, how often did you participate in sitting activities such as reading, watching TV or doing handcrafts?

[0.] NEVER	[1.] SELDOM	[2.] SOMETIMES	[3.] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#2	↓	↓	↓

1a. What were these activities?

____

1b. On average, how many hours per day did you engage in these sitting activities?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

2. Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

[0.] NEVER	[1.] SELDOM	[2.] SOMETIMES	[3.] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#3	↓	↓	↓

2a. On average, how many hours per day did you spend walking?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

3. Over the past 7 days, how often did you engage in light sport or recreational activities such as bowling, golf with a cart, shuffleboard, fishing from a boat or pier or other similar activities?

[0.] NEVER	[1.] SELDOM	[2.] SOMETIMES	[3.] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#4	↓	↓	↓

3a. What were these activities?
____

3b. On average, how many hours per day did you engage in these light sport or recreational activities?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

4. Over the past 7 days, how often did you engage in moderate sport and recreational activities such as doubles tennis, ballroom dancing, hunting, ice skating, golf without a cart, softball or other similar activities?

[0.] NEVER	[1.] SELDOM	[2.] SOMETIMES	[3.] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#5	↓	↓	↓

4a. What were these activities?
____

4b. On average, how many hours per day did you engage in these moderate sport and recreational activities?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

5. Over the past 7 days, how often did you engage in strenuous sport and recreational activities such as jogging, swimming, cycling, singles tennis, aerobic dance, skiing (downhill or cross-country) or other similar activities?

[0.] NEVER	[1.] SELDOM	[2.] SOMETIMES	[3.] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#6	↓	↓	↓

5a. What were these activities?
____

5b. On average, how many hours per day did you engage in these strenuous sport and recreational activities?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

6. Over the past 7 days, how often did you do any exercises specifically to increase muscle strength and endurance, such as lifting weights or pushups, etc.?

[0.] NEVER	[1.] SELDOM	[2.] SOMETIMES	[3.] OFTEN
↓	(1-2 DAYS)	(3-4 DAYS)	(5-7 DAYS)
GO TO Q.#7	↓	↓	↓

6a. What were these activities?
____

6b. On average, how many hours per day did you engage in exercises to increase muscle strength and endurance?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

HOUSEHOLD ACTIVITY

7. During the past 7 days, have you done any light housework, such as dusting or washing dishes?

   [1.] NO [2.] YES

8. During the past 7 days, have you done any heavy housework or chores, such as vacuuming, scrubbing floors, washing windows, or carrying wood?

   [1.] NO [2.] YES

9. During the past 7 days, did you engage in any of the following activities?

   Please answer YES or NO for each item.

		NO	YES
a.	Home repairs like painting, wallpapering, electrical work, etc.	1	2
b.	Lawn work or yard care, including snow or leaf removal, wood chopping, etc.	1	2
c.	Outdoor gardening	1	2
d.	Caring for an other person, such as children, dependent spouse, or an other adult	1	2

WORK-RELATED ACTIVITY

10. During the past 7 days, did you work for pay or as a volunteer?

[1.] NO [2.] YES

10a. How many hours per week did you work for pay and/or as a volunteer?

_______________ HOURS

10b. Which of the following categories best describes the amount of physical activity required on your job and/or volunteer work?

[1] Mainly sitting with slight arm movements. [**Examples:** office worker, watchmaker, seated assembly line worker, bus driver, etc.]

[2] Sitting or standing with some walking. [**Examples:** cashier, general office worker, light tool and machinery worker.]

[3] Walking, with some handling of materials generally weighing less than 50 pounds. [**Examples:** mailman, waiter/waitress, construction worker, heavy tool and machinery worker.]

[4] Walking and heavy manual work often requiring handling of materials weighing over 50 pounds. [**Examples:** lumberjack, stone mason, farm or general laborer.]

Appendix M.3 Additional information and normative data for PASE.

In the context of falls, a recent study from Iran suggested no significant difference in PASE scores between individuals who had fallen or not; but noted increased age and comorbidities resulted in lower PASE scores [(597).] Weaknesses of the measure include its lack of relationship to metabolic equivalents [(596)]; vulnerability to recall bias and reporting difficulties caused by anxious, depressed or cognitively impaired older adults (792). However, criterion and construct validity has been demonstrated (ibid.; [(596)] along with positive ratings for reliability [(596)]. Table M.1 shows normative data from the developers of the PASE.

Table M.1. Normative data from the developers of the PASE.

Mean PASE scores for the total sample and by age group				
Age	Leisure exercise	usehold	Occupation	Total PASE score
Total sample	31.5 ± 22.7	76.0 ± 42.7	17.7 ± 42.7	125.2 ± 79.9
Age ≤ 70 yrs	29.6 ± 22.9	78.8 ± 41.5	34.5 ± 60.9	142.9 ± 98.5
Age > 70 yrs	33.1 ± 23.7	73.6 ± 45.6	4.1 ± 6.3	110.8 ± 62.2

Legend: yrs.: years. (Additional information: Reference, Washburn et al., (1999); *n* = 20; mean age for women=72.4± 4.2 years / median range for men age=69-80 years; community-dwelling older adults).

Appendix N Systems Usability Scale

Introduction

The SUS is versatile, allowing use over a range of technologies or interfaces, is quick to administer and score, and is cost-effective as it is non-proprietary [900]. Studies have established its reliability (.91 coefficient alpha where a typical minimum reliability goal is .70) and concurrent validity [901]. Three modifications from the original were adopted for this study. An eleventh question has been added which addresses user-friendliness of the product, and the word “cumbersome” (item 8) has been replaced with “awkward”, to facilitate ease of use for non-English speakers [902]. The word “system” was replaced with “exergame”.

Appendix N.1 Scoring the System Usability Scale [903].

All odd numbered items (except item 11) had one point subtracted from the response. All even numbered items had the response subtracted from five. All converted responses were summed and multiplied by 2.5 to yield a score of between 0 and 100. Scores of ≥70 signify that the system under survey is passable in terms of its usability [599].

Appendix N.2 System Usability Scale.

Instructions[77] (900):

Please check the box that reflects your immediate response to each statement. Don't think too long about each statement. If you don't know how to respond, simply check box 3.

1. I think that I would like to use this exercise-game frequently.

Strongly disagree   Strongly agree

1	2	3	4	5

2. I found the exercise-game unnecessarily complex.

Strongly disagree   Strongly agree

1	2	3	4	5

3. I thought the exercise-game was easy to use.

Strongly disagree   Strongly agree

1	2	3	4	5

4. I think that I would need the support of a technical person to be able to use this exercise-game.

Strongly disagree   Strongly agree

1	2	3	4	5

[77] Adapted after 904. Nawaz A, Skjæret N, Ystmark K, Helbostad JL, Vereijken B, Svanæs D, editors. Assessing seniors' user experience (UX) of exergames for balance training. Proceedings of the 8th Nordic conference on human-computer interaction: fun, fast, foundational; 2014; Helsinki, Finland: ACM.

5. I found the various functions in this exercise-game were well integrated.

Strongly disagree Strongly agree

1 2 3 4 5

6. I thought there was too much inconsistency in this exercise-game.

Strongly disagree Strongly agree

1 2 3 4 5

7. I would imagine that most people would learn to use this exercise-game very quickly.

Strongly disagree Strongly agree

1 2 3 4 5

8. I think the exercise-game was very difficult to use.

Strongly disagree Strongly agree

1 2 3 4 5

9. I felt very confident using the exercise-game.

Strongly disagree Strongly agree

1 2 3 4 5

10. I needed to learn a lot before I can get started to use this game on my own.

Strongly disagree				Strongly agree
1	2	3	4	5

11. Overall, I would rate the user-friendliness of the programme as:

○	○	○	○	○	○	○
Worst imaginable	Awful	Poor	OK	Good	Excellent	Best imaginable

Appendix O Borg Rating of Perceived Exertion Scale

The Borg RPE [601] examines perceived exertion during exercise. Although validated on healthy adults, it is frequently used in rehabilitation settings and has fair criterion and construct validity [603]. Perhaps due to its ease of use, it is increasingly used with older adults [602]. The Borg has very strong correlations with physiological endpoints and good concurrent validity [602]. The Borg RPE is shown below.

Rating of Perceived Exertion Borg RPE Scale		
6		How you feel when lying in bed or sitting in a chair relaxed. Little or no effort.
7	Very, very light	
8		
9	Very light	
10		
11	Fairly light	
12		Target range: How you should feel with exercise or activity.
13	Somewhat hard	
14		
15	Hard	
16		
17	Very hard	How you felt with the hardest work you have ever done.
18		
19	Very, very hard	
20	Maximum exertion	Don't work this hard!

Retrieved 16.2.2016 from: http://www.bing.com/images/search?q=borg+ratings+of+perceived+exertion+scale&view=detailv2&id=FB3CE61EB81F1090567A5AB7BC462C8B9E992C3E&selectedindex=1&ccid=rGE3SbF3&simid=608039757932923972&thid=OIP.Mac613749b177ea9e55431cdba42c319fH0&mode=overlay&first=1

Appendix P Five Times Sit to Stand Test

The FTSST is applicable in most populations and settings; and is quick to administer and score [(905)]. The FTSST has good to high test-retest reliability (MA pooled ICC 0.81) [(884)]. The test is moderately responsive (MCID[78] = ≥2.3s) and correlates with TUG and preferred gait speed in vestibular patients [(906)] and other populations [(907)]. Normative values, which may be used as standard mean values are 11.4s for adults aged 60 – 69 years; 12.6s for ages 70 – 79 years and 12.7s for 80 – 89-year olds; while cut-offs between 12-16s imply fall risk in the general older adult population [(610)].

Prolonged scores on the FTSST are associated with ADL-related disability and loss of independence [(908)]. A recent SR suggested that individuals who fallen had slower overall times, reduced linear velocity and maximum power than those with no falls [(611)]. These changes were most apparent when the chair was armless, and individuals had to rise as quickly as possible [(611)]. The latter considerations were included in this design. The method and instructions [(905)] are provided below.

Method and instructions

The chair used should had no arms and the seat measured between 43 – 47cm from the floor. The participant sat on the chair with the arms folded across the chest. Upon the word “Go” the participant rose fully to standing and then resumed a seated position five times, as fast as possible. Timing commenced on the word “Go” and was stopped when the participant’s buttocks were firmly on the seat and back against the backrest of the chair. Additional instructions not to ‘brace’ against the back of the chair (to assist the stand) were given and participants reinforced and encouraged to complete the task as rapidly as possible.

[78] Minimum Clinically Important Difference.

Appendix Q Frailty and Injuries: Cooperative Studies of Intervention Technique (FICSIT-4)

The FICSIT-4 [615] comprises tests of static balance in standard Romberg, semi-tandem and full tandem (sharpened) Romberg positions, with eyes open and closed and SLS.

Changes for this study.

The test was adapted by asking participants to attempt to maintain each Romberg position for 30s and SLS for 20s (embedded in the Mini-BESTest). The Jendrassik manoeuvre (hands clasped, fingers intertwined, abducting arms to produce tension) was used for all Romberg positions [616]. Each position was demonstrated to the participant prior to him/her attempting the pose. The researcher/research assistant stood close to the participants in a position to prevent falls and injury but did not interfere with the tests. A gait belt was used for all static and dynamic balance activities. No talking occurred during the tests to allow the participant to concentrate on the activity. Participants were assisted into the position if necessary and allowed to steady themselves. Support was removed once the participant indicated s/he was ready for timing to commence.

The test was discontinued if: the feet or arms moved out of position for any of the Romberg tests, and/ or if eyes were opened in an eyes closed condition. SLS was discontinued as soon as one foot touched the other calf for support or the participant lost balance (see Mini-BESTest criteria).

Scoring was a simple recording of the number of seconds the participant held each position without meeting stopping criteria.

FICSIT-4 method and instructions.

F1: Standard Romberg eyes open

Instruction: stand with your feet tightly together and hands together, fingers inter-twined as if you are singing in the choir. Look straight ahead and hold the position for 30s if possible.

F2: Standard Romberg eyes closed

Instruction: now do the same again but close your eyes once you feel you have got your balance.

F3: Semi-tandem eyes open

Instruction: place the heel of one foot to the side of the first toe of the opposite foot (angling of foot not permitted). You can choose which foot you want to put forward. Hold your hands as if you are singing in the choir. Look straight ahead and hold the position for 30s if possible.

F4: Semi-tandem eyes closed

Instruction: place the heel of one foot to the side of the first toe of the opposite foot (angling of foot not permitted). You can choose which foot you want to put forward. Hold your hands as if you are singing in the choir. When you have got your balance, close your eyes and hold the position for 30s if possible.

F5: Full tandem (sharpened Romberg) eyes open

Instruction: place the heel of one foot directly in front of the other foot (angling of foot not permitted). You can choose which foot you want to put forward. Hold your hands as if you are singing in the choir. Look straight ahead and hold the position for 30s if possible.

F6: Full tandem (sharpened Romberg) eyes closed

Instruction: place the heel of one foot directly in front of the other foot (angling of foot not permitted). You can choose which foot you want to put forward. Hold your hands as if you are singing in the choir. When you have got your balance, close your eyes and hold the position for 30s if possible.

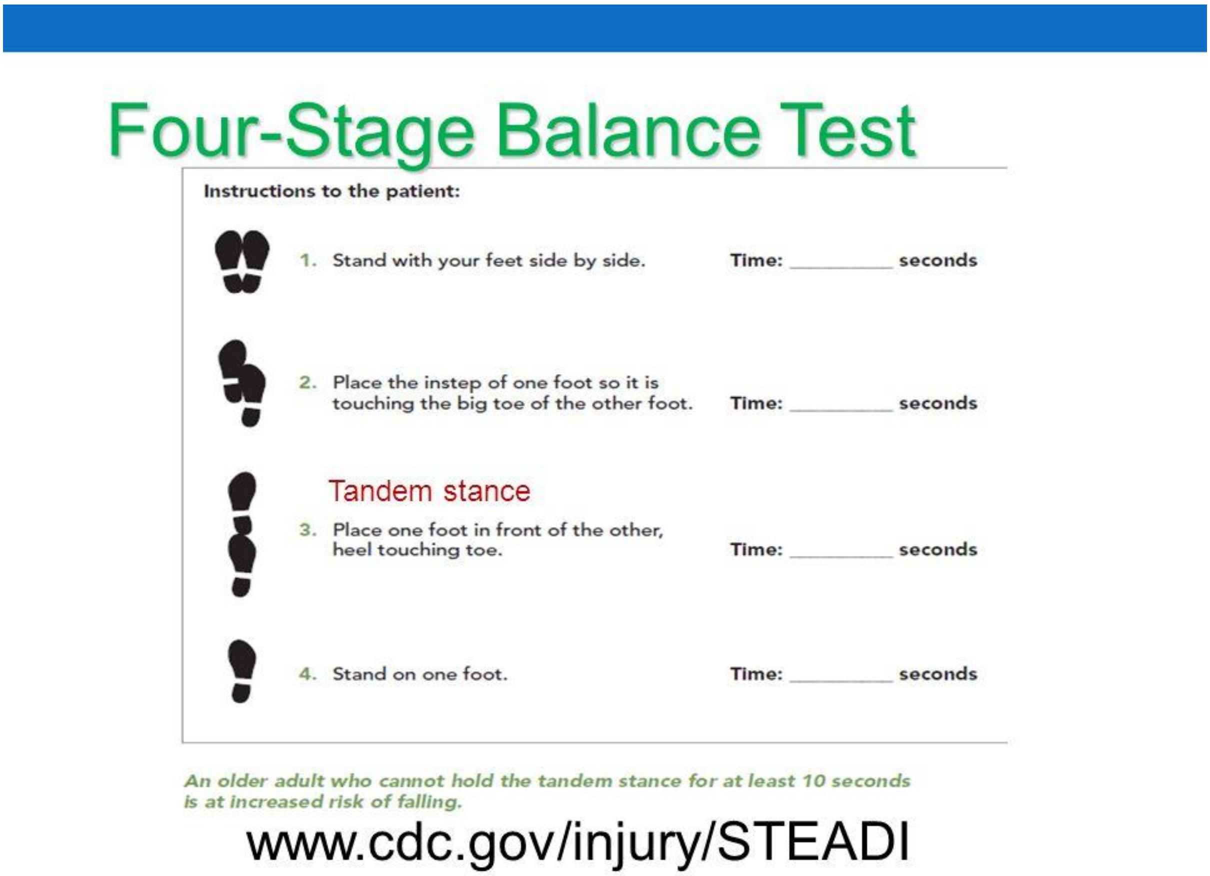
F7: single leg stance

See item 3 on Mini-BESTest.

In some ways the FICSIT-4 test is a more sophisticated version of the 4-Stage Balance test recommended by the STEADI initiative from the Centers for Disease

Control and Prevention. The 4-Stage Balance test is attached here to illustrate the foot positions used.

STEADI 4-Stage Balance Test.



Reference: downloaded 22.5.2019 from https://images.slideplayer.com/34/10181168/slides/slide_20.jpg

Appendix Table 5 (616, p. 70) is reproduced with permission granted from publishers on 27.3.2019 and shows mean data for the following tests:

- Standing on foam eyes closed (item 8 on the Mini-BESTest); also known as condition 4 on the M-CTSIB
- SLS (item 3 on the Mini-BESTest and item F7 on the FICSIT-4)
- Tandem Romberg eyes closed (item F6 on the FICSIT-4).

Table Q.1. Normative data for static tests of balance per decade of life

Table 2. Descriptive characteristics of 318 asymptomatic adults for measures of quasi-static balance.

Standing on foam (eyes closed)

Decade	*Mean*	*SD*	*Median*	*Perc 05*	*Interquartile range*	*Perc 95*	*Valid N*	*% 30 s*	*% 10 s*
3	30.00	.00	30.00	30.00	30.00 – 30.00	30.00	N = 74	100	100
4	30.00	.00	30.00	30.00	30.00 – 30.00	30.00	N = 43	100	100
5	30.00	.00	30.00	30.00	30.00 – 30.00	30.00	N = 32	100	100
6	30.00	.00	30.00	30.00	30.00 – 30.00	30.00	N = 30	100	100
7	26.02	8.42	30.00	6.20	30.00 – 30.00	30.00	N = 56	80	89
8	19.82	10.52	30.00	1.70	9.22 – 30.00	30.00	N = 56	46	75

Tandem Romberg (eyes closed)

Decade	*Mean*	*SD*	*Median*	*Perc 05*	*Interquartile range*	*Perc 95*	*Valid N*	*% 30 s*	*% 10 s*
3	29.94	.43	30.00	30.00	30.00 – 30.00	30.00	N = 58	98	100
4	30.00	.00	30.00	30.00	30.00 – 30.00	30.00	N = 42	100	100
5	28.82	4.66	30.00	11.46	30.00 – 30.00	30.00	N = 32	94	97
6	28.03	4.87	30.00	13.57	29.70 – 30.00	30.00	N = 28	82	100
7	17.96	10.33	16.50	4.18	7.66 – 30.00	30.00	N = 56	36	64
8	13.20	9.50	11.26	2.27	4.68 – 18.74	30.00	N = 56	16	54

One leg standing (eyes open)

Decade	*Mean*	*SD*	*Median*	*Perc 05*	*Interquartile range*	*Perc 95*	*Valid N*	*% 30 s*	*% 10 s*
3	30.00	.00	30.00	30.00	30.00 – 30.00	30.00	N = 74	100	100
4	30.00	.00	30.00	30.00	30.00 – 30.00	30.00	N = 43	100	100
5	29.64	2.06	30.00	25.91	30.00 – 30.00	30.00	N = 32	97	100
6	30.00	.00	30.00	30.00	30.00 – 30.00	30.00	N = 30	100	100
7	27.74	5.25	30.00	11.59	30.00 – 30.00	30.00	N = 56	80	95
8	21.43	10.08	26.33	2.05	13.04 – 30.00	30.00	N = 56	48	86

One leg standing (eyes closed)

Decade	*Mean*	*SD*	*Median*	*Perc 05*	*Interquartile range*	*Perc 95*	*Valid N*	*% 30 s*	*% 10 s*
3	27.52	6.45	30.00	9.45	30.00 – 30.00	30.00	N = 74	86	96
4	27.48	6.48	30.00	8.46	30.00 – 30.00	30.00	N = 43	86	95
5	21.77	9.09	24.75	3.94	10.90 – 30.00	30.00	N = 31	45	90
6	19.92	9.81	20.90	3.78	10.55 – 30.00	30.00	N = 29	38	79
7	8.93	7.54	5.66	1.61	3.32 – 12.13	28.33	N = 56	4	34
8	4.87	3.46	3.93	1.18	2.87 – 6.03	11.78	N = 56	0	5

SD: standard deviation; Perc: percentile; N: number of subjects;%: percentage of subjects reaching 10 or 30 seconds.

Appendix R Ethical Clearance and Trial Registration Documents

Appendix R.1 UCT Human Research Ethics Committee clearance for RCT.

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

02 March 2016

HREC REF: 818/2015

Dr D Shamley
Clinical Research Centre
L51, OMB

Dear Dr Shamley

PROJECT TITLE: THE FEASIBILITY AND POTENTIAL EFFECTIVENESS OF A CONVENTIONAL AND VIDEO EXERCISE BASED INTERVENTION TO ALTER BALANCE RELATED OUTCOMES INCLUDING FALL RISK: A CLUSTER RANDOMIZED PHASE II CLINICAL TRIAL (PhD candidate - Ms C Rogers)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th March 2017.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the student Christine Rogers will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

pp T.Burgess

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI),and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Appendix R.2 Annual Progress Report/Renewal.

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30/03/18
☐ Not approved	See attached comments		
Signature Chairperson of the HREC	pp TBurgess	Date Signed	07/04/2017

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	29.3.2017		
HREC REF Number	818/2015	Current Ethics Approval was granted until	30.3.2017
Protocol title	The feasibility and potential effectiveness of a conventional and video exercise-based intervention to alter balance related outcomes including fall risk: a cluster randomized Phase II clinical trial		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	☐ Yes √☐ No		
If yes, could you please provide the HREC Ref's for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Dr D Shamley. Ph.D. student: C Rogers		
Department / Office Internal Mail Address	Clinical Research Centre L51 Old Main Building Groote Schuur Hospital		
C Rogers details	F45 Old Main Building Groote Schuur Hospital		

HUMAN RESEARCH ETHICS COMMITTEE
27 MAR 2017
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

1.1 Does this protocol receive US Federal funding?	☐ Yes	√☐ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	☐ Yes	√☐ No

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Appendix R.3 Registration with Pan African Clinical Trials Registry.

15 March 2016

To Whom It May Concern:

RE: The feasibility and potential effectiveness of a conventional and video exercise based intervention to alter balance related outcomes including fall risk: a cluster randomised Phase II clinical trial.

As project manager for the Pan African Clinical Trial Registry (www.pactr.org) database, it is my pleasure to inform you that your application to our registry has been accepted. Your unique identification number for the registry is **PACTR201603001513802**

Please be advised that you are responsible for updating your trial, or for informing us of changes to your trial.

Additionally, please provide us with copies of your ethical clearance letters as we must have these on file (via email, post or fax) at your earliest convenience if you have not already done so.

Please do not hesitate to contact us at +27 21 938 0835 or email epienaar@mrc.ac.za should you have any questions.

Yours faithfully,

Elizabeth D Pienaar
www.pactr.org Project Manager
+27 021 938 0835

PACTR
PAN AFRICAN CLINICAL TRIALS REGISTRY

THE SOUTH AFRICAN MEDICAL RESEARCH COUNCIL
Cochrane South Africa | PO Box 19070, Tygerberg, 7505
Tel: +27 (0)21 938 0438 | Email: cochrane@mrc.co.za | Web: www.southafrica.cochrane.org

Appendix R.4 UCT Human Research Ethics Committee clearance for focus groups.

HUMAN RESEARCH ETHICS COMMITTEE
0 1 NOV 2017
HEALTH SCIENCES FACULTY

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS006: Protocol Amendment

HREC office use only (FWA00001637; IRB00001938)		
☐ Approved	☐ Type of review: Expedited	☐ Full committee
This serves as notification that all changes and documentation described below are approved.		
Signature Chairperson of the HREC		Date 1/11/2017

Note: All major amendments must include a local **PI Synopsis** justifying the changes for the amendment. Please note that incomplete amendment submissions will not be reviewed.

Comments from the HREC to the Principal Investigator:
Note: The approval of this protocol amendment does not grant annual approval. Please complete the FHS016 / FHS017 form for annual approval at least one month before study expiration.

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	28.8.2017		
HREC REF Number	818/2015		
Protocol title	THE FEASIBILITY AND POTENTIAL EFFECTIVENESS OF A CONVENTIONAL AND VIDEO EXERCISE BASED INTERVENTION TO ALTER BALANCE RELATED OUTCOMES INCLUDING FALL RISK: A CLUSTER RANDOMIZED PHASE II CLINICAL TRIAL		
Protocol number (if applicable)			
Principal Investigator	Dr Delva Shamley		
Department / Office Internal Mail Address	Clinical Research Centre Old Main Building Delva.shamley@uct.ac.za student: Christine.Rogers@uct.ac.za		
1.1 Is this a major or a minor amendment? (see FHS006hlp) Major (tick box) Minor (tick box)		☐ Major	x☐ Minor
1.2 Does this protocol receive US Federal funding?		☐ Yes	x☐ No

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

1.3 If the amendment is a major amendment <u>and</u> receives US Federal Funding, does the amendment require full committee approval? **Note:** Any protocol amendments for **Full Committee** review MUST be submitted on the monthly HREC submission dates.	☐ Yes	☐ No

2. List of Proposed Amendments with Revised Version Numbers and Dates

Please itemise on the page below, all amendments with revised version numbers and dates, which need approval. This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary.
Revised protocol attached.

3. Protocol status (tick ✓)

☐	Open to enrolment
☐	No participants have been enrolled
√☐ ☐ √☐ ☐	Closed to enrolment (tick ✓) Research-related activities are ongoing Research-related activities are complete, long-term follow-up only Research-related activities are complete, data analysis only

4. Proposed changes will affect: (tick ✓ all the categories that apply)

	Protocol
√☐	Study objectives, design (including investigator's brochure, clinical activities, study length)
√☐	Study instruments, questionnaires, interview schedules
☐	Sample size
☐	Recruitment methods
☐	Eligibility criteria (inclusion and exclusion criteria)
☐	Drug/device (composition, amount, schedule, route of administration, combination with other drugs/devices, safety information)
√☐	Data collection/ analysis
☐	Principal Investigator. (Please attach revised conflict of interest and PI declaration statements. Refer: sections 7 and 8.4 in the New Protocol Application Form FHS013)
√☐	Consent form and information sheet

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

☐	Recruitment materials (e.g. advertisements)
☐	Administrative (e.g. change in sponsor's name, change in contact information)
√☐	Other. Please specify: **use of focus groups will force change of methodology to mixed methods. Attached proposal covers these changes and outlines focus group method.**

4.1 In your opinion, will there be any increase in risk, discomfort or inconvenience to participants?	☐ Yes	√☐ No
If yes, please provide a detailed justification/explanation:		
No. Participants are eager to voice their opinions of the experience of the interventions		

4.2 What follow-up action do you propose for participants who are already enrolled in the study?	
√☐	Inform current participants as soon as possible
√☐	Re-consent current participants with revised consent/assent forms (append)
☐	No action required
√☐	Other. Please describe: **invite them to join focus groups**

5. Detailed description of the change(s) NEW PROTOCOL ATTACHED

Please attach, for each amendment, a summary of all changes which clearly indicates:

i. Old wording (e.g. ~~strikethrough~~ text, CHANGED FROM and CHANGED TO)
ii. New wording (e.g. *italicized*, **bold**, tracked)
iii. Detailed rationale/ justification/ explanation for each change

6. Ethics Review Levy – cost including vat

Cost for Major Amendments - R3 659.10 (Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from charges)	
For invoicing purposes, please provide:	
Sponsor's name	
Contact person	
Address	
Telephone number	
Email Address	

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

7. Signature

My signature certifies that I will maintain the anonymity and/ or confidentiality of information collected in this research. If at any time I want to share or re-use the information for purposes other than those disclosed in the original approval, I will seek further approval from the HREC.			
Signature of PI		Date	01-11-17

Appendix R.5 Certification of Good Clinical Practice qualification.

Good Clinical Practice Certificate 2015

This is to certify that

CHRISTINE ROGERS

Registration number: AU 0000094

Successfully completed the following ***Level 2*** course

Good Clinical Practice: Beginners' Course

(Activity No: GCP-Beg/2015)

The above-mentioned practitioner qualifies for

21 CEUs (of which 8 are Ethics CEUs)

Facilitator: Marijke Geldenhuys

Date: 08 & 09 September 2015

MGeldenhuys

CREDE

Clinical Research Education and Development

Teaching Clinical Research to All

Accreditation: GCP provider: MT-15/001; SACRA/GCP/76/2013

"This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors."

This certificate is valid for 3 years.

Appendix E.5 continued. Renewal of Good Clinical Practice qualification 2018.

Good Clinical Practice Certificate 2018

This is to certify that

CHRISTINE ROGERS

Registration Number: AU0000094

Successfully completed the following ***Level 2*** course

Good Clinical Practice: Refresher Course

Facilitator: Dr HD Geldenhuys

Date: 13 Dec 2018

CREDE

Clinical Research Education and Development

Teaching Clinical Research to All

Accredited by SMLTSA appointed by the PBMT HPCSA: MTS 18/066

"This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors."

This certificate is valid for 3 years.

Appendix R.6 Confidentiality agreement for research staff.

Department of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Tel: +27 (0) 21 406 6315

E-mail: Christine.Rogers@uct.ac.za

Internet: www.uct.ac.za

Date: / /2016

Confidentiality agreement

I, ________________________________ [name of research assistant], agree to assist the primary investigator with this study by assisting with either: implementation of the two intervention programmes or performing the outcome measures during and at the end of the clinical trial. I agree to maintain full confidentiality when performing these tasks.

Specifically, I agree to:

1. keep all research information shared with me confidential by not discussing or sharing the information in any form or format with anyone other than the primary investigator;
2. hold in strictest confidence the identification of any individual that may be revealed during the course of performing the research tasks;
3. not make copies of any raw data in any form or format, unless specifically requested to do so by the primary investigator;
4. keep all raw data that contains identifying information in any form or format secure while it is in my possession. This includes:
    - keeping all digitized raw data in computer password-protected files and other raw data in a locked file;
    - closing any computer programs and documents of the raw data when temporarily away from the computer;

5. give all raw data in any form or format to the primary investigator when I have completed the research tasks;
6. destroy all research information in any form or format that is not returnable to the primary investigator (e.g., information stored on my computer hard drive) upon completion of the research tasks.

In addition, I agree to:

7. read the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (*go to http://ohsr.od.nih.gov/guidelines/belmont.html)*,*
8. accept, having understood, the responsibility to comply with the standards and requirements stipulated in the approved UCT Faculty of Health Sciences Human Research Ethics (UCT HREC) application for this project to protect the rights and welfare of the participants.
9. not initiate changes in the implementation of the protocol without prior UCT HREC review; which is the responsibility of the primary investigator.
10. promptly report any unanticipated problems in the research that involve risks to the participants or others. The primary investigator will immediately report these problems to the UCT HREC.
11. seek, document, and maintain records of informed consent from the participants as stipulated by the UCT HREC
12. not enrol subjects in this research project prior to its review and approval by UCT HREC.
13. understand that it is my primary responsibility to safeguard the rights and welfare of research participants, and that the participants' rights and welfare must take precedence over the goals and requirements of the research.

Printed name of research assistant____

Telephone number:_______________________

Signature of research assistant_________________Date __________

Printed name of primary investigator________________________________

Signature of primary investigator___________________________________Date_________

Retrieved 28 July 2014 and adapted from: http://www.google.co.za/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CCAQFjAB&url=http%3A%2F%2Finside.augsburg.edu%2Firb%2Ffiles%2F2012%2F09%2FResearch-Assistant-Condidentiality-Agreement.docx&ei=937XU8DKOabe7Aajl4FI&usg=AFQjCNG9HugXluRAci3IR_2xZDza9cuP2g

Appendix R.7 Singapore Statement on research integrity.

Singapore Statement on Research Integrity

Preamble. The value and benefits of research are vitally dependent on the integrity of research. While there can be and are national and disciplinary differences in the way research is organized and conducted, there are also principles and professional responsibilities that are fundamental to the integrity of research wherever it is undertaken.

PRINCIPLES

Honesty in all aspects of research

Accountability in the conduct of research

Professional courtesy and fairness in working with others

Good stewardship of research on behalf of others

RESPONSIBILITIES

1. Integrity: Researchers should take responsibility for the trustworthiness of their research.

2. Adherence to Regulations: Researchers should be aware of and adhere to regulations and policies related to research.

3. Research Methods: Researchers should employ appropriate research methods, base conclusions on critical analysis of the evidence and report findings and interpretations fully and objectively.

4. Research Records: Researchers should keep clear, accurate records of all research in ways that will allow verification and replication of their work by others.

5. Research Findings: Researchers should share data and findings openly and promptly, as soon as they have had an opportunity to establish priority and ownership claims.

6. Authorship: Researchers should take responsibility for their contributions to all publications, funding applications, reports and other representations of their research. Lists of authors should include all those and only those who meet applicable authorship criteria.

7. Publication Acknowledgement: Researchers should acknowledge in publications the names and roles of those who made significant contributions to the research, including writers, funders, sponsors, and others, but do not meet authorship criteria.

8. Peer Review: Researchers should provide fair, prompt and rigorous evaluations and respect confidentiality when reviewing others' work.

9. Conflict of Interest: Researchers should disclose financial and other conflicts of interest that could compromise the trustworthiness of their work in research proposals, publications and public communications as well as in all review activities.

10. Public Communication: Researchers should limit professional comments to their recognized expertise when engaged in public discussions about the application and importance of research findings and clearly distinguish professional comments from opinions based on personal views.

11. Reporting Irresponsible Research Practices: Researchers should report to the appropriate authorities any suspected research misconduct, including fabrication, falsification or plagiarism, and other irresponsible research practices that undermine the trustworthiness of research, such as carelessness, improperly listing authors, failing to report conflicting data, or the use of misleading analytical methods.

12. Responding to Irresponsible Research Practices: Research institutions, as well as journals, professional organizations and agencies that have commitments to research, should have procedures for responding to allegations of misconduct and other irresponsible research practices and for protecting those who report such behavior in good faith. When misconduct or other irresponsible research practice is confirmed, appropriate actions should be taken promptly, including correcting the research record.

13. Research Environments: Research institutions should create and sustain environments that encourage integrity through education, clear policies, and reasonable standards for advancement, while fostering work environments that support research integrity.

14. Societal Considerations: Researchers and research institutions should recognize that they have an ethical obligation to weigh societal benefits against risks inherent in their work.

The Singapore Statement on Research Integrity was developed as part of the 2nd World Conference on Research Integrity, 21-24 July 2010, in Singapore, as a global guide to the responsible conduct of research. It is not a regulatory document and does not represent the official policies of the countries and organizations that funded and/or participated in the Conference. For official policies, guidance, and regulations relating to research integrity, appropriate national bodies and organizations should be consulted. Available at: **www.singaporestatement.org**

Retrieved 28 March 2019 from www.singaporestatement.org

Appendix R.8 Application for UCT No-fault insurance.

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS022: UCT No-Fault Insurance for Research-related Bodily Injury Risk Assessment Form

HREC office use only (FWA00001637; IRB00001938)								
Noted and filed. This serves as acknowledgement of the Risk Assessment Form for UCT No-Fault Insurance for Research-related Bodily Injury.								
☐ Approved	Risk Assessment Form	Risk Category/Score	A	☐	B	☐	C	☐
☐ Not Approved			ABPI	☐	N/A	☐		
Chairperson of the HREC signature			Date					

Comments to PI from the HREC

Principal Investigator to complete the following:

1. General information

HREC REF Number	818/2015
Protocol Title	The feasibility and potential effectiveness of a conventional and video exercise based exercise programme to alter balance related outcomes including fall risk: a Phase II cluster randomized control trial
Principal Investigator	Dr D Shamley/Prof S Amosun Ph.D. candidate: C Rogers
Department / Office Internal Mail Address	Department of Health and Rehabilitation Sciences, F45, Old Main Building, Groote Schuur Hospital
Email Address	Christine.Rogers@uct.ac.za

2. Protocol information

2.1 Is this a protocol for which insurance for research-related bodily injury would be appropriate?	☒ Yes ☐ No
2.1.1 If 'yes', please indicate the type of insurance cover:	
☐ ABPI-compliant sponsor's insurance policy **Note: Please attach a copy of the sponsor's insurance policy & submit a signed copy of this form. No further part of the risk assessment form must be completed.**	☒ UCT No-Fault's insurance policy **Note: Please complete all sections of the risk assessment form.**

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

2.1.2 If 'no', please justify:
☐ Patient folder or document review ☐ Study involves secondary data analysis only ☐ Qualitative research study ☐ Purely observational study ☐ No human participants involved in the research study **Note: Please submit a signed copy of this form. <u>No further part of the risk assessment form must be completed.</u>**

3. Protocol-specific risk assessment

Note: This section must only be completed if there is no ABPI-compliant sponsor's insurance policy for the research study; and if insurance for research-related bodily injury would be appropriate.

3.1 Will participants be active on the study and exposed to on-going risk in **<u>2017</u>**?	☒ Yes ☐ No	
3.1.1 If 'yes', please confirm the total number of participants that will be active on the study and exposed to on-going risk in the **<u>2017 calendar year</u>**. **Note: Even if a participant has multiple study visits, please only count them as one.**	Total number of participants 100	
3.2 Does the study involve participants outside South African borders that are not insured by another sponsor or local mechanism in that country?	☐ Yes ☒ No	
3.2.1 If 'yes', please confirm the country/countries and the number of participants that will be active on the study in the **<u>2017 calendar year</u>** for each country:	Country Click here to enter text.	Number of participants Click here to enter text.
	Country Click here to enter text.	Number of participants Click here to enter text.
	Country Click here to enter text.	Number of participants Click here to enter text.
	Country Click here to enter text.	Number of participants Click here to enter text.

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

3.3. Please identify the potential risks to bodily injury. For each risk:

1. Rate the probability or likelihood of occurrence of each risk. Rate this on a scale of 1-5 (descriptors below).
2. Rate the impact of the risk if it happens. Rate this on a scale of 1-5 (descriptors below).
3. Assess each risk by multiplying probability by the magnitude of risk.

Please determine the risk assessment score, as the sum of all individual risk assessment scores.

Note: Injury is defined as bodily harm. The term does not include: impairment of mental processes or emotional distress; injuries from normal diagnostic or therapeutic procedures or interventions which are performed as part of patient management; injuries from the normal course of a disease or condition; or injuries resulting from non-compliance with study procedures.

Risk description (Please add more rows if additional potential risks are identified)	Probability of occurrence 1 – Remote 2 – Unlikely 3 – Possible 4 – Likely 5 – Certain	Impact of risk 1 – Low 2 – Moderate 3 – Significant 4 – Severe 5 – Catastrophic	Risk assessment (Probability x Impact)
Musculo-skeletal pain/stiffness	2	1	2
Injurious falls – note population has a one in three risk of falls by merit of age alone	3	Range from 1-5 depending on injury	3-15
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
RISK ASSESSMENT SCORE			17

4. Signature

My signature certifies that the above is complete and correct.

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Signature of PI		Date	2016/11/30

Appendix S Record of Unmasking of Intervention Allocation Group

This question asks whether you are aware/unaware of which intervention group this participant belongs to in the trial

(Please tick one box only)

□ I do not know which group the participant is in

□ I have guessed the participant is in the Wii Fit group

□ I have guessed the participant is in the Otago Exercise Programme group

□ The participant has told me s/he is in the Wii Fit group

□ The participant has told me s/he is in the Otago Exercise Programme group

Participant study number: ……………………….

Initials of outcome assessor:…………………………………

Date: …………………………..

Appendix T Reporting of Adverse Events

FHS008: Internal Adverse Event or Unanticipated Problem reporting

HREC office use only (FWA00001637; IRB00001938)			
☐ Report is noted and filed - no further action required.			
This serves as notification that all changes and documentation described below are noted and approved.			
Chairperson of the HREC signature		Date	

Principal Investigator to complete the following:

1. **Protocol Information**

Date	
HREC REF	
Project Title	
Protocol number (if applicable)	
Principal	
Department / Office Internal Mail Address	

2. **Documents for approval**

Please itemise on the page below, all documents including revised version numbers and dates, which need to be noted or approved. This page will be detached, signed and returned to the PI as notification of the HREC's approval. (If any protocol amendments occur please separately complete the FHS006 form)

3. **Description of Internal Adverse Event (tick √)**

Definitions and timelines for reporting internal (on site) adverse events and unanticipated problems are posted on the HREC website.

☐	Fatal or life-threatening adverse event or drug reaction
☐	Serious and unexpected, non-fatal adverse event or drug reaction
☐	Expected adverse event or drug reaction occurring at a greater than expected
☐	Serious and unanticipated adverse device reaction
☐	Unanticipated problem that increases risk of harm to participants
☐	New information that might impact the conduct of a clinical study

3.1 Please provide a brief description of the event

3.2 This report is	☐ Initial	☐ Follow up

3.3 In the opinion of the local PI, is this event related to the study drug, device, or procedure? (tick √ one)	
☐	Not related
☐	Unlikely
☐	Possibly
☐	Probably
☐	Definitely

3.4 Action taken (tick √ all that apply)	
☐	Hospitalisation
☐	Study treatment altered (e.g. drug dose changed)
☐	Study treatment stopped/ device removed
☐	Study blind broken
☐	Monitoring progress
☐	Removed from study
☐	Other. Describe in Section 2.1

3.5 Outcome (tick √ all that apply)	
☐	Complete resolution
☐	Ongoing/ unresolved
☐	Partial recovery
☐	Disability or impairment (permanent)
☐	Disability or impairment (may improve with time)
☐	Death
☐	Other. Describe in Section 2.1

4. Follow-up actions

MCC notified	☐ Yes	☐ No
Are any protocol revisions required?	☐ Yes	☐ No
Should the consent/assent form(s) be amended?	☐ Yes	☐ No
Will currently enrolled participants be notified of this event?	☐ Yes	☐ No
Note: If yes to any of the above, please enclose an Amendment Form (FHS006) and revised documents with all revisions highlighted in bold or italics		

5. Signature

My signature certifies that I will maintain the anonymity and/ or confidentiality of information collected in this research. If at any time I want to share or re-use the information for purposes other than those disclosed in the original approval, I will seek further approval from the HREC.			
Signature of PI		Date	

Appendix U Capacity of Individuals to Participate in Decision-making

A vulnerable state is a condition in which people may be unable to protect themselves from harm [645, 909]. Vulnerability may result from either extrinsic factors, such as social status; or intrinsic influences such as the presence of medical or psychological illnesses or even older age [645] [909]. Vulnerability decreases a person's threshold for exploitation [645] [909]. As understanding the ramifications of participation is essential before an individual can decide to participate, some level of reasoning is required [910]. In this study, the target group of participants was older adults, which is some cases may raise issues such as possible diminishment of the capacity to give informed consent [652]. For example, numbers of people with dementia, associated with disorders of memory and thinking, are increasing as the world population ages [911, 912].

The first foundation of informed consent, disclosure of information, is described in the main section of this report. Regard for a potential participant's capacity to promote their own interests, and steps to protect him/her from potential exploitation or harm [909, 913] is presented here. The capacity to decide regarding self-determination, in this case to enrol in a clinical trial or not, comprises the following processes:

- Understanding information about the research, including potential risks and benefits [652, 870, 914].
- Applying knowledge of the study to the participant's individual situation and his/her important values [644, 914, 915].
- Processing the information and potential consequences of the decision to be made, and rationalising alternative courses of action [652].
- Communicating a free and informed decision about participation [652].

As detailed in the Methodology Chapter, potential participants were screened for cognitive decline which may challenge understanding the information provided [916] and the ability to give informed consent. Screening tests are not substitutions for diagnostic tests of cognitive function but serve as a useful base-line [652]. The selection of the Mini-Cog screening test was made in line with ethical principles in that it, compared to other measures such as the Mini Mental State Examination, is relatively free from bias from ageing, educational, linguistic and cultural factors [573, [886, 917] making the Mini-Cog suitable to use in a heterogeneous study population. Assessment of the individual's capacity to make a decision was conducted after information regarding the study has been given and all questions answered [652] and consent taken. Those failing the Mini-Cog were excluded in order protect potentially vulnerable individuals from being exposed to risks they may not comprehend, and possible harm.

Proxy consent for individuals failing the Mini-Cog, proxy consent was not sought. Under South African law, proxy decision making for adults is not permissible unless the proxy is a court-appointed curator [918]; and implementing legal strategies to permit incapacitated adults to participate in this research was inappropriate. Furthermore, individuals without the capacity to make their own decisions regarding participation, may not have been able to undergo an intervention such as an exercise programme without a high level of direction. Simple and mostly indirect supervision was envisaged as part of the study procedures. Finally, research should only be conducted when there is a reasonable chance that the population on whom it is performed will benefit from the results [650]. In the case of diminished capacity, a proxy would be required to accept any potential risks to the participant [652], which when contrasted with possible benefit, given the constraints of the person's condition, may be less assured.

Appendix U.1 Strategies to enhance the informed consent process.

Informed consent documents are often complex and use legal terms, making them difficult to read and understand [919, 920]. Information given was written in an understandable format [910], using plain English and the use of medical or legal jargon avoided [921]. A Flesch-Kincaid analysis [922] was conducted on the information sheets and informed consent documents to assess readability and accessibility of the documents. Results were at a Grade 9.3 level which is equivalent to having attended senior year high school [923]; and thus compatible with the minimum educational entrance requirement for the study. In addition, use of language, sensitivity to older adults' educational and cultural backgrounds and their attitude to falls and fall prevention [256, 924], were considered.

Appendix U.2 Beneficence.

The well-being of research participants is essential. Beneficence also requires that the demands inherent in research, for example, possible inconvenience or discomfort to the participants, are balanced against the benefits [(925)]. This is discussed further under risks and benefits for participants in the Methodology Chapter. The concept of promoting good is embraced by conducting a relevant research study, with established clinical equipoise and the intention of disseminating the results [(926)].

Appendix U.3 Non-maleficence.

Doing no harm is one of the Hippocratic tenets [(644)]. Potential sources of harm, and mechanisms to manage these include:

- *Physical harm, for example, worsening symptoms or side effects from treatment [(926)].* The study population have done either more exercise than previously, or a different type of exercise, for example, weight bearing. There are substantial benefits from exercise in older adults, so it was anticipated that the benefits would outweigh any temporary change in symptoms; or side effects from interventions, for example, muscle aches from re-conditioning muscles.
- *Causing stigma to either groups or individuals [(926)]*. To reduce any possible stigma concerning falls and fall prevention, the interventions were presented as exercise programmes designed to enhance healthy living. Promotion of ageing-in-place [79] and maintenance of independence for as long as possible [(254)] attempted to reduce judgements on those who chose to enrol.

[79] Residing in one's own home for as long as one is able to care for oneself 927. Mynatt ED, Melenhorst AS, Fisk AD, Rogers WA. Awareness technologies for aging in place: understanding user needs and attributes. Pervasive Computing. 2004;3:36-41.

Appendix V Example of Participant Referral for Further Services

Department of Health and Rehabilitation Sciences
Faculty of Health Sciences
Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,
Observatory 7925
Tel: +27 (0) 21 406 6315 Fax: +086 611 0725
E-mail: Christine.Rogers@uct.ac.za
Internet: www.uct.ac.za

………/……../…………

Dear ……………………………….

Thank you for agreeing to be assessed as part of my clinical trial. As we discussed, you have/have not been assessed as suitable/not suitable to participate in the exercise/costs trial. We will remain in contact regarding the trial.

Aside from, and completely separate to any commitment to the clinical trial, we discussed your possible need to see a physiotherapist. This letter acts as your referral. The therapists I can recommend are (in alphabetical order): Terry Douglas, Kenilworth, on 021 761 2713; Athene Irving, Constantia, on 079 895 3653; and Marcelle Pienaar, Constantiaberg, 021 797 1777. Please feel free to contact any of these specially trained therapists for an assessment and/ or treatment. I have worked with all these therapists and can recommend them all equally. Please note that this referral is a clinical/therapeutic recommendation. It is up to you to decide if you wish to proceed or not. Unfortunately, such a consultation is completely separate from the trial and any expenses related to assessment and treatment in the therapist's private capacity are for your account and will not be paid for as part of the trial.

Your test results showed a score of …………/28 on the MiniBESTest and ………/24 on the Dynamic Gait Index. Timed Up and Go simple was achieved in ……… seconds and in ………… seconds for the cognitive condition. In addition, you should make the physiotherapist aware of the following:

……………………………………………………………………………………………………
……………………………………………………………………………………………………
……………………………………………………………………………………………………
……………………………………………………………………………………………………
……………………………………………………………………………………………………
………

Thank you again for your interest in the trial,
Best wishes

Christine Rogers

Appendix W Focus Groups

Appendix W.1 Thank you letter to site managers and permission to hold focus group.

Department of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Tel: +27 (0) 21 406 6315

E-mail: Christine.Rogers@uct.ac.za

Internet: www.uct.ac.za

29.7.2017

Dear ……………………………. (site manager)

Re: fall prevention clinical trial and focus groups

Thank you so much for your interest in the trial so far. Just to remind you, my name is Christine Rogers, I am a doctoral degree student at UCT and the purpose of this study is for research. You very kindly provided me with information about your site and access to the residents. I would like to thank you so much for this. You may be aware that some residents started the exercise programme, and either continued with it; or for some reason decided it was not for them. I have received very valuable feedback about residents' experiences and I am interested to learn more about this.

I would like to host something called a focus group and would like to request access to the common room at your site in order to hold the group. This letter explains what is requested in more detail. It is followed by an informed consent form.

What is this part of the research about?

I will be running a small group of between six and eight people at a time that suits the residence. All the participants in the group will come from your residence, and I would like to meet in the communal area (e.g. residents' lounge), which I will book with you in advance. The group will start by having some refreshments and settling in. Then I will guide the group in some activities which are described in more detail below.

What will the residents have to do?

Once residents have agreed to join the group and signed the consent

They will be asked to think about three things:

- Their attitude to falls and any thoughts about fall prevention
- their experience of the exercise intervention (whether good or bad – I'd like to know!)
- What if anything, made them leave the programme OR continue with it

Then they will put their thoughts or the most important ideas on sticky notes. After that we will discuss as a small group. Everyone is encouraged to participate and have his or her say. I will chair the group to make sure all the areas are covered in the time we have. To finish, we will look at the sticky notes again and arrange them on a big sheet of paper in order of the most important to the least important.

What else do I as a manager need to know?

- As always, the residents' is entirely voluntary. They do not have to agree to join the group. Residents will be contacted by a research assistant with whom they do not have a therapeutic relationship, so they don't feel obliged in any way. If residents agree to participate and arrive, they may leave at any time without having to explain why.
- Unfortunately, we cannot pay participants for their participation, but they will be given refreshments and a small token of my appreciation for their time.
- I expect the discussion to take about 90 minutes plus time for tea, so residents need to allow about two hours of their time overall.
- The discussion session will be audio-recorded. The conversation will be written out in full and then analysed. Names will not be used in the write up, rather residents will be given a pseudonym.
- Unlike the other parts of the research programme so far, residents will know who the other members of the group are. This means that while I can protect their identity and privacy in any write-up of the results, the other group participants will know who everyone is and what they think. I will ask everyone to keep the session confidential to "outsiders" but cannot do more than this.

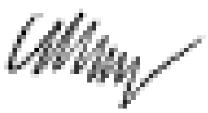
What about risks and benefits?

- While there is no direct benefit for the residents, their experience will give me valuable feedback about the study and the design of any future studies.
- It is unlikely that much personal or distressing information will be revealed in the group. However, should residents become emotional or upset I will offer immediate psychological first aid after the session and a referral if requested.
- There is a potential risk in terms of a breach of confidentiality in the group. I will ask everyone present to keep the group's confidence but cannot guarantee they do so.
- Residents' names will never be entered into the report; and the site will not be identifiable, so it will not be possible for anyone reading the report to trace thoughts and comments back to individuals.
- These precautions, plus the voluntary nature of the study, make the risk/benefit ratio acceptable

Please do feel free to ask any questions you might have. As you know, the overall project has approval from our Human Research Ethics Committee (reference number HREC 818/2015) and permission to conduct this part of the trial has been granted.

Should you have any questions please don't hesitate to ask. My supervisor's names and contact details appear below; as do the details of the Chair of the Ethics Committee.

Thank you again for your time and co-operation



Christine Rogers
Student: Christine Rogers, Telephone 021 406 6315. Email: Christine.Rogers@uct.ac.za

Supervisors:

Prof Dele Amosun: Telephone 021 406 6628 Email: Seyi.Amosun@uct.ac.za
Dr Delva Shamley: Telephone 021 650 1975 Email: Delva.Shamley@uct.ac.za

If you have any ethical queries or concerns, in particular regarding individual rights or the welfare of any research participant, please contact

Faculty of Health Sciences Human Research Ethics Committee
Telephone: 021 406 6492
Email: sumayah.ariefdien@uct.ac.za

Appendix W.2 Interview schedule for focus group discussions.

Topic: Falls and fall management

Are you concerned about falling?

What do you think might contribute to your risk of falling?

Do you know of any strategies to prevent or manage the risk of falling?

Topic: Trial interventions and adherence

Sample questions adapted from Wollesheim, Merkes, Shields, Liamputtong, Wallis, Reynolds, et al., [(928)]:

Why did you join the programme?

Why have you stayed or left the programme?

What was good about the intervention?

What was hard about the intervention?

Probes:

What did you like about it?

What did you dislike about it?

What would you change?

Would you do it again/recommend it/like this to be provided permanently for you

Appendix X Additional Data for Results Chapter

Appendix X.1 Site recruitment.

Error! Reference source not found. shows site recruitment process from the initial contact to the recruitment presentation. S imilar processes were conducted for all sites.

Table X.1. Recruitment processes from initial contact to recruitment presentation.

Date (dd.mm.yyyy)	Type of communication and recipient	Purpose of the Communication/Activity	Duration of the Activity	Outcome/s
01.11.2016	Phone call to Site C reception.	Establish initial interest, ascertain name of manager.	Five minutes.	Manager’s email address obtained.
18.11.2016	Email to manager.	Set up appointment to introduce study to Site manager/s.	Two emails each way to finalise appointment, 20 minutes.	Appointment set up for 23.11.2016.
23.11.2016	Face to face appointment between researcher and site manager.	Discuss study, obtain Site manager’s informed consent, set up date for presentation.	One hour, in person. Forty-minute commute to and from Site C.	Presentation date set, documentation provided in hard copy (previously emailed).

23.11.2016 – 13.12.2016	Emails with management.	Three emails, follow up done.	Twenty minutes.	Indication of interest from manager obtained and signed, date of presentation postponed due to prior commitments on Site, posters to promote recruitment presentation delivered.
13.12.2016	Phone call to Site C manager.	Confirmation of Site C participation and date of recruitment presentation.	Five minutes.	Site C management volunteered to provide some snacks for the residents attending the recruitment presentation. These supplemented those provided by the researcher. (Note, researcher provided all refreshments at all other Sites). Site C permitted the recruitment presentation to proceed prior to formal site induction due to the timing of

				the presentation and impending Christmas holidays[80].
19.12.2016	Recruitment presentation to residents and management at Site C.	Set-up of venue (audio-visual presentation set up, catering set up, meet-and-greet prior to presentation). Presentation and post-presentation question time.	One hour prior to presentation + research assistant. One hour, researcher only.	Pool of interested individuals willing to be contacted for explanation of study.

[80] Christmas falls in summer in South Africa and frequently long vacations are taken at this time. Older adults may join their children on holiday or host visitors during this period. For many industries (except service and tourism industries), annual breaks are scheduled from approximately 15 December to 10 January (Reference: https://www.safcec.org.za/page/Builders_Break, retrieved 6 December 2018).

	Completion of indication of interest forms.	Thirty minutes researcher + research assistant.	
	Clear up venue and catering.	Thirty minutes researcher and research assistant.	

Appendix X.2 Procedures completed at site initiation visits.

Table X.2 gives details of procedures conducted at site initiation visits.

Table X.2. Details of site inspection and enrolment procedures.

Document /Activity	Yes	No	N/A	Comments
Ensure signed and dated curriculum vitae are available for study site staff.			x	Offered and declined by all sites.
Familiarize staff with the protocol.	x			Managers and nursing staff, where available, were present at site initiation meetings.
Familiarize staff with the two interventions.	x			Both interventions were explained. Cluster randomization of the interventions was described. Intervention allocation was revealed immediately before the interventions commenced, as WBB equipment had to be installed (Sites B and C).
Ensure that a trial agreement has been signed and agreed with site.	x			Site and managerial consent documents signed for all sites.
Ensure indemnity/insurance is available for trial site.			x	Study covered by UCT's no-fault insurance policy.
Ensure ethics clearance approval has been granted for the study, contact details of ethics committee and reference number provided to site.	x			Copy of ethical clearance documentation and reference number provided in introductory pack. Repeated clearance for the focus groups was provided and managers and participants re-consented.

Ensure adequate study staff is available.	x			One physiotherapist delivered both interventions. One research assistant assisted with outcome measures at three and six months. Participants were not exposed to a high staff turnover and could build relationships, particularly with the researcher (present at every visit) and physiotherapist.
Discuss and determine the responsibilities of the staff in the clinical trial team.	x			Staff were provided with a pack of outcome measures and the protocol. Research staff signed confidentiality agreements and were blinded to the site allocation.
Familiarize staff with GCP requirements	x			Documentation provided in site pack.
Check that facilities that are required are available and functional.	x			Sites B and C did not have a television in the required location. The researcher provided a television, mounting bracket and extension cables for Site B. Site C's board of trustees purchased a television and screens for privacy. A diary was provided next to each WBB, so participants could book sessions.
Locate a suitable place to store the equipment.	x			WBB situated in a games room at Site B and a screened off area in a communal hall at Site C. Participants undergoing OEP (Site A and Site D) stored their pamphlets and weights (ankle cuffs) in their homes.
Ensure materials and documents for the trial have been received and securely stored.	x			Sent electronically and personally delivered in hard copy to all sites.
Prepare and maintain investigator's file.	x			Protocol and data collection sheets available throughout trial.

Appendix X.3 Demographic and self-assessment scores collected at base-line and their impact on adherence.

Table X.3 shows an analysis of demographic factors and scores from questionnaires with the potential to influence adherence.

Table X.3. Demographic and SAS data and impact on adherence.

Variable	Adherence at three months: WBB (*n* = 4)	Attrition at three months: WBB (*n* = 6)	Adherence at three months: OEP (*n* = 5)	Attrition at three months: OEP (*n* = 6)	Within-group WBB *p*-values	Within-group OEP *p*-values
Age (years, months)	77.3 (4.6)	74.8 (6.6)	78.8 (3.8)	83.5 (5.9)	.547	.163
Gender (female)	4 (100%)	5 (83.3%)	3 (60%)	4 (66.7%	1.00[d]	1.00[d]
Education (> matric)	4 (100%)	3 (50%)	3 (75%)[b]	3 (50%)	.200[d]	.571[d]
Functional Comorbidities Index score	2.8 (1.5)	3.5 (1.6)	3.8 (1.3)	4.8 (1.3)	.486	.228
Fallen in past year (yes)	2 (50%)	4 (66.7%)	2 (40%)	2 (33.3%)	1.00[d]	1.00[d]
Single/recurrent fall (single)	2 (100%)	2 (50%)	1 (50%)	1 (50%)	.467[d]	1.00[d]
Number of falls past year	1 (0)	1.5 (0.6)	1.5 (0.7)	2.5 (2.1)	.312	.592
SEE baseline	8.3 (1.1)	6.9 (1.8)	6.3 (1.5)	7.2 (2)	.196	.427
SEE 3-months	1.3 (0.5)	1 (0)	1.2 (0.4)	1 (0)	.476[e]	.429[e]
EQ-5D 3-L score baseline	1.2 (0.2)	1.1 (0.1)	1.1 (0.1)	1.4 (0.2)	.393	.059
EQ-5D VAS baseline	83 (7.3)	87.2 (4.2)	80.8 (6.6)	73.5 (11.4)	.277	.240
EQ-5D 3-L score 3-months	1.1 (0.1)	1.1 (0.2)	1 (0.1)	1.3 (0.3)	.713	.085
EQ-5D VAS 3-months	89 (11.6)	83.3 (12.1)	84.4 (9.2)	73.5 (12.2)	.482	.136
PASE score baseline	69 (16.7)	79.5 (51.1)	77.9 (31)	59.8 (26.4)	.706	.322
PASE score 3-months	56.3 (19.9)	63.6 (42.4)	81.3 (31.2)	53.1 (35.6)	.758	.201

Mini-Cog score	4.3 (1)	4.7 (0.8)	4.6 (0.9)	4.5 (1.2)	.480	.883
GDS	0.5 (0.6)	1.4 (2.6)[a]	0.4 (0.9)	2.4 (2.3)[c]	.525	.108
FRAT-up score	0.4 (0.1)	0.4 (0.1)	0.4 (0.1)	0.4 (0.1)	.689	.733

Appendix Table W.3 data and legend

[a]Data based on 5 participants. [b]Data based on 4 participants. [c]Data based on 5 participants. [d]Fisher's Exact test performed. [e]Wilcoxon signed-rank test performed. For continuous variables, means are presented with standard deviation in parentheses. For categorical variables, actual numbers are presented with proportions in parentheses.

Legend: SEE: Self Efficacy for Exercise; EQ-5D-3L: EuroQOL quality of life score; EQ-5D-3L VAS: EuroQOL quality of life Visual Analogue Scale; PASE: Physical Activity Scale for Elderly; GDS: Geriatric Depression Scale; FRAT-up: Fall Risk Assessment Tool for community-dwelling elders.

Appendix Y

Table Y.1. Breakdown of feasibility study costs.

Item and description	Cost and comments
Programme-related costs	
Consumables for both programmes	
Recruitment presentation refreshments (all sites).	R2 156
Site recruitment phone calls. Average five calls/site during business hours. Average R2.50/call for five minutes. Ten minutes for first call to each site, then five minutes per follow up call x four calls per site	R100 maximum. Some calls made using Broadband connection. Once sites were recruited, most communication was via email.
Participant recruitment phone calls (average of two calls per participant screened). In South Africa, unanswered telephone calls incur a charge.	Number of potential participants interested = 102 x 2 calls per participant/x 2.50 per call = R510
Printing of intervention programmes, assessment packs for sites and participants, exercise/fall calendars, stickers and magnetic clips for calendars to be stuck to participants' refrigerators	R7 169.63
Test purchase	
PASE purchased 2014 US$125	R1 388 (using 2014 exchange rate)
Equipment – OEP intervention	
Ankle weight cuffs one set/OEP participant	R2 190
Equipment – WBB intervention	
Television, bracket for wall mounting and extension cable Site B	R3 676
Television, bracket for wall mounting and extension cable Site C	R0 (bought by Board of Trustees)
Wii equipment (balance board, interface, remote controls); two complete units	R2 700
Batteries for remote control (two boxes/site x 2 sites)	R366.40

Item and description	Cost and comments
Physical end-point assessment equipment	
Ankle incline board (Mini-BESTest)	R2 776
Stopwatches x3 (timed tests)	R450
Traffic cones (DGI)	R75
Metal measuring tape (Mini-BESTest, DGI)	R114
Airex Balance Pad (Mini-BESTest)	R856
Sundries: Hand-sanitiser, tissues, clipboards, pens, box for Mini-BESTest, simple lunches/snacks for research assistant when data collecting all day	Materials: R400 Lunches: R600
Research personnel training and staff costs	
Researcher training (2015): CREDE Good Clinical Practice Training (required for a registered RCT).	R2 970
Qualification update course (2018)	R2 088.16
Clinical Investigator Certification Course	R4 200
Researcher's personal insurance/professional indemnity. This personal cover is in addition to UCT's no fault insurance, for which there was no direct charge.	R895 per year x 3 years: R2 685
Researcher's registration with professional statutory body (essential for practice as an audiologist)	2016 (data collection commenced): R1 378 2017 (data collection continued): R1 543 2018 (data collection continued): R1 642
Physiotherapist OEP on-line training registration fee	R503
Physiotherapist OEP training: time 4 hours. Hourly rate R400	R1 600

Item and description	Cost and comments
Physiotherapist WBB training: time 6 hours.	R2 400
Hourly rate R400	
Physiotherapist time for both interventions (contact time including follow-up, telephone call follow-up).	104 hours
Hourly rate R400	R41 600
Researcher's hours eligibility/consent interview 1.5 hours per appointment	132 hours
Hourly rate senior lecturer level: R378.17 per hour (contract basis)	R49 918.44
Researcher's hours following up participants at three and six months	34 participants at three months R9 643
45 minutes per participant (0.75 [minutes] x 34 participants @ R378.17)	
	31 participants at six months
Rate per hour at senior lecturer level: R378.17 (contract basis)	R8 792.42
Research assistant following up participants at three and six months	34 participants at three months R5 100
45 minutes per participant	
Hours rounded to per hour/part thereof as casual employee	31 participants at six months
Hourly rate at junior research fellow level: R150	R4 650
Focus group expenses	
Focus group refreshments (3 sites)	R1 260
Gifts for focus group participants (pens, document folders)	R478.21

Item and description	Cost and comments
Focus group facilitator and assistant	Two staff, 6 hours total
Hourly rate at junior research fellow level: R150	R1 800
	1.5 hours total
Calls to set up appointments	R225
Hourly rate at junior research fellow level: R150	27 hours
Focus group transcription (three groups of 90 minutes each)	R4 050
Hourly rate at junior research fellow level: R150	
Database, data capture and analysis	
Redcap Database site construction	R7 128
Data capture	
Data consolidation meeting with researcher	3 hours
Database training/quality assurance	3.5 hours
Data entry	86 hours
Hourly rate at junior research fellow level: R150	
Total hours = 93	R13 875
Statistician support	
Total of 28 hours at a staff discounted rate of R300 per hour (initial briefing by researcher, design, computation, consultation with researcher)	R8 400
Grand total	**R 203 456.26**

REFERENCES

1. Romli MH, Tan MP, Mackenzie L, Lovarini M, Suttanon P, Clemson L. Falls amongst older people in Southeast Asia: a scoping review. Public Health. 2017;145:96-112.
2. Rydwik E, Bergland A, Forsén L, Frändin K. Psychometric properties of Timed Up and Go in elderly people: a systematic review. Phys Occup Ther Geriatr. 2011;29(2):102-25.
3. Romero S, Bishop MD, Velozo CA, Light K. Minimum detectable change of the Berg Balance Scale and Dynamic Gait Index in older persons at risk for falling. J Geriatr Phys Ther. 2011;34(3):131-7.
4. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ (Clinical research ed). 2014;348:g1687.
5. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007;19(6):349-57.
6. Wright WG, Agah MR, Darvish K, Keshner EA. Head stabilization shows visual and inertial dependence during passive stimulation: Implications for virtual rehabilitation. Neural Systems and Rehabilitation Engineering, IEEE Transactions on. 2013;21(2):191-7.
7. 2018. Activities of Daily Living.
8. Lusardi MM, Fritz S, Middleton A, Allison L, Wingood M, Phillips E, et al. Determining risk of falls in community dwelling older adults: A systematic review and meta-analysis using Posttest Probability. J Geriatr Phys Ther. 2017;40(1):1-36.
9. Center for Cancer Research NHI. Adverse events: documenting, recording and reporting 2018 [Available from: clinicaltrialtools.vc.ons.org/file_depot/0-10000000/0-10000/1338/folder/1119270/Adverse+Events.pdf.
10. Phillips R, Hazell L, Sauzet O, Cornelius V. Analysis and reporting of adverse events in randomised controlled trials: a review. BMJ Open. 2019;9(2):e024537.
11. Association AS-L-H. Guidelines for manual pure-tone threshold audiometry. Washington, DC; 2005.
12. Avin KG, Hanke TA, Kirk-Sanchez N, McDonough CM, Shubert TE, Hardage J, et al. Management of falls in community-dwelling older adults: clinical guidance statement from the Academy of Geriatric Physical Therapy of the American Physical Therapy Association. Phys Ther. 2015;95(6):815-34.
13. Eibling D. Balance disorders in older adults. Clin Geriatr Med. 2018;34(2):175-81.
14. Von Brevern M, Bertholon P, Brandt T, Fife T, Imai T, Nuti D, et al. Benign paroxysmal positional vertigo: diagnostic criteria. J Vestib Res. 2015;25(3, 4):105-17.
15. Liu Y, Wang W, Zhang Ab, Bai X, Zhang S. Epley and Semont maneuvers for posterior canal benign paroxysmal positional vertigo: A network meta-analysis. The Laryngoscope. 2016;126(4):951-5.
16. Campbell B, Kimura K, Yawn R, Bennett M. Pathophysiology and diagnosis of BPPV. In: Babu S., Schutt C., D. B, editors. Diagnosis and Treatment of Vestibular Disorders. Cham, Switzerland: Springer; 2019. p. 141-50.
17. Fallahzadeh Abarghuei A, Fadavi-Ghaffari M, Tousi S, Amini M, Salehi AR. Effect of Cawthorne and Cooksey exercises on balance and quality of life of 60 to 80 year-old individuals in Shiraz: A randomized clinical trial. Med J Islam Repub Iran. 2018;32(1):429-33.
18. Kundakci B, Sultana A, Taylor AJ, Alshehri MA. The effectiveness of exercise-based vestibular rehabilitation in adult patients with chronic dizziness: A systematic review. F1000Research. 2018;7.
19. Barry E, Galvin R, Keogh C, Horgan F, Fahey T. Is the Timed Up and Go test a useful predictor of risk of falls in community dwelling older adults: a systematic review and meta-analysis. BMC Geriatr. 2014;14:14.

20. Barrett P, Twitchin S, Kletchko S, Ryan F. The living environments of community-dwelling older people who become frail: another look at the living standards of older New Zealanders survey. Social Policy Journal of New Zealand: Te Puna Whakaaro. 2006;28:133-57.
21. Collard RM, Boter H, Schoevers RA, Oude Voshaar RC. Prevalence of frailty in community-dwelling older persons: a systematic review. J Am Geriatr Soc. 2012;60(8):1487-92.
22. Henderson S, Horne M, Hills R, Kendall E. Cultural competence in healthcare in the community: a concept analysis. Health Soc Care Community. 2018;26(4):590-603.
23. Organisation WH. Falls fact sheet 344. 2018.
24. Murray CJL, Abraham J, Ali MK, Alvarado M, Atkinson C, Baddour LM, et al. The state of US health, 1990-2010: burden of diseases, injuries, and risk factors. JAMA. 2013;310(6):591-606.
25. Haagsma JA, Graetz N, Bolliger I, Naghavi M, Higashi H, Mullany EC, et al. The global burden of injury: incidence, mortality, disability-adjusted life years and time trends from the Global Burden of Disease study 2013. Inj Prev. 2016;22(1):3-18.
26. Homedes N. The disability-adjusted life year (DALY) definition, measurement and potential use (English). Washington, DC: World Bank.; 1996. Contract No.: Report.
27. Agrawal Y. Dizziness demographics and population health In: Kesser BW, Gleason AT, editors. Dizziness and Vertigo across the Lifespan St Louis, Missouri: Elsevier Health Sciences.; 2018. p. 1-8.
28. Li KZ, Bherer L, Mirelman A, Maidan I, Hausdorff JM. Cognitive involvement in balance, gait and dual-tasking in aging: A focused review from a neuroscience of aging perspective. Front Neurol. 2018;9.
29. Riska KM, Hall CD. Reliability and normative data for the dynamic visual acuity test for vestibular screening. Otol Neurotol. 2016;37(5):545-52.
30. Scherer M, Schubert MC. High-velocity angular Vestibulo-Ocular Reflex adaptation to position error signals. J Neurol Phys Ther. 2010;34(2):82-6.
31. Kenny RA, Romero-Ortuno R, Kumar P. Falls in older adults. Medicine. 2017;45(1):28-33.
32. Lamb SE, Jørstad-Stein EC, Hauer K, Becker C. Development of a common outcome data set for fall injury prevention trials: the Prevention of Falls Network Europe consensus. Journal of the American Geriatric Society. 2005;53:1618-22.
33. Kiely DK, Kim DH, Gross AL, Habtemariam DA, Leveille SG, Li W, et al. Fall risk is not black and white. J Health Dispar Res Prac. 2015;8(3):72-84.
34. Gillespie LD, Gillespie WJ, Robertson MC, Lamb SE, Cumming RG, Rowe BH. Interventions for preventing falls in elderly people (Review). London, United Kingdom: John Wiley & Sons Ltd.; 2009. Contract No.: Report.
35. Rubenstein lZ, Stevens JA, Scott V. Interventions to prevent falls among older people. In: Doll IS, Bonzo SE, Sleet DA, Mercy JA, Haas EN, editors. Handbook of injury and violence prevention. New York,NY: Springer.; 2007. p. 37-53.
36. Araújo ER, Martins LB, editors. Environmental risks associated with falls on sidewalks: A systematic review. Occupational Safety and Hygiene V; 2017 April 10-11, 2017; Guimarães, Portugal: CRC Press.
37. Shen L. Fatalism and locus of control as a consideration when designing health and risk messages 2017 [Available from: https://oxfordre.com/communication/view/10.1093/acrefore/9780190228613.001.0001/acrefore-9780190228613-e-341.
38. Nageeb S, Vu M, Malik S, Quinn MT, Cursio J, Padela AI. Adapting a religious health fatalism measure for use in Muslim populations. PLoS One. 2018;13(11):e0206898.
39. Kojima G. Quick and simple FRAIL scale predicts incident activities of daily living (ADL) and instrumental ADL (IADL) disabilities: a systematic review and meta-analysis. J Am Med Dir Assoc. 2018;19:1063-8.

40. Wallace LMK, Theou O, Rockwood K. Frailty, cognition, and falls. In: Montero-Odasso M, Camicioli R, editors. Falls and cognition in older persons: Fundamentals, assessment and therapeutic options. Cham, Switzerland: Springer International Publishing; 2020. p. 67-83.
41. Confraria H, Godinho MM, Wang L. Determinants of citation impact: A comparative analysis of the Global South versus the Global North. Research Policy. 2017;46(1):265-79.
42. Arnold SA, Stewart AM, Moor HM, Karl RC, Reneker JC. The effectiveness of vestibular rehabilitation interventions in treating unilateral peripheral vestibular disorders: A systematic review. Physiother Res Int. 2017;22(3):1-15.
43. McCambridge J, Witton J, Elbourne DR. Systematic review of the Hawthorne effect: new concepts are needed to study research participation effects. J Clin Epidemiol. 2014;67(3):267-77.
44. Bank TW. What is an international dollar? 2018.
45. Jacob S. The internal ear. Head and Neck. In S. Jacob (2008), Human Anatomy: a clinically orientated approach2019.
46. Ralston M, Schatz E, Naidoo N, Kowal P. Including older adults in Development Goals: Is subjective wellbeing the answer? A case study of older South Africans. J Dev Stud. 2018;54(4):702-18.
47. Beltrán-Sánchez H, Razak F, Subramanian SV. Going beyond the disability-based morbidity definition in the compression of morbidity framework. Global Health Action. 2014;7(1):24766.
48. Merriam-Webster D. Mortality definition.
49. VandenBos GR. Publication Manual of the American Psychological Association. 6th ed. Washington, D. C.: American Psychological Association; 2010.
50. Gorman M. Development and rights of older people. In: J Randal TG, Ewing D, editors. The Ageing and Development Report 1ed. London: Routlege; 2017. p. 21-39.
51. Mol A, Hoang PTSB, Sharmin S, Reijnierse EM, van Wezel RJ, Meskers CG, et al. Orthostatic hypotension and falls in older adults: a systematic review and meta-analysis. J Am Med Dir Assoc. 2018;20(5):589-97.
52. Freeman R, Wieling W, Axelrod FB, Benditt DG, Benarroch E, Biaggioni I, et al. Consensus statement on the definition of orthostatic hypotension, neurally mediated syncope and the postural tachycardia syndrome. Clin Auton Res. 2011;21:69-72.
53. Thomas S, Mackintosh S, Halbert J. Does the ‘Otago exercise programme’reduce mortality and falls in older adults?: A systematic review and meta-analysis. Age Ageing. 2010;39(6):681-7.
54. Wrynn A. On the margins: Therapeutic massage, physical education and Physical Therapy defining a profession. The International Journal of the History of Sport. 2014;31(15):1882-95.
55. Studer M. Dual-task rehabilitation. Topics in Geriatric Rehabilitation. 2018;34(1):54-64.
56. Morin L, Johnell K, Laroche M-L, Fastbom J, Wastesson JW. The epidemiology of polypharmacy in older adults: register-based prospective cohort study. Clin Epidemiol. 2018;10:289 -98.
57. Wastesson JW, Morin L, Tan EC, Johnell K. An update on the clinical consequences of polypharmacy in older adults: a narrative review. Expert Opin Drug Saf. 2018;17(12):1185-96.
58. Gutiérrez-Valencia M, Izquierdo M, Cesari M, Casas-Herrero Á, Inzitari M, Martínez-Velilla N. The relationship between frailty and polypharmacy in older people: A systematic review. Br J Clin Pharmacol. 2018;84(7):1432-44.
59. Nordvik Ø, Heggdal POL, Brännström J, Vassbotn F, Aarstad AK, Aarstad HJ. Generic quality of life in persons with hearing loss: a systematic literature review. BMC Ear, Nose and Throat Disorders. 2018;18(1):1.
60. Jalali MM, Gerami H, Heidarzadeh A, Soleimani R. Balance performance in older adults and its relationship with falling. Aging Clin Exp Res. 2015;27(3):287-96.
61. Gras LZ, Ganley KJ, Bosch PR, Mayer JE, Pohl PS. Convergent validity of the Sharpened Romberg. Phys Occup Ther Geriatr. 2017;35(2):99-108.
62. Gras LZ, Pohl PS, Epidy J, Godin B, Hoessle N. Use of the Sharpened Romberg as a screening for fall risk: A pilot study. Topics in Geriatric Rehabilitation. 2017;33(2):113-7.

63. Dogra S, Ashe MC, Biddle SJH, Brown WJ, Buman MP, Chastin S, et al. Sedentary time in older men and women: an international consensus statement and research priorities. Br J Sports Med. 2017;51(21):1526-32.
64. Tjernström F, Zur O, Jahn K. Current concepts and future approaches to vestibular rehabilitation. J Neurol. 2016;263(1):65-70.
65. Lacour M, Bernard-Demanze L. Interaction between vestibular compensation mechanisms and vestibular rehabilitation therapy: 10 recommendations for optimal functional recovery. Front Neurol. 2015;5:285.
66. Rego P, Moreira PM, Reis LP, editors. Serious games for rehabilitation. A survey and a classification towards a taxonomy. 5th Iberian conference on information systems and technologies; 2010 June 2010: Information Systems and Technologies (CISTI).
67. Stodel M. But what will people think?: Getting beyond social desirability bias by increasing cognitive load. Int J Market Res. 2015;57(2):313-22.
68. Brignole M, Moya A, de Lange FJ, Deharo J-C, Elliott PM, Fanciulli A, et al. 2018 ESC Guidelines for the diagnosis and management of syncope. Eur Heart J. 2018;39(21):1883-948.
69. Sambala EZ, Cooper S, Manderson L. Ubuntu as a framework for ethical decision making in Africa: Responding to epidemics. Ethics Behav. 2020;30(1):1-13.
70. Opperman C. Ubuntu ethics: Putting your culture first in the hospital workplace. South African Journal of Bioethics and Law. 2019;12(1):3-4.
71. King LA, Horak FB. The role of the vestibular system in postural control. In: Herdman SJ, Clendaniel RA, editors. Vestibular Rehabilitaton. 4th ed. New Delhi, India: Jaypee Brothers Medical Publishers; 2014. p. 29-44.
72. King WM. Getting ahead of oneself: Anticipation and the vestibulo-ocular reflex. Neuroscience. 2013;236:210-9.
73. Deveze A, Bernard-Demanze L, Xavier F, Lavieille JP, Elziere M. Vestibular compensation and vestibular rehabilitation. Current concepts and new trends. Clin Neurophys. 2014;44(1):49-57.
74. Huppert D, Brandt T. Dizziness and vertigo syndromes viewed with a historical eye. J Neurol. 2018;265(1):127-33.
75. van Vugt VA, van der Horst HE, Payne RA, Maarsingh OR. Chronic vertigo: treat with exercise, not drugs. BMJ. 2017;358:410-2.
76. Alghadir AH, Iqbal ZA, Whitney SL. An update on vestibular physical therapy. J Chin Med Assoc. 2013;76(1):1-8.
77. Robinson HS, Dagfinrud H. Reliability and screening ability of the StarT Back screening tool in patients with low back pain in physiotherapy practice, a cohort study. BMC Musculoskelet Disord. 2017;18(1):232.
78. Wessel RN, Wolterbeek N, Fermont AJM, Lavrijsen L, van Mameren H, de Bie RA. Responsiveness and disease specificity of the Western Ontario Rotator Cuff index. Journal of Orthopaedics. 2018;15(2):337-42.
79. Jones R, Jones RO, McCowan C, Montgomery AA, Fahey T. The external validity of published randomized controlled trials in primary care. BMC Fam Pract. 2009;10(1):5.
80. Bland JM, Altman DG. Statistics notes. The odds ratio. BMJ (Clinical research ed). 2000;320(7247):1468.
81. Stucki G, Bickenbach J, Gutenbrunner C, Melvin J. Rehabilitation: the health strategy of the 21st century. J Rehabil Med. 2018;50(4):309-16.
82. Malik AN. Exer-Gaming: A novel tool in stroke rehabilitation. Journal of Riphah College of Rehabilitation Sciences. 2015;3(2):48-9.
83. Xiong S, Zhang P, Gao Z. Effects of exergaming on preschoolers' executive functions and perceived competence: A pilot randomized trial. Journal of Clinical Medicine. 2019;8(4):12.
84. Narváez F, Marín-Castrillón DM, Cuenca M, Latta M. Development and implementation of technologies for physical telerehabilitation in Latin America: a systematic review of literature, programs and projects. Tecno Lógicas. 2017;20(40):155-76.

85. Van Biljon A, Longhurst G. The influence of exergaming on the functional fitness in overweight and obese children. African Journal for Physical Health Education, Recreation and Dance. 2012;18(Issue-4_2):984-91.
86. Smits-Engelsman BC, Jelsma LD, Ferguson GD. The effect of exergames on functional strength, anaerobic fitness, balance and agility in children with and without motor coordination difficulties living in low-income communities. Human Movement Science. 2017;55:327-37.
87. Cheng KK, Metcalfe A. Qualitative methods and process evaluation in clinical trials context: Where to head to? International Journal of Qualitative Methods. 2018;17:1-4.
88. Vaismoradi M, Jones J, Turunen H, Snelgrove S. Theme development in qualitative content analysis and thematic analysis. Journal of Nursing Education and Practice. 2016;6(5):100-10.
89. Tan PJ, Tan MP. Characteristics of fall recurrence: recurrence of the Malaysian Falls Assessment and Intervention Trial (MyFAIT). Age Ageing. 2017;46(Suppl. 1):i34.
90. Liew LK, Tan MP, Tan PJ, Mat S, Majid LA, Hill KD, et al. The Modified Otago Exercises prevent grip strength deterioration among older fallers in the Malaysian Falls Assessment and Intervention Trial (MyFAIT). J Geriatr Phys Ther. 2019;42(3):123-9.
91. Mat S, Ng C, Tan M. Effect of the Otago exercises on postural balance and fear of falling among older fallers with knee osteoarthritis. Osteoarthritis Cartilage. 2016;24:S66.
92. Mat S, Ng CT, Tan PJ, Ramli N, Fadzli F, Rozalli FI, et al. Effect of modified Otago Exercises on postural balance, fear of falling, and fall risk in older fallers with knee osteoarthritis and impaired gait and balance: A secondary analysis. PM&R. 2018;10(3):254-62.
93. Bank TW. The World Bank in Malaysia 2019 [updated March 2019. Available from: https://www.worldbank.org/en/country/malaysia/overview.
94. Forsythe L, Heckert A, Margolis MK, Schrandt S, Frank L. Methods and impact of engagement in research, from theory to practice and back again: early findings from the Patient-Centered Outcomes Research Institute. Qual Life Res. 2018;27(1):17-31.
95. Boisvert I, Clemesha J, Lundmark E, Crome E, Barr C, McMahon CM. Decision-making in audiology: Balancing evidence-based practice and patient-centered care. Trends in Hearing. 2017;21:1-14.
96. Haddad YK, Bergen G, Florence C. Estimating the economic burden related to older adult falls by state. J Public Health Manag Pract. 2019;25(2):E17-24.
97. Alonge O, Hyder AA. Reducing the global burden of childhood unintentional injuries. Arch Dis Child. 2014;99(1):62-9.
98. Verma SK, Willetts JL, Corns HL, Marucci-Wellman HR, Lombardi DA, Courtney TK. Falls and fall-related injuries among community-dwelling adults in the United States. PLoS One. 2016;11(3):e0150939.
99. Harmon KJ, Hakenewerth AM, Waller AE, Ising A, Tintinalli JE. Begin risk assessment for falls in women at 45, not 65. Inj Prev. 2019;25(3):184-6.
100. Shen Y, Tay YC, Teo EWK, Liu N, Lam SW, Ong MEH. 240 Association between the elderly frequent attender to the Emergency Department and 30-Day mortality: A retrospective study over 10 Years. Ann Emerg Med. 2017;70(4):S96.
101. Alqahtani BA, Alshehri MM, Hoover JC, Alenazi AM. Prevalence of falls among older adults in the Gulf Cooperation Council countries: A systematic review and meta-analysis. Arch Gerontol Geriatr. 2019;83:169-74.
102. Ambrose AF, Paul G, Hausdorff JM. Risk factors for falls among older adults: a review of the literature. Maturitas. 2013;75(1):51-61.
103. Frith J, Davison J. Falls. Rev Clin Gerontol. 2013;23(02):101-17.
104. Skelton DA, Hauer K, Lamb S. Re: 'Falls Definition Validation'. Age Ageing. 2007;36(1):111-2.
105. Copsey B, Hopewell S, Becker C, Cameron ID, Lamb SE. Appraising the uptake and use of recommendations for a common outcome data set for clinical trials: a case study in fall injury prevention. Trials. 2016;17(1):131.

106. Lima CA, Ricci NA, Nogueira EC, Perracini MR. The Berg Balance Scale as a clinical screening tool to predict fall risk in older adults: a systematic review. Physiotherapy. 2018;104(4):383-91.
107. Gazibara T, Kurtagic I, Kisic-Tepavcevic D, Nurkovic S, Kovacevic N, Gazibara T, et al. Falls, risk factors and fear of falling among persons older than 65 years of age. Psychogeriatrics. 2017;17(4):215-23.
108. Kosma M. An expanded framework to determine physical activity and falls risks among diverse older adults. Res Aging. 2014;36(1):95-114.
109. Li F, Eckstrom E, Harmer P, Fitzgerald K, Voit J, Cameron KA. Exercise and fall prevention: Narrowing the research-to-practice gap and enhancing integration of clinical and community practice. J Am Geriatr Soc. 2016;64(2):425-31.
110. Paul S. Falls: Prevention and Management. In: Nair BKR, editor. Geriatric Medicine A problem-based approach. Singapore: Springer; 2018. p. 109-19.
111. Tichenor M, Sridhar D. Metric partnerships: global burden of disease estimates within the World Bank, the World Health Organisation and the Institute for Health Metrics and Evaluation. Wellcome Open Research. 2019;4(35).
112. Timsina LR, Willetts JL, Brennan MJ, Marucci-Wellman H, Lombardi DA, Courtney TK, et al. Circumstances of fall-related injuries by age and gender among community-dwelling adults in the United States. PLoS One. 2017;12(5):e0176561.
113. Centers for Disease C. Falls are leading cause of injury and death in older Americans 2016 [Available from: https://www.cdc.gov/media/releases/2016/p0922-older-adult-falls.html.
114. Hartholt KA, Lee R, Burns ER, Van Beeck EF. Mortality from falls among US adults aged 75 years or older, 2000-2016. JAMA. 2019;321(21):2131-3.
115. Raina P, Sohel N, Oremus M, Shannon H, Mony P, Kumar R, et al. Assessing global risk factors for non-fatal injuries from road traffic accidents and falls in adults aged 35–70 years in 17 countries: a cross-sectional analysis of the Prospective Urban Rural Epidemiological (PURE) study. Inj Prev. 2016;22(2):92-8.
116. Vellios N, Van Walbeek C. Self-reported alcohol use and binge drinking in South Africa: Evidence from the National Income Dynamics Study, 2014-2015. S Afr Med J. 2018;108(1):33-9.
117. Kassebaum NJ, Arora M, Barber RM, Bhutta ZA, Brown J, Carter A, et al. Global, regional, and national disability-adjusted life-years (DALYs) for 315 diseases and injuries and healthy life expectancy (HALE), 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. The Lancet. 2016;388(10053):1603-58.
118. Mokdad AH, Mensah GA, Krish V, Glenn SD, Miller-Petrie MK, Lopez AD, et al. Global, regional, national, and subnational big data to inform health equity research: perspectives from the Global Burden of Disease Study 2017. Ethn Dis. 2019;29(Suppl 1):159-72.
119. Statssa. World Populataion Day: How does South Africa compare? 2019 [Available from: http://www.statssa.gov.za/?p=12324.
120. Statssa. Mid-year population estimates 2018. Pretoria, South Africa: STATS SA; 2018 23 July 2018. Contract No.: Statistical Release P0302.
121. Gore PG, Kingston A, Johnson GR, Kirkwood TB, Jagger C. New horizons in the compression of functional decline. Age Ageing. 2018;47(6):764-8.
122. Sudharsanan N, Bloom DE, editors. The demography of aging in low-and middle-income countries: chronological versus functional perspectives. Future directions for the demography of aging: proceedings of a workshop, E-Book, The National Academies Press, Washington, DC, available at https://www nap edu/read/25064; 2018.
123. Peltzer K, Phaswana-Mafuya N. Physical inactivity and associated factors in older adults in South Africa: geriatrics. African Journal for Physical Health Education, Recreation and Dance. 2012;18(3):447-60.
124. Chang AY, Skirbekk VF, Tyrovolas S, Kassebaum NJ, Dieleman JL. Measuring population ageing: an analysis of the Global Burden of Disease Study 2017. The Lancet Public Health. 2019;4(3):e159-e67.

125. Roser M, Ritchie H. Burden of Disease. 2018 [Available from: https://ourworldindata.org/burden-of-disease' [Online Resource].
126. Atella V, Belotti F, Cricelli CA, Dankova D, Kopinska J, Palma A, et al. The 'Double Expansion of Morbidity' hypothesis: Evidence from Italy. 2018 February 2018. Contract No.: 396.
127. Ackerman IN, Soh S-E, Barker AL. Opportunities for cross-disciplinary care partnerships in physiotherapy. J Physiother. 2018;64(2):69-71.
128. Hicks GE. Addressing balance, mobility, and falls: Are we moving the needle on fall prevention? The Journals of Gerontology: Series A. 2019;74(9):1487-8.
129. Lewis BA, Napolitano MA, Buman MP, Williams DM, Nigg CR. Future directions in physical activity intervention research: expanding our focus to sedentary behaviors, technology, and dissemination. J Behav Med. 2017;40(1):112-26.
130. Gennuso KP, Thraen-Borowski KM, Gangnon RE, Colbert LH. Patterns of sedentary behavior and physical function in older adults. Aging Clin Exp Res. 2016;28(5):943-50.
131. Barr AL, Young EH, Sandhu MS. Objective measurement of physical activity: improving the evidence base to address non-communicable diseases in Africa. BMJ Global Health. 2018;3(5):e001044.
132. Hulteen RM, Smith JJ, Morgan PJ, Barnett LM, Hallal PC, Colyvas K, et al. Global participation in sport and leisure-time physical activities: A systematic review and meta-analysis. Prev Med. 2017;95:14-25.
133. Joubert J, Norman R, Lambert EV, Groenewald P, Schneider M, Bull F, et al. Estimating the burden of disease attributable to physical inactivity in South Africa in 2000. S Afr Med J. 2007;97(8):725-31.
134. Malambo P, Kengne AP, Lambert EV, De Villiers A, Puoane T. Prevalence and socio-demographic correlates of physical activity levels among South African adults in Cape Town and Mount Frere communities in 2008-2009. Archives of Public Health. 2016;74(1):54.
135. Ozemek C, Lavie CJ, Rognmo Ø. Global physical activity levels-Need for intervention. Prog Cardiovasc Dis. 2019;62:102-7.
136. Bowen PG, Mankowski RT, Harper SA, Buford TW. Exercise is medicine as a vital sign: challenges and opportunities. Translational Journal of the American College of Sports Medicine. 2019;4(1):1-7.
137. Ndinda C, Ndhlovu TP, Juma P, Asiki G, Kyobutungi C. The evolution of non-communicable diseases policies in post-apartheid South Africa. BMC Public Health. 2018;18(1):956.
138. LeBlanc AG, Chaput J-P. Pokémon Go: A game changer for the physical inactivity crisis? Prev Med. 2017;101:235-7.
139. Fell N, Clark A, Jackson J, Angwin C, Farrar I, Bishop C, et al. The evolution of a community-wide interprofessional fall prevention partnership: Fall prevention as a vehicle for community and university collaboration and interprofessional education. Journal of Interprofessional Education & Practice. 2017;8:47-51.
140. Stucki G, Bickenbach J, Gutenbrunner C, Melvin J. Rehabilitation: The health strategy of the 21st century. J Rehabil Med. 2017.
141. Pullar J, Allen L, Townsend N, Williams J, Foster C, Roberts N, et al. The impact of poverty reduction and development interventions on non-communicable diseases and their behavioural risk factors in low and lower-middle income countries: a systematic review. PLoS One. 2018;13(2):e0193378.
142. Organisation WH. Alma Ata Declaration. Geneva: World Health Organisation; 1978.
143. Morris LD, Grimmer KA, Twizeyemariya A, Coetzee M, Leibbrandt DC, Louw QA. Health system challenges affecting rehabilitation services in South Africa. Disabil Rehabil. 2019 aop:1-7.
144. Ding D, Lawson KD, Kolbe-Alexander TL, Finkelstein EA, Katzmarzyk PT, Van Mechelen W, et al. The economic burden of physical inactivity: a global analysis of major non-communicable diseases. The Lancet. 2016;388(10051):1311-24.

145. Jiam NTL, Li C, Agrawal Y. Hearing loss and falls: A systematic review and meta-analysis. The Laryngoscope. 2016;126(11):2587-96.
146. Shayman CS, Earhart GM, Hullar TE. Improvements in gait with hearing aids and cochlear implants. Otol Neurotol. 2017;38(4):484-6.
147. Criter RE, Honaker JA. Falls in the audiology clinic: a pilot study. J Am Acad Audiol. 2013;24(10):1001-5.
148. Rutherford BR, Brewster K, Golub JS, Kim AH, Roose SP. Sensation and psychiatry: Linking age-related hearing loss to late-life depression and cognitive decline. Am J Psychiatry. 2017;175(3):215-24.
149. Criter RE, Honaker JA. Audiology patient fall statistics and risk factors compared to non-audiology patients. Int J Audiol. 2016;55(10):564-70.
150. Criter RE, Honaker JA. Fall risk screening protocol for older hearing clinic patients. Int J Audiol. 2017;56(10):767-74.
151. Johnson CE, Newman CW, Danhauer JL, Williams VA. Screening for hearing loss, risk of falls: a hassle-free approach: plain questions and uncomplicated testing can save you time and safeguard your patients. These tools will help. J Fam Pract. 2009;58(9):471-8.
152. Nelson MD, Akin FW, Riska KM, Andresen K, Mondelli SS. Vestibular assessment and rehabilitation: Ten-year survey trends of audiologists' opinions and practice. J Am Acad Audiol. 2016;27(2):126-40.
153. Jilla AM, Roberts RA, Johnson CE. Teaching patient-centered counseling skills for assessment, diagnosis, and management of Benign Paroxysmal Positional Vertigo. Seminars in Hearing. 2018;39(01):52-66.
154. Seedat T, Khoza-Shangase K, Sebothoma B. Vestibular assessment and management in adults: current practice by South African audiologists. Hearing, Balance and Communication. 2018;16(2):88-100.
155. Jacobson GP. Assessing the risk of falls in the elderly: above and beyond the ENG. The Hearing Journal. 2001;54(6):10-2.
156. Bassett AM, Honaker JA. Audiologist's role within the changing climate of fall prevention: Are we ready? Perspectives of the ASHA Special Interest Groups. 2016;1(8):4-13.
157. Africa HPCoS. Statement regarding special licensing vestibular practice. 2018.
158. Hall CD, Meldrum D. The aging vestibular system: Implications for rehabilitation. In: Jacobson GP, Shephard NTT, editors. Balance Function Assessmet and Management. 2nd ed. San Diego, CA.: Plural Publishing Inc.; 2016. p. 793-808.
159. Anson E, Jeka J. Perspectives on aging vestibular function. Front Neurol. 2016;6:269.
160. Herdman SJ, Clendaniel R. Vestibular rehabilitation. 4th ed. Philadelphia: FA Davis; 2014.
161. Agrawal Y. Age-related vestibular loss: current understanding and future research directions. Front Neurol. 2017;8:443.
162. Liston MB, Bamiou D-E, Martin F, Hopper A, Koohi N, Luxon L, et al. Peripheral vestibular dysfunction is prevalent in older adults experiencing multiple non-syncopal falls versus age-matched non-fallers: a pilot study. Age Ageing. 2014;43(1):38-43.
163. Hall CD, Herdman SJ, Whitney SL, Cass SP, Clendaniel RA, Fife TD, et al. Vestibular rehabilitation for peripheral vestibular hypofunction: An Evidence-Based Clinical Practice Guideline. J Neurol Phys Ther. 2016;40(2):124-55.
164. Allen D, Ribeiro L, Arshad Q, Seemungal BM. Age-related vestibular loss: Current understanding and future research directions. Front Neurol. 2017;7:231.
165. Jacobson GP, McCaslin DL, Grantham SL, Piker EG. Significant vestibular system impairment is common in a cohort of elderly patients referred for assessment of falls risk. J Am Acad Audiol. 2008;19(10):799-807.
166. van de Berg R, Rosengren S, Kingma H. Laboratory examinations for the vestibular system. Curr Opin Neurol. 2018;31(1):111-6.

167. Health Professions Council of South Africa. Professional Board of Speech L, Hearing P. Guidelines for planning speech therapy and audiology services at all levels of care. Professional Board for Speech, Language and Hearing. 2018.
168. Criter RE, Patterson JN, Honaker JA. Audiologists' role in assessing risk of falls. SIG 8 Perspectives on Public Health Issues Related to Hearing and Balance. 2013;14(1):22-34.
169. Criter RE, Honaker JA. Identifying balance measures most likely to identify recent falls. J Geriatr Phys Ther. 2016;39(1):30-7.
170. Danhauer JL, Johnson CE, Newman CW, Williams VA, Van Vliet D. An open letter to Dennis: we can do more to educate our patients about falls risk. Audiology Today. 2011;23(5):58-69.
171. Gans R, Citron D, Frazer G, Harrington-Gans P, Jacobson G, McDonald J, et al. The audiologist's role in the diagnosis and treatment of vestibular disorders. Audiology Today. 2005;17(1):17-9.
172. Honaker J, Criter R, Patterson J. Life in balance: By assessing older patients' risk of falling and offering advice to reduce the likelihood of falls inside and outside the home, audiologists can help keep patients active and upright. The ASHA Leader. 2013;18(12):40-6.
173. Jacobson GP. Development of a clinic for the assessment of risk of falls in elderly patients. Seminars in Hearing. 2002;23:161-78.
174. Wolf-Klein GP, Silverstone FA, Basavaraju N, Foley CJ, Pascaru A, Ma PH. Prevention of falls in the elderly population. Arch Phys Med Rehabil. 1988;69(9):689-91.
175. Hull RH. Aural rehabilitation: What's in a name? The Hearing Journal. 2018;71(1):40-3.
176. Babatunde F, MacDermid J, MacIntyre N. Characteristics of therapeutic alliance in musculoskeletal physiotherapy and occupational therapy practice: a scoping review of the literature. BMC Health Serv Res. 2017;17(1):375.
177. Dunlap PM, Holmberg JM, Whitney SL. Vestibular rehabilitation: advances in peripheral and central vestibular disorders. Curr Opin Neurol. 2019;32(1):137-44.
178. Hall CD, Heusel-Gillig L, Tusa RJ, Herdman SJ. Efficacy of gaze stability exercises in older adults with dizziness. J Neurol Phys Ther. 2010;34(2):64-9.
179. Hall CD, Rouse S, Atlee R, Sesay M, Echt K, Akin F. Efficacy of gaze stability exercises in older adults with non-vestibular dizziness. Phys Ther. 2017.
180. Isaacs B. The challenge of geriatric medicine (p. 64). Oxford, United Kingdom: Oxford Medical Publications; 1992. p. 64.
181. Browne W, Nair BKR. Physiology of ageing. In: Nair BKR, editor. Geriatric Medicine A problem-based approach. Singapore: Springer; 2018. p. 15-26.
182. Tiedemann A, Sherrington C. Exercise to maximise postural control and reduce the risk of falls in older age. Locomotion and Posture in Older Adults: Springer; 2017. p. 279-90.
183. O'Connell M, Kenny RA, Donoghue O. Measures of health and function that predict future falls. Dublin, Ireland: Trinity College; 2017.
184. Katz S. Ageing, risk and the falling body. In: Twigg J, Martin W, editors. Routledge Handbook of Cultural Gerontology. Abingdon, UK: Routledge; 2015. p. 165-72.
185. Buatois S, Perret-Guillaume C, Gueguen R, Miget P, Vançon G, Perrin P, et al. A simple clinical scale to stratify risk of recurrent falls in community-dwelling adults aged 65 years and older. Phys Ther. 2010;90:550-60.
186. Rossat A, Fantino B, Nitenberg C, Annweiler C, Poujol L, Herrmann FR, et al. Risk factors for falling in community-dwelling older adults: which of them are associated with the recurrence of falls? . J Nutr Health Ageing. 2010;14(9):787-91.
187. El Miedany Y, El Gaafary M, Toth M, Palmer D, Ahmed I. Falls risk assessment score (FRAS): time to rethink. J Clin Gerontol Geriatr. 2011;2(1):21-6.
188. Klenk J, Becker C, Palumbo P, Schwickert L, Rapp K, Helbostad JL, et al. Conceptualizing a dynamic fall risk model including intrinsic risks and exposures. J Am Med Dir Assoc. 2017;18(11):921-7.

189. Moreira MN, Bilton TL, Dias RC, Ferriolli E, Perracini MR. What are the main physical functioning factors associated with falls among older people with different perceived fall risk? Physiother Res Int. 2016;22(2):11.
190. Deems DA, Deems RO, O'Malley Jr BW. Managing challenges in an aging vestibular system: Rehabilitation strategies normalize balance function in a cohort of patients up to 99 years. Ear Nose Throat J. 2019;98(1):37-43.
191. Fernandes VLS, Ribeiro DM, Fernandes LC, Menezes RLd. Postural changes versus balance control and falls in community-living older adults: a systematic review. Fisioterapia em Movimento. 2018;31:15.
192. Kesser BW, Gleason AT. Multisensory imbalance and presbystasis. In: Babu S, Schutt C, Bojrab D, editors. Diagnosis and Treatment of Vestibular Disorders. Cham, Switzerland: Springer; 2019. p. 331-52.
193. Florence CS, Bergen G, Atherly A, Burns E, Stevens J, Drake C. Medical costs of fatal and nonfatal falls in older adults. J Am Geriatr Soc. 2018;66(4):
693-98.
194. Agrawal Y, Carey JP, Della Santina CC, Schubert MC, Minor LB. Disorders of balance and vestibular function in US adults. Arch Intern Med. 2009;169(10):938-44.
195. Marchetti GF, Whitney SL, Redfern MS, Furman JM. Factors associated with balance confidence in older adults with health conditions affecting the balance and vestibular system. Arch Phys Med Rehabil. 2011;92(11):1884-91.
196. Tuunainen E, J. R, P. J, Pyykko I. Risk factors of falls in community dwelling active elderly. Auris Nasis Larynx. 2014;41(1):10-6.
197. Zalewski CK. Aging of the human vestibular system. Semin Hear. 2015;36(3):175-96.
198. Alyono JC. Vertigo and dizziness: Understanding and managing fall risk. Otolaryngol Clin North Am. 2018;51(4):725-40.
199. Lindell E, Kollén L, Johansson M, Karlsson T, Rydén L, Zettergren A, et al. Dizziness and its association with walking speed and falls efficacy among older men and women in an urban population. Aging Clin Exp Res. 2019 aop:1-8.
200. Deandrea S, Lucenteforte E, Bravi F, Foschi R, La Vecchia C, Negri E. Risk factors for falls in community-dwelling older people. A systematic review and meta-analysis Epidemiology. 2010;21(5):658-68.
201. Lord SR, Sherrington C, Menz HB, Close JC. Falls in older people: risk factors and strategies for prevention. Cambridge, UK: Cambridge University Press; 2007.
202. Muir SW, Berg K, Chesworth B, Klar N, Speechley M. Quantifying the magnitude of risk for balance impairment on falls in community-dwelling older adults: a systematic review and meta-analysis. J Clin Epidemiol. 2010;63(4):389-406.
203. Lundin-Olsson L. Community-dwelling older adults with balance impairment show a moderate increase in fall risk, although further research is required to refine how balance measurement can be used in clinical practice. Evid Based Nurs. 2010;13(3):96-7.
204. Tinetti ME, Kumar C. The patient who falls. J Am Med Assoc. 2010;303(3):258-66.
205. Downs S, Marquez J, Chiarelli P. The Berg Balance Scale has high intra- and inter-rater reliability but absolute reliability varies across the scale: a systematic review. J Physiother. 2013;59(2):93-9.
206. Downs S, Marquez J, Chiarelli P. Normative scores on the Berg Balance Scale decline after age 70 years in healthy community-dwelling people: a systematic review. J Physiother. 2014;60(2):85-9.
207. Langley FA, Mackintosh SFH. Functional balance assessment of older community dwelling adults: a systematic review of the literature. Internet Journal of Allied Health Sciences and Practice. 2007;5(4):13.

208. Muir SW, Berg K, Chesworth B, Speechley M. Use of the Berg Balance Scale for predicting multiple falls in community-dwelling elderly people: a prospective study. Phys Ther. 2008;88(4):449-59.
209. Park S-H, Lee Y-S. The diagnostic accuracy of the Berg balance scale in predicting falls. West J Nurs Res. 2017;39(11):1502-25.
210. Sibley KM, Howe T, Lamb SE, Lord SR, Maki BE, Rose DJ, et al. Recommendations for a core outcome set for measuring standing balance in adult populations: a consensus-based approach. PLoS One. 2015;10(3):e0120568.
211. Studenski SA. Falls In: Fillit HM, Rockwood K, Woodhouse K, editors. Brocklehurst's textbook of geriatric medicine and gerontology. 7th ed. Philadelphia, PA: Saunders Elsevier.; 2010. p. 894-902.
212. Morley JE. White matter lesions (leukoaraiosis): a major cause of falls. J Am Med Dir Assoc. 2015;16(6):441-3.
213. Matsumura BA, Ambrose AF. Balance in the elderly. Clin Geriatr Med. 2006;22(2):395-412.
214. Sturnieks DL, St George R, Lord SR. Balance disorders in the elderly. Clin Neurophysiol. 2008;38(6):467-78.
215. Smith E, Cusack T, Cunningham C, Blake C. The influence of a cognitive dual task on the gait parameters of healthy older adults: a systematic review and meta-analysis. J Aging Phys Act. 2017;25(4):671-86.
216. Ciorba A, Hatzopoulos S, Bianchini C, Aimoni C, Skarzynski H, Skarzynski PH. Genetics of presbycusis and presbystasis. Int J Immunopath Ph. 2015;28(1):29-35.
217. Walther LE, Westhofen M. Presbyvertigo-aging of otoconia and vestibular sensory cells. J Vestib Res. 2007;17(2, 3):89-92.
218. Belal A, Glorig A. Dysequilibrium of ageing (presbyastasis). The Journal of Laryngology and Otology. 1986;100(9):1037-41.
219. Agrawal Y, Van de Berg R, Wuyts F, Walther L, Magnusson M, Oh E, et al. Presbyvestibulopathy: diagnostic criteria consensus document of the classification committee of the Barany Society. J Vestib Res. 2019;29(4):161-70.
220. Smith PF. The vestibular system and cognition. Curr Opin Neurol. 2017;30(1):84-9.
221. Ishiyama G. Imbalance and vertigo: The aging human vestibular periphery. Semin Neurol. 2009;29(5):491-9.
222. Anson ER, Bigelow RT, Carey JP, Xue Q-L, Studenski S, Schubert MC, et al. Aging increases compensatory saccade amplitude in the video head impulse test. Front Neurol. 2016;7:113.
223. Chiarovano E, Vidal P-P, Magnani C, Lamas G, Curthoys IS, De Waele C. Absence of rotation perception during warm water caloric irrigation in some seniors with postural instability. Front Neurol. 2016;7:4.
224. Jacobson GP, McCaslin DL, Piker EG, Gruenwald J, Grantham S, Tegel L. Insensitivity of the "Romberg test of standing balance on firm and compliant support surfaces" to the results of caloric and VEMP tests. Ear Hear. 2011;32(6):e1-e5.
225. Ceria-Ulep CD, Grove J, Chen R, Masaki KH, Rodriguez BL, Donlon TA, et al. Physical aspects of healthy aging: assessments of three measures of balance for studies in middle-aged and older adults. Curr Gerontol Geriatr Res 2010;2010:1-8.
226. Casani AP, Navari E. Dizziness and prevention of falls in the elderly. Geriatric Care. 2017;3(4):75-7.
227. Hansson EE, Beckman A. Fractures among patients with dizziness–a ten-year follow-up. BMC Geriatr. 2018;18(1):35.
228. Bovo R, Castiglione A, Martini A. Rehabilitation in diseases of the sense organs in older adults: Hearing and balance. In: Masiero S, Carraro U, editors. Rehabilitation medicine for elderly patients. Cham, Switzerland: Springer; 2018. p. 299-304.
229. Lee PG, Jackson EA, Richardson CR. Exercise prescriptions in older adults. Am Fam Physician. 2017;95(7):425-32.

230. Kammerlind A-SC, Bravell ME, Fransson EI. Prevalence of and factors related to mild and substantial dizziness in community-dwelling older adults: a cross-sectional study. BMC Geriatr. 2016;16(1):159.
231. Teixeira AR, Wender MH, Gonçalves AK, Freitas CdLR, Santos AMPVd, Soldera CLC. Dizziness, physical exercise, falls, and depression in adults and the elderly. Int Arch Otorhinolaryngol. 2016;20(2):124-31.
232. Martins TF, Mancini PC, Souza LdMd, Santos JN. Prevalence of dizziness in the population of Minas Gerais, Brazil, and its association with demographic and socioeconomic characteristics and health status. Braz J Otorhinolaryngol. 2017;83(1):29-37.
233. Hamed AF, Mohammed NA, Aly H. Elderly falls prevalence and associated factors in Sohag Governorate. Egypt J Comm Med. 2017;35(4):1-13.
234. Dillon CF, Gu Q, Hoffman HJ, Ko CW. Vision, hearing, balance, and sensory impairment in Americans aged 70 years and over: United States, 1999-2006. NCHS data brief. 2010;(31):1-8.
235. Kollén L, Hörder H, Möller C, Frändin K. Physical functioning in older persons with dizziness: a population-based study. Aging Clin Exp Res. 2017;29(2):197-205.
236. Harun A, Semenov YR, Agrawal Y. Vestibular function and activities of daily living: analysis of the 1999 to 2004 National Health and Nutrition Examination Surveys. Gerontol Geriatr Med. 2015;1:1-8.
237. Thibaud M, Bloch F, Tournoux-Facon C, Brèque C, Rigaud AS, Dugué B, et al. Impact of physical activity and sedentary behaviour on fall risks in older people: a systematic review and meta-analysis of observational studies. Eur Rev Aging Phys Act. 2012;9(1):5-15.
238. Kalula SZ, Ferreira M, Swingler GH, Badri M. Risk factors for falls in older adults in a South African urban community. BMC Geriatr. 2016;16(1):1.
239. Kalula SZ, Ferreira M, Swingler GH, Badri M, Sayer AA. Methodological challenges in a study on falls in an older population of Cape Town, South Africa. Afr Health Sci. 2017;17(3):912-22.
240. Kalula SZ, Ferreira M, Swingler GH, Badri M. Ethnic differences in rates and causes of falls in an urban community-dwelling older population in South Africa. J Am Geriatr Soc. 2015;63(2):403-4.
241. Loganathan A, Ng CJ, Tan MP, Low WY. Barriers faced by healthcare professionals when managing falls in older people in Kuala Lumpur, Malaysia: a qualitative study. BMJ Open. 2015;5(11):008460.
242. Rogers C, Caine A, Fortuin K, Jordaan K, Ningiza N, Paton M. The relationship between self-reported physical activity, falls and measures of fall risk in independent adults 65 years and older. Cape Town, South Africa: University of Cape Town; 2016.
243. Rogers C, Doolabh N, Gumede L, Labuschagne S, Lalu L, Nkosi T, et al. Pilot study on fall occurrence in community-dwelling individuals, in the Cape Town Metropolitan Area, aged 40 years and older Cape Town, South Africa: University of Cape Town; 2013.
244. Bloch F, Thibaud M, Dugué B, Brèque C, Rigaud AS, Kemoun G. Episodes of falling among elderly people: a systematic review and meta-analysis of social and demographic pre-disposing characteristics. Clinics. 2010;65(9):895-903.
245. Ellis R, Kosma M, Fabre JM, Moore DS, Wood RH. Proximal determinants of falls risk among independent-living older adults. Res Aging. 2013;35(4):420-36.
246. Chen TY, Tan PJ, Chan A. Ethnicity predicts falls among community-dwelling older adults in Singapore. Geriatr Gerontol Internat. 2018;18(1):72-9.
247. Burns E, Kakara R. Deaths from falls among persons aged≥ 65 Years—United States, 2007–2016. Morbid Mortal Wkly Rep. 2018;67(18):509-14.
248. Kwon SC, Han BH, Kranick JA, Wyatt LC, Blaum CS, Stella SY, et al. Racial and ethnic difference in falls among older adults: results from the California health interview survey. J Racial Ethnic Health Dispar. 2018;5(2):271-8.
249. Bekibele C, Gureje O. Fall incidence in a population of elderly persons in Nigeria. Gerontology. 2010;56(3):278-83.

250. Thakkar R, Alper Z, Patel J, Sadang R, Skeete K, Sklar D, et al. Falls and balance/mobility outcomes in racially-diverse community-dwelling older adults. Arch Phys Med Rehabil. 2019;100(10):e76.
251. Stark SL, Silianoff TJ, Kim HL, Conte JW, Morris JC. Tailored calendar journals to ascertain falls among older adults. OTJR. 2015;35(1):53-9.
252. Nyman SR. Psychosocial issues in engaging older people with physical activity interventions for the prevention of falls. Can J Ageing. 2011;30(1):45-55.
253. Freiberger E, de Vreede P. Falls recall—limitations of the most used inclusion criteria. Eur Rev Aging Phys Act. 2011;8(2):105-8.
254. Clark L, Thoreson S, Goss CW, Zimmer LM, Marosits M, DiGuiseppi G. Understanding fall meaning and context in marketing balance classes to older adults. J Appl Gerontol. 2013;31(1):96-119.
255. Gardiner S, Glogowska M, Stoddart C, Pendlebury S, Lasserson D, Jackson D. Older people's experiences of falling and perceived risk of falls in the community: A narrative synthesis of qualitative research. Int J Older People Nurs. 2017;12(4).
256. Yardley L, Donovan-Hall M, Francis K, Todd C. Older people's views of advice about falls prevention: a qualitative study. Health Educ Res. 2006;21(4):508-17.
257. Williams JS, Kowal P, Hestekin H, O'Driscoll T, Peltzer K, Yawson A, et al. Prevalence, risk factors and disability associated with fall-related injury in older adults in low-and middle-incomecountries: results from the WHO Study on global AGEing and adult health (SAGE). BMC Med. 2015;13(1):1.
258. Edusei AK, Owusu-Ansah FE, Dogbe JA, Morgan J, Sarpong K. Perspectives in musculoskeletal injury management by traditional bone setters in Ashanti, Ghana. Afr J Disabil. 2015;4(1).
259. Onyemaechi NO, Lasebikan OA, Elachi IC, Popoola SO, Oluwadiya KS. Patronage of traditional bonesetters in Makurdi, north-central Nigeria. Patient Prefer Adherence. 2015;9:275-9.
260. Tantray M-d, Masood QM, Mushtaq QD, Baba AN, Kotwal H, Waris Q, et al. Orthopedic trauma care by traditional bone setters in developing nations: An observational hospital study from Kashmir. Inter J Curr Trends Sci Tech. 2018;8(02):20402-7.
261. de Dios Robinson J. Injury from traditional bonesetter fracture treatment. In: de Dios Robinson J, editor. Orthopaedic trauma in the austere environment: A practical guide to care in the humanitarian setting. Cham, Switzerland: Springer; 2016. p. 121-30.
262. Shumway-Cook A, Ciol MA, Hoffman J, Dudgeon BJ, Yorkston K, Chan L. Falls in the Medicare population: incidence, associated factors, and impact on health care. Phys Ther. 2009;89(4):324-32.
263. Reyes-Ortiz CA, Al Snih S, Markides KS. Falls among elderly persons in Latin America and the Caribbean and among elderly Mexican-Americans. Rev Panam Salud Publica. 2005;17(5-6):362-9.
264. Kwan MMS, Close JC, Wong AKW, Lord SR. Falls incidence, risk factors, and consequences in Chinese older people: a systematic review. J Am Geriatr Soc. 2011;59(3):536-43.
265. Ntagungira EK. Epidemiology of and risk factors for falls among the community-dwelling elderly people in selected districts of Umutara Province, Republic of Rwanda

itle: University of the Western Cape; 2005.
266. Rishworth A, Elliott SJ. Ageing in low-and middle-income countries. In: Skinner M, GJ A, MP C, editors. Geographical gerontology Perspectives, concepts, approaches. 1 ed. Oxford, United Kingdom: Routledge; 2017. p. 110-22.
267. Ghodsi SM, Roudsari BS, Abdollahi M, Shadman M. Fall-related injuries in the elderly in Tehran. Inj Control Saf Promot. 2003;34(11):809-14.
268. Amin A, Shawis T, Haines R, Merza R, Barawy O. Falls in older people: A perspective from Kurdistan of Iraq. Mid E J Age Ageing. 2014;11(4):20-2.
269. Small J, Aldwin C, Kowal P, Chatterji S, Pruchno R. Aging and HIV-related caregiving in Sub-Saharan Africa: A social ecological approach. Gerontologist. 2017;59(3):e223-40.
270. Fitzpatrick MC, Gray GE, Galvani AP. The challenge of vanquishing HIV for the next generation—Facing the future. JAMA Pediatr. 2018;172(7):609-14.

271. Gibson W, Hunter KF, Camicioli R, Booth J, Skelton DA, Dumoulin C, et al. The association between lower urinary tract symptoms and falls: Forming a theoretical model for a research agenda. Neurourol Urodyn. 2017;37(1):501-9.
272. Rose D. Predicting the risk of falls and promoting balance in older adults. Ann Rheum Dis. 2017;76(Suppl 2):30.
273. Larson EB. Evidence supports action to prevent injurious falls in older adults. JAMA. 2017;318(17):1659-60.
274. Organisation WH. Falls Fact sheet. 2017.
275. Sri-On J, Tirrell GP, Bean JF, Lipsitz LA, Liu SW. Revisit, subsequent hospitalization, recurrent fall, and death within 6 months after a fall among elderly Emergency Department patients. Ann Emerg Med. 2017;70(4):521.e2.
276. Scanaill C, Garattini C, Greene BR, McGrath MJ. Technology innovation enabling falls risk assessment in a community setting Ageing Int. 2011;36(2):217-31.
277. Bhattacharya B, Maung A, Schuster K, Davis KA. The older they are the harder they fall: Injury patterns and outcomes by age after ground level falls. Injury. 2016;47(9):1955-9.
278. Siracuse JJ, Odell DD, Gondek SP, Odom SR, Kasper EM, Hauser CJ, et al. Health care and socioeconomic impact of falls in the elderly. Am J Surg. 2012;203(3):335-8.
279. Granhed H, Altgärde E, Akyürek LM, David P. Injuries sustained by falls - A review. J Trauma Acute Care. 2017;2:1-5.
280. Pohl P, Nordin E, Lundquist A, Bergström U, Lundin-Olsson L. Community-dwelling older people with an injurious fall are likely to sustain new injurious falls within 5 years-a prospective long-term follow-up study. BMC Geriatr. 2014;14(1):1.
281. Fu WW, Fu TS, Jing R, McFaull SR, Cusimano MD. Predictors of falls and mortality among elderly adults with traumatic brain injury: A nationwide, population-based study. PLoS One. 2017;12(4):e0175868.
282. Albrecht JS, Al Kibria G, Gruber-Baldini A, Magaziner J. Risk of mortality in individuals with hip fracture and traumatic brain injury. J Am Geriatr Soc. 2019;67(1):124-7.
283. Khow KSF, Visvanathan R. Falls in the aging population. Clin Geriatr Med. 2017;33(3):357-68.
284. Fernandez MA, Griffin XL, Costa ML. Management of hip fracture. Br Med Bull. 2015;115(1):165-72.
285. Zanker J, Duque G. Rapid geriatric assessment of hip fracture. Clin Geriatr Med. 2017;33(3):369-82.
286. Paruk FG, editor Risk factors and outcomes of osteoporotic hip fractures in older persons in the eThekwini region of South Africa. Africa Ageing: Beyond Madrid + 10; 2012; Cape Town, South Africa.
287. Williams E, Maseko L, Buchanan H. Rehabilitation-Strengthening advocacy for change. It's time to act. S Afr J Occup Ther. 2017;47(3):2.
288. Finlayson ML, Peterson EW. Falls, aging and disability. Phys Med Rehabil Clin N Am. 2010;21(2):357-73.
289. Nuotio M, Luukkaala T. Factors associated with changes in mobility and living arrangements in a comprehensive geriatric outpatient assessment after hip fracture. Disabil Rehabil. 2015;38(12):1125 - 33.
290. Parry SW, Steen N, Galloway SR, Kenny RA, Bond J. Falls and confidence related quality of life outcome measures in an older British cohort. Postgrad Med J. 2001;77(904):103-8.
291. Betker AL, Szturm T, Moussavie ZK, Nett C. Video game –based exercises for balance rehabilitation: A single subject design. Arch Phys Med Rehabil. 2006;87(8):1141-9.
292. Lavedán A, Viladrosa M, Jürschik P, Botigué T, Nuín C, Masot O, et al. Fear of falling in community-dwelling older adults: A cause of falls, a consequence, or both? PLoS One. 2018;13(3):e0194967.

293. Denkinger MD, Lukas A, Nikolaus T, Hauer K. Factors associated with fear of falling and associated activity restriction in community-dwelling older adults: a systematic review. Am J Geriatr Psychiatry. 2015;23(1):72-86.
294. Auais M, French S, Alvarado B, Pirkle C, Belanger E, Guralnik J. Fear of falling predicts incidence of functional disability two years later: A perspective from an international cohort study. J Gerontol A Biol Sci Med Sci. 2017;73(9):1212-5.
295. Furman JM, Raz Y, Whitney SL. Geriatric vestibulopathy assessment and management. Curr Opin Otolaryngol Head Neck Surg. 2010;18(5):386-91.
296. Heinrich S, Rapp K, Rissmann U, Becker C, König HH. Cost of falls in old age: a systematic review. Osteoporos Int. 2010;21(6):891-902.
297. Pothula VB, Chew F, Lesser THJ, Sharma AK. Falls and vestibular impairment. Clin Otolaryngol Allied Sci. 2004;29(2):179-82.
298. Burns E, Kakara R, Stevens M, Bergen G. Changes in older adult falls, fall injuries, and fall fatalities across the United States - 2012 - 2016. Innov Aging. 2018;2(Suppl 1):896.
299. Houry D, Florence C, Baldwin G, Stevens J, McClure R. The CDC Injury Center's response to the growing public health problem of falls among older adults. Am J Lifestyle Med. 2016;10(1):74-7.
300. Gyllensvärd H. Cost-effectiveness of injury prevention-a systematic review of municipality based interventions. Cost Eff Resour Alloc. 2010;8(1):17.
301. Apt NA. Preface. In: Makoni S, Stroeken K, editors. Ageing in Africa: Sociolinguistic and anthropological approaches. Downloaded 2 May 2018 from: https://books.google.co.za/books?hl=en&lr=&id=QTg7DwAAQBAJ&oi=fnd&pg=PT7&dq=Africa+%2B+ageing&ots=PYIQMTMWgv&sig=6Vkri6kIZrjJkU2tkJOWEN8na_Y#v=onepage&q=Africa%20%2B%20ageing&f=false: Routledge; 2017.
302. Shetty P. Grey matter: ageing in developing countries. Lancet. 2012;379(9823):1285-7.
303. Aboderin I. Ageing Africa: opportunities for development. In: J. Beard SBDBLFPHAK, Olshansky J, editors. Global population ageing: peril or promise Programme on the global demography of aging (PGDA Working paper no 89) World Economic Forum Global Agenda Council on Ageing Society. 161. Geneva, Switzerland: World Economic Forum.; 2012. p. 69-73.
304. Naja S, Makhlouf M, Chehab M. An ageing world of the 21st century: a literature review. Int J Community Med Public Health. 2017;4(12):4363-9.
305. Bloom DE, Mitgang E, Osher B, Grundy EM, Murphy M, Brown L, et al. Demography of ageing. In: J-P Michel BLBFCM, Walston JD, editors. Ageing population and policy. 3 ed. Oxford, U.K: Oxford University Press; 2018. p. 3-10.
306. Beard JR, Biggs S, Bloom DE, Fried LP, Hogan P, Kalache A, et al. Introduction. . In: In J. Beard SBDBLFPHAK, Olshansky J, editors. Global population ageing: peril or promise Programme on the global demography of aging (PGDA Working paper no 89),World Economic Forum Global Agenda Council on Ageing Society. Geneva, Switzerland:: World Economic Forum.; 2012. p. 4-13.
307. da Silva Francisco AA. 'Gerontogrowth'and population ageing in Africa and the Global AgeWatch Index. J Econ Ageing. 2017;9:78-89.
308. Hornby-Turner YC, Peel NM, Hubbard RE. Health assets in older age: a systematic review. BMJ Open. 2017;7(5):013226.
309. Makiwane M, Gumede NA, Makoae M, Vawda M. Family in a changing South Africa: structures, functions and the welfare of members. S Afr Rev Sociology. 2017;48(2):49-69.
310. Apt NA. Aging in Africa: past experiences and strategic direction Ageing Int. 2012;37(1):93-103.
311. Bloom DE, Mahal A, Rosenberg L. Design and operation of health systems in developing countries. Geneva, Switzerland: World Economic Forum.; 2012. Contract No.: Report.
312. Lombard A, Kruger E. Older persons: the case of South Africa. Ageing Int. 2009;34(3):119-35.
313. Pillay NK, Maharaj P. Population ageing in Africa. In: Maharaj P, editor. Aging and Health in Africa International perspectives on ageing (4). New York: Springer; 2013. p. 11-51.

314. Zverev Y. Attitude towards older people among Malawian medical and nursing students. Educ Gerontol. 2013;39(1):57-66.
315. Noyoo N. Reflecting on the human rights of older persons in South Africa. J Hum Rights Soc. 2017;2(4):108-16.
316. Hamoudi A, Thomas D. Pension income and the well-being of children and grandchildren: New evidence from South Africa Los Angeles, CA: California Center for Population Research; 2005. Contract No.: Web Page.
317. Mayosi BM, Benatar SR. Health and health care in South Africa—20 years after Mandela. N Engl J Med. 2014;371(14):1344-53.
318. Ralston M. The role of older persons' environment in aging well: Quality of life, illness, and community context in South Africa. Gerontologist. 2017;58(1):111-20.
319. Rheeder P, Morris-Paxton AA, Ewing RG, Woods D. The noncommunicable disease outcomes of primary healthcare screening in two rural subdistricts of the Eastern Cape Province, South Africa. Afr J Prim Health Care Fam Med. 2017;9(1):e7.
320. Lewitte K, Singh A. Aging in South Africa. In: Bonder BR, Dal Bello-Haas V, editors. Functional performance in older adults. 4th ed. Philadelphia. PA: FA Davis; 2018. p. 53-8.
321. Abera Abaerei A, Ncayiyana J, Levin J. Health-care utilization and associated factors in Gauteng province, South Africa. Glob Health Action. 2017;10(1):1305765.
322. Aboderin I. Understanding and advancing the health of older populations in sub-Saharan Africa: policy perspectives and evidence needs. Public Health Rev. 2010;32:357-76.
323. Phaswana-Mafuya N, Peltzer K, Chirinda W, Kose Z, Hoosain E, Ramlagan S, et al. Self-rated health and associated factors among older South Africans: evidence from the study on global ageing and adult health. Glob Health Action. 2013;6:1-10.
324. Saka S, Oosthuizen F, Nlooto M. National Policies and older people's healthcare in Sub-Saharan Africa: A scoping review. Ann Glob Health. 2019;85(1):1-7.
325. Baerecke L, Clarke S. An evaluation of service centres for older persons in the Western Cape. Cape Town South Africa: Western Cape Department of Social Development; 2015. Contract No.: Report.
326. Schneider EC, Shubert TE, Harmon KJ. Addressing the escalating public health issue of falls among older adults. N C Med J. 2010;71(6):547-52.
327. Dellinger A. Older adult falls: Effective approaches to prevention. Curr Trauma Rep. 2017;3(2):118-23.
328. Kalula SZ, Scott V, Dowd A, Brodrick K. Falls and fall prevention programmes in developing countries: Environmental scan for the adaption of the Canadian Falls prevention curriculum for developing countries J Safety Res. 2011;42(6):461-72.
329. Burton E, Farrier K, Hill KD, Codde J, Airey P, Hill A-M. Effectiveness of peers in delivering programs or motivating older people to increase their participation in physical activity: Systematic review and meta-analysis. J Sports Sci. 2018;36(6):666-78.
330. Boongird C, Keesukphan P, Phiphadthakusolkul S, Rattanasiri S, Thakkinstian A. Effects of a simple home-based exercise program on fall prevention in older adults: A 12-month primary care setting, randomized controlled trial. Geriatr Gerontol Internat. 2017;17(11):2157-63.
331. Dadgari A, Hamid TA, Hakim MN, Chaman R, Mousavi SA, Hin LP, et al. Randomized control trials on Otago Exercise Program (OEP) to reduce falls among elderly community dwellers in Shahroud, Iran. Iran Red Crescent Med J. 2016;18:e26340.
332. Health Do. National Guideline on the prevention of falls of older persons. In: Health NDo, editor. Cape Town: Government Communication and Information Systems; 2000.
333. Kalula SZ. A WHO report on falls among older persons. Prevention of falls in older persons: Africa case study. 2006.
334. Ross RCKC. Health defined: Health promotion, protection and prevention. In: Edelman CL, Mandle CL, Kudzma EC, editors. Health promotion throughout the life span-E-Book. 9 ed. St Louis, Missouri: Elsevier Health Sciences; 2017. p. 1-22.

335. Olupot-Olupot P, Namuyodi D, Obbo JSO, Meadway J. Multidrug resistant tuberculosis (MDR-TB) in emerging economies in Sub-Saharan Africa: clinicians' public health concerns. J Public Health Emerg. 2017;1(1:43):4.
336. Kane J, Landes M, Carroll C, Nolen A, Sodhi S. A systematic review of primary care models for non-communicable disease interventions in Sub-Saharan Africa. BMC Fam Pract. 2017;18(1):46.
337. Williams R, Krakauer R. The challenge of non-communicable diseases and geriatric conditions. In: Beard J, Biggs S, Bloom D, Fried L, Hogan P, Kalache A, et al., editors. Global population ageing: peril or promise Programme on the global demography of aging (PGDA Working paper no 89) World Economic Forum Global Agenda Council on Ageing Society. Geneva, Switzerland: World Economic Forum.; 2012. p. 78-81.
338. Richard L, Gauvin L, Gosselin C, Ducharme F, Sapinski JP, Trudel M. Integrating the ecological approach in health promotion for older adults: a survey of programs aimed at elder abuse prevention, falls prevention, and appropriate medication use. Intl J Public Health. 2008;53(1):45-56.
339. Troutman-Jordan M, Heath L. The impact of health education and health promotion on management of chronic health conditions in older adults: Opportunities for innovation. Act Adapt Aging. 2017;41(1):1-13.
340. Fabre JM, Ellis R, Kosma M, Wood RH. Falls risk factors and a compendium of falls risk screening instruments. J Geriatr Phys Ther. 2010;33(4):184-97.
341. Smith EM, Shah AA. Screening for geriatric syndromes: Falls, urinary/fecal incontinence, and osteoporosis. Clin Geriatr Med. 2018;34(1):55-67.
342. Allen K, Glasby J. "The billion dollar question": embedding prevention in older people's services – 10 "high impact" changes. Birmingham, United Kingdom: Health Services Management Centre: University of Birmingham; 2010. Contract No.: Report.
343. Ganz DA, Alkema GE, Wu S. It takes a village to prevent falls: reconceptualising fall prevention and management for older adults. Inj Prev. 2008;14(4):266-71.
344. Markle-Reid MF, Keller HH, Browne G. Health promotion for the community-living older adult. In: Fillit HM, Rockwood K, Woodhouse K, editors. Brocklehurst's textbook of geriatric medicine and gerontology. 7th ed. Philadelphia: Saunders Elsevier.; 2010. p. 835-47.
345. Phelan EA, Mahoney JE, Voit JC, Stevens JA. Assessment and management of fall risk in primary care settings. Med Clin North Am. 2015;99(2):281-93.
346. Bongue B, Dupré C, Beauchet O, Rossat A, Fantino B, Colvez A. A screening tool with five risk factors was developed for fall-risk prediction in community-dwelling elderly. J Clin Epidemiol. 2011;64(10):1152-60.
347. van Rhyn B, Barwick A. Health practitioners' perceptions of falls and fall prevention in older people: A metasynthesis. Qual Health Res. 2019;29(1):69-79.
348. Ambrose AF, Cruz L, Paul G. Falls and fractures: A systematic approach to screening and prevention. Maturitas. 2015;82(1):85-93.
349. Jones TS, Ghosh TS, Horn K, Smith J, Vogt RL. Primary care physicians perceptions and practices regarding fall prevention in adult's 65 years and over. Accid Anal Prev. 2011;43(5):1605-9.
350. Phelan EA, Aerts S, Dowler D, Eckstrom E, Casey CM. Adoption of evidence-based fall prevention practices in primary care for older adults with a history of falls. Front Public Health. 2016;4.
351. Haar AS. Community-dwelling older people and falls reporting: A qualitative descriptive study. Dunedin, New Zealand: University of Otago; 2018.
352. Lee DCA, Day L, Hill K, Clemson L, McDermott F, Haines TP. What factors influence older adults to discuss falls with their health-care providers? Health Expect. 2015;18(5):1593-609.
353. Palumbo P, Palmerini L, Bandinelli S, Chiari L. Fall risk assessment tools for elderly living in the community: can we do better? PLoS One. 2015;10(12):e0146247.
354. Gates S, Smith LA, Fisher JD, Lamb SE. Systematic review of accuracy of screening instruments for predicting fall risk among independently living older adults. J Rehabil Res Dev. 2008;45(8):1105-16.

355. Finnegan S, Bruce J, Skelton DA, Withers EJ, Lamb SE, Pre FITSG. Development and delivery of an exercise programme for falls prevention: the Prevention of Falls Injury Trial (PreFIT). Physiotherapy. 2017;104(1):72-9.
356. Shimada H, Suzukawa M, Ishizaki T, Kobayashi K, Kim H, Suzuki T. Relationship between subjective fall risk assessment and falls and fall-related fractures in frail elderly people. BMC Geriatrics, 11:40. 2011.
357. Skelton DA, Todd CJ. Thoughts on effective falls prevention intervention on a population basis. J Public Health. 2005;13(4):196-202.
358. Winston FK, Puzino K, Romer D. Precision prevention: time to move beyond universal interventions. Inj Prev. 2016;22(2):87-91.
359. Sniehotta FF, Araújo-Soares V, Brown J, Kelly MP, Michie S, West R. Complex systems and individual-level approaches to population health: a false dichotomy? Lancet Public Health. 2017;2(9):e397.
360. Dlungwane T, Voce A, Searle R, Stevens F. Master of Public Health programmes in South Africa: Issues and challenges. Public Health Rev. 2017;38(1):5.
361. Bateman C. Denying reality no longer an option. Stark HR report. S Afr Med J. 2011;101:700-2.
362. Benatar S, Sullivan T, Brown A. Why equity in health and in access to health care are elusive: Insights from Canada and South Africa. Glob Public Health. 2017;13(11):1533-57.
363. Labonte R, Sanders D, Mathole T, Crush J, Chikanda A, Dambisya Y, et al. Health worker migration from South Africa: causes, consequences and policy responses. Hum Resour Health. 2015;13(1):92.
364. Frehywot S, Park C, Infanzon A. Medical diaspora: an underused entity in low-and middle-income countries' health system development. Hum Resour Health. 2019;17(1):56.
365. Freer J. Sustainable development goals and the human resources crisis. Int Health. 2017;9(1):1-2.
366. Kottek A, Bates T, Spetz MPPJ. The roles and value of geriatricians in healthcare teams: A landscape analysis. San Francisco, CA: UCSF Health Workforce Research Center on Long-Term Care.; 2017. Contract No.: Report.
367. Frost L, Liddie Navarro A, Lynch M, Campbell M, Orcutt M, Trelfa A, et al. Care of the elderly: Survey of teaching in an aging Sub-Saharan Africa. Gerontol Geriatr Educ. 2015;36(1):14-29.
368. Kalula SZ, De Villiers L, Ross K, Ferreira M. Management of older patients presenting after a fall-an accident and emergency department audit. S Afr Med J. 2006;96(8):718-21.
369. Sallis RE. Exercise is medicine and physicians need to prescribe it! Br J Sports Med. 2009;43(1):3-4.
370. Montero-Odasso M, Hogan DB. Falls & fall-related injuries special interest group: a call to action. Can J Geri. 2016;19(4):202.
371. Carlson C, Merel SE, Yukawa M. Geriatric syndromes and geriatric assessment for the generalist. Med Clin N Am. 2015;99(2):263-79.
372. Tinetti ME, Williams CS, Gill TM. Dizziness among older adults: A possible geriatric syndrome. Ann Intern Med. 2000;132(5):337-44.
373. Ahearn DJ, Umapathy D. Vestibular impairment in older people frequently contributes to dizziness as part of a geriatric syndrome. Clin Med (Northfield Il). 2015;15(1):25-30.
374. Rose DJ. Preventing falls among older adults: no "one size suits all" intervention strategy. J Rehabil Res Dev. 2008;45(8):1153-66.
375. Davis JC, Robertson MC, Ashe MC, Liu-Ambrose T, Khan KM, Marra CA. Does a home-based strength and balance programme in people aged ≥ 80 years provide the best value for money to prevent falls?: A systematic review of economic evaluations of falls prevention interventions. Br J Sports Med. 2010;44:80-9.

376. Evans WJ. Exercise for successful aging. In: Fillit HM, Rockwood KW, editors. Brocklehurst's textbook of geriatric medicine and gerontology. 7th ed. Philadelphia: Saunders Elsevier.; 2010. p. 864.
377. Howe TE, Rochester L, Neil F, Skelton DA, Ballinger C. Exercise for improving balance in older people (Review). London. United Kingdom: John Wiley & Sons Ltd; 2011.
378. Hill KD, Hunter SW, Batchelor FA, Cavalheri V, Burton E. Individualized home-based exercise programs for older people to reduce falls and improve physical performance: A systematic review and meta-analysis. Maturitas. 2015;82(1):72-84.
379. Sherrington C, Tiedemann A, Fairhall N, Close JCT, Lord SR. Exercise to prevent falls in older adults: an updated meta-analysis and best practice recommendations. NSW Public Health Bull. 2011;22(4):78-83.
380. Zilcha-Mano S. Is the alliance really therapeutic? Revisiting this question in light of recent methodological advances. Am Psychol. 2017;72(4):311.
381. Boutron I, Guittet L, Estellat C, Moher D, Hróbjartsson A, Ravaud P. Reporting methods of blinding in randomised trials assessing nonpharmacological treatments. PLoS Med. 2007;2013(4e).
382. Nyman SR, Victor CR. Older people's participation in and engagement with falls prevention interventions in community settings: an augment to the Cochrane systematic review Age Ageing. 2012;41(1):16-23.
383. Sherrington C, Whitney JC, Lord SR, Herbert RD, Cumming RG, Close JCT. Effective exercise for the prevention of falls: a systematic review and meta-analysis. J Am Geriatr Soc. 2008;56(12):2234-43.
384. Balzer K, Bremer M, Schramm S, Lühmann D, Raspe H. Falls prevention in the elderly. GMS Health Technol Assess. 2012;8:18.
385. Quicke JG, Foster NE, Ogollah RO, Croft PR, Holden MA. Relationship between attitudes and beliefs and physical activity in older adults with knee pain: Secondary analysis of a randomised controlled trial. Arthritis Care Res. 2017;69(8):1192-200.
386. Ries JD, Echternach JL, Nof L, Blodgett MC. Test-retest reliability and Minimal Detectable Change scores for the Timed "Up & Go" test, the Six-Minute Walk Test and gait speed in people with Alzheimer disease. Phys Ther. 2009;89(6):569-79.
387. Makizako H, Shimada H, Doi T, Tsutsumimoto K, Nakakubo S, Hotta R, et al. Predictive cutoff values of the Five-Times Sit-to-Stand Test and the Timed "Up & Go" Test for disability incidence in older people dwelling in the community. Phys Ther. 2017;97(4):417-24.
388. Tricco AC, Thomas SM, Veroniki AA, Hamid JS, Cogo E, Strifler L, et al. Comparisons of interventions for preventing falls in older adults: a systematic review and meta-analysis. JAMA. 2017;318(17):1687-99.
389. Stubbs B, Brefka S, Denkinger MD. What works to prevent falls in community-dwelling older adults? Umbrella review of meta-analyses of randomized controlled trials. Phys Ther. 2015;95(8):1095-110.
390. Lyons BP, Hall RJ. Outcomes of a falls prevention education program among older adults in Grenada. J Community Health. 2016;41(5):1021-6.
391. Michael YL, Whitlock EP, Lin JS, Fu R, O'Connor EA, Gold R. Primary care–relevant interventions to prevent falling in older adults: a systematic evidence review for the US Preventive Services Task Force. Ann Intern Med. 2010;153(12):815-25.
392. Sherrington C, Tiedemann A, Fairhall NJ, Hopewell S, Michaleff ZA, Howard K, et al. Exercise for preventing falls in older people living in the community. Wiley Online Library; 2016. Contract No.: Report.
393. Sherrington C, Fairhall NJ, Wallbank GK, Tiedemann A, Michaleff ZA, Howard K, et al. Exercise for preventing falls in older people living in the community. Cochrane Database Syst Rev. 2019(1).
394. Robertson MC, Campbell AJ, Gardner M, Devlin N. Preventing injuries in older people by preventing falls: a meta-analysis of individual-level data. J Am Geriatr Soc. 2002;50(5):905-11.

395. Schwenk M, Lauenroth A, Stock C, Moreno RR, Oster P, McHugh G, et al. Definitions and methods of measuring and reporting on injurious falls in randomised controlled fall prevention trials: a systematic review. BMC Med Res Methodol. 2012;12(1):50.
396. Shubert TE. Evidence-based exercise prescription for balance and falls prevention: a current review of the literature. J Geriatr Phys Ther. 2011;34(3):100-8.
397. Voukelatos A, Merom D, Sherrington C, Rissel C, Cumming RG, Lord SR. The impact of a home-based walking programme on falls in older people: the Easy Steps randomised controlled trial. Age Ageing. 2015;44(3):377-83.
398. Robertson MC. Granting permission to use Otago Exercise Programme. In: Christine Rogers ve, editor. 2012.
399. Gillespie LD, Robertson MC, Gillespie WJ, Sherrington C, Gates S, Clemson LM, et al. Interventions for preventing falls in older people living in the community. The Cochrane Library. 2012.
400. Grossman DC, Curry SJ, Owens DK, Barry MJ, Caughey AB, Davidson KW, et al. Interventions to prevent falls in community-dwelling older adults: US Preventive Services Task Force recommendation statement. JAMA. 2018;319(16):1696-704.
401. Shubert TE, Smith ML, Jiang L, Ory MG. Disseminating the Otago exercise program in the United States: perceived and actual physical performance improvements from participants. J Appl Gerontol. 2018;37(1):79-98.
402. Page FT, Batra FA, Palmer FR. Cost analysis of a community-based fall prevention program being delivered in south Florida. Fam Community Health. 2012;35(3):264-70.
403. Mahoney JE. “Stepping On”: stepping over the chasm from research to practice. Front Public Health. 2015;3:148.
404. Schneider EC, Beattie BL. Building the older adult fall prevention movement–steps and lessons learned. Front Public Health. 2015;3:194.
405. European Falls P. Home page. 2018.
406. Healthier S. The prevention and managment of falls in the community. A framework for action for Scotland 2014/2016. Edinburgh, Scotland: APS Group, Scottish Government; 2014. Report No.: 9781-784128029 Contract No.: Report.
407. Ryan AM. Collaboration on ageing. National falls and bone health project: AFFINITY. 2018.
408. Leipzig RM, Whitlock EP, Wolff TA, Barton MB, Michael YL, Harris R, et al. Reconsidering the approach to prevention recommendations for older adults. Ann Intern Med. 2010;153(12):809-14.
409. Liu-Ambrose T, Donaldson MG, Ahamed Y, Graf P, Cook WL, Close J, et al. Otago home-based strength and balance retraining improves executive functioning in older fallers: a randomized controlled trial. J Am Geriatr Soc. 2008;56(10):1821-30.
410. Grabiner MD, Crenshaw JR, Hurt CP, Rosenblatt NJ, Troy KL. Exercise-based fall prevention: can you be a bit more specific? Exerc Sport Sci Rev. 2014;42(4):161-8.
411. Cho J, Smith ML, Ahn S, Kim K, Appiah B, Ory MG. Effects of an evidence-based falls risk-reduction program on physical activity and falls efficacy among oldest-old adults. Front Public Health. 2015;3:182.
412. Stevens JA. A CDC compendium of effective fall interventions: what works for community-dwelling older adults 2nd ed. Atlanta, GA: Centers for Disease Control and Prevention, National Center for Injury Prevention and Control; 2010.
413. Shubert TE, Smith ML, Ory MG, Clarke CB, Bomberger SA, Roberts E, et al. Translation of the Otago Exercise Program for adoption and implementation in the United States. Front Public Health. 2015;2.
414. Albornos-Muñoz L, Moreno-Casbas T, Sánchez-Pablo C, Bays-Moneo A, Fernández-Domínguez JC, Rich-Ruiz M, et al. Efficacy of the Otago Exercise Programme to reduce falls in community-dwelling adults aged 65-80 years old when delivered as group or individual training. J Adv Nurs. 2018;74(7):1700-11.

415. Shubert TE, Smith ML, Goto L, Jiang L, Ory MG. Otago Exercise Program in the United States: Comparison of 2 Implementation Models. Phys Ther. 2017;97(2):187-97.
416. Davis JC, Hsu CL, Cheung W, Brasher PMA, Li LC, Khan KM, et al. Can the Otago falls prevention program be delivered by video? A feasibility study. BMJ Open Sport & Exercise Medicine. 2016;2(1):e000059.
417. Howes SC, Charles DK, Marley J, Pedlow K, McDonough SM. Gaming for health: Systematic review and meta-analysis of the physical and cognitive effects of active computer gaming in older adults. Phys Ther. 2017;97(12):1122-37.
418. Kyrdalen IL, Moen K, Røysland AS, Helbostad JL. The Otago Exercise Program performed as group training versus home training in fall-prone older people: A randomized controlled trial. Physiother Res Int. 2014;19(2):108-16.
419. Yang XJ, Hill K, Moore K, William S, Dowson L, Borschmann K, et al. Effectiveness of a targeted exercise intervention in reversing older people's mild balance dysfunction: a randomised controlled trial. Phys Ther. 2012;92(1):24-37.
420. Park Y, Chang M. Effects of the Otago exercise program on fall efficacy, activities of daily living and quality of life in elderly stroke patients. J Phys Ther Sci. 2016;28(1):190-3.
421. Abdulrazaq S, O'Neill T, Stanmore EK, Oldham J, Skelton D, Pilling M, et al. AB1111 A prospective cohort study measuring cost-benefit analysis of the Otago Exercise programme in community dwelling adults with rheumatoid arthritis. Ann Rheum Dis. 2017;76(Suppl. 2):1444.
422. Renfro M, Bainbridge DB, Smith ML. Validation of evidence-based fall prevention programs for adults with intellectual and/or developmental disorders: a modified Otago exercise program. Front Public Health. 2016;4:261.
423. Iliffe S, Kendrick D, Morris R, Masud T, Gage H, Skelton D, et al. Multicentre cluster randomised trial comparing a community group exercise programme and home-based exercise with usual care for people aged 65 years and over in primary care. England: National Institute of Health Research; 2014. Report No.: 2046-4924 Contract No.: Report.
424. Son NK, Ryu YU, Jeong HW, Jang YH, Kim HD. Comparison of 2 different exercise approaches: Tai Chi versus Otago, in community-dwelling older women. J Geriatr Phys Ther. 2016;39(2):51-7.
425. Taylor LM, Kerse N, Frakking T, Maddison R. Active video games for improving physical performance measures in older people: a meta-analysis. J Geriatr Phys Ther. 2018;41(2):108-23.
426. Liu-Ambrose T, Nagamatsu LS, Hsu CL, Bolandzadeh N. Emerging concept: 'central benefit model' of exercise in falls prevention. Br J Sports Med. 2013;47(2):115-7.
427. Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P. CONSORT statement for randomized trials of nonpharmacologic treatments: a 2017 update and a CONSORT extension for nonpharmacologic trial abstracts. Ann Intern Med. 2017;167(1):40-7.
428. Patel NN, Pachpute S. The effects of Otago Exercise Programme for fall prevention in elderly people. Int J Physiother. 2015;2(4):633-9.
429. Suttanon P, Piriyaprasarth P, Krootnark K, Aranyavalai T. Effectiveness of falls prevention intervention programme in community-dwelling older people in Thailand: Randomized controlled trial. Hong Kong Physiother J. 2018;38(01):1-11.
430. Tan PJ, Khoo EM, Chinna K, Hill KD, Poi PJH, Tan MP. An individually-tailored multifactorial intervention program for older fallers in a middle-income developing country: Malaysian Falls Assessment and Intervention Trial (MyFAIT). BMC Geriatr. 2014;14(1):78.
431. Tan PJ, Khoo EM, Chinna K, Saedon NIz, Zakaria MI, Zahedi AZA, et al. Individually-tailored multifactorial intervention to reduce falls in the Malaysian Falls Assessment and Intervention Trial (MyFAIT): A randomized controlled trial. PLoS One. 2018;13(8):e0199219.
432. Gross CP, Mallory R, Heiat A, Krumholz H. Reporting the recruitment process in clinical trials: who are these patients and how did they get there? . Ann Intern Med. 2002;137(1):10-6.
433. Frick KD, Kung JY, Parrish JM, Narrett MJ. Evaluating the cost-effectiveness of fall prevention programs that reduce fall-related hip fractures in older adults. J Am Geriatr Soc. 2010;58(1):136-41.

434. Davis JC, Robertson MC, Comans T, Scuffham PA. Guidelines for conducting and reporting economic evaluation of fall prevention strategies. Osteoporos Int. 2011;22(9):2449-59.
435. Carande-Kulis V, Stevens JA, Florence CS, Beattie BL, Arias I. A cost–benefit analysis of three older adult fall prevention interventions. J Saf Res. 2015;52:65-70.
436. Ghimire E, Colligan EM, Howell B, Perlroth D, Marrufo G, Rusev E, et al. Effects of a community-based fall management program on Medicare cost savings. Am J Prev Med. 2015;49(6):e116.
437. Meyer JC, Schellack N, Stokes J, Lancaster R, Zeeman H, Defty D, et al. Ongoing initiatives to improve the quality and efficiency of medicine use within the public healthcare system in South Africa: a preliminary study. Front Pharmacol. 2017;8:751.
438. Seabe D, Burger R. Building bridges or deepening divides: Resources and formal volunteering in post-apartheid South Africa. Stellenbosch, South Africa: Department of Economics, University of Stellenbosch, and Bureau for Economic Research; 2017. Contract No.: Report.
439. Hoffmann N, Metz T. What can the capabilities approach learn from an Ubuntu ethic? A relational approach to development theory. World Dev. 2017;97:153-64.
440. Wouters P, van Oostendorp H. Overview of instructional techniques to facilitate learning and motivation of serious games. In: Wouters P, van Oostendorp H, editors. Instructional techniques to facilitate learning and motivation of serious games. Cham, Switzerland: Springer; 2017. p. 1-16.
441. Bonnechère B. Serious Games in Physical Rehabilitation. From theory to practice. Cham, Switzerland: Springer; 2018.
442. Tahmosybayat R, Baker K, Godfrey A, Caplan N, Barry G. A systematic review and meta-analysis of outcome measures to assess postural control in older adults who undertake exergaming. Maturitas. 2017;98:35-45.
443. Ijaz K, Ahmadpour N, Calvo RA, editors. New directions in designing exergames for the whole family. Proceedings of the 29th Australian Conference on Computer-Human Interaction; 2017 2017; Brisbane, Australia: ACM.
444. Nintendo. IR information 2019 [Available from: https://www.nintendo.co.jp/ir/en/finance/software/wii.html.
445. Millington B. Exergaming in retirement centres and the integration of media and physical literacies. J Aging Stud. 2015;35:160-8.
446. Kaufman D, Sauvé L, Renaud L, Sixsmith A, Mortenson B. Older adults' digital gameplay. Simul Gaming. 2016;47(4):465-89.
447. Wiemeyer J, Kliem A. Serious games in prevention and rehabilitation – a new panacea for elderly people? . Eur Rev Ageing Phys Act. 2012;9(1):41-50.
448. Griffiths MD, Kuss DJ, Ortiz de Gortari AB. Videogames as therapy: An updated selective review of the medical and psychological literature. Int J Priv Health Info Manage. 2017;5(2):71-96.
449. Lange BS, Requejo P, Flynn SM, Rizzo AA, Valero-Cuevas FJ, Baker L, et al. The potential of virtual reality and gaming to assist successful aging with disability. Phys Med Rehabil Clin N Am. 2010;21(2):339-56.
450. Nguyen TTH, Ishmatova D, Tapanainen T, Liukkonen TN, Katajapuu N, Makila T, et al., editors. Impact of serious games on health and well-being of elderly: a systematic review. Proceedings of the 50th Hawaii Internationaal Conference on System Sciences; 2017 2017; Hilton Waikoloa Village, Waikoloa, Hawaii: HICSS.
451. Betts LR, Hill R, Gardner SE. "There's not enough knowledge out there": Examining older adults' perceptions of digital technology use and digital inclusion classes. J Appl Gerontol. 2017;38(8):1147-66.
452. Brown JA, editor Digital gaming perceptions among older adult non-gamers. Human Aspects of IT for the Aged Population Applications, Services and Contexts ITAP 2017; 2017 2017. Cham, Switzerland: Springer.

453. Pope Z, Gao Z. Negative aspects of emerging technologies in physical activity promotion. In: Gao Z, editor. Technology in Physical Activity and Health Promotion. Abingdon United Kindom: Routledge; 2017. p. 223-33.
454. Baker S, Warburton J, Hodgkin S, Pascal J. The supportive network: rural disadvantaged older people and ICT. Ageing Soc. 2017;37(6):1291-309.
455. Greyling T. Internet access and its relationship to subjective well-being in a developing region. S Afr J Econ Manage Sci. 2018;21(1):1-12.
456. Everatt D. Quality of life in the Gauteng City-Region, South Africa. Soc Indic Res. 2017;130(1):71-86.
457. Wittenberg M. Wages and wage inequality in South Africa 1994–2011: Part 2–Inequality measurement and trends. S Afr J Econ. 2017;85(2):298-318.
458. Bornman E. Information society and digital divide in South Africa: results of longitudinal surveys. Inf Comm Soc. 2016;19(2):264-78.
459. Gabriels H, Horn A. The relationship between access to Information and Communications Technology (ICT) and poverty in South Africa. Africanus. 2014;44(1):21-33.
460. Kappen DL, Mirza-Babaei P, Nacke LE. Older adults' physical activity and exergames: A systematic review. Int J Hum–Comput Int. 2018;35(2):140 - 67.
461. Hays K, O'Dell DR, Cuthbert JP, Tefertiller C, Natale A. Virtual-reality based therapy for balance deficits during Traumatic Brain Injury inpatient rehabilitation. Arch Phys Med Rehabil. 2015;96(10):e44.
462. Ferraz DD, Trippo K, Dominguez A, Santos A, Oliveira Filho J. Nintendo Wii training on postural balance and mobility rehabilitation of adults with Parkinson's disease: a systematic review. Fisioterapia em Movimento. 2017;30:383-93.
463. Negrini S, Bissolotti L, Ferraris A, Noro F, Bishop MD, Villafane JH. Nintendo Wii Fit for balance rehabilitation in patients with Parkinson's disease: A comparative study. J Bodyw Mov Ther. 2017;21(1):117-23.
464. Karasu AU, Batur EB, Karataş GK. Effectiveness of Wii-based rehabilitation in stroke: A randomized controlled study. J Rehabil Med. 2018;50(5):406-12.
465. Prosperini L, Fortuna D, Giannì C, Leonardi L, Marchetti MR, Pozzilli C. Home-based balance training using the Wii balance board: a randomized, crossover pilot study in multiple sclerosis. Neurorehabil Neural Repair. 2013;27(6):516-25.
466. Thomas S, Fazakarley L, Thomas PW, Brenton S, Collyer S, Perring S, et al. Testing the feasibility and acceptability of using the Nintendo Wii in the home to increase activity levels, vitality and well-being in people with multiple sclerosis (Mii-vitaliSe): protocol for a pilot randomised controlled study. BMJ Open. 2014;4(5):005172.
467. Bergeron M, Lortie CL, Guitton MJ. Use of virtual reality tools for vestibular disorders rehabilitation: A comprehensive analysis. Adv Med. 2015;2015:9.
468. Booth V, Masud T, Connell L, Bath-Hextall F. The effectiveness of virtual reality interventions in improving balance in adults with impaired balance compared with standard or no treatment: a systematic review and meta-analysis. Clin Rehabil. 2014;28(5):419-31.
469. Manlapaz DG, Sole G, Jayakaran P, Chapple CM. A narrative synthesis of Nintendo Wii Fit gaming protocol in addressing balance among healthy older adults: what system works? Games Health J. 2017;6(2):65-74.
470. Padala KP, Padala PR, Lensing SY, Dennis RA, Bopp MM, Parkes CM, et al. Efficacy of Wii-Fit on static and dynamic balance in community dwelling older veterans: a randomized controlled pilot trial. J Aging Res. 2017;2017:1-9.
471. Phillips JS, Fitzgerald J, Phillis D, Underwood A, Nunney I, Bath A. Vestibular rehabilitation using video gaming in adults with dizziness: a pilot study. J Laryngol Otol. 2018;132(3):202-6.
472. Kwok BC, Pua YH. Effects of WiiActive exercises on fear of falling and functional outcomes in community-dwelling older adults: a randomised control trial. Age Ageing. 2016;45(5):621-8.

473. Papegaaij S, Morang F, Steenbrink F. Virtual and augmented reality based balance and gait training. Amsterdam, The Netherlands: Motek; 2017.
474. Baranowski T. Exergaming: hope for future physical activity? Or blight on mankind? J Sport Health Sci. 2017;6(1):44-6.
475. Bower KJ, Clark RA, McGinley JL, Martin CL, Miller KJ. Clinical feasibility of the Nintendo Wii for balance training post-stroke: a phase II randomized controlled trial in an inpatient setting. Clin Rehabil. 2014;28(9):912-23.
476. Quadros XH, Rao S, Dharmaraj SK. Additional virtual reality sitting balance training using XBox Kinect™ in patients with neurological disorders: A pilot study. J Clin Diagn Res. 2017;11(10):YM03.
477. Lee S, Kim W, Park T, Peng W. The psychological effects of playing exergames: A systematic review. Cyberpsychol, Beha Soc Netw. 2017;20(9):513-32.
478. Jahn K, Saul A, Elstner M, Sapa K, Kellerer S. Vestibular rehabilitation therapy and Nintendo Wii balance board training both improve postural control in bilateral vestibulopathy. J Neurol. 2018;265(1):70-3.
479. Bateni H. Changes in balance in older adults based on use of physical therapy vs. the WiiFit gaming system: a preliminary study. Physiotherapy. 2011;98(3):211-6.
480. Howes S, Charles D, Holmes D, Pedlow K, Wilson I, McDonough S. Older adults' experience of falls prevention exercise delivered using active gaming and virtual reality. Physiotherapy. 2017;103:e4-e5.
481. Crossan A, McKelvey N, Curran K. Mobile technologies impact on economic development in Sub-Saharan Africa. In: Khosrow-Pour M, editor. Advanced Methodologies and Technologies in Network Architecture, Mobile Computing, and Data Analytics. 2. Hershey, PA: IGI Global; 2019. p. 1031-9.
482. Mansouri S, Raggad BG. Risk of telemedicine infeasibility: An evidential reasoning approach. Health Sci. 2017;6(10):76-86.
483. Marston HR, Smith ST. Interactive videogame technologies to support independence in the elderly: A narrative review. Games Health J. 2012;1(2):139-52.
484. Williams MA, Soiza RL, Jenkinson A, Stewart A. Exercising with Computers in Later Life (EXCELL) – pilot and feasibility study of the acceptability of the Nintendo WiiFit in community-dwelling fallers. BMC Res Notes. 2010;3(238).
485. Agmon M, Perry CK, Phelan E, Demiris G, Nguyen HQ. A pilot study of Wii Fit Exergames to improve balance in older adults J Geriatr Phys Ther. 2011;34(4):161-7.
486. Laver K, Ratcliffe J, George S, Burgess L, Crotty M. Is the Nintendo Wii Fit really acceptable to older people?: a discrete choice experiment. BMC Geriatr. 2011;11:64.
487. Heick JD, Flewelling S, Blau R, Geller J, Lynskey JV. Wii Fit and balance. Does the Wii Fit improve balance in community-dwelling older adults? . Top Geriatr Rehabil. 2012;28(3):217-22.
488. Anderson F, Annett M, Bischof WF. Lean on Wii: Physical rehabilitation with virtual reality and Wii Peripherals. Stud Health Technol Inform. 2010;154:181-4.
489. Nitz JC, Kuys S, Isles R, Fu S. Is the Wii Fit a new generation tool for improving balance, health and well-being? A pilot study. Climacteric. 2010;13(5):487-91.
490. Owens SG, Garner JC, Loftin JM, van Blerk N, Ermin K. Changes in physical activity and fitness after three months of home Wii Fit use. J Strength Cond Res. 2011;25(11):3191-7.
491. Coudeyre E. High tech-low cost, the growing place of WII in rehabilitation. Ann Phys Rehabil Med. 2017;60(6):361-2.
492. Gras lZ, Hummer AD, Hine ER. Reliability and validity of the Nintendo Wii Fit J Cyber Ther Rehabil. 2009;2:329-35.
493. Smith ST, Schoene D. The use of exercise-based videogames for training and rehabilitation of physical function in older adults: current practice and guidelines for future research. Aging Health. 2012;8(3):243-52.

494. Lyons EJ, Tate DH, Ward DS, Bowling JM, Ribisl KM, Kalyararaman S. Energy expenditure and enjoyment during video game play: difference by game type. Med Sci Sports Exerc. 2011;43(10):1987-93.
495. Worley JR, Rogers SN, Kraemer RR. Metabolic responses to Wii Fit video games at different game levels. J Strength Cond Res. 2011;25(3):689-93.
496. Peng W, Crouse JC, Lin JH. Using active video games for physical activity promotion: a systematic review of the current state of research. Health Edu Behav. 2012;40(2):171-92.
497. Velazquez A, Martínez-García AI, Favela J, Ochoa SF. Adaptive exergames to support active aging: An action research study. Perv Mob Comput. 2017;34(Jan 2017):60-78.
498. Hasselmann V, Oesch P, Fernandez-Luque L, Bachmann S. Are exergames promoting mobility an attractive alternative to conventional self-regulated exercises for elderly people in a rehabilitation setting? Study protocol of a randomized controlled trial.(Clinical report). BMC Geriatr. 2015;15(1).
499. Salmon JP, Dolan SM, Drake RS, Wilson GC, Klein RM, Eskes GA. A survey of video game preferences in adults: building better games for older adults. Entertain comput. 2017;21:45-64.
500. Skjæret-Maroni N, Vonstad EK, Ihlen EAF, Tan X-C, Helbostad JL, Vereijken B. Exergaming in older adults: movement characteristics while playing stepping games. Front Psychol. 2016;7.
501. Bush M, Dougherty W. Assessment of vestibular rehabilitation therapy training and practice patterns. J Comm Health. 2015;40(4):802-7.
502. Sienko KH, Whitney SL, Carender WJ, Wall Iii C. The role of sensory augmentation for people with vestibular deficits: real-time balance aid and/or rehabilitation device? J Vestib Res. 2017;27(1):63-76.
503. Yue W, Qi G. Progress in research on Vestibular Rehabilitation Therapy. Inf Int. 2016;5(4):119-24.
504. Kirazli Y, Karapolat H, Celebisoy N, Kirazli T. Is Vestibular Rehabilitation as effective in bilateral vestibular dysfunction as in unilateral vestibular dysfunction? Eur J Phys Rehabil Med. 2014;50(6):657-63.
505. McDonnell MN, Hillier SL. Vestibular rehabilitation for unilateral peripheral vestibular dysfunction. Cochrane Database Syst Rev. 2015(1).
506. Rossi-Izquierdo M, Gayoso-Diz P, Santos-Pérez S, Del-Río-Valeiras M, Faraldo-García A, Vaamonde-Sánchez-Andrade I, et al. Vestibular rehabilitation in elderly patients with postural instability: reducing the number of falls—a randomized clinical trial. Aging Clin Exp Res. 2018;30(11):1353-61.
507. Robertson MC, Campbell AJ. Optimisation of ACC's fall prevention programmes for older people. Dunedin, New Zealand: Dunedin School of Medicine, University of Otago; 2008. Contract No.: Report.
508. Whitney SL, Alghwiri A, Alghadir A. Physical therapy for persons with vestibular disorders. Curr Opin Neurol. 2015;28(1):61-8.
509. Okubo Y, Osuka Y, Jung S, Rafael F, Tsujimoto T, Aiba T, et al. Walking can be more effective than balance training in fall prevention among community-dwelling older adults. Geriatri Gerontol Int. 2016;16(1):118-25.
510. National Heart L, Blood I. Aim for a healthy weight body mass index calculator. National Institute of Health, US Department of Health and Human Services; 2018.
511. Saklayen M. The global epidemic of the Metabolic Syndrome. Curr Hypertens Rep. 2018;20(2):1-8.
512. Stacey N, Tugendhaft A, Hofman K. Sugary beverage taxation in South Africa: Household expenditure, demand system elasticities, and policy implications. Prev Med. 2017;105:S26-S31.
513. Merom D, Pye V, Macniven R, van DP, Milat A, Sherrington C, et al. Prevalence and correlates of participation in fall prevention exercise/physical activity by older adults. Prev Med. 2012;55(6):613-7.

514. Taylor MJD, Lindsverk H, Nygaard M, Hunt J, Shanks J, Griffin M, et al. Comparing the energy expenditure of Wii-Fit-based therapy with that of traditional physiotherapy in an older adult population. J Am Geriatr Soc. 2014;62(1):203-5.
515. Mullins NM, Tessmer KA, McCarroll ML, Peppel BP. Physiological and perceptual responses to Nintendo® Wii Fit™ in young and older adults. Int J Exerc Sci. 2012;5(1):79-92.
516. Scherr J, Wolfarth B, Christle JW, Pressler A, Wagenpfeil S, Halle M. Associations between Borg's rating of perceived exertion and physiological measures of exercise intensity. Eur J Appl Physiol. 2013;113(1):147-55.
517. Yoo S, Ackad C, Heywood T, Kay J, editors. Evaluating the actual and perceived exertion provided by virtual reality games. Proceedings of the 2017 CHI Conference Extended Abstracts on Human Factors in Computing Systems; 2017 2017: ACM.
518. Pollock BS, Barkley JE, Potenzini N, Desalvo RM, Buser SL, Otterstetter R, et al. Validity of Borg Ratings of Perceived Exertion during active video game play. Int J Exerc Sci. 2013;6(2):164-70.
519. Lohse K, Shirzad N, Verster A, Hodges N, Van der Loos HF. Video games and rehabilitation: using design principles to enhance engagement in physical therapy. J Neurol Phys Ther. 2013;37(4):166-75.
520. Gallant MP, Tartaglia M, Hardman S, Burke K. Using Tai Chi to reduce fall risk factors among older adults: An evaluation of a community-based implementation. J Appl Gerontol. 2019;38(7):983-98.
521. Swanenburg J, Wild K, Straumann D, De Bruin ED. Exergaming in a moving virtual world to train vestibular functions and gait; a proof-of-concept-study with older adults. Front Physiol. 2018;9.
522. Herdman SJ, Whitney SL. Physical therapy treatment of vestibular hypofunction. In: Herdman SJ, Clendaniel RA, editors. Vestibular Rehabilitation. 4th ed. New Delhi, India: Jaypee Brothers Medical Publishers; 2014. p. 359-92.
523. Sinclair J, Hingston P, Masek M, editors. Considerations for the design of exergames. Proceedings of the 5th international conference on Computer graphics and interactive techniques in Australia and Southeast Asia; 2007: ACM.
524. Huang H-C, Edwin Cheng T, Wong M-K, Chiu H-Y, Lee C-Y, Teng C-I. Who intends to play exergames? The flow-theoretic perspective. J Electron Commer Re. 2018;19(2):154-63.
525. Nickel A. Designing better exergames: Application of flow concepts and the FITT principle to full body exertion video games and flexible challenge systems. Charlotte: The University of North Carolina; 2013.
526. Sweetser P, Johnson D, Wyeth P, Anwar A, Meng Y, Ozdowska A. GameFlow in different game genres and platforms. Computers in Entertainment (CIE). 2017;15(3):1.
527. Marston HR, Kroll M, Fink D, Gschwind YJ. Flow experience of older adults using the iStoppFalls exergame. Games Cult. 2016;11(1-2):201-22.
528. Kliem A, Wiemeyer J. Comparison of a traditional and a video game based balance training program. Int J Comput Sci Sport. 2010;9(2):80-91.
529. Macera CA, Cavanaugh A, Bellettiere J. State of the art review: Physical activity and older adults. Am J Lifestyle Med. 2017;11(1):42-57.
530. Room J, Hannink E, Dawes H, Barker K. What interventions are used to improve exercise adherence in older people and what behavioural techniques are they based on? A systematic review. BMJ Open. 2017;7(12):019221.
531. Pereles L, Jackson R, Rosenal T, Nixon L. Listening with a narrative ear: Insights from a study of fall stories in older adults. Canadian Family Physician Medecin de Famille Canadien. 2017;63(1):e50.
532. Viken H, Reitlo LS, Zisko N, Nauman J, Aspvik NP, Ingebrigtsen JE, et al. Predictors of dropout in exercise trials in older adults: The Generation 100 Study. , Publish Ahead of Print. Med Sci Sports Exerc. 2018;In Press.

533. Simek EM, McPhate L, Haines TP. Adherence to and efficacy of home exercise programs to prevent falls: a systematic review and meta-analysis of the impact of exercise program characteristics. Prev Med. 2012;55(4):262-75.
534. Picorelli AMA, Pereira LSM, Pereira DS, Felício D, Sherrington C. Adherence to exercise programs for older people is influenced by program characteristics and personal factors: a systematic review. J Physiother. 2014;60(3):151-6.
535. Valenzuela T, Okubo Y, Woodbury A, Lord SR, Delbaere K. Adherence to technology-based exercise programs in older adults: a systematic review. J Geriatr Phys Ther. 2018;41(1):49-61.
536. Franco MR, Tong A, Howard K, Sherrington C, Ferreira PH, Pinto RZ, et al. Older people's perspectives on participation in physical activity: a systematic review and thematic synthesis of qualitative literature. Br J Sports Med. 2015;49(19):1268-76.
537. Child S, Goodwin V, Garside R, Jones-Hughes T, Boddy K, Stein K. Factors influencing the implementation of fall-prevention programmes: a systematic review and synthesis of qualitative studies. Implementation science. 2012;7(1):91.
538. Pyae A, Liukkonen TN, Mika L, Kattimeri C, Cauberghe V, Smed J. Investigating the Finnish elderly people's attitudes and motivation towards digital game-based physical exercises. Finnish Journal of eHealth and eWelfare. 2017;9(4):265-83.
539. Plano Clark VL, Schumacher K, West C, Edrington J, Dunn LB, Harzstark A, et al. Practices for embedding an interpretive qualitative approach within a randomized clinical trial. Journal of Mixed Methods Research. 2013;7(3):219-42.
540. Bishop FL, Yardley L. Qualitative assessment. In: Ayers S, Baum A, McManus C, Newman S, Wallston K, Weinman J, et al., editors. Cambridge Handbook of Psychology, Health and Medicine 2ed. Cambridge United Kingdom: Cambridge Univeristy Press; 2017. p. 314-8.
541. Creswell JW, Fetters MD, Ivankova NV. Designing a mixed methods study in primary care. Ann Fam Med. 2004;2(1):7-12.
542. Bonell C, Moore G, Warren E, Moore L. Are randomised controlled trials positivist? Reviewing the social science and philosophy literature to assess positivist tendencies of trials of social interventions in public health and health services. Trials. 2018;19(1):238.
543. Whitehead AL, Sully BG, Campbell M. Pilot and feasibility studies: is there a difference from each other and from a randomised controlled trial? Contemp Clin Trials. 2014;38(1):130-3.
544. Dixon JR. The International Conference on Harmonization Good Clinical Practice Guideline. Qual Assur. 1999;6(2):65-74.
545. P. C, P. D, S. M, S. M, I. N, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Br Med J. 2008;337(a 1655).
546. Pawson R. The shrinking scope of pragmatic trials: a methodological reflection on their domain of applicability. J Clin Epidemiol. 2018;107:71-6.
547. Mohajan HK. Qualitative research methodology in social sciences and related subjects. Journal of Economic Development, Environment and People. 2018;7(1):23-48.
548. Poels K, De Kort Y, Ijsselsteijn W, editors. It is always a lot of fun!: exploring dimensions of digital game experience using focus group methodology. Proceedings of the 2007 conference on Future Play; 2007 2007: ACM.
549. Yardley L, Ainsworth B, Arden-Close E, Muller I. The person-based approach to enhancing the acceptability and feasibility of interventions. Pilot and Feasibility Studies. 2015;1(1):37.
550. O'Cathain A, Hoddinott P, Lewin S, Thomas KJ, Young B, Adamson J, et al. Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. Pilot and Feasibility Studies. 2015;1(1):32.
551. Bravo P, Edwards A, Barr PJ, Scholl I, Elwyn G, McAllister M. Conceptualising patient empowerment: a mixed methods study. BMC Health Serv Res. 2015;15(1):252.
552. Leask CF, Sandlund M, Skelton D, Altenburg TM, Cardon G, Chinapaw MJ, et al. Framework, principles and recommendations for utilising participatory methodologies in the co-creation and evaluation of public health interventions. Research Involvement and Engagement. 2019;5(2).

553. Heerkens YF, de Weerd M, Huber M, de Brouwer CP, van der Veen S, Perenboom RJ, et al. Reconsideration of the scheme of the International Classification of Functioning, Disability and Health: incentives from the Netherlands for a global debate. Disabil Rehabil. 2018;40(5):603-11.
554. Huber M, Knottnerus JA, Green L, Horst Hvd, Jadad AR, Kromhout D, et al. How should we define health? BMJ. 2011;343:d4163.
555. Ramani S, Mann K. Introducing medical educators to qualitative study design: Twelve tips from inception to completion. Med Teach. 2016;38(5):456-63.
556. Creswell JW, Poth CN. Qualitative inquiry and research design: Choosing among five approaches. 4th ed. Thousand Oaks, CA: Sage Publications; 2017.
557. Eldridge SM, Lancaster GA, Campbell MJ, Thabane L, Hopewell S, Coleman CL, et al. Defining feasibility and pilot studies in preparation for randomised controlled trials: development of a conceptual framework. PLoS One. 2016;11(3):e0150205.
558. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, et al. How we design feasibility studies. Am J Prev Med. 2009;36(5):452-7.
559. Eldridge SM, Costelloe CE, Kahan BC, Lancaster GA, Kerry SM. How big should the pilot study for my cluster randomised trial be? Stat Methods Med Res. 2016;25(3):1039-56.
560. Bugge C, Williams B, Hagen S, Logan J, Glazener C, Pringle S, et al. A process for Decision-making after Pilot and feasibility Trials (ADePT): development following a feasibility study of a complex intervention for pelvic organ prolapse. Trials. 2013;14(1):353.
561. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. Pilot and Feasibility Studies. 2016;2:32.
562. Abbott JH. The distinction between randomized clinical trials (RCTs) and preliminary feasibility and pilot studies: what they are and are not. J Orthop Sports Phys Ther. 2014;44(8):555-8.
563. Ribeiro DC, Milosavljevic S, Abbott JH. Sample size estimation for cluster randomized controlled trials. Musculoskeletal Science and Practice. 2018;34:108-11.
564. Moberg J, Kramer M. A brief history of the cluster randomised trial design. J R Soc Med. 2015;108(5):192-8.
565. Krauss A. Why all randomised controlled trials produce biased results. Ann Med. 2018;50(4):312-22.
566. Setia MS. Methodology series module 5: Sampling strategies. Indian J Dermatol. 2016;61(5):505.
567. Wilding MJ, Seegert L, Rupcic S, Griffin M, Kachnowski S, Parasuraman S. Falling short: recruiting elderly individuals for a fall study. Ageing Research Reviews. 2013;12(2):552-60.
568. Campbell AJ, Robertson MC. Rethinking individual and community fall prevention strategies: a meta-regression comparing single and multifactorial interventions Age Ageing. 2007;36:656-62.
569. Hyde JS, Bigler RS, Joel D, Tate CC, van Anders SM. The future of sex and gender in psychology: Five challenges to the gender binary. Am Psychol. 2019;74(2):171-93.
570. Talley KMC, Wyman JF, Gross CR, Lindquist RA, Gaugler JE. Change in balance confidence and its associations with increasing disability in older community-dwelling women at risk for falling. J Aging Health. 2014;26:616-36.
571. Ferrucci L, Guralnik JM, Studenski S, Fried LP, Cutler GB, Walston JD. Designing randomized, controlled trials aimed at preventing or delaying functional decline and disability in frail, older persons: a consensus report. J Am Geriatr Soc. 2004;52(4):625-34.
572. Sinha SK, Detsky AS. Measure, promote and reward mobility to prevent falls in older patients. J Am Med Assoc. 2012;308:2573-4.
573. Borson S, Scanlan JM, Watanabe J, Tu SP, Lessig M. Simplifying detection of cognitive impairment: Comparison of the Mini-Cog and Mini-Mental State Examination in a multi-ethnic sample Journal of the American Geriatric Society. 2005;53:871-4.

574. Laudisio A, Antonelli Incalzi R, Gemma A, Marzetti E, Pozzi G, Padua L, et al. Definition of a Geriatric Depression Scale cutoff based upon quality of life: a population-based study. Int J Geriatr Psychiatry. 2018;33(1):e58-e64.
575. Helgadóttir B, Hallgren M, Kullberg CL, Forsell Y. Sticking with it? Factors associated with exercise adherence in people with mild to moderate depression. Psychol Sport Exerc. 2018;35:104-10.
576. Meldrum D, Herdman S, Moloney R, Murray D, Duffy D, Malone K, et al. Effectiveness of conventional versus virtual reality based vestibular rehabilitation in the treatment of dizziness, gait and balance impairment in adults with unilateral peripheral vestibular loss: a randomised controlled trial. BMC Ear, Nose and Throat Disorders. 2012;12:3.
577. Billingham SA, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. BMC Med Res Methodol. 2013;13:104.
578. Borson S, Scanlan J, Brush M, Vitaliano P, Dokmak A. The Mini-Cog: a cognitive 'vital signs" measure for dementia screening in multi-lingual elderly. Int J Geriatr Psychiatry. 2000;15:1021-7.
579. Doerflinger DMC. How to try this: The Mini Cog. Am J Nurs. 2007;107:62-71.
580. Chan CC, Newton HT, Gill SS, Herrmann N, Smailagic N, Nikolaou V, et al. Mini-Cog for the diagnosis of Alzheimer's disease dementia and other dementias within a primary care setting. 2018. Report No.: CD011415. Contract No.: 2.
581. Tsoi KK, Chan JY, Hirai HW, Wong SY, Kwok TC. Cognitive tests to detect dementia: a systematic review and meta-analysis. JAMA Internal Medicine. 2015;175(9):1450-8.
582. Holsinger T, Plassman BL, Stechuchak KM, Burke JR, Coffman CJ, Williams JW. Screening for cognitive impairment: comparing the performance of four instruments in primary care. Journal of the American Geriatric Society. 2012;60:1036.
583. Borson S, Scanlan JM, Chen P, Ganguli M. The Mini-Cog as a screen for dementia: validation in a population-based sample. Journal of the American Geriatric Society. 2003;51:1451-4.
584. Sheikh JI, Yesavage JA. Geriatric Depression Scale (GDS): recent evidence and development of a shorter version. Clinical Gerontologist: The Journal of Aging and Mental Health. 1986;5(1-2):165-73.
585. Friedman B, Heisel MJ, Delavan RL. Psychometric properties of the 15-item Geriatric Depression Scale in functionally impaired, cognitively intact, community-dwelling elderly primary care patients. Journal of the American Geriatric Society. 2005;53:1570-6.
586. Chiang KS, Green KE, Cox EO. Rasch analysis of the Geriatric Depression Scale-Short Form. The Gerontologist. 2009;49:262-75.
587. Pocklington C, Gilbody S, Manea L, McMillan D. The diagnostic accuracy of brief versions of the Geriatric Depression Scale: a systematic review and meta-analysis. Int J Geriatr Psychiatry. 2016;31(8):837-57.
588. Groll DL, To T, Bombardier C, Wright JG. The development of a comorbidity index with physical function as the outcome. J Clin Epidemiol. 2005;58(6):595-602.
589. EuroQol.org. EQ-5D-3L Self-complete on paper: EuroQol.org; 2019 [Available from: https://euroqol.org/eq-5d-instruments/eq-5d-5l-available-modes-of-administration/self-complete-on-paper/.
590. van Leeuwen KM, Jansen AP, Muntinga ME, Bosmans JE, Westerman MJ, van Tulder MW, et al. Exploration of the content validity and feasibility of the EQ-5D-3L, ICECAP-O and ASCOT in older adults. BMC Health Serv Res. 2015;15(1):201.
591. Payakachat N, Ali MM, Tilford JM. Can the EQ-5D detect meaningful change? A systematic review. Pharmacoeconomics. 2015;33(11):1137-54.
592. Resnick B, Jenkins LS. Testing the reliability and validity of the self-efficacy for exercise scale. Nurs Res. 2000;49(3):154-9.
593. Picha KJ. The assessment and utilization of patients' self-efficacy for exercise during rehabilitation. Lexington, Kentucky: University of Kentucky; 2018.

594. Washburn RA, McAuley E, Katula J, Mihalko SL, Boileau RA. The physical activity scale for the elderly (PASE): evidence for validity. J Clin Epidemiol. 1999;52(7):643-51.
595. Müller AM, Ansari P, Ebrahim NA, Khoo S. Physical activity and aging research: a bibliometric analysis. J Aging Phys Act. 2016;24(3):476-83.
596. Forsén L, Loland NW, Vuillemin A, Chinapaw MJM, van Poppel MNM, Mokkink LB, et al. Self-administered physical activity questionnaires for the elderly. Sports Med. 2010;40(7):601-23.
597. Safarpour M, Hosseini SR, Fotouhi A, Zeraati H, Mohamadzade M, Bijani A. Physical activity in the elderly with fall experience over the past year: Results from Amirkola Health and Ageing Project. Iranian Journal of Health Sciences. 2019;7(1):1-8.
598. Brooke J. SUS – a quick and dirty usability scale. In: P.W. Jordan BT, I. L. McClelland & B. A. Weerdmeester (Eds.), editor. Usability evaluation in industry. London, U.K.: Taylor & Francis; 1996. p. 189-94.
599. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the System Usability Scale. Int J Hum Comput Interact. 2008;24:574-94.
600. Lewis JR. The system usability scale: past, present, and future. International Journal of Human–Computer Interaction. 2018;34(7):577-90.
601. Borg GA. Psychophysical bases of perceived exertion. Med Sci Sports Exerc. 1982;14(5):377-81.
602. Cabral LL, Lopes PB, Wolf R, Stefanello JMF, Pereira G. A systematic review of cross-cultural adaptation and validation of Borg's Rating of Perceived Exertion scale. Journal of Physical Education. 2017;28:e2853.
603. Frost R, Levati S, McClurg D, Brady M, Williams B. What adherence measures should be used in trials of home-based rehabilitation interventions? A systematic review of the validity, reliability, and acceptability of measures. Arch Phys Med Rehabil. 2017;98(6):1241-56. e45.
604. King F, Horak F. On the MiniBESTest: scoring and the reporting of total scores. Phys Ther. 2013;93:571-5.
605. Yingyongyudha A, Saengsirisuwan V, Panichaporn W, Boonsinsukh R. The Mini-Balance Evaluation Systems Test (Mini-BESTest) demonstrates higher accuracy in identifying older adult participants with history of falls than do the BESTest, Berg Balance Scale, or Timed Up and Go Test. J Geriatr Phys Ther. 2016;39(2):64-70.
606. M. SK, T. H, E. LS, R. LS, E. MB, J. RD, et al. Recommendations for a core outcome set for measuring standing balance in adult populations: a consensus-based approach. PLoS One. 2015;10(3):e.0120568.
607. PE M, MB G, JM P, NG Z, IC A, RC F, et al. Use of the BESTest and the Mini-BESTest for fall risk prediction in community-dwelling older adults between 60 and 102 years of age. J Geriatr Phys Ther. 2019;aop:6.
608. Di Carlo S, Bravini E, Vercelli S, Massazza G, Ferriero G. The Mini-BESTest: a review of psychometric properties. Int J Rehabil Res. 2016;39(2):97-105.
609. Podsiadlo D, Richardson S. The timed “Up & Go”: a test of basic functional mobility for frail elderly persons. J Am Geriatr Soc. 1991;39(2):142-8.
610. Bohannon RW. Reference values for the five-repetition sit-to-stand test: a descriptive meta-analysis of data from elders. Percept Mot Skills. 2006;103(1):215-22.
611. Watt AA, Clark C, Williams JM. Differences in sit-to-stand, standing sway and stairs between community-dwelling fallers and non-fallers: a review of the literature. Phys Ther Rev. 2018;23(4-5):1-18.
612. Shumway-Cook A. Motor control : theory and practical applications. Woollacott MH, editor. Baltimore, Md: Williams and Wilkins; 1995.
613. Neptune R, Vistamehr A. Dynamic balance during human movement: Measurement and control mechanisms. J Biomech Eng. 2019;141(7).
614. Shumway-Cook A, Taylor CS, Matsuda PN, Studer MT, Whetten BK. Expanding the scoring system for the Dynamic Gait Index. Phys Ther. 2013;93(11):1493-506.

615. Rossiter-Fornoff JE, Wolf SL, Wolfson LI, Buchner DM, Group F. A cross-sectional validation study of the FICSIT common data base static balance measures. The Journals of Gerontology Series A: Biological Sciences and Medical Sciences. 1995;50(6):M297.
616. Vereeck L, Wuyts F, Truijen S, Van de Heyning P. Clinical assessment of balance: normative data, and gender and age effects. Int J Audiol. 2008;47(2):67-75.
617. Milanese S. The use of RCTs in manual therapy – are we trying to fit a round peg in a square hole? . Man Ther. 2011;16:403-5.
618. Armijo-Olivo S, Saltaji H, da Costa BR, Fuentes J, Ha C, Cummings GG. What is the influence of randomisation sequence generation and allocation concealment on treatment effects of physical therapy trials? A meta-epidemiological study. BMJ Open. 2015;5(9):e008562.
619. Polit DF, Gillespie BM, Griffin R. Deliberate ignorance. A systematic review of blinding in nursing clinical trials. Nurs Res. 2011;60:9-16.
620. Page SJ, Persch AC. Recruitment, retention and blinding in clinical trials The American Journal of Occupational Therapy. 2013;67:154-61.
621. Armijo-Olivo S, Fuentes J, da Costa BR, Saltaji H, Ha C, Cummings GG. Blinding in physical therapy trials and its association with treatment effects: a meta-epidemiological study. Am J Phys Med Rehabil. 2017;96(1):34-44.
622. Colagiuri B. Participant expectancies in double-blind randomised placebo-controlled trials: potential limitations to trial validity. Clinical Trials. 2010;7:246-55.
623. Kimberlin CL, Winterstein AG. Validity and reliability of measurement instruments used in research. Am J Health Syst Pharm. 2008;65(23):2276-84.
624. Sedgwick P, Greenwood N. Understanding the Hawthorne effect. BMJ. 2015;351:h4672.
625. Abrahamse W. Research designs for measuring the effectiveness of interventions. In: Gifford R, editor. Research methods for environmental psychology. Chichester. UK: Wiley & Sons; 2016. p. 291 - 306.
626. Mansournia MA, Altman DG. Invited commentary: methodological issues in the design and analysis of randomised trials. British Journal of Sports Medicine. 2018;52(9):553-5.
627. MK C, G P, DR E, DG A. CONSORT 2010 Statement: extension to cluster randomised trials. Br Med J. 2012;345(e5561).
628. Bassler D, Briel M, Montori VM, Lane M, Glasziou P, Zhou Q, et al. Stopping randomized trials early for benefit and estimation of treatment effects. J Am Med Assoc. 2010;303:1180-7.
629. Health Do. Guidelines for good practice in the conduct of clinical trials with human participants in South Africa. Pretoria, South Africa: Department of Health; 2006.
630. Chen A, Vinluan J, Retegan C, McCahy P. Implementing error rate checks to improve the data quality in the Victorian Audit of Surgical Mortality. Comput Biol Med. 2019;106:40-5.
631. Hong MK, Yao HH, Pedersen JS, Peters JS, Costello AJ, Murphy DG, et al. Error rates in a clinical data repository: lessons from the transition to electronic data transfer—a descriptive study. BMJ Open. 2013;3(5):e002406.
632. Cattelani L, Palumbo P, Palmerini L, Bandinelli S, Becker C, Chesani F, et al. FRAT-up, a Web-based fall-risk assessment tool for elderly people living in the community. J Med Internet Res. 2015;17(2):e41.
633. Palumbo P, Klenk J, Cattelani L, Bandinelli S, Ferrucci L, Rapp K, et al. Predictive performance of a fall risk assessment tool for community-dwelling older people (FRAT-up) in 4 European cohorts. J Am Med Dir Assoc. 2016;17(12):1106-13.
634. Ewald B. Making sense of equivalence and non-inferiority trials. Australian Prescriber. 2013;36:170-3.
635. Gupta SK. Intention-to-treat concept: a review. Perspectives in Clinical Research. 2011;2(3):109-12.
636. Rooshenas L, Paramasivan S, Jepson M, Donovan JL. Intensive triangulation of qualitative research and quantitative data to improve recruitment to randomized trials: The QuinteT approach. Qual Health Res. 2019;29(5):672-9.

637. Hussein A. The use of triangulation in social sciences research: Can qualitative and quantitative methods be combined? Journal of Comparative Social Work. 2015;4(1):1-12.
638. Tonkin-Crine S, Anthierens S, Hood K, Yardley L, Cals JW, Francis NA, et al. Discrepancies between qualitative and quantitative evaluation of randomised controlled trial results: achieving clarity through mixed methods triangulation. Implementation Science. 2015;11(1):66.
639. Kern FG. The trials and tribulations of applied triangulation: weighing different data sources. Journal of Mixed Methods Research. 2018;12(2):166-81.
640. World Medical A. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191-4.
641. Resnik DB, Shamoo AE. The Singapore Statement on research integrity. Accountability in Research. 2011;18(2):71-5.
642. Taljaard M, Weijer C, Grimshaw JM, Eccles MP, Ottawa Ethics of Cluster Randomised Trials Consensus G. The Ottawa Statement on the ethical design and conduct of cluster randomised trials: precis for researchers and research ethics committees. BMJ Clinical Research. 2013;346:f2838.
643. Buccini LD, Iverson D, Caputi P, Jones C, Gho S. Assessing clinical trial informed consent comprehension in non-cognitively impaired adults: a systematic review of instruments. Research Ethics Review. 2009;5:3-8.
644. Kornblau BL, Burkhardt A. Ethics in rehabilitation: a clinical perspective. Thorofare, NJ: Slack Incorporated; 2012.
645. Dhai A. Vulnerability exploited and a population betrayed. South African Journal of Bioethics and Law. 2012;5:62-3.
646. Chatters R, Newbould L, Sprange K, Hind D, Mountain G, Shortland K, et al. Recruitment of older adults to three preventative lifestyle improvement studies. Trials. 2018;19(1):121.
647. Harriss DJ, Atkinson G. Update- ethical standards in sports and exercise science research. Int J Sports Med. 2011;32:819-21.
648. Jalink MB, Heineman E, Pierie JP, ten Cate Hoedemaker HO. Nintendo related injuries and other problems: review. BMJ (Clinical Research ed). 2014;349:g7267.
649. Sparks DA, Couglin LM, Chase DM. Did too much Wii cause your patient's injury? . The Journal of Family Practice. 2011;60(7):404-10.
650. Singh JA. The challenge of discharging research ethics duties in resource-constrained settings. PLoS Med. 2011;8.
651. Ross LF, Loup A, Nelson RM, Botkin JR, Kost R, Smith GR, et al. Human subjects protections in community-engaged research: A research ethics framework. Journal on Empirical Research on Human Research Ethics. 2010;5(1):5-17.
652. Dunn LB, Misra S. Research ethics in geriatric psychiatry. Psychiatr Clin North Am. 2009;32:395-411.
653. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. Nurs Health Sci. 2013;15(3):398-405.
654. Schreier M. Qualitative content analysis. In: Flick U, editor. The Sage Handbook of Qualitative Data Analysis. London, UK: Sage; 2014. p. 170-83.
655. Ryan KE, Gandha T, Culbertson MJ, Carlson C. Focus group evidence: Implications for design and analysis. American Journal of Evaluation. 2014;35(3):328-45.
656. Fusch PI, Ness LR. Are we there yet? Data saturation in qualitative research. The Qualitative Report. 2015;20(9):1408-16.
657. Liamputtong P. Focus group methodology: Principle and practice. London, UK: Sage Publications; 2011.
658. Nyumba T, Wilson K, Derrick CJ, Mukherjee N. The use of focus group discussion methodology: Insights from two decades of application in conservation. Methods Ecol Evol. 2018;9(1):20-32.
659. Gill P, Stewart K, Treasure E, Chadwick B. Methods of data collection in qualitative research: interviews and focus groups. Br Dent J. 2008;204(6):291-5.

660. Moser A, Korstjens I. Series: Practical guidance to qualitative research. Part 3: Sampling, data collection and analysis. European Journal of General Practice. 2018;24(1):9-18.
661. Etikan I, Musa SA, Alkassim RS. Comparison of convenience sampling and purposive sampling. American Journal of Theoretical and Applied Statistics. 2016;5(1):1-4.
662. Kahan BC, Rehal S, Cro S. Risk of selection bias in randomised trials. Trials. 2015;16(1):405.
663. Onwuegbuzie AJ, Dickinson WB, Leech NL, Zoran AG. A qualitative framework for collecting and analyzing data in focus group research. International Journal of Qualitative Methods. 2009;8(3):1-21.
664. Nagle B, Williams N. Methodology brief: Introduction to focus groups 2013 [1]. Available from: http://www.mmgconnect.com/projects/userfiles/File/FocusGroupBrief.pdf.
665. Cho JY, Lee E-H. Reducing confusion about grounded theory and qualitative content analysis: Similarities and differences. The Qualitative Report. 2014;19(32):1-20.
666. Korstjens I, Moser A. Series: Practical guidance to qualitative research. Part 4: Trustworthiness and publishing. European Journal of General Practice. 2018;24(1):120-4.
667. Mabuza LH, Govender I, Ogunbanjo GA, Mash B. African Primary Care Research: Qualitative data analysis and writing results. African Journal of Primary Health Care & Family Medicine. 2014;6(1):1-5.
668. Graneheim UH, Lindgren B-M, Lundman B. Methodological challenges in qualitative content analysis: A discussion paper. Nurse Educ Today. 2017;56:29-34.
669. M S. Qualitative content analysis. In: Flick U, editor. The SAGE handbook of qualitative data analysis. Los Angeles: Sage; 2013. p. 170-83.
670. Burnard P, Gill P, Stewart K, Treasure E, Chadwick B. Analysing and presenting qualitative data. Br Dent J. 2008;204(8):429-32.
671. Bengtsson M. How to plan and perform a qualitative study using content analysis. NursingPlus Open. 2016;2:8-14.
672. Braun V, Clarke V. Successful qualitative research: A practical guide for beginners. London, UK: Sage; 2013.
673. Strudwick R. Labelling patients. Radiography. 2016;22(1):50-5.
674. Zbar AP. Sacral neuromodulation and peripheral nerve stimulation in patients with anal incontinence: an overview of techniques, complications and troubleshooting. Gastroenterol Rep. 2014;2(2):112-20.
675. Volpe D, Signorini M, Marchetto A, Lynch T, Morris ME. A comparison of Irish set dancing and exercises for people with Parkinson's disease: a phase II feasibility study. BMC Geriatr. 2013;13(1):54.
676. Hooper R, Forbes A, Hemming K, Takeda A, Beresford L. Analysis of cluster randomised trials with an assessment of outcome at baseline. BMJ. 2018;360:k1121.
677. Rutterford C, Copas A, Eldridge S. Methods for sample size determination in cluster randomized trials. Int J Epidemiol. 2015;44(3):1051-67.
678. Koo TK, Li MY. A guideline of selecting and reporting intraclass correlation coefficients for reliability research. J Chiropr Med. 2016;15(2):155-63.
679. Martins AC, Santos C, Silva C, Baltazar D, Moreira J, Tavares N. Does modified Otago exercise program improves balance in older people? A systematic review. Preventive Medicine Reports. 2018;11:231-9.
680. de Amorim JSC, Leite RC, Brizola R, Yonamine CY. Virtual reality therapy for rehabilitation of balance in the elderly: a systematic review and meta-analysis. Advances in Rheumatology. 2018;58(1):18.
681. Reis E, Postolache G, Teixeira L, Arriaga P, Lima ML, Postolache O. Exergames for motor rehabilitation in older adults: an umbrella review. Phys Ther Rev. 2019;24(3-4):84-99.
682. Oliveira JAd, Guaratto TF, Bacha JMR, Evangelista RA, Bocalini DS, Greve JMDA, et al. Virtual reality in the rehabilitation of the balance in the elderly. Manual Therapy, Posturology & Rehabilitation Journal. 2018;15:481.

683. Tobaigy A, Alshehri MA, Timmons S, Helal OF. The feasibility of using exergames as a rehabilitation tool: the attitudes, awareness, opinions and experiences of physiotherapists, and older people towards exergames. Journal of Physical Therapy Science. 2018;30(4):555-62.
684. Day HR, El-Setouhy M, El-Shinawi M, Assem A, Ismail M, Salem M, et al. Young Egyptians' perceptions, attitudes and knowledge of injuries. Inj Prev. 2010;16(5):348-51.
685. Perfetti AR. Fate and the clinic: a multidisciplinary consideration of fatalism in health behaviour. Med Humanit. 2018;44(1):59-62.
686. Maercker A, Ben-Ezra M, Esparza OA, Augsburger M. Fatalism as a traditional cultural belief potentially relevant to trauma sequelae: Measurement equivalence, extent and associations in six countries. European Journal of Psychotraumatology. 2019;10(1):1657371.
687. Cook J, Chatfield K, Schroeder D. Promoting equity and preventing exploitation in international research: The aims, work, and output of the TRUST Project. In: Koporc Z, editor. Ethics and Integrity in Health and Life Sciences Research. 4. Bingley, United Kingdom: Emerald Publishing Limited; 2018. p. 11-31.
688. Bocarro J, Stodolska M. Researcher and advocate: Using research to promote social justice change: Leisure research symposium. Journal of Leisure Research. 2013;45(1):2-6.
689. Rispel LC, Blaauw D, Ditlopo P, White J. Human resources for health and universal health coverage: progress, complexities and contestations. South African Health Review. 2018;2018(1):13-21.
690. Bainbridge R, Tsey K, McCalman J, Kinchin I, Saunders V, Lui FW, et al. No one’s discussing the elephant in the room: contemplating questions of research impact and benefit in Aboriginal and Torres Strait Islander Australian health research. BMC Public Health. 2015;15(1):696.
691. Fergusson D, Monfaredi Z, Pussegoda K, Garritty C, Lyddiatt A, Shea B, et al. The prevalence of patient engagement in published trials: a systematic review. Research Involvement and Engagement. 2018;4(1):17.
692. McElfish PA, Goulden PA, Bursac Z, Hudson J, Purvis RS, Kim Yeary KH, et al. Engagement practices that join scientific methods with community wisdom: designing a patient-centered, randomized control trial with a Pacific Islander community. Nurs Inq. 2017;24(2):1-11.
693. Blease C, Bishop F, Kaptchuk TJ. Informed consent and clinical trials: where is the placebo effect? BMJ. 2017;356:j463.
694. Resnik DB. The ethics of research with human subjects: Protecting people, advancing science, promoting trust. Cham, Switzerland: Springer; 2018.
695. Mkhize N. Ubuntu-Botho approach to ethics: An invitation to dialogue. In: Nortje N, Jongh Jd, Hoffmann W, editors. African Perspectives on Ethics for Healthcare Professionals. Advances in Global Bioethics. Cham, Switzerland: Springer; 2018. p. 25-48.
696. Wilson E, Kenny A, Dickson-Swift V. Ethical challenges of community based participatory research: exploring researchers’ experience. International Journal of Social Research Methodology. 2018;21(1):7-24.
697. Kraft SA, Constantine M, Magnus D, Porter KM, Lee SS-J, Green M, et al. A randomized study of multimedia informational aids for research on medical practices: implications for informed consent. Clinical Trials. 2017;14(1):94-102.
698. Committee FoHSHRE. H3Africa Guidelines for Informed Consent Cape Town: H3 Africa Working Group on Ethics and Research Issues for Human Heridity and Health Africa (H3Africa) Consortium; [August 2013:[Available from: http://www.health.uct.ac.za/sites/default/files/image_tool/images/116/H3Africa%20Guidelines%20on%20Informed%20Consent%20August%202013_0.pdf.
699. Kraemer RR, Landefeld CS. Exercise programs in older adults—A prescription for fall reduction. JAMA Internal Medicine. 2019;179(3):405-6.
700. Hughes JP, Heagerty PJ, Xia F, Ren Y. Robust inference for the Stepped Wedge Design. Biometrics. 2019aop:1-12.

701. Wellek S, Donner-Banzhoff N, König J, Mildenberger P, Blettner M. Planning and analysis of trials using a Stepped Wedge Design: Part 26 of a series on evaluation of scientific publications. Deutsches Ärzteblatt International. 2019;116(26):453-8.
702. Sacristán JA, Aguarón A, Avendaño-Solá C, Garrido P, Carrión J, Gutiérrez A, et al. Patient involvement in clinical research: why, when, and how. Patient Preference and Adherence. 2016;10:631-40.
703. Bassier I, Woolard I. Exclusive growth: Rapidly increasing top incomes amidst low national growth in South Africa. Cape Town: SALDRU, University of Cape Town; 2018.
704. Farham B. Strengthening our health system. SAMJ: South African Medical Journal. 2018;108(12):1003.
705. Lloyd-Sherlock P. Long-term care for older people in South Africa: The enduring legacies of apartheid and HIV/AIDS. J Soc Policy. 2019;48(1):147-67.
706. Kelly G, Mrengqwa L, Geffen L. “They don’t care about us”: older people’s experiences of primary healthcare in Cape Town, South Africa. BMC Geriatr. 2019;19(1):98.
707. DiSogra RM. The impact of pharmaceutical side effects on audiological and vestibular measurements. Seminars in Hearing. 2019;40(02):97-103.
708. Kim HA, Bisdorff A, Bronstein AM, Lempert T, Rossi-Izquierdo M, Staab JP, et al. Hemodynamic orthostatic dizziness/vertigo: Diagnostic criteria. J Vestib Res. 2019;29(2-3):45-56.
709. Bergen G. Falls and fall injuries among adults aged≥ 65 years—United States, 2014. MMWR Morbidity and mortality weekly report. 2016;65(37):993-8.
710. Nascimento CFd, Duarte YAO, Lebrao ML, Chiavegatto Filho ADP. Individual and neighborhood factors associated with functional mobility and falls in elderly residents of São Paulo, Brazil: A multilevel analysis. J Aging Health. 2018;30(1):118-39.
711. Begum R. To find out the prevalence and various risk factors for falls in older adults (60-75 Years) Community NCR Delhi. Indian Journal of Physiotherapy & Occupational Therapy. 2019;13(1):1-5.
712. Sotoudeh GR, Mohammadi R, Mosallanezhad Z, Viitasara E, Soares JJ. The prevalence, circumstances and consequences of unintentional falls among elderly Iranians: A population study. Arch Gerontol Geriatr. 2018;79:123-30.
713. Blain H, Bernard PL, Boubakri C, Bousquet J. Fall Prevention. In: Michel J-P, editor. Prevention of chronic diseases and age-related disability. Practical issues in geriatrics. Cham, Switzerland: Springer; 2019. p. 137-47.
714. Jahn K. The aging vestibular system: Dizziness and imbalance in the elderly. In: Pothier D, Lea J, editors. Vestibular disorders. 82. Basel, Switzerland: Karger Publishers; 2019. p. 143-9.
715. Mol A, Reijnierse EM, Hoang PTSB, van Wezel RJ, Meskers CG, Maier AB. Orthostatic hypotension and physical functioning in older adults: A systematic review and meta-analysis. Ageing Research Reviews. 2018;48:122-44.
716. Lai S-W. Orthostatic hypotension and falls. Am J Hypertens. 2019;32(6):e10-e.
717. Saka SA, Oosthuizen F, Nlooto M. Potential inappropriate prescribing and associated factors among older persons in Nigeria and South Africa. Int J Clin Pharm. 2019;41(1):207-14.
718. Chen Y, Zhu L-L, Zhou Q. Effects of drug pharmacokinetic/pharmacodynamic properties, characteristics of medication use, and relevant pharmacological interventions on fall risk in elderly patients. Ther Clin Risk Manag. 2014;10:437-48.
719. Waring R, Harris R, Mitchell S. Drug metabolism in the elderly: A multifactorial problem? Maturitas. 2017;100:27-32.
720. Goodwin J, Kaskie B. De-Prescribing: What the evidence is telling us. Public Policy & Aging Report. 2018;28(4):106-7.
721. De Man J, Mayega RW, Sarkar N, Waweru E, Leyse M, Van Olmen J, et al. Patient-centered care and people-centered health systems in sub-Saharan Africa: Why so little of something so badly needed? Int J Pers Cent Med. 2016;6(3):162-73.

722. Matthews M, Van Wyk J. Speaking the language of the patient: Indigenous language policy and practice. South African Family Practice. 2016;58(1):30-1.
723. Tkatch R, Hudson J, Schaeffer J, Yeh CS. Non-pharmacologic approaches to reducing polypharmacy in older adults. Public Policy. 2018;28(4):140-2.
724. Zia A, Kamaruzzaman SB, Tan MP. Polypharmacy and falls in older people: balancing evidence-based medicine against falls risk. Postgrad Med. 2015;127(3):330-7.
725. Knapen J, Vancampfort D, Moriën Y, Marchal Y. Exercise therapy improves both mental and physical health in patients with major depression. Disabil Rehabil. 2015;37(16):1490-5.
726. Stonerock GL, Hoffman BM, Smith PJ, Blumenthal JA. Exercise as treatment for anxiety: systematic review and analysis. Ann Behav Med. 2015;49(4):542-56.
727. Stubbs B, Vancampfort D, Rosenbaum S, Firth J, Cosco T, Veronese N, et al. An examination of the anxiolytic effects of exercise for people with anxiety and stress-related disorders: A meta-analysis. Psychiatry Res. 2017;249:102-8.
728. Mudrak J, Stochl J, Slepicka P, Elavsky S. Physical activity, self-efficacy, and quality of life in older Czech adults. European Journal of Ageing. 2016;13(1):5-14.
729. Shaheen M, Puri S, Tandon N. Physical activity measurement in elderly: The Indian scenario. Journal of Physical Activity Research. 2016;1(1):9-14.
730. Ayvat E, Kilinc M, Kirdi N. The Turkish version of the Physical Activity Scale for the Elderly (PASE): its cultural adaptation, validation, and reliability. Turkish Journal of Medical Sciences. 2017;47(3):908-15.
731. Dickie K, Micklesfield LK, Chantler S, Lambert EV, Goedecke JH. Cardiorespiratory fitness and light-intensity physical activity are independently associated with reduced cardiovascular disease risk in urban black South African Women: A cross-sectional study. Metab Syndr Relat Disord. 2016;14(1):23-32.
732. McPhee JS, French DP, Jackson D, Nazroo J, Pendleton N, Degens H. Physical activity in older age: perspectives for healthy ageing and frailty. Biogerontology. 2016;17(3):567-80.
733. Musumeci A, Pignataro A, Ferlito E, Lazzari V, Zatti H, Masiero S. Exercise for frail older adults. In: Masiero S, Carraro U, editors. Rehabilitation medicine for elderly patients. Practical Issues in Geriatrics. Cham, Switzerland: Springer International Publishing; 2018. p. 63-74.
734. Ju J, Jiang Y, Zhou P, Li L, Ye X, Wu H, et al. Evaluation of the reliability and validity for X16 balance testing scale for the elderly. BMC Geriatr. 2018;18(1):112.
735. Xiao Q, Keadle SK, Berrigan D, Matthews CE. A prospective investigation of neighborhood socioeconomic deprivation and physical activity and sedentary behavior in older adults. Prev Med. 2018;111:14-20.
736. Frontera WR. Physical activity and rehabilitation in elderly. In: Masiero S, Carraro U, editors. Rehabilitation medicine for elderly patients. Practical Issues in Geriatrics. Cham, Switzerland: Springer International Publishing; 2018. p. 3-13.
737. Tanyi PL, Pelser A. The missing link: Finding space for gerontology content into university curricula in South Africa. Gerontol Geriatr Educ. 2019;40(4):491-507.
738. Essuman A, Agyemang FA, Mate-Kole CC. Long-term care for older adults in Africa: Whither now? J Am Med Dir Assoc. 2018;19(9):728-30.
739. De Pietro C, Camenzind P, Sturny I, Crivelli L, Edwards-Garavoglia S, Spranger A, et al. Switzerland: health system review. Health Systems in Transition. 2015;17(4):1-288, xix.
740. Stringhini S, Carmeli C, Jokela M, Avendaño M, McCrory C, d'Errico A, et al. Socioeconomic status, non-communicable disease risk factors, and walking speed in older adults: multi-cohort population based study. BMJ. 2018;360:k1046.
741. Shoko M. New approaches to measuring ageing in South Africa. In: P Mensah DK, S Hachigonta, A Roodt, editor. Systems analysis approach for complex global challenges. Cham, Switzerland: Springer; 2018. p. 315-29.
742. Amosun SL, Doyle-Baker PK. What can Sub-Saharan Africa learn from Canada's investment in active healthy ageing? A narrative view. Malawi Med J. 2019;31(1):95-8.

743. Tunzi Z, Simo-Kengne BD. Estimating the future health care cost of population aging in South Africa. Development Southern Africa. 2019;aop:1-17.
744. Bedford O, Yeh K-H. The history and the future of the psychology of filial piety: Chinese norms to contextualized personality construct. Front Psychol. 2019;10:100.
745. Morris D, Jenkins G. Preparing physical and occupational therapists to be health promotion practitioners: A call for action. Int J Environ Res Public Health. 2018;15(2):12.
746. Nunez L, Koehnke J, Williams AL. Interprofessional collaboration: How audiologists contribute to population health. The Hearing Journal. 2019;72(7):12-3.
747. Naidoo N, Barnes R, Mlenzana N, Mostert K, Amosun S. Physiotherapy in rehabilitation and prohabilitation across the lifespan. S Afr Med J. 2019;109(3):142-4.
748. Bello AI, Adegoke BO. Ethics in physiotherapy practice–An African perspective. In: Nortje N, De Jongh J-C, Hoffman W, editors. African Perspectives on Ethics for Healthcare Professionals. Advancing Global Bioethics. 13. Cham, Switzerland: Springer; 2018. p. 133-46.
749. Ellapen TJ, Paul Y, Barnard M, Swanepoel M, Hammill HV, Strydom GL. Are there sufficient number of exercise therapists in South Africa in order to equitably manage the Noncommunicable Disease epidemic? Int Q Community Health Educ. 2019;39(2):127-32.
750. Amosun SL, Maart S, Naidoo N. Addressing change in physiotherapy education in South Africa. The South African journal of physiotherapy. 2018;74(1):431.
751. Health Do. Regulations relating to the undergraduate curriculum and professional examinations board of audiology. In: Health Do, editor. Cape Town: Government Press; 2014.
752. Lebina L, Alaba O, Kawonga M, Oni T. Process evaluation of fidelity and costs of implementing the Integrated Chronic Disease Management model in South Africa: mixed methods study protocol. BMJ Open. 2019;9(6):e029277.
753. Nesengani TV, Downing C, Poggenpoel M, Stein C. Professional nurses' experiences of caring for patients in public health clinics in Ekurhuleni, South Africa. African Journal of Primary Health Care & Family Medicine. 2019;11(1):11.
754. Organisation WH. *WHO Global Report on Fall Prevention in Older Age*. Geneva, Switzerland: WHO; 2007. Report No.: 978 924 156 353 6.
755. Hayes RJ, Moulton LH. Cluster randomised trials. Boca Raton, FL: Chapman and Hall/CRC; 2017.
756. Bolzern J, Mnyama N, Bosanquet K, Torgerson D. Comparing evidence of selection bias between cluster-randomised and individually randomised controlled trials: a systematic review and meta-analysis. The Lancet. 2018;392:S21.
757. Bompart F. Healthy volunteers for clinical trials in resource-poor settings: National registries can address ethical and safety concerns. Camb Q Healthc Ethics. 2019;28(1):134-43.
758. Whiteside K, Flett L, Mitchell A, Fairhurst C, Cockayne S, Rodgers S, et al. Using pens as an incentive for trial recruitment of older adults: An embedded randomised controlled trial. F1000Research. 2019;8.
759. Winter SS, Page-Reeves JM, Page KA, Haozous E, Solares A, Cordova CN, et al. Inclusion of special populations in clinical research: important considerations and guidelines. Journal of clinical and translational research. 2018;4(1):56.
760. Fiero MH, Huang S, Oren E, Bell ML. Statistical analysis and handling of missing data in cluster randomized trials: a systematic review. Trials. 2016;17(1):72.
761. Kumbhare D, Alavinia M, Furlan J. Hypothesis testing in superiority, noninferiority, and equivalence clinical trials: Implications in physical medicine and rehabilitation. Am J Phys Med Rehabil. 2019;98(3):226-30.
762. Cattadori G, Segurini C, Picozzi A, Padeletti L, Anzà C. Exercise and heart failure: an update. ESC Heart Failure. 2018;5(2):222-32.
763. Peugh JL, Strotman D, McGrady M, Rausch J, Kashikar-Zuck S. Beyond intent to treat (ITT): a complier average causal effect (CACE) estimation primer. J Sch Psychol. 2017;60:7-24.

764. Knox CR, Lall R, Hansen Z, Lamb SE. Treatment compliance and effectiveness of a cognitive behavioural intervention for low back pain: a complier average causal effect approach to the BeST data set. BMC Musculoskelet Disord. 2014;15(1):17.
765. Carmody T, Greer TL, Walker R, Rethorst CD, Trivedi MH. A complier average causal effect analysis of the Stimulant Reduction Intervention using dosed exercise study. Contemporary Clinical Trials Communications. 2018;10:1-8.
766. Gruber JS, Arnold BF, Reygadas F, Hubbard AE, Colford Jr JM. Estimation of treatment efficacy with complier average causal effects (CACE) in a randomized stepped wedge trial. Am J Epidemiol. 2014;179(9):1134-42.
767. Gardner CL. Adherence: A concept analysis. International Journal of Nursing Knowledge. 2015;26(2):96-101.
768. Myers ND, Prilleltensky I, Hill CR, Feltz DL. Well-being self-efficacy and complier average causal effect estimation: A substantive-methodological synergy. Psychol Sport Exerc. 2017;30:135-44.
769. Fairhall N, Sherrington C, Cameron ID, Kurrle SE, Lord SR, Lockwood K, et al. A multifactorial intervention for frail older people is more than twice as effective among those who are compliant: complier average causal effect analysis of a randomised trial. J Physiother. 2017;63(1):40-4.
770. Mangione K. What will it take to motivate older adults and caregivers to engage in regular physical activity at a level sufficient to result in benefits? Annu Rev Gerontol Geriatr. 2016;36(1):XV.
771. Farlie MK, Robins L, Keating JL, Molloy E, Haines TP. Intensity of challenge to the balance system is not reported in the prescription of balance exercises in randomised trials: a systematic review. J Physiother. 2013;59(4):227-35.
772. Alsubaie SF, Whitney SL, Furman JM, Marchetti GF, Sienko KH, Klatt BN, et al. Reliability and validity of Ratings of Perceived Difficulty during performance of static standing balance exercises. Phys Ther. 2019;99(10):1381-93.
773. Farlie MK, Robins L, Haas R, Keating JL, Molloy E, Haines TP. Programme frequency, type, time and duration do not explain the effects of balance exercise in older adults: a systematic review with a meta-regression analysis. Br J Sports Med. 2019;53(16):996-1002.
774. Lesinski M, Hortobágyi T, Muehlbauer T, Gollhofer A, Granacher U. Effects of balance training on balance performance in healthy older adults: a systematic review and meta-analysis. Sports Med. 2015;45(12):1721-38.
775. King LA, Wilhelm J, Chen Y, Blehm R, Nutt J, Chen Z, et al. Effects of group, individual, and home exercise in persons with Parkinson Disease: A randomized clinical trial. J Neurol Phys Ther. 2015;39(4):204-12.
776. Beauchamp MR, Ruissen GR, Dunlop WL, Estabrooks PA, Harden SM, Wolf SA, et al. Group-based physical activity for older adults (GOAL) randomized controlled trial: Exercise adherence outcomes. Health Psychol. 2018;37(5):451-61.
777. Hwang J, Wang L, Siever J, Medico TD, Jones CA. Loneliness and social isolation among older adults in a community exercise program: a qualitative study. Aging Ment Health. 2019;23(6):736-42.
778. Zhang F, Hausknecht S, Schell R, Kaufman D, editors. Can a Wii bowling tournament improve older adults' attitudes towards digital games? 8th International Conference of Computer Supported Education CSEDU (2); 2016: SCITEPRESS Science and Technology Publications Ltd.
779. Wu Z, Li J, Theng Y-L. Examining the influencing factors of exercise intention among older adults: A controlled study between exergame and traditional exercise. Cyberpsychology, Behavior, and Social Networking. 2015;18(9):521-7.
780. Arkkukangas M, Sundler AJ, Söderlund A, Eriksson S, Johansson A-C. Older persons' experiences of a home-based exercise program with behavioral change support. Physiother Theory Pract. 2017;33(12):905-13.
781. Arkkukangas M, Soderlund A, Eriksson S, Johansson AC. Fall preventive exercise with or without behavior change support for community-dwelling older adults: A Randomized Controlled Trial with short-term follow-up. J Geriatr Phys Ther. 2017;42:9-17.

782. Aazh H. Feasibility of conducting a randomized controlled trial to evaluate the effect of motivational interviewing on hearing-aid use. Int J Audiol. 2016;55(3):149-56.
783. Weineland SM, Andersson G, Lunner T, Carlbring P, Hesser H, Ingo E, et al. Bridging the gap between hearing screening and successful rehabilitation: research protocol of a randomized controlled trial of motivational interviewing via internet. Am J Audiol. 2015;24(3):302-6.
784. Ferguson M, Maidment D, Russell N, Gregory M, Nicholson R. Motivational engagement in first-time hearing aid users: A feasibility study. Int J Audiol. 2016;55(sup3):S23-S33.
785. Arkkukangas M, Hultgren S. Implementation of motivational interviewing in a fall prevention exercise program: experiences from a randomized controlled trial. BMC Res Notes. 2019;12(1):270.
786. Arkkukangas M, Söderlund A, Eriksson S, Johansson A-C. One-Year adherence to the Otago Exercise Programme with or without motivational interviewing in community-dwelling older people. J Aging Phys Act. 2018;26:390-5.
787. Arkkukangas M, Söderlund A, Eriksson S, Johansson A-C. Fall preventive exercise with or without behavior change support for community-dwelling older adults: A randomized controlled trial with short-term follow-up. J Geriatr Phys Ther. 2019;42(1):9-17.
788. Arkkukangas M, Johnson ST, Hellström K, Anens E, Tonkonogi M, Larsson U. Fall-prevention exercises with or without behavior change support for community-dwelling older adults: A 2-year follow-up of a randomized controlled trial. J Aging Phys Act. 2019;1(aop):1-8.
789. McGaughey RE, Zeltmann SM, McMurtrey ME. Motivations and obstacles to smartphone use by the elderly: developing a research framework. International Journal of Electronic Finance. 2013;7(3-4):177-95.
790. Seifert A, Schlomann A, Rietz C, Schelling HR. The use of mobile devices for physical activity tracking in older adults' everyday life. Digital Health. 2017;3:12.
791. Czaja SJ. Usability of technology for older adults: Where are we and where do we need to be. Journal of Usability Studies. 2019;14(2):61-4.
792. Falck RS, McDonald SM, Beets MW, Brazendale K, Liu-Ambrose T. Measurement of physical activity in older adult interventions: a systematic review. British Journal of Sports Medicine. 2016;50(8):464-70.
793. Greenhalgh T. Health literacy: towards system level solutions. BMJ. 2015;350:h1026.
794. Grady C. Enduring and emerging challenges of informed consent. N Engl J Med. 2015;372(9):855-62.
795. Mercieca-Bebber R, King MT, Calvert MJ, Stockler MR, Friedlander M. The importance of patient-reported outcomes in clinical trials and strategies for future optimization. Patient Related Outcome Measures. 2018;9:353-67.
796. McKenna SP. It is time for an organised, scientific approach to the application of patient-reported outcome measures in clinical studies and trials. Clin Rheumatol. 2019;38(2):611-5.
797. EuroQol.org. EQ 5D 2019 [14 May 2019]. Available from: https://euroqol.org/.
798. Pardasaney PK, Slavin MD, Wagenaar RC, Latham NK, Ni P, Jette AM. Conceptual limitations of balance measures for community-dwelling older adults. Phys Ther. 2013;93(10):1351-68.
799. Marques A, Almeida S, Carvalho J, Cruz J, Oliveira A, Jacome C. Reliability, validity, and ability to identify fall status of the Balance Evaluation Systems Test, Mini–Balance Evaluation Systems Test, and Brief–Balance Evaluation Systems Test in older people living in the community. Arch Phys Med Rehabil. 2016;97(12):2166-73. e1.
800. Coni A, Mellone S, Colpo M, Bandinelli S, Chiari L. A Factor Analysis model of the instrumented Timed Up and Go test for physical capability assessment. Gait Posture. 2018;66:S11-S2.
801. Tomas-Carus P, Biehl-Printes C, Pereira C, Veiga G, Costa A, Collado-Mateo D. Dual task performance and history of falls in community-dwelling older adults. Exp Gerontol. 2019;120:35-9.
802. Spaull N, Kotze J. Starting behind and staying behind in South Africa: The case of insurmountable learning deficits in mathematics. Int J Educ Dev. 2015;41:13-24.

803. Balasubramanian CK. The Community Balance and Mobility Scale alleviates the ceiling effects observed in the currently used gait and balance assessments for the community-dwelling older adults. J Geriatr Phys Ther. 2015;38(2):78-89.
804. Gordt K, Mikolaizak AS, Nerz C, Barz C, Gerhardy T, Weber M, et al. German version of the Community Balance and Mobility Scale. Z Gerontol Geriatr. 2019;52(1):28-36.
805. Weber M, Van Ancum J, Bergquist R, Taraldsen K, Gordt K, Mikolaizak AS, et al. Concurrent validity and reliability of the Community Balance and Mobility scale in young-older adults. BMC Geriatr. 2018;18(1):156.
806. Zur O, Shaki T, Carmeli E. Concurrent validity and reliability of a new balance scale used in older adults. In: Polorski M, editor. Respiratory Medicine and Science. Advances in Experimental Medicine and Biology. Cham, Switzerland: Springer; 2015. p. 63-70.
807. Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, McCormick JB. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. BMC Med Ethics. 2013;14(1):28.
808. Rivera-Torres S, Fahey TD, Rivera MA. Adherence to exercise programs in older adults: Informative report. Gerontology and Geriatric Medicine. 2019;5:1-10.
809. Polit DF, Gillespie BM. Intention-to-treat in randomized controlled trials: Recommendations for a total trial strategy. Res Nurs Health. 2010;33(4):355-68.
810. Jorgensen MG, Laessoe U, Hendriksen C, Nielsen OBF, Aagaard P. Efficacy of Nintendo Wii training on mechanical leg muscle function and postural balance in community-dwelling older adults: a randomized controlled trial. J Gerontol Ser A: Biomed Sci Med Sci. 2012;68(7):845-52.
811. Cho HL, Danis M, Grady C. The ethics of uninsured participants accessing healthcare in biomedical research: A literature review. Clinical Trials. 2018;15(5):509-21.
812. LH L, L S, HH L, H L. The physical effect of exergames in healthy elderly - A systematic review. Games Health Jl. 2013;2(4):205-12.
813. Bieryla KA, Dold NM. Feasibility of Wii Fit training to improve clinical measures of balance in older adults. Clin Interv Aging. 2013;8:775-81.
814. Pluchino A, Lee SY, Asfour S, Roos BA, Signorile JF. Pilot study comparing changes in postural control after training using a video game balance board program and two standard activity-based balance intervention programs. Arch Phys Med Rehabil. 2012;93:1138-46.
815. Montero-Alía P, Miralles-Basseda R, López-Jiménez T, Muñoz-Ortiz L, Jiménez-González M, Prat-Rovira J, et al. Controlled trial of balance training using a video game console in community-dwelling older adults. Age Ageing. 2019;48(4):506-12.
816. Miller KJ, Adair BS, Pearce AJ, Said CM, Ozanne E, Morris MM. Effectiveness and feasibility of virtual reality and gaming system use at home by older adults for enabling physical activity to improve health-related domains: a systematic review. Age Ageing. 2013;43(2):188-95.
817. Van Diest M, Stegenga J, Wörtche H, Verkerke GJ, Postema K, Lamoth C. Exergames for unsupervised balance training at home: a pilot study in healthy older adults. Gait Posture. 2016;44:161-7.
818. Caronni A, Picardi M, Aristidou E, Antoniotti P, Pintavalle G, Redaelli V, et al. How do patients improve their timed up and go test? Responsiveness to rehabilitation of the TUG test in elderly neurological patients. Gait Posture. 2019;70:33-8.
819. Calin-Jageman RJ, Cumming G. The New Statistics for better science: Ask how much, how uncertain, and what else is known. The American Statistician. 2019;73:271-80.
820. Brustio PR, Liubicich ME, Chiabrero M, Rabaglietti E. Dancing in the golden age: a study on physical function, quality of life, and social engagement. Geriatric Nursing. 2018;39(6):635-9.
821. Jin J. Prevention of falls in older adults. JAMA. 2018;319(16):1734-.
822. Whipple MO, Hamel AV, Talley KM. Fear of falling among community-dwelling older adults: A scoping review to identify effective evidence-based interventions. Geriatric Nursing. 2018;39(2):170-7.

823. Tahmosybayat R, Baker K, Godfrey A, Caplan N, Barry G. Movements of older adults during exergaming interventions that are associated with the Systems Framework for Postural Control: A systematic review. Maturitas. 2018;111:90-9.
824. Gomes GCV, do Socorro Simões M, Lin SM, Bacha JMR, Viveiro LAP, Varise EM, et al. Feasibility, safety, acceptability, and functional outcomes of playing Nintendo Wii Fit PlusTM for frail older adults: A randomized feasibility clinical trial. Maturitas. 2018;118:20-8.
825. Appiah-Kubi K, Wright W. Vestibular training promotes adaptation of multisensory integration in postural control. Gait Posture. 2019;73:215-20.
826. Rossi-Izquierdo M, Gayoso-Diz P, Santos-Pérez S, Del-Río-Valeiras M, Faraldo-García A, Vaamonde-Sánchez-Andrade I, et al. Prognostic factors that modify outcomes of vestibular rehabilitation in elderly patients with falls. Aging Clin Exp Res. 2019;aop.
827. Ueta Y, Matsugi A, Oku K, Okuno K, Tamaru Y, Nomura S, et al. Gaze stabilization exercises derive sensory reweighting of vestibular for postural control. Journal of Physical Therapy Science. 2017;29(9):1494-6.
828. Bugli B. The role of physical therapy exercises in recovery. In: Babu S, Schutt C, Bojrab D, editors. Diagnosis and treatment of vestibular disorders. Cham, Switzerland: Springer; 2019. p. 377-82.
829. Dolenc E, Rotar-Pavlič D. Frailty assessment scales for the elderly and their application in primary care: A systematic literature review. Slovenian Journal of Public Health. 2019;58(2):91-100.
830. Kidd T, Mold F, Jones C, Ream E, Grosvenor W, Sund-Levander M, et al. What are the most effective interventions to improve physical performance in pre-frail and frail adults? A systematic review of randomised control trials. BMC Geriatr. 2019;19(1):184.
831. Muñoz JE, Gonçalves A, Rúbio Gouveia É, Cameirão MS, Bermudez i Badia S. Lessons learned from gamifying functional fitness training through human-centered cesign methods in older adults. Games for Health Journal. 2019;aop.
832. Hargittai E, Piper AM, Morris MR. From internet access to internet skills: digital inequality among older adults. Universal Access in the Information Society. 2018;18(4):881-90.
833. Berkowsky RW, Sharit J, Czaja SJ. Factors predicting decisions about technology adoption among older adults. Innovation in Aging. 2018;1(3):igy002.
834. Jojo Z. Mathematics education system in South Africa. Education Systems Around the World: IntechOpen; 2019.
835. Cruz M, Kugel JD, Hewitt L, Salamat A. Perceptions of older adults on the use of an interactive video game in promoting health and well-being. The Open Journal of Occupational Therapy. 2018;6(3):3.
836. Louw Q, Grimmer K, Dizon J, Machingaidze S, Parker H, Ernstzen D. Building capacity in primary care rehabilitation clinical practice guidelines: a South African initiative. Health Res Policy Syst. 2018;16(1):1-11.
837. Wicht C. Future geriatric needs in South Africa-hospital and teaching aspects. S Afr Med J. 1977;51(13):440-2.
838. Frieson CW, Tan MP, Ory MG, Smith ML. Editorial: Evidence-based practices to reduce falls and fall-related injuries among older adults. Frontiers in Public Health. 2018;6(222).
839. Couper I, Ray S, Blaauw D, Ng'wena G, Muchiri L, Oyungu E, et al. Curriculum and training needs of mid-level health workers in Africa: a situational review from Kenya, Nigeria, South Africa and Uganda. BMC Health Serv Res. 2018;18(1):553.
840. Hansen A. The development of a tool to support the work of the Rehabilitation care worker in documenting information about rehabilitation and health needs among persons with disability in home and community setting. Cape Town: Faculty of Health Sciences; 2018.
841. Burton E, Lewin G, O'Connell H, Petrich M, Boyle E, Hill KD. Can community care workers deliver a falls prevention exercise program? A feasibility study. Clin Interv Aging. 2018;13:485-95.

842. Kalu ME, Vlachantoni A, Norman KE. Knowledge about risk factors for falls and practice about fall prevention in older adults among physiotherapists in Nigeria. Physiother Res Int. 2019;24(1):e1742.
843. Shubert TE, Smith ML, Schneider EC, Wilson AD, Ory MG. Commentary: Public health system perspective on implementation of evidence-based fall-prevention strategies for older adults. Frontiers in Public Health. 2016;4(252).
844. Brennan C, Greenhalgh J, Pawson R. Guidance on guidelines: Understanding the evidence on the uptake of health care guidelines. J Eval Clin Pract. 2018;24(1):105-16.
845. Stander J, Grimmer K, Brink Y. Factors influencing clinical practice guideline uptake by South African physiotherapists: A qualitative investigation of barriers and facilitators. J Eval Clin Pract. 2019 aop.
846. Chen Y, Wang C, Shang H, Yang K, Norris SL. Clinical practice guidelines in China. BMJ. 2018;360:j5158.
847. Alnaim L, Almazrou S. A study of barriers and facilitators of clinical practice guidelines implementation among physicians. Indian J Pharm Sci. 2018;79(6):923-9.
848. Wilkinson M, Wilkinson T, Kredo T, MacQuilkan K, Mudara C, Winch A, et al. South African clinical practice guidelines: A landscape analysis. S Afr Med J. 2018;108(1):23-7.
849. Smith ML, Chaudhary S, Nieb S, Bayakly R, Graham K, Head E. Commentary: Building the older adult fall prevention movement – steps and lessons learned. Frontiers in Public Health. 2016;4(277).
850. Dietler D, Leuenberger A, Bempong N-E, Campbell-Lendrum D, Cramer C, Eggen RIL, et al. Health in the 2030 Agenda for Sustainable Development: from framework to action, transforming challenges into opportunities. Journal of global health. 2019;9(2):020201-.
851. Agyepong IA, Sewankambo N, Binagwaho A, Coll-Seck AM, Corrah T, Ezeh A, et al. The path to longer and healthier lives for all Africans by 2030: the Lancet Commission on the future of health in sub-Saharan Africa. The Lancet. 2017;390(10114):2803-59.
852. Wahl H-W, Deeg D, Litwin H. Successful ageing as a persistent priority in ageing research. European Journal of Ageing. 2016;13(1):1-3.
853. Van Der Pas S, Ramklass S, O'Leary B, Anderson S, Keating N, Cassim B. Features of home and neighbourhood and the liveability of older South Africans. European Journal of Ageing. 2015;12(3):215-27.
854. Hauer K, Lamb SE, Jorstad EC, Todd C, Becker C. Systematic review of definitions and methods of measuring falls in randomised controlled fall prevention trials. Age Ageing. 2006;35(1):5-10.
855. Orces CH. Prevalence and determinants of falls among older adults in Ecuador: An analysis of the SABE I Survey. Current Gerontology and Geriatrics Research. 2013;2013:495468.
856. Coimbra AMV, Ricci NA, Coimbra IB, Costallat L. Falls in the elderly of the Family Health Program. Arch Gerontol Geriatr. 2010;51:317-22.
857. Siqueira FV, Facchini LA, Silveira DSd, Piccini RX, Tomasi E, Thumé E, et al. Prevalence of falls in elderly in Brazil: a countrywide analysis. Cad Saude Publica. 2011;27(9):1819-26.
858. Dsouza SA, Rajashekar B, Dsouza HS, Kumar KB. Falls in Indian older adults: a barrier to active ageing. Asian J Gerontol Geriatr. 2014;9(1):1-8.
859. Sharma PK, Bunker CH, Singh T, Ganguly E, Reddy PS, Newman AB, et al. Burden and correlates of falls among rural elders of south India: Mobility and Independent Living in Elders Study. Current Gerontology and Geriatrics Research. 2017;2017.
860. Gamage N, Rathnayake N, Alwis G. Knowledge and perception of falls among community dwelling elderly: A study from southern Sri Lanka. Current Gerontology and Geriatrics Research. 2018;2018:1-8.
861. Assantachai P, Praditsuwan R, Chatthanawaree W, Pisalsarakij D, Thamlikitkul V. Risk factors for falls in the Thai elderly in an urban community. Journal of the Medical Association of Thailand = Chotmaihet thangphaet. 2003;86(2):124-30.

862. Almegbel FY, Alotaibi IM, Alhusain FA, Masuadi EM, Al Sulami SL, Aloushan AF, et al. Period prevalence, risk factors and consequent injuries of falling among the Saudi elderly living in Riyadh, Saudi Arabia: a cross-sectional study. BMJ Open. 2018;8(1).
863. Salarvand S, Birjandi M, Shamshiri M. Assessing prevalence of fallings and their relation with chronic conditions for older people living in Khoramabad, Iran. The Horizon of Medical Sciences. 2008;13(4):59-65.
864. Kamel MH, Abdulmajeed AA, Ismail SE-S. Risk factors of falls among elderly living in urban Suez-Egypt. Pan Afr Med J. 2013;14(1).
865. Halil M, Ulger Z, Cankurtaran M, Shorbagi A, Yavuz BB, Dede D, et al. Falls and the elderly: Is there any difference in the developing world?: A cross-sectional study from Turkey. Arch Gerontol Geriatr. 2006;43(3):351-9.
866. Sparling PB, Howard BJ, Dunstan DW, Owen N. Recommendations for physical activity in older adults. BMJ: British Medical Journal (Online). 2015;350.
867. Cress ME, Buchner DM, Prohaska T, Rimmer J, Brown M, Macera C, et al. Best practices for physical activity programs and behavior counseling in older adult populations. Eur Rev Aging Phys Act. 2006;3(1):34-42.
868. Persch AC, Page SJ. Protocol development, treatment fidelity, adherence to treatment, and quality control. Am J Occup Ther. 2013;67(2):146-53.
869. McHenry JC, Insel KC, Einstein GO, Vidrine AN, Koerner KM, Morrow DG. Recruitment of older adults: success may be in the details. The Gerontologist. 2012;55(5):845-53.
870. Bayer A. Methodological problems of research in older people. In: H. M. Fillit, Rockwood K, Woodhouse K, editors. Brocklehurst's textbook of geriatric medicine and gerontology. 7th Ed. ed. Philadelphia: Saunders Elsevier; 2010. p. 23-9.
871. Wang-Hsu E, Smith SS. Interrater and Test-Retest Reliability and Minimal Detectable Change of the Balance Evaluation Systems Test (BESTest) and Subsystems With Community-Dwelling Older Adults. J Geriatr Phys Ther. 2018;41(3):173-9.
872. Sibley KM, Straus SE, Inness EL, Salbach NM, Jaglal SB. Balance assessment practices and use of standardized balance measures among Ontario physical therapists. Phys Ther. 2011;91(11):1583-91.
873. Anson E, Thompson E, Ma L, Jeka J. Reliability and fall risk detection for the BESTest and Mini-BESTest in older adults. J Geriatr Phys Ther. 2019;42:81-8.
874. Obuchowski NA, Bullen JA. Receiver operating characteristic (ROC) curves: review of methods with applications in diagnostic medicine. Phys Med Biol. 2018;63(7):07TR1.
875. Yingyongyudha A, Panichaporn W, Boonsinsukh R. The Mini Balance Evaluation System Test (Mini-BESTest) for predicting recurrent fall in active older adults from 1-year prospective study. Thai Pharmaceutical and Health Science Journal. 2018;13(4):164-70.
876. Potter K, Brandfass K. The Mini-Balance Evaluation Systems Test (Mini-BESTest). J Physiother. 2015;61(4):225.
877. Tong Y, Tian X, Wang Y, Han J, Waddington G, Adams R. Cognitive dual-task Timed-Up-and-Go test as a predictor of falls in the community-dwelling elderly. J Sci Med Sport. 2018;21:S80.
878. Nightingale CJ, Mitchell SN, Butterfield SA. Validation of the Timed Up and Go Test for assessing balance variables in adults aged 65 and older. J Aging Phys Act. 2018;27(2):230-3.
879. Ibrahim A, Singh DKA, Shahar S. 'Timed Up and Go'test: Age, gender and cognitive impairment stratified normative values of older adults. PLoS One. 2017;12(10):e0185641.
880. Whitney SL, Herdman SJ. Physical therapy assessment of vestibular hypofunction. In: Herdman SJ, editor. Vestibular Rehabilitation. 2nd ed. Philadelphia, PA:: F. A. Davis Co.; 2000. p. 272-99.
881. Neptune R, Vistamehr A. Dynamic balance during human movement: Measurement and control mechanisms. J Biomech Eng. 2019;41(7).
882. Middleton A, Fritz SL, Lusardi M. Walking speed: the functional vital sign. J Aging Phys Act. 2015;23(2):314-22.

883. Van Abbema R, De Greef M, Crajé C, Krijnen W, Hobbelen H, Van Der Schans C. What type, or combination of exercise can improve preferred gait speed in older adults? A meta-analysis. BMC Geriatr. 2015;15(1):72.
884. Bohannon RW, Andrews AW. Normal walking speed: a descriptive meta-analysis. Physiotherapy. 2011;97(3):182-9.
885. Lipsitz LA, Jonsson PV, Kelley MM, Koestner JS. Causes and correlates of recurrent falls in ambulatory frail elderly. J Gerontol. 1991;46(4):M114-M22.
886. Milne A, Culverwell A, Guss R, Tuppen J, Whelton R. Screening for dementia in primary care: a review of the use, efficacy and quality of measures. Int Psychogeriatr. 2008;20(5):911-26.
887. Parker C, Philp I. Screening for cognitive impairment among older people in black and minority ethnic groups. Age Ageing. 2004;33(5):447-52.
888. Ismail Z, Rajji TK, Shulman KI. Brief cognitive screening instruments: an update. Int J Geriatr Psychiatry. 2009;25:120.
889. Ehreke L, Luppa M, König HH, Riedel-Heller SG. Is the Clock Drawing Test a screening tool for the diagnosis of mild cognitive impairment? A systematic review. Int Psychogeriatr. 2010;22:56-63.
890. Ismail Z, Rajji TK, Shulman KI. Brief cognitive screening instruments: an update. Int J Geriatr Psychiatry. 2010;25(2):111-20.
891. Montorio I, Izal M. The Geriatric Depression Scale: A review of its development and utility. Int Psychogeriatr. 1996;8(1):103-12.
892. Siu AL, Bibbins-Domingo K, Grossman DC, Baumann LC, Davidson KW, Ebell M, et al. Screening for depression in adults: US Preventive Services Task Force recommendation statement. JAMA. 2016;315(4):380-7.
893. Pedraza O, Dotson VM, Willis FB, Graff-Radford NR, Lucas JA. Internal consistency and test-retest stability of the Geriatric Depression Scale-Short Form in African American older adults. Journal of Psychopathology and Behavioral Assessment. 2009;31:416.
894. Izal M, Montorio I, Nuevo R, Pérez-Rojo G, Cabrera I. Optimising the diagnostic performance of the Geriatric Depression Scale. Psychiatry Res. 2010;178(1):142-6.
895. Kurlowicz L, Greenberg SA. The Geriatric Depression Scale (GDS). AJN The American Journal of Nursing. 2007;107(10):67-8.
896. Greenberg SA. How to try this: The Geriatric Depression Scale Short Form. AJN The American Journal of Nursing. 2007;107(10):60-9.
897. Devlin NJ, Brooks R. EQ-5D and the EuroQol group: past, present and future. Applied Health Economics and Health Policy. 2017;15(2):127-37.
898. Barnes RY, Jelsma J, Parker R. Improvements in health-related quality of life and function in middle-aged women with chronic diseases of lifestyle after participating in a non-pharmacological intervention programme: A pragmatic randomised controlled trial. African Journal of Disability (Online). 2019;8:1-14.
899. Jelsma J, Maart S. Should additional domains be added to the EQ-5D health-related quality of life instrument for community-based studies? An analytical descriptive study. Population health metrics. 2015;13(1):13.
900. Bangor A, Kortum P, Miller J. Determining what individual SUS scores mean: Adding an adjective rating scale. Journal of Usability Studies. 2009;4(3):114-23.
901. Lewis JR, Sauro J, editors. The factor structure of the system usability scale. International Conference on Human Centered Design; 2009. Berlin, Germany: Springer-Verlag.
902. Finstad K. The System Usability Scale and non-native English speakers. Journal of Usability Studies. 2006;1(4):185-8.
903. Sauro J. Measuring usability with the System Usability Scale. 2011 [Available from: https://www.measuringusability.com/sus.php.
904. Nawaz A, Skjæret N, Ystmark K, Helbostad JL, Vereijken B, Svanæs D, editors. Assessing seniors' user experience (UX) of exergames for balance training. Proceedings of the 8th Nordic conference on human-computer interaction: fun, fast, foundational; 2014; Helsinki, Finland: ACM.

905. Paul SS, Canning CG. Five-repetition sit-to-stand. J Physiother. 2014;60(3):168.
906. Meretta BM, Whitney SL, Marchetti GF, Sparto PJ, Muirhead RJ. The five times sit to stand test: responsiveness to change and concurrent validity in adults undergoing vestibular rehabilitation. J Vestib Res. 2006;16(4, 5):233-43.
907. Bohannon RW. Measurement of sit-to-stand among older adults. Topics in Geriatric Rehabilitation. 2012;28(1):11-6.
908. Zhang F, Ferrucci L, Culham E, Metter EJ, Guralnik J, Deshpande N. Performance on five times sit-to-stand task as a predictor of subsequent falls and disability in older persons. J Aging Health. 2013;25(3):478-92.
909. Biros M. Capacity, vulnerability, and informed consent for research. The Journal of Law, Medicine & Ethics. 2018;46(1):72-8.
910. Hansen TWR. Advanced clinical medicine requires advanced clinical ethics Neonatology. 2012;101(1):8-12.
911. Galvin JE, Sadowsky CH. Practical guidelines for the recognition and diagnosis of dementia. . J Am Board Fam Med. 2012;25(3):367-82.
912. Jensen JS, Reiter-Theil S, Celio DA, Jakob M, Vach W, Saxer FJ. Handling of informed consent and patient inclusion in research with geriatric trauma patients–a matter of protection or disrespect? Clin Interv Aging. 2019;14:321-34.
913. Shamoo AE, Resnik DB. Responsible conduct of research. 2nd edition ed. New York: Oxford University Press; 2009.
914. Dugas M, Graham JE. Is consent for research genuinely informed? Using decision aid tools to obtain informed consent in the global south. Journal of Global Ethics. 2011;7:349-59.
915. Dickens BM, Cook RJ. Challenges of ethical research in resource-poor settings. International Journal of Gynecology and Obstetrics. 2003;80:79-86.
916. DuBois JM, Beskow L, Campbell J, Dugosh K, Festinger D, Hartz S, et al. Restoring balance: a consensus statement on the protection of vulnerable research participants. Am J Public Health. 2012;102:2220-5.
917. Milian M, Leiherr AM, Straten G, Müller S, Leyhe T, Eschweiler GW. The Mini-Cog versus the Mini-Mental State Examination and the Clock Drawing Test in daily clinical practice: screening value in a German Memory Clinic. Int Psychogeriatr. 2012;24(5):766-74.
918. Pope A. Ethical and legal issues regarding consent in research with adult stroke patients. . The Journal of Nervous and Mental Disease. 2012;200(3):250-4.
919. Benatar JR, Mortimer J, Stretton M, Stewart RAH. A booklet on participants' rights to improve consent for clinical research: A randomised control trial PLoS One. 2012;7(e47023).
920. Silaigwana B, Wassenaar D. Research Ethics Committees' oversight of biomedical research in South Africa: A thematic analysis of ethical issues raised during Ethics Review of non-expedited protocols. Journal of Empirical Research on Human Research Ethics. 2019;14:107-16.
921. Cascella PW, Aliotta F. Strategies to enhance the informed consent process for communication disorders researchers. Communication Disorders Quarterly. 2014;35:248-51.
922. Brewer JC. Measuring text readability using reading level. In: Khosrow-Pour M, editor. Advanced methodologies and technologies in modern education delivery. Hershey, PA: IGI Global; 2019. p. 93-103.
923. Honey-Jones C, Birch B. PD53-10 Readability and comprehension levels of patient information and comprehension of patient information sheets used in Research Ethics Committee applications. The Journal of Urology. 2019;201(Supplement 4):e934-e5.
924. Tuvemo Johnson S, Martin C, Anens E, Johansson A-C, Hellström K. Older adults' opinions on fall prevention in relation to physical activity level. J Appl Gerontol. 2018;37(1):58-78.
925. Newman E, Kaloupek D. Overview of research addressing ethical dimensions of participating in Traumatic Stress Studies: Autonomy and beneficence. J Trauma Stress. 2009;22(6):595-602.
926. Sim J. Addressing conflicts in research ethics: Consent and risk of harm. . Physiother Res Int. 2010;15:80-7.

927. Mynatt ED, Melenhorst AS, Fisk AD, Rogers WA. Awareness technologies for aging in place: understanding user needs and attributes. Pervasive Computing. 2004;3:36-41.
928. Wollersheim D, Merkes M, Shields N, Liamputtong P, Wallis L, Reynolds F, et al. Physical and psychosocial effects of Wii video game use among older women. International Journal of Emerging Technologies and Society. 2010;8(2):85.