THE EFFECTS OF SUPERVISED VERSUS NON-SUPERVISED PILATES MAT EXERCISES ON NON-SPECIFIC CHRONIC LOW BACK PAIN

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EXECUTIVE SUMMARY

Purpose: Chronic non-specific low back pain (NSCLBP) is a common low back condition affecting a large proportion of the population suffering from low back pain (LBP). Exercise therapy is recommended as the first line treatment for NSCLBP but no type of exercise has been found to be more effective than another in improving pain and function outcomes. Low back pain trials have compared heterogeneous exercise types to date. Pilates mat classes are a popular form of exercise taught by therapists. The aim of this study was to compare outcomes of an eight-week supervised Pilates mat programme with those of a similar non-supervised home exercise programme with regard to pain intensity, function, medication use, health related quality of life, adherence, and participant satisfaction with such exercise programmes in treating NSCLBP.

Method: A randomised control trial was done to compare the effect of a supervised Pilates mat programme with a non-supervised home programme of similar exercises. The programmes were comparable for both the type of exercise and the participation duration of programmes (per week) and included the same fourteen exercises with gradual progressions. The Pilates classes were held twice a week for a 45 minute class and the home programme required doing the exercises for 30 minutes, three times a week, for an eight-week period. All participants were women who had been suffering from NSCLBP for longer than six weeks and who had volunteered to participate, or were referred by a therapist. The participants were screened and randomly allocated to the respective groups: a supervised exercise group (SEG) and a home exercise group (HEG). All the individual sessions and the supervised classes were held at a multi-disciplinary centre, which housed both a private physiotherapy practice and a Pilates studio. Outcome measures were measured at baseline, four weeks, eight weeks and 12 weeks by an assessor who was blinded to group allocation. The primary outcomes of pain and function were measured using the Pain Intensity Numeric Rating Scale (PI-NRS) and the Roland Morris Disability Questionnaire (RMDQ) respectively. Change in medication was measured as a percentage change in medication; mobility of the pelvis and lumbar spine was measured using the fingertip-to-floor (FTF) test; health-related quality of life was assessed using the EQ-5D questionnaire, and the confidence to perform certain tasks was measured using the pain self-efficacy questionnaire (PSEQ). Additionally, patient satisfaction was measured at eight weeks using the Better Backs Patient Satisfaction Questionnaire, and adherence was measured by calculating a percentage of the maximum adherence.

Results: Thirty-eight participants (n=38) started and completed the study. Half of the participants (n=19) participated in the supervised programme and the other half (n=19) participated in the home programme. The mean age of the participants was 38 years, and both groups were comparable in

terms of socio-demographics and anthropometric characteristics at baseline. The length of time since onset of LBP was not normally distributed in either group. The Mann-Whitney U test indicated that the ranking of the time since onset was significantly different between the groups ($z=-2.19$, $p=.029$), with the SEG having a shorter duration since onset of pain. As per the inclusion criteria, all participants reported a 2.75 or greater score on the average pain score of the PI-NRS or a score of 4 or more on the RMDQ at baseline. The results showed no significant differences in the outcome scores between the two groups at baseline. The Shapiro Wilks test was used on numerical data, and the Mann-Whitney U test was used on data that were not normally distributed. The repeated measures ANOVA did not find a significant effect of group/time interaction for the primary outcome pain. However, the effect of time was significant ($p<.001$), and thus a post hoc Tukey test was performed to see where the differences lay. The Mann-Whitney U test was used to assess the primary outcome, viz. function, and the test demonstrated no difference between the groups at any time point; however, the Friedman ANOVA found a significant difference in the rank ordering of the function scores of both groups combined (ANOVA Chi Square ($n = 38$, $df = 3$) $= 68.79$ $p >.001$). A post hoc sign test indicated that there were significant differences between each of the time points. Similarly, the effect of time was also significant for the EQ-5D index ($p<.001$) with the biggest improvement at eight weeks in both groups; for the EQ-5D VAS, the effect of time was also significant ($p=.007$), with the biggest improvement at week eight in the SEG and week 12 in the HEG.

The results of the change in medication use, FTF test and PSE outcomes indicate improvements, although no significant within-group differences were found. All the outcome measures moved in the same direction, demonstrating improvements over the period of the intervention. However, there was no group effect, but a time effect. The average adherence rate was 70% in both the SEG and the HEG, and there was no difference in adherence between the two groups. A t-test with separate variance estimates indicated a significant difference in patient satisfaction between the two groups, with the SEG reporting better satisfaction.

During the course of the interventions, there was an improvement in both pain intensity and function; however, there was a greater change in function, despite the pain. At the end of the eight-week Pilates mat programme, the ‘worst’ pain scores had dropped 3/10 points on the PI-NRS in the SEG and 2.5/10 points in the HEG, and the ‘average’ pain scores had dropped 2/10 points in the SEG and 1.75/10 points in the HEG respectively, which represents a clinically meaningful change in pain. A significant improvement in the RMDQ scores (4 points) was evident from baseline to eight weeks, in both the SEG and the HEG, which also indicates a clinically meaningful improvement in function. The patterns of improvement in outcomes demonstrated an earlier improvement for the SEG at eight weeks (the end of the exercise intervention), and a continued improvement for the HEG up to 12 weeks (four weeks post completion of the intervention). These improved outcomes were maintained for four weeks post the exercise programmes.

Conclusion: The findings of this trial suggest that, although neither was proved superior, both a supervised and a non-supervised Pilates mat programme performed for an eight-week period were associated with an improvement in pain intensity and function, medication use, ROM, health-related disability and PSE outcomes in NSCLBP. It is therefore suggested that either supervised or non-supervised Pilates programmes might be a useful inclusion in the treatment of NSCLBP and that the choice of method of delivery be tailored to the individual circumstances of the patient. However, as there was no control group that did not receive any intervention, causality was not proved and further research is necessary to establish definitively whether both forms of intervention were actually the cause of the improvement. In addition, the long-term effects of such programmes need to be established.

Keywords: chronic non-specific low back pain (NSCLBP), Pilates, exercise therapy, supervised exercise, home exercise programme, pain intensity, function.

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Abbreviations

AHPCSA	Allied Health Professionals Council of South Africa
BMI	Body Mass Index
BPI	Brief Pain Inventory
CBT	Cognitive Behavioural Therapy
CLBP	Chronic Low Back Pain
EO	*Obliquus Externus*
EQ-5D	EQ-5D Health Questionnaire
FABs	Fear-avoidance Beliefs
FABQ	Fear-avoidance Beliefs Questionnaire
FITT	Frequency, Intensity, Time (duration), Type
GET	Graded Exercise Therapy
HEG	Home Exercise Group
HPCSA	Health Professionals Council of South Africa
HRQoL	Health related quality of life
ICF	International Classification of Functioning, Disability and Health
LBP	Low Back Pain
LRS	Lumbosacral radicular syndrome
MDC	Magnitude of Detectable Change
MCID	Minimal Clinically Important Difference
MF	*Multifidus*
MRI	Magnetic Resonance Imaging
NRS	Numeric Rating Scale
NSAID	Non-Steroidal Anti-Inflammatory
NSLBP	Non-Specific Low Back Pain

NSCLBP	Non-Specific Chronic Low Back Pain
ODQ	Oswestry Disability Questionnaire
OE	*Obliquus Externus*
OI	*Obliquus Internus*
QUE	Quebec Back Pain Disability Scale
PAR-Q	Patient Activity Readiness Questionnaire
PEDro	Physiotherapy Evidence Database
PDI	Pain Disability Index
PI-NRS	Pain Intensity Numeric Rating Scale
PSEQ	Pain Self-Efficacy Questionnaire
RMDQ	Roland Morris Disability Questionnaire
RCT	Randomised Controlled Trial
ROM	Range of Movement
SD	Standard Deviation
SEG	Supervised Exercise Group
SLR	Straight Leg Raise
TrA	*Transversus Abdominis*
VAS	Visual Analogue Scale
WHO	World Health Organisation

Definitions of Terms

BMI	Body Mass Index – This is a measure for the human body shape based on an individual's mass and height. BMI was calculated in the current study as per the formula described by Armstrong et al.[1]
CBT	Cognitive Behavioural Therapy – The name refers to behaviour therapy, cognitive therapy, and to therapy based upon a combination of basic behavioural and cognitive principles and research. Cognitive behavioural therapy approaches encompass a range of interventions, including exercise, which aim to change behaviour directly by using models of learning, and to change behaviour indirectly by changing beliefs.[2]
CLBP	Chronic Low Back Pain – Low back pain which has been present for longer than six weeks.[3]
FABs	Fear-avoidance Beliefs – Fear of pain is hypothesized to result in avoidance behaviour. There is little evidence to link such fear states with poor prognosis,[4] but there is some evidence to suggest that fear may play a role when pain has become persistent and chronic.[4]
FITT	Frequency, Intensity, Time (duration), Type – Recommendations for the frequency, intensity, time (duration) and type of exercises used in the current study were based on the FITT principle.[5]
GET	Graded Exercise Therapy – Activity pacing (or the use of graded exercises) involves modifying behaviour, with the aim of improving activity levels and managing symptoms whilst reducing relapses.[6]
HEG	Home Exercise Group – This group participated in a non-supervised Pilates home exercise programme.
ICF	International Classification of Functioning, Disability and Health – It has been advocated that the bio-psycho-social measurement of health should not only address the impairment by means of tests but also consider the impact of all contributing factors, as outlined by the ICF domains: activity limitation, participation restriction and environmental and personal factors.[7]

MDC Magnitude of Detectable Change – This is associated with measurement error and represents the minimum amount of change required between two scores to indicate whether a true change has taken place. Investigators report that the MDC necessary at the 90% confidence interval level is 4-5 RMDQ points,[8] for scores falling across the entire range of the scale.[9] Childs et al[10] suggest that clinicians can be confident that a 2-point change on the PI-NRS represents a clinically meaningful change.

MCID Minimal Clinically Important Difference – This is defined as an estimate of the minimal change in score, which is indicative of a change, in e.g. function, that is important to the patient.[11]

NSLBP Non-Specific Low Back Pain – This is not a diagnosis *per se*, but it describes a heterogeneous group of patients with back pain for which there is no definitive cause.[12]

NSCLBP Non-Specific Chronic Low Back Pain – The definition includes a variety of different conditions, some with identifiable pathology, and thus there have been many attempts to identify sub-groups within NSLBP. There is little correlation between the anatomical identification of pain generators, actual pathology and clinical syndromes.[13] In the literature, the terms chronic low back pain (CLBP) and NSCLBP are used interchangeably, but NSCLBP is actually a more accurate description of this large group of back pain sufferers (as part of the diagnostic triage).[13]

PEDro Physiotherapy Evidence Database – This scale has been used to rate the quality of over 3000 RCTs in the PEDro database and in several systematic reviews[14] The criteria assessed by the scale include: eligibility; random and concealed allocation; groups similar at baseline; subject, therapist and assessor blinding; less than 15% dropouts; intention to treat analysis and between-group statistical comparisons.

RCT Randomised Controlled Trial – The participants were allocated to either the supervised exercise group or the home exercise group by a computer-generated random process.[15]

SEG Supervised Exercise Group – This group participated in a Pilates mat programme.

1. Introduction

1.1 Background to Research

Low back pain (LBP) is a common musculoskeletal disorder[16] and health problem.[17] In developed countries, lifetime prevalence rates lie between 49% and 80%.[18] The prevalence of this disabling and costly condition is also rising on the African continent, with a mean average lifetime prevalence rate of 62% reported among adults.[19]

Significant disabilities and costs are associated with LBP in industrialized countries.[18,20,21] Low back pain is the second greatest cause of disability in the United States of America (USA)[22] and data suggest that, in spite of large expenditure on LBP, the related disabilities continue to increase.[23] Approximately 10% to 20% of patients with LBP develop chronic LBP (CLBP),[24] which is generally defined as back pain and disability persisting for more than three months,[25,26] although more than six weeks has also been proposed.[3,27] Chronic LBP is a symptom rather than a clinical diagnosis, and the disorder is associated with different stages of impairment, disability and chronicity. Adopting a bio-psycho-social approach to treating CLBP has thus been advocated.[28] Non-specific CLBP (NSCLBP) is a sub-group of LBP; this diagnosis is only made after excluding a patho-anatomical cause. Such a cause can only be identified in 8 to 15% of cases; the majority are diagnosed as having non-specific CLBP.[28] Despite attempts to manage NSCLBP, treatment has low success rates.[28,29]

Exercise therapy is one of the few evidence-based treatments available for NSCLBP,[25,26,30,31] and it is thus recommended as a first line treatment for NSCLBP.[27] Moreover, it is non-invasive, and it empowers patients in managing their own back pain. Physiotherapy favours exercise in conjunction with advice as the most common treatment intervention for NSCLBP,[32] and this approach supports the bio-psycho-social understanding of LBP management.[27] There is hence an on-going need to investigate effective therapeutic exercise interventions for this subgroup.[33,34]

Numerous trials describe the characteristics of exercise programmes that aim to decrease pain and disability for people with NSCLBP.[29,35] These studies include comparisons between general exercise and specific exercise,[36-39] individual and group exercise,[30,40,41] and supervised and non-supervised home exercise,[25] and they also investigate patient motivation and preference.[42] Nonetheless, little consensus exists as to which programme design is most likely to induce and maintain exercise benefits.[43] More recently published trials on exercise

benefits for NSCLBP have measured pain and function scores, but they have also measured general health,[44-47] participant satisfaction,[36] adherence,[45] fear-avoidance beliefs[48,49] and participants' pain coping skills.[45] Exercise is purported to decrease fear-avoidance behaviour and facilitate functional improvements, despite on-going pain.[32]

The importance of outcome measures to assess the effectiveness of various therapies for NSCLBP has been highlighted in the literature.[50,51] In accordance with the International Classification of Functioning, Disability and Health (ICF)[52] of the World Health Organisation (WHO), the health of an individual is based on the categories of impairment, activity and participation and personal factors taken against a contextual or environmental back drop. Given that all these categories can be influenced by NSCLBP, outcome measures must adequately reflect the diverse effects and influences that treatment programmes may have.[43] The five recommended domains are pain severity, back-specific function, health status, work disability and satisfaction.[51] LBP and function outcomes are most commonly assessed and various psycho-social measures have been described.

A Cochrane review[26] dated 2005 examined various exercise approaches for LBP, and found no conclusive evidence in favour of one type of exercise over another. This is consistent with the results of a recent study showing that two different exercise approaches had similar effects on pain and function scores in NSCLBP.[40] This suggests that exercise design and good implementation are more important than the specific type of exercise.

The use of Pilates exercises for back rehabilitation is growing, as more of the physiotherapy profession are becoming proficient in teaching it. Pilates mat exercises, which require little equipment and which can be taught individually or in group classes, have become particularly popular. Home exercise programmes and Pilates mat classes both incorporate stretching and strengthening exercises in specific functional positions, which are reportedly beneficial interventions for LBP.[38] These programmes both improve function and decrease pain in adults with NSCLBP across clinical trials.[29] However, a recent systematic review[53] has highlighted the lack of well-designed clinical trials investigating the effects of clinical Pilates on pain and function outcomes in NSCLBP. A lack of homogeneity in control interventions used[54] further makes it difficult to compare interventions.

In South Africa, many medical aid societies limit the number of physiotherapy treatments covered in view of limited available resources,[55] which makes low cost approaches to management of NSCLBP even more important. Home exercise programmes and Pilates

group exercise programmes are two recognised approaches. The current literature has shown that supervised exercise interventions have significant advantages over non-supervised interventions, such as improving adherence,[26,31,56] increasing participant satisfaction,[57-59] meeting participants' needs[26] and allowing for individual correction and reassurance,[32,60] all these benefits are limited in non-supervised exercise, such as home programmes. No study was found that compared the functional impact of Pilates exercises performed in a supervised programme with that of a non-supervised programme. With no evidence to suggest the superior effectiveness of a particular exercise approach,[29] however, this study was designed to compare a non-supervised Pilates home exercise programme with a supervised Pilates mat exercise programme. Both programmes include the same standard exercises to allow for easier comparison. So far, no study has directly compared the results of each of these programmes in the treatment of NSCLBP.

1.2 Research Questions

The principal research question was to establish whether the context, home-based or supervised, of Pilates mat exercises influenced the impact on function. It was hypothesised that the supervised group would benefit most from the programmes. The research questions that arose out of the above discussion were therefore investigated with regard to a group of participants with NSCLBP:

1.2.1 Is there a difference in pain intensity, function, medication use, range of movement (ROM) and quality of life outcome measures in participants of a supervised Pilates-type exercise programme compared with those of a non-supervised, comparable home exercise programme?

1.2.2 Do participants in the supervised and the non-supervised programmes differ with regard to their adherence to the exercise programmes?

1.2.3 Is there a difference in patient satisfaction between the two exercise programmes?

1.2.4 Is there a change in the outcome measures over time, which may be associated with participation in either programme?

1.3 Aim and Objectives

The aim of this study was to compare outcomes of an eight-week supervised Pilates mat programme with those of a similar non-supervised home exercise programme with regard to

pain intensity, function, quality of life, adherence, and participant satisfaction with such exercise programmes in treating NSCLBP.

In patients with NSCLBP, pain is the predominant symptom for which patients seek treatment.

Therefore the primary objective of this study was:

- To determine if there was a significant difference in pain intensity and function between participants in a supervised exercise group (SEG) taking part in a Pilates mat programme and participants in a home exercise group (HEG) following a similar non-supervised programme. Outcomes were measured at baseline, four, eight and 12 weeks, by using the Pain Intensity Numeric Rating Scale (PI-NRS) and the Roland Morris Disability Questionnaire (RMDQ).

The secondary objectives were:

- To compare the SEG and HEG groups with respect to measurements at baseline, four, eight and 12 weeks for the following parameters:
    - Change in medication use
    - Mobility when bending forward, as measured by the fingertip-to-floor (FTF) test
    - Health related quality of life, as measured by the EQ-5D Health Questionnaire (EQ-5D)
    - Confidence in performing certain tasks, as measured by the Pain Self-Efficacy Questionnaire (PSEQ)
- To determine:
    - If there were significant group*time interactions for the two groups with regard to pain intensity, medication use, ROM, function, health and confidence in performing certain tasks over time
    - If there was a difference between the two groups in Patient satisfaction measured at eight weeks, utilising the Better Backs Patient Satisfaction Questionnaire
- To compare:
    - Adherence to an eight-week exercise intervention between the two groups measured as a percentage of maximum adherence
- To establish:

- If participation in either of the two programmes was associated with improvement in the outcome measures from baseline to the end of the programmes.

1.4 Research Setting

The study took place in a physiotherapy practice and a Pilates studio housed within a multi-disciplinary centre in the city of Cape Town. The clients seeking physiotherapy assistance at the practice are middle income earners who are either self-referred or referred by medical practitioners and colleagues from the surrounding areas. The services offered include general outpatient physiotherapy, as well as individual and group Pilates classes; the facility can cater for group sessions of up to 10 members per group. The centre is on a busy road, and accessible by public transport. The supervised classes were held at times suitable for the participants, as determined by email.

1.5 Significance of the Study

This study gathered important information regarding pain levels, function and health status in the treatment of NSCLBP, whilst also investigating participant adherence and satisfaction with these two exercise programme approaches. Low back pain is a widespread and recurring problem and, given the limited benefits available from the medical aid societies,[55] physiotherapists need to assess and categorise NSCLBP accurately in order to maximise the impact of a chosen intervention in the management of NSCLBP. This study thus investigated and compared outcomes relating to pain, function and quality of life between these two exercise programmes for this particular sub-group of CLBP patients.

2. Literature Review

2.1 Introduction

Low back pain is a common and costly musculoskeletal health problem.[16,17] Although various interventions are used to treat NSCLBP, exercise therapy is the one most supported by research. This study investigates and compares two similar types of therapeutic exercise for the treatment of NSCLBP, and this literature review is limited to those aspects of LBP that are relevant to this study.

To source the appropriate literature for this review, a keyword search was conducted, utilising the following databases: PubMed, CINAHL, PEDro, Science Direct, Medline and Cochrane. Keywords included were: low back pain, chronic low back pain, non-specific low back pain, motor control exercise, exercise, Pilates, supervised exercise, home programmes, numeric rating scale (NRS), RMDQ, EQ-5D, pain self-efficacy, patient satisfaction, adherence. The references of relevant articles were scrutinized to identify further leads to additional articles, which were then accessed via the above mentioned databases. Articles were limited to those published in English.

The literature on back pain is diverse, and it is challenging to review because of the ambiguity and inconsistency of LBP definitions for this heterogeneous group. Therefore, this literature review will be structured around LBP as defined and classified according to the diagnostic triage. The diagnostic triage[13] categorises LBP into three distinct sub-groups, namely, non-specific LBP (NSLBP), radicular LBP, and serious spinal pathology; these definitions are summarised in Table 1. Thereafter, the pathology, prognosis and therapeutic management of non-specific chronic low back pain (NSCLBP) are discussed. Pilates exercise is defined and factors affecting treatment outcomes are described. Lastly, supervised programmes and home programmes are compared and evaluated, before the selection of specific outcome measures chosen for this study is motivated.

2.2 Epidemiology of LBP

Low back pain is a common problem not only in South Africa, but also around the world. Surveys have examined back pain as a symptom in the general population, as a form of disability, as a reason for health care, or in terms of short- or long-term work loss.[13] Croft et al[24] summed up the epidemiology of LBP by suggesting that LBP should be viewed as “a

chronic problem with an untidy pattern of grumbling symptoms and periods of relative freedom from pain and disability interspersed with acute episodes, exacerbations and recurrences" (page 1359). There are two consistent observations about LBP: firstly, a previous episode of LBP is the strongest risk factor for a new episode, and, secondly, by the age of 30 years, almost half the population will have experienced a substantive episode of LBP.[24]

2.2.1 Prevalence of LBP

Prevalence estimates of LBP vary considerably, and are affected by study populations and disparities in diagnosis.[47] It has been suggested that a standardized definition of LBP will assist further reviews on prevalence, and enable more accurate comparisons between countries.[61] Dionne et al[62] recommends asking patients the following questions when assessing prevalence in LBP studies: "In the past four weeks, have you had pain in your low back? If yes, was this pain bad enough to limit your usual activities or change your daily routine for more than one day?" (page 98). Most surveys define LBP as pain occurring between "the lower margins of the twelfth ribs to the low gluteal folds".[13,62]

In developed countries, point prevalence rates range from 12% to 35%, whereas lifetime prevalence rates range from 49% to 80%.[18] In central and southern Africa, these prevalence rates are rising, with a mean point prevalence of 32% and a mean average lifetime prevalence rate of 62% reported among adults.[19]

Low back pain is most prevalent among women.[61] In a study that recruited 5789 participants between the ages of 25 and 79,[63] from a well-defined area in northern Sweden, 41% of the participants reported having LBP (of these 55% were women and 45% men). In the same study, CLBP was the most frequently occurring problem, with 43% women reporting continuous LBP for more than six months compared to 37% of the men.

Low back pain is also more prevalent between the ages of 40 and 80 years.[61] Bjorck-van Dijken et al[63] found that individuals with LBP within this age group tended to experience physically heavier workloads at work and to engage in less physical activity during leisure time. This finding supports the introduction of therapeutic exercise for this group of patients in an attempt to increase activity levels and to help influence pain intensity and function positively.

2.2.2 Impact of LBP

Given the prevalence statistics mentioned in Section 2.2.1 and the economic impact of LBP,[20] it is evident that LBP is a major problem throughout the world and that it is furthermore associated with considerable direct and indirect costs.[64]

In the case of aging populations, it is estimated that the absolute number of people with LBP is likely to increase substantially over the coming decades.[61,65] LBP is also one of the main causes of work absenteeism.[66] Middle-age represents some of the most productive years of a person's working life, and LBP thus has a major economic impact on many individuals, families and businesses.[18]

Significant disabilities and costs are associated with LBP in industrialized countries.[18,20,21] LBP is the second greatest cause of disability in the USA[22] and the most common cause of long-term disability in Westernised industrialised countries;[44] furthermore, data suggests that, in spite of large expenditure on LBP, related disabilities continue to increase.[23] In addition, the likelihood of being pain-free 12 months after the onset of an initial LBP episode is only 42%.[67] Henchke et al[68] similarly found that, even among those whose pain does resolve completely, recurrence during the next 12 months is relatively common.

The results of systematic reviews of the epidemiology of LBP globally suggest that further research is needed to identify effective interventions to prevent and treat LBP.[47]

2.2.3 Definitions of LBP and Classification of LBP

This section will define LBP, before mentioning three sub-categories of LBP, namely, NSLBP, lumbosacral radicular syndrome (LRS) and serious spinal pathology; all of these have been classified using the diagnostic triage. Thereafter, chronic low back pain will be defined, and the various definitions relating to the chronicity (i.e. time duration) are discussed. NSCLBP is defined and sub-groups are mentioned.

a) LBP defined according to underlying pathology

Defining LBP is very important. Furthermore, establishing correct sub-groups of LBP is one of the highest research priorities in LBP research.[69] The accepted definition of LBP is pain occurring from the "lower margins of the twelfth ribs to the low gluteal folds".[13] All guidelines reviewed by Koes et al[70] recommend a diagnostic triage, where patients are classified and allocated to one of these three categories of LBP:

1. NSLBP,

2. LRS and

3. Suspected or confirmed serious spinal pathology

Some guidelines for the assessment of LBP, e.g. the Australian and the New Zealand guidelines, do not distinguish between NSLBP and LRS; however, utilisation of the diagnostic triage is proposed as best practice, and thus it is implemented in the classification of LBP patients for this study.

Non-specific low back pain is not a diagnosis *per se*, but it describes a heterogeneous group of patients with back pain for which there is no definitive cause.[12] This sub-category of LBP forms the first group of the triage (Table 1) and it was from this category that the participants in this study were chosen. In this group, there is little correlation between the anatomical identification of pain generators, actual pathology and clinical syndromes.[13] The use of the term 'non-specific' suggests that structural changes are not present or, if present, that they are not directly linked to the clinical symptoms. However, NSLBP does typically include conditions such as degenerative facet joints, spondylosis and lumbar disc disease, although it excludes any condition with nerve root involvement. The definition moreover includes a variety of different conditions, some with identifiable pathology; in fact, there have been many attempts to identify sub-groups within NSLBP.[28] Further research is needed to identify more accurately the underlying mechanisms associated with NSLBP, particularly when the condition is chronic.

The review by Luisterburg[71] highlights the fact that LRS is a diagnosis that includes nerve root/radicular pain (Table 1) and that this thus forms the second group of the triage. When present, nerve root pain is often the patient's main complaint and is usually greater than the back pain.[13]

The third group is made up of those LBP sufferers who have a serious spinal pathology, which may cause back pain or, less commonly, nerve root pain.[13]

Table 1: Classification of back pain with reference to: the diagnostic triage[13, 73] and the duration of pain[13, 3, 74, 26, 27]

Diagnostic Triage of LBP	
1.	NSLBP *– diagnosis by exclusion[39]
2.	Lumbosacral radicular syndrome (LRS) – diagnosis by inclusion[71]
3.	Serious spinal pathology
Duration of Pain	
1.	NSLBP *– diagnosis by exclusion[39]
2.	Sub-acute: 6-12 weeks[74] Chronic persistent: * > 6 weeks.[3] Chronic recurrent and chronic intermittent (episodic): > 6 weeks[72]
3.	Chronic LBP: > 12 weeks, either chronic persistent or chronic intermittent[13,26,27]

b) LBP classified according to duration and chronicity

The three low back pain sub-groups listed in Table 1 can fit into any of the pain duration categories. Chronicity in low back pain can be defined in terms of the length of time that the patient experiences persistent symptoms, either constantly or intermittently. Low back pain has further been characterized as an episodic disease, as the pain may subside and disappear for a while and then recur or re-appear a few months or years later.[24] The pain may also linger for some time and flare up periodically.[75] If these flare-ups are bothersome, this may prompt the patient to seek medical care or to take time off work.[76] Most people will suffer from LBP at least once in their life, and many of them will experience more than one episode lasting for more than 24 hours, preceded and followed by a period of at least one month without LBP.[77,76] LBP episode duration at baseline consultation is defined by time since the patient's last pain-free month.[78] This episodic presentation becomes important when choosing participants for a research study.

Various definitions are used in the literature to express the chronicity of LBP according to the duration of the symptoms. Chronic recurrent pain is defined as recurrent episodes of pain interspersed with pain-free periods extending over months or even years.[65] The revised version of the New Zealand guidelines for acute LBP now also includes recurrent and intermittent LBP, whereas the Dutch guidelines simply refer to patients who do not follow the normal course of recovery after three weeks from an acute exacerbation.[70]

c) NSCLBP

After an acute episode of LBP, most authors report that it takes six weeks to recover.[27,79] However, others state that the typical recovery time is longer, up to two months[80] with smaller improvements up to three months.[81] It is estimated that 85% of the LBP patients seen in primary care have NSLBP.[82,83] O'Sullivan[28] reports that a small but significant group of this NSLBP population become chronically impaired and disabled, a condition that is then labelled NSCLBP. The general consensus is that, of those who experience an acute episode, 75% will recover within one year,[67] whereas approximately 10 to 25% of patients with LBP will go on to develop NSCLBP.[24] The consequence of this is that pain and disability can typically be on-going, and that recurrences are common.[81] These LBP recurrences are not only common after an initial episode, but patients also perceive their recurrent episodes as worsening, with the location of the pain changing in a discernible pattern during onset and recovery.[84] NSCLBP, therefore, manifests as a continuation of an initial episode of NSLBP or as periodic recurrences and remissions.[81] It is the chronic condition that is seen so commonly in the clinics. In addition, there are currently no clear predictive criteria for who will develop NSCLBP, and consequently no specific treatment approach to deal with all the factors contributing to the chronic pain.[85]

The definition of chronic low back pain is contested, as it is variously defined as back pain that lasts for longer than six weeks[3] or longer than 12 weeks.[26,27,31] The Cochrane Protocol[86] defines NSCLBP as a condition in which back pain, muscle tension or stiffness last longer than 12 weeks. In contrast, Hettinga et al,[3] who proposed the duration of pain for longer than six weeks as a defining feature of NSCLBP, based their evidence on the fact that six weeks was beyond the period of spontaneous recovery for most back pain. Beyond six weeks, the acute inflammation has died down. As the current study wished to have an impact on function beyond the stage of spontaneous recovery from back pain, the intervention was only started after six weeks. This was relevant for the timing of therapeutic exercise to prevent further chronicity, and was therefore selected as one of the criteria to be used when selecting participants in this study of individuals with NSCLBP.

The current study concentrated on those clients who had chronic symptoms (i.e. symptoms lasting for more than six weeks) after a first time or a recurrent episode of LBP. The chronic symptoms of the recurrent episodes were either persistent (constant) or intermittent.[72] In the literature, the terms chronic low back pain (CLBP) and NSCLBP are used interchangeably, but NSCLBP is actually a more accurate description of this large group of back pain sufferers

(as part of the diagnostic triage) (Table 1). The term NSCLBP has been used throughout this study, except where the chronic LBP sufferers referred to in a particular study fall within the other two groups of LBP, as classified by the diagnostic triage.

d) Sub-groups

NSCLBP is a disorder that is associated with different stages of impairment, disability and chronicity.[28] Some authors suggest that individuals with NSCLBP are a homogeneous group, but others suggest that treatment outcomes may be improved by using sub-grouping to guide decision-making around appropriate treatments and interventions.[87] Other authors have disputed the relevance of this sub-grouping though, as patients' status becomes more stable, particularly in patients with NSCLBP, where the association between signs and symptoms and function weakens with increasing time from onset.[88] Severeijns[89] suggests that sub-grouping may be less important among patients with chronic symptoms, or that it may be more effectively performed according to psycho-social factors.[89] This is supported by the finding that the recommendations regarding the assessment of psycho-social risk factors for chronicity are firmer in the current guidelines for the management of NSCLBP than they were a decade ago.[70]

Despite the controversy, it appears that there is evidence in the literature to support the broad sub-grouping of NSCLBP disorders according to physical,[90] neuro-physiological,[91] and cognitive factors,[92] as well as lifestyle behaviours.[63,93] Further research is needed to improve identification of the underlying mechanisms associated with NSLBP and NSCLBP.[28]

2.3 Disability associated with Non-Specific Chronic Low Back Pain (NSCLBP)

As mentioned in Section 2.2.3, NSCLBP is a common condition. This section deals with the definition and the need to consider sub-groups within this broad diagnostic category. The International Classification of Functioning, Disability and Health (ICF) will be used as a framework within which to discuss the impact of NSCLBP, and will thus be described first. Thereafter, the pathology of NSCLBP is presented, the bio-psycho-social model of dealing with chronic pain is introduced, and the prognosis and therapeutic management of NSCLBP is discussed.

2.3.1 ICF Framework

The ICF provides a unified language for the description of health conditions in rehabilitation and therefore a common framework for all health professionals.[7] To optimize interventions

aimed at maintaining function and minimizing disability, a proper and comprehensive understanding of the patients' functioning and health status is needed.[94,95] The ICF framework fits into the bio-psycho-social model of measuring all the aspects that could contribute to back pain. It is based on an integrative and functional model of health that provides a holistic, multi-dimensional and interdisciplinary understanding of health-related conditions.[95] This model includes not only measuring the impairment, but also the limitations of activity and participation restrictions in exercise and leisure activities, or in daily life, and the contributing personal and environmental factors, as all of these play a role in the pain experience and the impact of disability. The ICF domains have been used in the current study to help categorize the various outcome measures chosen and are discussed in Section 2.5.

2.3.2 Pathology of NSCLBP – Impairments of Body Structure and Function

An understanding of the underlying pathology not only assists the therapist in targeting those structures that are most likely to be a problem, but also guides treatment choices. This section firstly outlines the anatomy and muscle function of this area of the body and secondly covers the alterations to the nervous system that can take place in response to chronic pain.

Only 8-15% of patients with LBP have an identified patho-anatomical diagnosis,[96] which results in the majority (up to 85%) of such patients being diagnosed as having NSLBP.[13] Under the umbrella definition of NSLBP, many common diagnoses are grouped, such as lumbago, myofascial syndromes, muscle spasms, mechanical LBP, back sprain and back strain.[97] According to a Cochrane protocol,[86] several different structures of the back have been implicated in symptoms of NSLBP, including the musculature, joints and discs; psycho-social factors and low general health have also been associated with persistent, disabling NSLBP.

Underlying much of clinical practice have been simplistic biomechanical and structural models of LBP, which have focused on structural diagnosis, such as spinal 'instability'.[28] This is based on the belief that LBP is a result of structural (i.e. degenerative), biomechanical and motor control deficits, resulting in segmental or regional instability of the lumbo-pelvic region.[28,98] It is now clear that there is little evidence (i.e. few outcome studies) to support the view that 'instability' underpins the basis of disabling NSLBP, namely NSCLBP.[28] As LBP becomes chronic, additional problems develop, which contribute to the condition becoming more complex to treat.

a) Muscle function

Muscle function comprises muscle strength (defined as how much force the muscle can generate),[99] muscle endurance (defined as the ability of a muscle to sustain repeated contractions for an extended period of time)[99] and neuro-muscular control (defined as the ability of the muscle to contract with correct timing and sequence, and to contract appropriately without extra co-contractions).[100] All or some of these muscle functions can be affected in NSCLBP. There is debate in the literature as to the primary underlying cause.

The inclusion of the contraction of trunk stabilising muscles in the treatment of LBP is rooted in the belief that these muscles are impaired in LBP.[100,101] Spinal stability involves two muscular mechanisms: local mechanisms, where deep, local muscles act to control movement at the intervertebral segment, and global mechanisms, where muscles control the movement of the spine both generally and at multiple segments.[102] Effective control of both mechanisms is necessary for efficient stabilization of the spine. Alterations in neuro-muscular control and the loss of normal patterns of spinal motion may cause pain.[102,103]

For example, a delay in the onset activation time of the *transversus abdominis (TrA)* muscle during rapid unilateral shoulder movements has been reported in individuals with NSCLBP.[59] In contrast, there is a tendency for earlier onset of the anterior abdominal wall muscles during rapid arm movements.[104] In addition to the altered onset of contraction, there is mounting evidence of an inability of the trunk muscles to relax,[105] as indicated by the increased co-contraction of trunk muscles,[101] as well as evidence of the hyperactivity of trunk muscles in NSCLBP disorders.[90] In LBP-afflicted sport populations, this over-activity may manifest as trunk muscle hypertrophy in specific muscles, such as the lumbar MF and *quadratus lumborum* muscles.[28]

If, as indicated in the literature, the timing of muscle contraction, particularly of the trunk stabilising muscles, and the poor ability to control appropriate contraction/relaxation cycles are major underlying impairments contributing to NSCLBP, then effective therapy must target these impairments. The deficits in the activation of the abdominal muscles can be modified with motor training. For example, training of the deep abdominal muscles in isolation from the other trunk muscles, as an initial phase of training, has been shown to improve the timing of activation of the trained muscles, and to reduce the symptoms and the recurrence of LBP.[106]

There is also a need for the therapist teaching therapeutic exercise to facilitate relaxation of these muscles if necessary. Pilates mat exercises target both these muscle impairments by emphasising correct abdominal stabilization during exercise. The cueing used when teaching Pilates exercises helps to facilitate the contraction or relaxation of the appropriate muscles during the exercise.

NSCLBP produces changes in the nervous system in addition to muscle dysfunction.

b) Alterations to the nervous system induced by chronic pain

Pain is the principal impairment of body structure, and acute pain is directly linked to impairment in strength and flexibility. However, the experience of chronic pain is different to that of acute pain and because the clients in this study had chronic pain, the changes that occur with chronic pain are discussed. This section will briefly highlight the alterations to the nervous system brought about by chronic pain.

Multiple mechanisms contribute to the pathogenesis of pain, each of which is subject to or an expression of neural plasticity – the capacity of neurons to change function, chemical profile, or structure.[91] Pain is not a passive consequence of the transfer of a defined peripheral input to a pain centre in the brain cortex.[91] It is rather an active process generated partly in the periphery and partly within the central nervous system by means of multiple plastic changes that together determine the gain of the system.[91] This modulation can take place peripherally, at the spinal cord or at the brain level and the cause of chronic pain may be due to faults in both the peripheral or central mechanisms that process and modulate pain.

An example of alterations to central processing is that *functional re-organisation* in both the somatosensory and the motor system of the brain is observed in neuropathic and musculoskeletal pain. This cortical re-organization has been demonstrated for NSCLBP, in which representation of the painful side of the back was enlarged and shifted medially as compared with representation in healthy controls.[107] This alteration may be linked to an abnormality with regard to the perceived size of the painful body part.[108] A distorted body image and tactile dysfunction have been similarly found in patients with NSCLBP.[109] The amount of re-organizational change was found to increase with chronicity.[110]

Disrupted spatial representation, which results in disrupted processing of stimuli that are delivered to healthy body parts, which are held in the affected space,[111] has been reported.

The painful body part is also perceived as having *poor voluntary movement* and *motor imagery performance*[111,112]- the ability of an individual to stimulate a given action mentally.

Other central mechanisms include *pain memories* that influence the processing of both painful and non-painful input to the somatosensory system as well as its effects on the motor system. Cortical plasticity related to chronic pain can be modified by behavioural interventions that provide feedback to the brain areas that were altered by somatosensory pain memories or by pharmacological agents that prevent or reverse maladaptive memory formation.[110]

Peripheral (e.g. inflammation) and central mechanisms (e.g. plasticity) might contribute to the pain experience of patients with NSCLBP and both thus need to be addressed within treatment. An intervention such as Pilates may target both the peripheral pain mechanisms by teaching improved muscle control and the central mechanisms by changing the perception of pain and improving motor imagery performance.

c) Bio-psycho-social model of chronic pain

The ICF replaces the medical understanding of the process of disablement with a bio-psycho-social model. In order to understand fully a person's perception and response to pain and illness, the interrelationships among biological changes, psychological status, and the sociocultural context all need to be considered.[65]

The bio-psycho-social model of illness, proposed by Engel[113] in 1977, has gained widespread acceptance within the spine care community.[96,114] This bio-psycho-social model is a scientific model that takes into account the missing dimensions of the bio-medical model of illness,[113] and it has been particularly influential in the area of chronic pain.[65] The bio-psycho-social model focuses on illness as distinct from disease, with illness being viewed as the complex interaction of biological, psychological and social factors.[65] As this model of health has become better understood, complex, inter-dependent relationships have emerged between the physical and biomedical features of LBP and the psychological and social factors that present concomitantly.[115]

It has been demonstrated that psychological/cognitive factors, such as depression, anxiety, distress and related emotions, have an important impact on back pain disability, especially in the development of persisting LBP.[116] Furthermore, persisting LBP develops far more

frequently in patients who have a high level of fear-avoidance, psychological distress and job dissatisfaction.[117]

In conclusion, the causes of NSCLBP are likely to be multi-factorial and incorporate impairments, activity limitations and environmental factors. Interventions aimed at helping patients should not be limited to a biological conception of pain but should take into account all dimensions of the individual.[118] Adopting a bio-psycho-social approach to treating NSCLBP has thus been advocated, and as Pilates incorporates an approach consistent with improving the general well-being of participants, it is likely that it will have an impact on all aspects of functioning.

2.3.3 Prognosis of NSCLBP

Various prognostic factors can affect recovery from LBP. Prognostic factors for recovery include impairments, such as symptom duration at baseline, and personal factors, such as pain beliefs, namely, fear-avoidance beliefs, pain self-efficacy and catastrophizing. These are discussed in this section. These pain beliefs are considered to be psycho-social risk factors, or 'yellow flags' (as they are commonly termed in the physiotherapy clinical context), and can act as barriers to recovery. It is therefore important to know about these, when treating chronic conditions such as NSCLBP, as they may have an effect on treatment outcomes.

Estimates of the prognosis of NSCLBP are based on a limited number of studies.[47] Specific predictors of poor outcome in patients with NSCLBP have been inconsistent across prognosis studies; however, multiple factors, including psycho-social variables, are commonly identified.[4] The recognition of these 'barriers' to recovery is important for guiding treatment choices.

a) Duration of impairment

Recovery from LBP is typically slow and incomplete and patients who do not make an early recovery are more likely to proceed to long-term disability. The prognostic factors for recovery from NSCLBP have been found to include symptom duration at baseline[67] and high disability or pain levels (impairment) at onset of chronicity[67] as important determinants of prognosis. The probability of recovery is considerably lower for chronic patients than it is for patients with acute LBP, which implies that better treatments must be developed for NSCLBP.[47]

Dunn et al,[78] for instance, followed 619 patients in a cohort study during a 12-month period. Low back pain episode duration at baseline consultation was defined by time since their last pain-free month. Those patients with a three years or longer duration at baseline took significantly longer to improve in their pain, disability and psychological scores than did those with shorter duration.[78] Therapeutic interventions could possibly assist with decreasing the development of long-term disability resulting from incomplete recovery.[68,119] The impact of duration on outcome informed the choice of participants in the current study, as they were only included if they had experienced LBP for at least six weeks since their last pain-free period.

b) Personal factors

In keeping with the bio-psycho-social model of pain, certain personal factors have been found to contribute to a poor prognosis for resolution of pain. These baseline psycho-social factors, or so-called yellow flags, represent potential 'barriers to recovery'.[31] It is recognised that psycho-social factors are usually the best predictors of chronicity, and that many of the learned behaviours apparent in chronic musculoskeletal pain have their genesis in the first few days and weeks of the problem.[120] Recent reviews consistently underline the role of psycho-social factors in predicting clinical outcomes.[115] These include previous sick leave due to LBP, low levels of education and higher perceived risk of persistent pain.[67] These beliefs, as well as the emotional significance attributed to the pain, are potential obstacles to recovery from back pain.[121] In support of this, Chou et al[73] suggest that psychological factors and emotional distress are stronger predictors of LBP outcomes than either physical examination findings or severity and duration of pain. Depression is consistently associated with the risk of developing NSCLBP,[4] with a hypothesized pathway of apathy, demotivation and low mood resulting in decreased activity and poor outcome.[2]

Individual pain beliefs and their influence on pain perception and response to treatment have also been implicated.[67] Main et al[121] examined the nature of pain perception and the role of cognitive and emotional processes in the interpretation of pain signals, thus giving meaning to pain and shaping one's responses to it. The authors mention two types of back pain beliefs that have a particularly strong influence: fear-avoidance beliefs and pain self-efficacy beliefs.[121] As these have direct relevance to the intervention that is to be tested, they are discussed below.

The fear-avoidance model

The best predictor of the course of LBP during the first two months appears to be the fear-avoidance model, which explores the relationship between impairment, activity and environmental and personal factors.[80] According to the fear-avoidance model of musculo-skeletal pain, a person with chronic pain may avoid activities, believing that if the movement hurts, they may be re-injuring themselves; this is termed fear avoidance.[4,66,122] This, in turn, may lead to disuse, which can be described as performing at a reduced level of physical activity in everyday life.[2] Decreased habitual physical activity levels result in the 'deconditioning syndrome', which describes the physical changes in strength, mobility, endurance and coordination, which can be caused by decreased activity, and is postulated to contribute to ongoing pain.[123] The fear-avoidance model is an attempt to underscore the importance of cognitive and behavioural factors in a chain of events linking the experience of pain to disability,[92] which is a key element in the bio-psycho-social model. Ryan[66] monitored 15 individuals with NSCLBP and 15 healthy control subjects in a cross-sectional study. Participants wore an activity monitor for seven days. Time spent walking and standing and the number of steps taken over a 24-hour day was monitored. It was found that the individuals with NSCLBP spent fewer hours walking and took fewer steps than did the healthy controls.[53] Ryan's[66] study highlights the difficulty of establishing a cause and effect for their activity, based on the fear-avoidance model, as it was not possible to identify clearly which was the cause and which the effect. Although fear of pain, which is hypothesized to result in avoidance behaviour, has been described as an obstacle to recovery in populations of patients with LBP, the findings of the systematic review performed by Pincus,[4] suggested that fear-avoidance may only play a role when pain has become persistent.[4] However, it is clear that decreased activity and NSCLBP are associated with each other, and that avoidance of activity plays a prominent role in this model, largely fuelled by the fear that the activity will cause harm and will worsen the pain problem.[92]

Researchers such as Waddell[124] and Boersma[92] have demonstrated the predictive value of the fear-avoidance concept in patients with chronic back pain,[80] particularly in the earlier stages of LBP.

It has also been suggested in the literature that patients with high levels of fear-avoidance beliefs could benefit from exercise programmes. This was demonstrated in a study by Klaber Moffett[125] who found that patients with high levels of fear-avoidance beliefs benefitted significantly from a Back Fitness Programme. Those patients who improved by more than

four points on the fear-avoidance beliefs questionnaire (FABQ) (physical section) at six weeks were three times more likely to function better at 12 months, as shown by improvements on the RMDQ. The paper suggested that introduction of exercise might shift the patient's perception of pain. A therapeutic exercise programme could thus make them engage in activity, to help change their behaviour and thus improve their confidence to move.

Self-efficacy beliefs

Cognitive behavioural theorists propose that avoidance behaviour due to fear of pain or re-injury leads to a vicious cycle characterised by a decreased self-efficacy, fear and further avoidance/disability.[126] Based on a prospective cohort design involving 1591 patients, Foster et al[115] confirmed the importance of psycho-social factors, specifically self-efficacy and self-regulation. They found that patients who expect their back problem to last for a long time, who hold weak beliefs and confidence in their own ability to control their back problem and who perceive that many symptoms are related to their back problem, are more likely to have poor clinical outcomes. This accords with the self-efficacy theory that, once a situation has been perceived as involving harm, loss, threat or challenge, and once individuals have considered a range of coping strategies open to them, what they do will be dependent on what they believe they can achieve.[121]

Conclusions regarding psycho-social factors

In summary, the key modifiable risk factors for NSCLBP appear to be psychological and behavioural factors that have a mediating effect on activity levels. Psychological constructs including catastrophising, passive coping, fear-avoidance and depression may lead to decreased activity levels, or to 'over-activity' for some LBP patients.[2] These changes in activity levels are seen to be involved in the development of NSCLBP. If patients' self-efficacy could be enhanced, they would be more likely to engage in activities, which were previously avoided due to fear. Hence, there is an interactive relationship between these cognitive variables. Exercise is one therapy available to LBP patients, which could help to influence these beliefs by helping them to change their behaviour through movement.

2.4 Therapeutic Management of NSCLBP

The goal of physiotherapy chronic pain management is to facilitate rehabilitation and to restore function, to allow the patient to re-engage with society, and to restore quality of life.[7] Chronic low back pain sufferers require a management approach to help facilitate both

physical adaptation and behavioural change. It is beyond the scope of this review to discuss all the different physiotherapy modalities and their supporting evidence. However, as the intervention under investigation relied on facilitating self-efficacy and exercise to bring about improvements in both impairments and a change in personal factors in the form of cognitive change, these will be specifically reviewed. This section will present the evidence in support of therapeutic exercise in general and the Pilates technique more specifically. The role of education and advice will be addressed in line with the bio-psycho-social model of intervention that was utilised in the current study. The importance of adherence will be discussed, as this may have a significant impact on the efficacy of intervention. Finally, supervised and non-supervised intervention programmes will be compared and discussed.

2.4.1 Exercise and NSCLBP

This section will define therapeutic exercise and include the evidence to support its use and discuss the benefits of exercise.

Therapeutic exercise can be defined as the prescription of a physical activity programme that involves the client undertaking voluntary muscle contraction and/or body movements, to relieve symptoms, improve function, and improve or retain health, and to slow the deterioration of health.[127] The definition of therapeutic exercise supports the inclusion of measurable outcomes to determine the effect of the exercise. The current study included a Pilates mat intervention and measured various outcomes to determine the effect of this programme on NSCLBP.

Therapeutic exercise therapy is one of the few evidence-based treatments for NSCLBP,[25,26,30,31] and is thus recommended as a first line treatment for NSCLBP.[27] Rainville et al[128] looked at several randomised controlled trials (RCTs) exploring the conservative management of NSCLBP. The authors concluded that exercise interventions with or without a cognitive component should be incorporated into the care of NSCLBP patients, both as a primary treatment and as a means of augmenting surgical outcomes.[128] However, although exercise has the most evidence supporting its efficacy in the treatment for NSCLBP,[86] as yet no specific exercise protocols have proved more effective than general exercise regimes.[25] Consequently, although there is a multitude of exercise programmes and interventions currently available to patients with NSCLBP,[85] little consensus exists as to which exercise programme design is most effective in encouraging and maintaining exercise benefits.[43] Most guidelines do not recommend a particular type of exercise for NSCLBP, but some state that

such exercises should be intense[70] and supervised,[70] and that exercise is more effective for chronic symptoms. There is hence an ongoing need to develop and validate effective therapeutic exercise interventions for this sub-group of LBP.[33,34]

a) Evidence supporting the use of exercise

Exercise is non-invasive, and it involves patients in managing their own back pain. Current evidence supports the use of exercise-based treatment approaches that encourage people with NSCLBP to take a physically active role in their recovery.[122]

Numerous trials describe the characteristics of exercise programmes that aim to decrease pain and disability for people with NSCLBP.[12,29,35] These studies include comparisons between general exercise and specific exercise,[36-39] individual and group exercise,[30,40,41,129] and supervised and non-supervised home exercise;[25] they also investigate patient motivation and preference.[42] The interventions that have been compared include general physical fitness, aerobic exercise, strengthening of specific muscles or groups of muscles, and various types of flexibility and stretching exercises.[86]

Recently, highly intensive aerobic exercise has been incorporated in the treatment of NSCLBP.[130] The use of aerobic aquatic exercise (deep water running) has been shown to be beneficial in the treatment of NSCLBP versus the usual GP care, comprising education and advice.[131] The results were maintained at one year follow-up. Rainville et al[128] compared various types of exercise used for the treatment of NSCLBP. The common thread in all of these studies is that exercise should be intense enough to accomplish physiological goals, and presented in such a way that patients have a real world experience of successful physical function with or without chronic pain. The focus of treatment should thus promote self-management strategies and rehabilitation as opposed to only cure-seeking strategies.[132]

The literature is not clear with regard to which exercise programmes are most effective for NSCLBP, which means that better randomised controlled trials are necessary to answer these questions. This is also emphasised by the European Guidelines, which suggest that the effectiveness of specific exercise programmes needs to be evaluated, especially programmes that are commonly utilised, but which have been inadequately researched.[97]

Although there is strong evidence that exercise therapy is effective for improving pain and function in NSCLBP, it seems that it does not matter what particular exercises patients with NSCLBP do, as long as they do *something.*

The current study included a programme of Pilates mat exercise and education to influence self-efficacy beliefs as well as to improve impairment and activity outcomes. There is growing support for the exercise form of Pilates and it was thus chosen as the therapeutic exercise for this study.

b) Mechanisms by which improvement might take place following therapeutic exercise

The mechanism of effect will vary, depending on the exercise type prescribed.[133] As a reduction in pain, psychological distress and fear-avoidance beliefs is significantly related to reductions in disability,[134] the benefits of exercise affect the various bio-psycho-social factors of NSCLBP in turn.

At an impairment level, therapeutic exercise may provide benefits to patients with NSCLBP through the voluntary contraction of specific muscle groups, movement of the whole body, activities that improve postural musculature, stabilization, neuro-coordination or a combination of all of these.[133] The physical benefits would include increased joint range and muscle strength, improved muscle function and enhanced range of motion. Improvements in muscular strength and endurance after active exercise may be due to increased neuro-muscular recruitment, increased volitional effort and practice effects, rather than increases in maximum strength or reductions in muscle fatigability.[135] Other physical benefits include analgesic effects,[114,136,137] which are in part due to the activation of the opioid system to release *B* Opioids, which are hypothesized to reduce both peripheral and central sensitization to pain by producing analgesic effects.[137] It has been postulated that the activation of the opioid system is less dependent on exercise intensity when chronic pain is present.[137]

At the level of personal factors, benefits of increased activity levels include increased self-efficacy[65] and reduced fear of activity.[125] Exercise is purported to decrease fear-avoidance behaviour and to facilitate functional improvements and confidence to move, despite on-going pain.[32,138] There is evidence that reductions in catastrophising are responsible for at least some of the apparent analgesic benefits of 'physical' treatments such as exercise.[114] In addition to the physical benefits of exercise therapy, there may be emotional and psychological benefits of exercise,[86] which also contribute to the health benefits.[133]

2.4.2 Advice and Education

In the light of the multiple factors contributing to NSCLBP, the holistic management of NSCLBP may need to include *educating* patients about pain, by informing them about pain

mechanisms and the injury[65,97,109] and setting clear guidelines for rehabilitation.[26] Within the realms of effective pain management programmes without *goal setting* and the application of acquired knowledge, little change in behaviour has been found to take place.[26,65] Moseley's[139] study found that an educational approach, combined with other manual techniques and/or exercise, will help to normalise the pain of NSCLBP patients and help to set the goals for further management. The use of informative booklets, such as *The Back Book*[140] and *Painful Yarns,*[141] to assist in pain education, is well-described.[142,143]

Physiotherapy favours therapeutic exercise in conjunction with advice and education as the most effective treatment interventions for NSCLBP,[32] and this approach supports the bio-psycho-social understanding of LBP management.[27] A national survey conducted in Ireland in 2007, using a sample of 600 physiotherapists found that advice was most commonly delivered as part of the exercise programme, and that core stabilization exercises were the most popular exercise type. The survey also highlighted the importance that NSCLBP patients place on the provision of exercise programme supervision, not only for enhancing adherence but also for general reassurance.[32]

There is strong evidence to support the use of *advice to remain active* in addition to specific advice relating to the most appropriate forms of exercise.[144] Advice to remain active is also encouraged by the European Guidelines for the management of NSCLBP (Koes et al 2010).[70]

Pain management approaches that include *patient involvement and activity* (e.g. graded exercise programmes and group support) have been reported to be beneficial for NSCLBP management.[26,145] A 2012 study by O'Sullivan[28] mentions that a stabilizing exercise programme for patients with NSCLBP specifically due to spondylolysis and spondylolisthesis[146] has been demonstrated to be effective in both improving movement and relieving pain. Macedo et al's 2009 study[39] found that motor control exercises had similar effects to graded activity for NSCLBP, on not only pain and disability outcomes, but also on function, global impression of change and quality of life scores in long-term follow-up.[40] These findings reflect the success of specific exercise programmes across pain and function domains. In patients where the psycho-social aspects of pain may result in barriers to improvement, programmes that include cognitive and behavioural aspects of pain may be beneficial. The findings of a study by Sullivan et al[145] suggest that a psycho-social risk reduction intervention that includes exercise can be an effective means of improving function

and facilitating return to work, especially in people who are at risk for prolonged pain-related disability.

Studies that have employed an approach to education that emphasizes cognitive-behavioural[147] or neuro-physiological[109] aspects have reported reduced disability, reduced health care utilisation, normalisation of pain cognitions, and increased self-efficacy.[139]

Cognitive processes that could be contributing to the NSCLBP[148] should not be ignored. There is growing evidence recommending *cognitive behavioural therapy* (CBT) and *graded exercise therapy* (GET) in the management of these complex conditions.[65,97] These CBT techniques proceed from the premise that an individual's interpretation and beliefs about his or her health condition and coping repertoire, with respect to pain and disability, will affect the degree of emotional and physical disability associated with the pain condition.[149] Cognitive behavioural therapy approaches encompass a range of interventions, including exercise, which aim, through the change in behaviour, to change the associated beliefs.[2] Historically, multimodal interventions have been based on a generic CBT approach with a general exercise component, without being tailored to identified physical and/or psychological impairments.[93] Activity pacing has been suggested to be a key aspect of both CBT and GET.[6] Activity pacing involves modifying behaviour, with the aim of improving activity levels and managing symptoms whilst reducing relapses.[6] Patients would thus keep activity logs of the prescribed exercise, and together with the therapist could then set appropriate progressions for these activities, thus ensuring that they were integrated functionally.[145] This approach promotes patient involvement in their care. The current study had similarities to GET, by the inclusion of exercise progressions, which were slow enough to allow patients to adapt to the exercise intensity and duration, whilst keeping activity logs of the prescribed exercise.

Combining a motor control training programme (such as Pilates) with individualized education about pain physiology (such as that found in *The Back Book*), has been found to be effective in reducing pain and disability associated with NSCLBP.[150]

2.4.3 Influence of Pain Beliefs on Physiotherapy Management of NSCLBP

Pain beliefs have been reported to influence treatment choices when it comes to the management of NSCLBP. PSE and FABs are discussed below. Less focus needs to be placed on treating the structure or signs and symptoms of a disorder in NSCLBP and more on

targeting the different combinations of beliefs, cognitions, pain experience, lifestyle and movement behaviours that underlie and drive disorders.[97] The possible reasons for the failure of current clinical practice to manage NSCLBP effectively are proposed to lie in two domains: 1) The failure to deal adequately with NSCLBP within a multi-dimensional bio-psycho-social frame-work, and 2) the lack of a multi-dimensional classification system directing person-centered targeted management for this large group of NSCLBP patients.[151] A recent systematic review concluded that few clinical trials have utilized targeted interventions for NSCLBP.[151] The few trials that have adopted a targeted bio-psycho-social approach to the management of NSCLBP have demonstrated a tendency for improved outcomes.[125] Considering the pointers mentioned above, this study included an assessment, which determined very specifically whether a prospective participant belonged to a NSCLBP group (as per the diagnostic triage). The therapeutic intervention included a physical component and an educational component (in the form of *The Back Book*). The outcome measures were specifically chosen to cover the various ICF domains, namely, impairment, activity and participation outcomes.

Addressing cognitive factors is now considered by many to be a fundamental aspect of physiotherapy treatment for NSCLBP.[125] Woby et al[152] conducted a study to determine the extent to which cognitive factors were differentially related to the levels of pain and disability reported by 183 NSCLBP patients presenting for physiotherapy. The findings of the Woby et al[152] study clearly show that there is a strong association between cognitive factors and the levels of pain and disability reported by NSCLBP patients. Functional self-efficacy emerged as a strong predictor of both pain intensity and disability.[152] Individuals with high self-efficacy may be more motivated to engage in health promoting behaviours and to adhere better to treatment recommendations.[65] This, in turn, may prevent them from becoming trapped in the negative spiral of activity avoidance, physical deconditioning and depression.

In the LBP literature, the two factors that are frequently proposed to mediate the relationship between pain intensity and disability are *pain self-efficacy (PSE) and fear of movement.* Self-efficacy describes the confidence the person has in his or her own ability to achieve a desired outcome.[153] Higher levels of self-efficacy have been found to be associated with lower levels of pain and disability in patients with chronic pain.[154] A study by Costa et al[155] investigated the extent to which PSE and/or fear of movement mediate the relationship between pain intensity and disability in 184 patients with recent onset NSLBP (less than six weeks). The study was a longitudinal design, and all patients completed measures for pain intensity,

disability, PSE and fear of movement. The authors concluded that PSE might be a more important variable than fear of movement beliefs in terms of understanding the relationship between pain and disability. It is worth noting that the patients for the study were included only if they reported a recent onset of NSCLBP, as the influence of modifiable factors such as PSE and FABs is likely to be different in patients with varying durations of LBP.[155] The findings of this study are in keeping with those from an earlier study, where the authors examined the relations between disability, as measured by the pain disability index and self-efficacy, fear-avoidance variables and pain intensity using a prospective study. Denison et al[156] suggested that self-efficacy beliefs are more important determinants of disability than fear-avoidance beliefs in primary health care patients with musculoskeletal pain. The authors' findings also suggest that pain-related beliefs, such as self-efficacy and fear-avoidance, in turn, are more important determinants of disability than pain intensity and pain duration in these patients.[156] Foster et al[115] compared how different psychological factors predict back pain outcomes six months after a primary care consultation. Of the psychological obstacles to recovery, low confidence in the patient's own ability to perform normal activities despite the pain was a better predictor of disability at six months than fear-avoidance, catastrophising or depression.[115]

Dolce et al[157] demonstrated that self-efficacy could be enhanced in patients with chronic pain who increased their level of exercise through a rehabilitation programme. Altmaier et al[158] found that in the rehabilitation of patients with LBP, improvements in self-efficacy significantly predicted better functioning and less reported pain.

2.4.4 Pilates Exercises

As there is little evidence to support one form of therapeutic exercise regime over another, this study was undertaken to determine if the form of intervention, supervised or home therapy, would influence outcome. As Pilates exercise appears to address both the impairments and personal factors that are most implicated in NSCLBP, this section defines Clinical Pilates, presents the principles and offers the evidence for its impact.

a) Description and definition

Pilates has been described as a mind-body exercise intervention that addresses both the physical and the mental aspects of pain by means of core strengthening, flexibility and relaxation,[159] muscle control and posture.[160]

The use of Pilates exercises for rehabilitation is growing, as more therapists become acquainted with this exercise form. Pilates is currently recommended by practitioners as an active functional treatment for back pain.[161] Many studies have reported positive effects on pain and function outcomes when comparing Pilates based exercise to other approaches, such as Back School,[162] normal activities,[163] usual care (defined as consultation with a physician and other specialists and healthcare professionals as necessary)[164] and drug therapy[165] for LBP.[166] However, a pilot study conducted by Taylor and Dean[167] in 2011 in the New Zealand setting suggested that an investigation is warranted into the effectiveness of physiotherapy prescribed Clinical Pilates that is used as an exercise intervention to treat NSCLBP.

Clinical Pilates developed from the conventional Pilates Method (developed by Joseph Pilates) and specifically targets core stabilising muscles. The exercises are gradually increased in complexity to help the patient to develop stabilization strategies during movement. The desired movement patterns are facilitated by the use of imagery. The aim of performing the exercises in different functional positions is to help the transfer of these gains to everyday movement and functional activities.[164] Mat Pilates sessions include the use of small apparatus, and the sequence of the exercises during a session provides an opportunity to train a variety of movement patterns and postures.

In this study, the principles of cueing the exercise to facilitate efficient movement was considered when developing the Pilates eight-week programme for both the supervised and the non-supervised groups. Different functional positions were used to mimic the positions, in which the participants would find themselves daily. Both the classes and the home programmes of exercises included progressions to challenge the participants. Progressions were introduced slowly enough to include repetition of movement and to allow for muscle adaptation to take place and for the development of stabilization strategies to develop.

b) Postulated effect of Pilates

Pilates exercises may be effective in that they target the impairments and personal factors discussed in Section 2.3.3. The impact on poor muscle activation, increased muscle activity, poor stabilisation of the trunk, central pain modulators and personal factors is discussed below.

The goal of achieving efficient movement and returning to functional movement and enhanced performance is the foundation of Pilates-evolved work.[168] Pilates-evolved exercises are thought to facilitate efficient movement behaviour by allowing the patient to be in a

position that minimizes unwanted muscle activity, which is often responsible for inefficient movement patterns and early fatigue, which can lead to injury. Most muscle recruitment during day-to-day activities occurs in postural muscles, which contain predominantly type 1 fibres. By activating postural muscles in the correct sequence, a therapist can assist a patient in improving the efficiency of their static and dynamic posture.[168] If a desired movement is challenged by a decrease in proprioception, individuals often over-recruit muscles in an attempt to stabilize. Although it has not been proved, it remains plausible that over-stabilization or faulty stabilization inhibits efficiency and can act as a hindrance to efficient movement.[168] Faulty stabilization, which is associated with NSCLBP, can be targeted with Pilates exercises. The Pilates exercises target relaxation, efficient stabiliser muscle use and enhanced motor control, which contribute to decreasing pain and improving function.

Pilates has similarities with spinal stabilization exercises,[169] as both aim to normalize spinal motor control;[170] moreover, both emphasise the activation and recruitment of TrA, *obliquus internus* (OI), *obliquus externus* (OE) and MF muscles.[164,171] Gladwell et al[163] describes the use of Pilates as the activation of core muscles (TrA, MF, pelvic floor muscles and diaphragm), with a slow progression into more dynamic motions. The objective of the Pilates method is to train these muscles sub-maximally to improve their tone and strength,[169] thus gradually decreasing abnormal muscle recruitment and compensation strategies over time. These muscles are activated in Pilates if taught by experienced instructors.[172] The spine is kept in a neutral position in which the local or deep spinal musculature is thought to be engaged at a more intense level (TrA, OI, and MF). The focus and specific verbal cueing on deep breathing structured into the exercises themselves helps to facilitate the contraction of the TrA and MF, which is reported in the literature to improve spine stability at the local level,[173] to improve control over the neutral zone on intervertebral motion,[103] and to stabilize the sacroiliac joint.[174]

Transversus abdominus muscle activation has been found to increase following an eight week, non-supervised Pilates mat exercise programme.[171] The increased activation of these muscles during activities of daily living has been linked to a reduction in back pain.[175] Muscolino and Cipriani[175] linked this finding to an increase in strength gains of the ‘core’ muscles, and an increased length of the spinal muscles supporting the lumbar spine. The strength gain and length gain of the ‘core’ muscles lead to decreased compression of the joints and an alteration in the tilt of the pelvis. This has been shown to result in changes in posture of the lumbar spine and to cause improvements in the neuro-muscular control of the

trunk and its relationship to limb movements.[163] The lengthening of the lumbar spine has been suggested to result in a concomitant lengthening of the thoracic spine, resulting in improved spinal posture.[175]

A key difference between Pilates and current trunk stabilization exercises is that Pilates increases mind-body awareness, control of movement and posture.[85] Joseph Pilates believed that the goal of a healthy person should be to attain a strong mind, and to use it to gain total control over his physical body.[176] This emphasis on cortical involvement may influence aspects of the central modulation of pain.

The important elements of improving back pain, including biological, educational and psychological aspects, are encompassed within the principles of Pilates training.[163] The traditional Pilates principles of centering, concentration, control, precision, flow and breathing are mentioned less in the literature when the studies have included participants with LBP versus healthy controls. A review of the Pilates literature by Wells et al[160] suggests that a greater emphasis may need to be placed on posture in people with LBP, whilst traditional principles, apart from breathing, may be less relevant.

There is growing evidence in the literature to support the use of Pilates to address both the physical and mental aspects of LBP management.

c) Evidence for Pilates

There is growing interest in the effects of Pilates on NSCLBP, as shown by the increased number of recent studies found in the literature looking at this topic; this growing interest also parallels the growing popularity of using Pilates as therapeutic exercise for LBP conditions. This section will cover the evidence in the literature in support of the exercise form of Pilates.

The latest research on Pilates and back pain found improvements in back pain [162-164,177] and disability scores,[162,164,178-180] following a Pilates intervention utilising either mat exercises or specialized exercise apparatus.[164] Moreover, the lowered disability scores were maintained for up to 12 months post intervention.[164]

The quality of these trials was assessed by means of the PEDro scale (values of 0–10), with scores extracted from the PEDro database.[181] Each satisfied item (except for item one, which, unlike the other scale items, pertains to external validity), contributes one point to the total PEDro score (range=0-10 points). This scale has been used to rate the quality of over 3000

RCTs in the PEDro database and in several systematic reviews.[14] The criteria assessed by the scale include: eligibility; random and concealed allocation; groups similar at baseline; subject, therapist and assessor blinding; less than 15% dropouts; intention to treat analysis and between-group statistical comparisons. The PEDro scale has adequate reliability.[14] The methodological quality of the studies varied between two to eight points on the PEDro scale, an 11-item scale (Table 2, Table 3). Eleven RCTs were found in this literature search; six of these trials compared a Pilates intervention with a minimal intervention (none or little exercise), whereas five compared Pilates with other therapeutic interventions (traditional lumbar stabilization; standard physiotherapy treatment; Back School; generic therapeutic exercise). Three of these RCTs reported significant improvements in pain outcomes, and two RCTs reported significant improvements in functional outcomes, in the short term. In one of these trials, the significant improvement in both pain and function outcomes was maintained in the long term (i.e. over a period of 12 months).[164]

Eight trials reported improvements in pain outcomes in the short term, three of which were significant;[164,178,182] seven trials reported improvements in functional outcomes in the short term, two of which were significant.[164,178] There were no studies in which there was no effect with regard to pain or functional outcomes. One study reported an improvement in health outcomes,[163] one study improvement in flexibility,[163] and another study an improvement in PSE, rating of effect and adherence,[45] all in the short term. These studies used outcome measures that fall mainly under the categories of impairment, function and participation, although one study did include personal outcomes (rating of effect and adherence). This same study had included outcomes across all the ICF domains.[45] The impairment outcomes included the PI-NRS and the VAS for pain and active lumbar flexion and extension and the sit and reach test for ROM. The functional outcome measures used were the RMDQ, the Oswestry Disability Questionnaire (ODQ) and the Quebec Back Pain Disability Scale (QUE). Participation outcomes included the SF-36 health related quality of life questionnaire and the PSEQ.

With regard to quality, two studies with a high PEDro score (8/10)[164,178] and one study with a lower PEDro Score (5/10)[182] found significant differences in pain and/or function scores between the groups they had studied. Most of the studies scored between five and eight out of 10, with one study scoring as low as two.[162]

A summary of the studies analysed and the PEDro scores obtained can be seen in Table 2 and Table 3.

Stolze et al[183] derived a clinical prediction rule (CPR) to identify which sub-group of LBP patients would benefit most from a Pilates-based intervention, and they found five predictors. The five variables identified included: total trunk flexion ROM of 70 degrees or less, duration of current LBP symptoms of six months or less, no leg symptoms on assessment, body mass index (BMI) of 25kg/m^2 or greater and hip average rotation ROM of 25 degrees or greater. If three or more of the five attributes were present, the probability of experiencing a positive outcome increased from 54% to 93%.[183] Eighty-one percent of the participants in Stolze et al's[183] study were female, which makes this CPR apply more to women than it does to men.

Table 2: Studies comparing Pilates versus minimal intervention

Author, Date	Subjects	Sample size	Inclusion	Exclusion	Outcome Measures	Intervention	Frequency	Results	PEDro score
Rydeard et al[164] 2006	Physically active, 20-55 year old male/female with NSCLBP	39	Longstanding persistent LBP (with or without leg pain > 6 wks. duration or recurring LBP to restrict functional activity Participation in 3x30 min per week -Grade 4 or less muscle strength of gluteus max muscle -Altered recruitment of the gluteus max in prone leg extension	Pregnancy; spinal surgery or fracture; inflammatory joint disease, rheumatic disease; chronic pain syndrome, overt neurological compromise; acute inflammatory disease; inability to speak or write English	Roland Morris Disability questionnaire (RMDQ/RMDQ-HK) 101 point numerical rating scale	(4 weeks) I= Pilates (n = 19) reformer and mat at clinic and home C= Control (n=21), no systematic exercise. Treatment from health care professionals as required.	3x week at clinic for 1 hour and 4x week home programme of 15 min	Significant decrease in functional disability and average pain intensity in the I group versus the C group post intervention. (95% CI) Improvements maintained for 12 months	8
Quinn et al[177] 2005	27-53 year olds. Gender not specified	22	CLBP > 6 months	Nothing specified	Oswestry disability questionnaire(ODQ) Range of movement (ROM) Flexibility Surface EMG	(12 Weeks) I= Pilates mat work (n=15) C= no exercise, only normal daily activity (n=7)	2x week for 24 sessions, 60 min	Improvement in pain scores at 3 months Decreased muscle activity in Para spinal muscles at 3 months	5

Gladwell et al[163] 2006	18-60 year old male/female with NSCLBP for > 12 weeks	49	CLBP for at least 12 weeks Medically fit to participate in activity	LBP attributed to a specific pathology e.g. disc herniation, tumour, infection, fracture, osteoporosis, structural deformity, inflammatory disorder, radicular syndrome or cauda equina. Spinal surgery; inability to walk without a walking aid; taking part in regular Pilates classes; LBP due to nerve root irritation	The Oswestry low back pain disability questionnaire (OSWDQ) Roland Morris Pain Rating Scale (RMVAS) and daily pain diaries Generic functional status measured with the SF-12 questionnaire Subjective improvement in symptoms during different functional movements Sports functioning questionnaire Physical tests -Stork stand test -Sit and reach test Daily diary on attendance, treatment, medication, additional exercise	(6 weeks) I = Pilates (n= 25) modified Pilates exercises C= Control (n= 24) no exercise, normal daily activities and pain relief	3x week; 1x hour class at clinic, 2x 30 min home	No improvements in function between groups Decrease in pain scores in the I group versus the C group post intervention Also, improvements in general health, proprioceptive balance and flexibility	5
MacIntyre[178] 2006	25-62 year old male/female Ratio: 25 females 7 males	32	Recurrent LBP >3 months	Previous Pilates training or spinal surgery; inflammatory disease; red flags on assessment; neurological compromise; inability to adhere to an exercise programme	Visual Analogue Scale (VAS) Roland Morris Disability Questionnaire (RMDQ)	(12 weeks) I= Stott Pilates mat work regime normal exercise allowed and PT as needed C=normal exercise routine and PT as needed	1 hour session/1wk at clinic and 10 min home programme 3x/wk. for 10 sessions.	Minimal significant improvements in pain scores between groups Significant changes in disability scores between baseline and 12 weeks	8

Limba da Fonsesca[182] 2009 Ratio:12 female/5 male	21-47 year old male/female with CLBP at least 6 months	28	Independent gait on assessment, LBP for at least 6 months	Neurological disease, major visual defects, leg-length discrepancy, history of ankylosing spondylosis, disc herniation, tumour, infection or fracture, cauda equine syndrome, spinal fusion, orthopaedic surgery to low limb within 1 year	Pain-visual analogue scale (VAS) VGRF parameters	I= Pilates mat work C= normal daily activities	2 x/wk for 15 sessions	Significant improvements in VAS and present pain immediately after the intervention. Significant increase of the middle support force of the left low limb during the fastest walking speed.	5
Miyamoto et al[180] 2011	18-60 year old male/female Ratio: females 70 males 16	86	NSCLBP for > 3 months	Contraindications for physical exercise (PARQ); previous regular Pilates training; pregnancy serious spinal pathology; spine surgery; nerve root compromise; physical therapy treatment in last 6 months	Pain numeric rating scale (PI-NRS) Roland Morris Disability Questionnaire (RMDQ) Patient–specific functional scale (PSFS) Global perceived effect (GPES) Kinesiophobia (Tampa Scale for Kinesiophobia)	(6 weeks) I=modified Pilates exercises, individual and supervised; educational booklet (n=43) C=educational booklet about anatomy of spine, pelvis and low back; recommendations about posture and ADL's.	1 hour session 2x week at clinic Phoned twice weekly	Small to moderate improvements in pain scores, disability and global impression of recovery at 6 weeks. No difference in specific disability and kinesiophobia at 6 weeks No between-group differences at 6 months	8

Table 3: Studies comparing Pilates versus therapeutic intervention

Author	Subjects	Sample size	Inclusion	Exclusion	Outcome Measures	Intervention	Frequency	Results	PEDro score
Gagnon et al[169] 2005	18-45 year old male/female with LBP Ratio: 9 female, 3 male	12	LBP	Serious spinal pathology preventing exercise; workers compensation and post MVA; positive neural signs, attendance at PT sessions elsewhere	Pain (VAS) Disability – Oswestry Disability Questionnaire (ODQ) AROM lumbar flex and ext.	I= Pilates mat work regime C= traditional dynamic lumbar stabilization exercises	30-45 min 1.43 x/week, 10.5 sessions and PT 30-45 min 1.46 x/week, 9.67 sessions and PT	Improvements in pain and disability scores in both groups. No significant differences between groups	5
Anderson[168] 2005	30-58 year old volunteers with CLBP Ratio: 10 female 11 male	21	LBP > 3 months	Pregnancy, weakness of the low extremities, recent abdominal surgery	Pain MBI Disability – Oswestry Questionnaire Functional self-efficacy (FSE) Trunk flexion and strength	(6 weeks) I = Pilates apparatus C= Therapeutic massage	50 min 2x week for 12 sessions 30 min 2x week for 12 sessions	Improvements in pain, disability, FSE and physical measures in both groups. No significant differences.	6
Donzelli et al[162] 2006	20-65 year old male/female receiving treatment for CLBP Ratio:26 female, 14 male	53	CLBP without peripheral irradiation for at least 3 months Negative Laseque test, SLR and Wassermann's test	Spinal surgery, radicular pain with positive Laseque , SLR and Wassermann's test Structural deformities like spondylolisthesis, stenosis, disc hernia, rheumatoid arthritis, conditions that mimic lumbago symptoms	Oswestry low back pain disability questionnaire (OLBPDQ) Visual analogue scale (VAS)	(10 days) I= Pilates Cova Tech Method (n=21) C= Control Back School (n=22)	10x consecutive sessions of 1 hour; exercise booklet to continue at home 10x consecutive sessions of 1 hour; exercise booklet to continue at home	Improved disability and pain scores in both groups at 1 month and 6 months	2

O'Brien[184] 2006	25-65 year old male and female with sub-acute LBP Ratio: 9 female 19 male	28	LBP	Nerve root compression; recent spinal fracture, tumour, infection, co-morbidities or contraindications to exercise	Pain – Visual analogue scale (VAS) Disability – Roland Morris Disability Questionnaire (RMDQ)	I= Pilates mat work and apparatus C= Standard PT (manual therapy, education, core stability exercises, stretches, McKenzie, IF, orthotics, taping)	1 hour 2x/week, 8 sessions 30 min 2x/week, 8 sessions	Improvements in pain and disability scores for both groups	7
Wajswelner et al[45] 2012	18-70 year old Community volunteers with CLBP > 3 months	83	Pain in the back with or without leg pain; average pain at screening > 4 on PI-NRS	Spinal pathology preventing participation; neural compromise; pregnancy; co-morbidity preventing exercise participation; previous participation in a Clinical Pilates programme or back exercise programme	Disability/Pain – Quebec scale Pain – PI-NRS Patient Specific Functional scale (PSFS) Pain self-efficacy questionnaire (PSEQ) Rating of beneficial effect of intervention Participant-perceived global rating of change in pain and function Health related quality of life – (SF-36) Adherence	(6 weeks) I= Tailor made, direction specific supervised Pilates programme on the reformer and trapeze and daily home exercises C= Supervised generic exercise group sessions at the clinic and daily home exercises	1 hour session 2x/week for 6 weeks, daily home exercises	General improvements in all outcome measures, but no significant differences between groups from baseline at 6,12 and 24 weeks	7

Recent systematic reviews and meta-analyses have highlighted the lack of well-designed clinical trials[53,54,185,186] to investigate the effects of Clinical Pilates on pain and functionality scores in NSCLBP. Aladro-Gonzalvo et al[187] suggest in their review of a number of studies that the low methodological quality of the studies and the heterogeneity of the physiotherapy treatments used in the control groups showed estimate bias of the effect of treatment for reducing disability in NSCLBP. Touche et al[188] report that it would be important to identify and specify which modifications and adaptations are needed for the classic Pilates Method to be used in a NSCLBP programme. There has also been little homogeneity in control interventions used in clinical trials,[54] thus making it difficult to compare the interventions.[185] As a result, there is inconclusive evidence that Pilates is indeed effective in reducing pain and disability in people with NSCLBP. This conclusion relates to the insufficient number and methodological quality of available primary studies, rather than to the methodological quality of the reviews.[144] Aladro-Gonzalvo et al[211] suggests that future studies should incorporate placebo controlled trials and intervention protocols that are comparable.

Donzelli et al,[162] in comparing the Pilates Cova Tech method to the Back School method, found a significant reduction in pain intensity and disability across the sample (Table 3). The results obtained with the Pilates method were comparable to those achieved with the Back School method, suggesting its usefulness as an alternative approach to the treatment of NSCLBP. However, the risk of bias in the Donzelli et al study,[162] as in the Quinn et al[177] and Gladwell et al studies[163] (Table 2), was high – the three studies obtained PEDro scores of 2/10, 5/10 and 5/10 respectively. A more methodologically sound study, that of Rydeard et al[164] (PEDro score 8/10), reported a significant decrease in LBP and disability, which was maintained for up to 12 months following the treatment intervention. The specific exercise training group participated in a four-week programme consisting of training on specialized Pilates exercise equipment, while the control group received the usual care, defined as a consultation with a physician and other health care professionals, as necessary (Table 2). Wajswelner et al[45] (PEDro score 7/10) did not find any improvements in pain and disability scores, however, when they compared a Pilates clinical programme with a generalized exercise programme of six weeks' duration (Table 3).

The heterogeneity of control groups, which has been reported by Touche et al,[188] makes it difficult to compare the interventions. Supervised exercise therapies are among the most commonly advocated treatments for NSCLBP.[21] Thus far, however, no studies have looked at the effects of a supervised Pilates mat programme, consisting of progressive therapeutic

exercises, on the treatment of NSCLBP, in comparison with a similar non-supervised Pilates home programme.

2.4.5 Factors Affecting Treatment Outcomes

Adherence to an exercise programme, the therapist-patient relationship and motivation are discussed below.

The maintenance of exercise-induced gains is often the most challenging aspect of exercise prescription, being intricately related to the successful integration of exercise science with behavioural techniques, in order to promote adherence and individual goal achievement.[1] One of the top priorities of the Research Priorities Project of the Chartered Society of Physiotherapy is to explore strategies to increase patients' adherence to exercise programmes.[69]

The effectiveness of the therapeutic intervention, as used in this study, relies on the *adherence* of the patients to the programme. Research has demonstrated a positive relationship between adherence to a rehabilitation programme and recovery from a variety of different musculoskeletal conditions,[189] including NSCLBP.[42] Friedrich et al[42] assessed the effect of a combined exercise and motivational programme (including the keeping of an exercise diary) on adherence, disability and pain in 93 patients with chronic and recurrent LBP. The patients in the combined exercise and motivation programme versus the standard exercise programme were significantly more likely to attend exercise sessions, and they reported low disability and pain scores at four and 12 months after the study. However, there was no difference between the group that received motivation and exercise compared to the group that received the exercise only with regard to long-term exercise compliance. Friedrich et al[190] found that, five years after a supervised motivated programme, the patients with chronic recurrent LBP continued to show significant improvements in disability, pain intensity and working ability compared to the standard exercise programme. Mannion et al,[30] too, examined factors associated with adherence and the relationship between adherence and outcome after a programme of physiotherapeutic spine stabilization exercises. Mannion et al[30] concluded that the benefits of rehabilitation depended largely on the patient's exercise behaviour outside of the formal physiotherapy sessions. This finding suggests that more effort should be invested in finding ways to improve patients' motivation to take responsibility for the success of their own therapy. Coppack et al[191] examined the effects of a goal-setting intervention to increase adherence. The authors took 48 military personnel

diagnosed with NSCLBP and conducted a mixed-model RCT. The findings from the Coppack[191] study provide partial support for the use of goal setting to enhance adherence in LBP rehabilitation. Powell et al[133] suggest that increasing the physical activity toward a desired level, in small and well-spaced increments, will reduce the incidence of adverse events and improve adherence. In this study, the intervention programme extended over an eight-week period and included progressive exercises to help challenge and motivate the participants.

The therapist-patient relationship, more recently known as the therapeutic alliance[192] moreover influences patient motivation on many levels.[42] The therapeutic alliance is an important determinant of treatment outcome and is considered central to the therapeutic process.[192] In order for physical therapy to be successful, the therapist must be able to motivate and the patient must be open to the motivational efforts of the therapist.[42,193] It also seems important that physical therapists carefully explore which problems patients encounter in their efforts to comply with their exercises and that they seek solutions to those problems in mutual cooperation with their clients.[194] Knowledge of the patients' priorities regarding the most important beliefs and perceptions that have high potential for adherence to home exercise may be helpful in improving the quality of care of patients with LBP.[195] Several phenomena, identified by Dean et al,[196] may hinder the adherence process: the pressure on time, as well as the balance between the self-management advocated by the physiotherapist and the passive treatment modalities requested by the patient.[196] Both physiotherapists and patients are faced with choices about how to prioritize their time.[196] The inclusion of both a supervised and a non-supervised Pilates mat programme in this study allowed for comparison between having a therapist present during the programme to help motivate the participants in the classes versus the self-motivation needed by the participants in the home-based exercise programme.

Instructing the patient how to perform the exercises forms part of the motivation. Schneiders et al[197] assessed the adherence to exercise therapy over a 14-day period by 96 patients with acute and sub-acute LBP. The patients who received their exercise instructions verbally, and those whose instructions were reinforced with clear written and illustrated material, showed a significantly higher level of adherence than did the controls who only received verbal instructions.[198] Limitations of the Kolt[198] study, which looked at the adherence of patients attending private physiotherapy clinics for rehabilitation of LBP, included that the non-exercise treatment was not standardized. Also, participants were aware that they were part of

a study assessing adherence to home exercise, which might have affected their normal behaviour, and the study furthermore relied on the patient's honesty in recording the exercise sessions performed, which is prone to recall and bias problems.[198]

2.4.6 Supervised and Non-Supervised Programmes

The advantages and disadvantages of a supervised intervention and a home intervention are tabled in this section. The current study looked at these two forms of intervention to determine the impact on outcomes.

Current literature has shown that supervised exercise interventions increase compliance,[26,31,56] improve outcomes and increase participant satisfaction;[57-59] they also meet participants' needs,[26] and allow for individual correction and reassurance.[32,60] All of these benefits are limited in non-supervised exercise, such as home programmes. Conversely, non-supervised exercise given as a home programme allows for greater flexibility and ease of implementation[199] and it does not need a special area for the exercise, saving on time and transport costs.[199]

Table 4: Comparisons of the advantages and disadvantages of SEG and HEG

SEG	HEG
Increased adherence[31,200]	Possibly compromised adherence[200]
Cost effective[97,129]	Cost effective[201]
Camaraderie /peer support[202]	Decreased attention[203]
Facilitate group therapeutic effect[129,144,145,200]	Greater self-discipline/self-motivation[204]
Transport costs[205]	No transport costs[199]
Set time allocation[199,173]	Flexibility of time[215,205]
Parking (disincentive)[205]	No parking[205]
Reassurance/accuracy of exercises[32,206]	No reassurance[199]
Accuracy in number of repetitions[144,199]	Self-responsibility for repetitions/frequency[195]
Structured class[129]	Unstructured individual session[129]
Pilates studio[129]	Room at home[199]
Inconvenience[205,199]	Convenience[12,201]

Both the supervised and the non-supervised sessions have their advantages and disadvantages (Table 4). Providing patients with a preference of which exercise programme to participate in may influence outcomes.[27]

Exercise consisting of individually designed programmes, including stretching and strengthening, which are delivered with supervision, appears to provide the greatest improvement in pain and function in NSCLBP.[31] Similarly, when compared to a general exercise programme, a programme that was individually tailored to the needs and capabilities of the specific patient was shown to be more effective in reducing the pain and disability experienced by sub-acute and NSCLBP patients.[41] It was also found that the prescription of home exercises alone was not effective for NSCLBP.[200] The European clinical guidelines recommend group supervised exercise therapy as an attractive first line option for treating large numbers of NSCLBP patients at low cost.[97] There is recent evidence to support group treatment that incorporates general strengthening, trunk stabilization and flexibility training in the treatment of NSCLBP.[85] Exercising in a group versus individual physiotherapy treatment furthermore offers a cost saving.[129]

Adherence to exercise prescription is usually poor, and thus supervision by a therapist is recommended.[200] If home exercises are prescribed, strategies to improve adherence should be used,[200] such as an interactive demonstration and practice, combined with diagrams and written instructions.[12] Patients' preferences and expectations should be considered when deciding which type of exercise to choose, because these factors may also influence outcomes of treatment.[207]

Bronfort et al[199] compared supervised exercise, spinal manipulation and home exercise in 301 individuals suffering from mechanical LBP of at least six weeks duration. Treatment went on for 12 weeks. Those who received the supervised trunk exercises were most satisfied with care and experienced the most gains in trunk muscle endurance and strength. The participants did not significantly differ, however, from those receiving chiropractic spinal manipulation or home exercise in terms of pain, disability and health measures in both the short (12 weeks) and long term (52 weeks).

Less costly and less time-consuming self-care interventions, such as home exercise, have been shown to be effective for acute and sub-acute LBP; however, the evidence to support their use for NSCLBP remains inconclusive.[201] In the light of the cost-advantages of supervised group exercises and home exercises, it is important to establish whether these

interventions are effective. This will allow physiotherapists to advise their patients as to the most efficient use of limited health care funds.

A management approach of therapeutic exercise (Pilates mat exercises) and education (in the form of an educational booklet, *The Back Book*)[147] was incorporated in the current study to target a specifically defined NSCLBP population who were required to have completed any form of manual therapy two weeks prior to participating in this study. The supervised and home exercise interventions had specific aims, namely, to target muscle and motor control dysfunctions that are known to exist in NSCLBP, and to improve the outcomes of pain and disability, ROM, health and PSE.

2.5 Outcome Measures

This section will group the various outcome measures used in this study within the ICF framework. The individual outcome measures are then discussed.

The value of outcome measures for assessing the effectiveness of various therapies has been highlighted in the literature,[51] as has the need to develop standard outcome measures to be used across clinical trials to allow easier evaluation of the efficacy and the effectiveness of treatments.[208,209] Outcome measures also provide participants taking part in a trial with a sense of progress and achievement.[12] The complexity of chronic pain and its negative impact on diverse aspects of function require the assessment of multiple outcome domains to evaluate treatments comprehensively.[210] A core set of outcome measures for use in LBP studies has been identified; they include the following domains: back-specific function, generic health status, pain, work disability and patient satisfaction.[51] These guidelines are deemed representative of the bio-psycho-social influences on CLBP and were thus considered when deciding on the outcome measures to be used for this study. It has been advocated that the bio-psycho-social measurement of health should not only address the impairment by means of tests but also consider the impact of all contributing factors, as outlined by the ICF domains: activity limitation, participation restriction and environmental and personal factors. The outcome measures for the current study were thus categorised into the various ICF domains[7] (Figure 1).

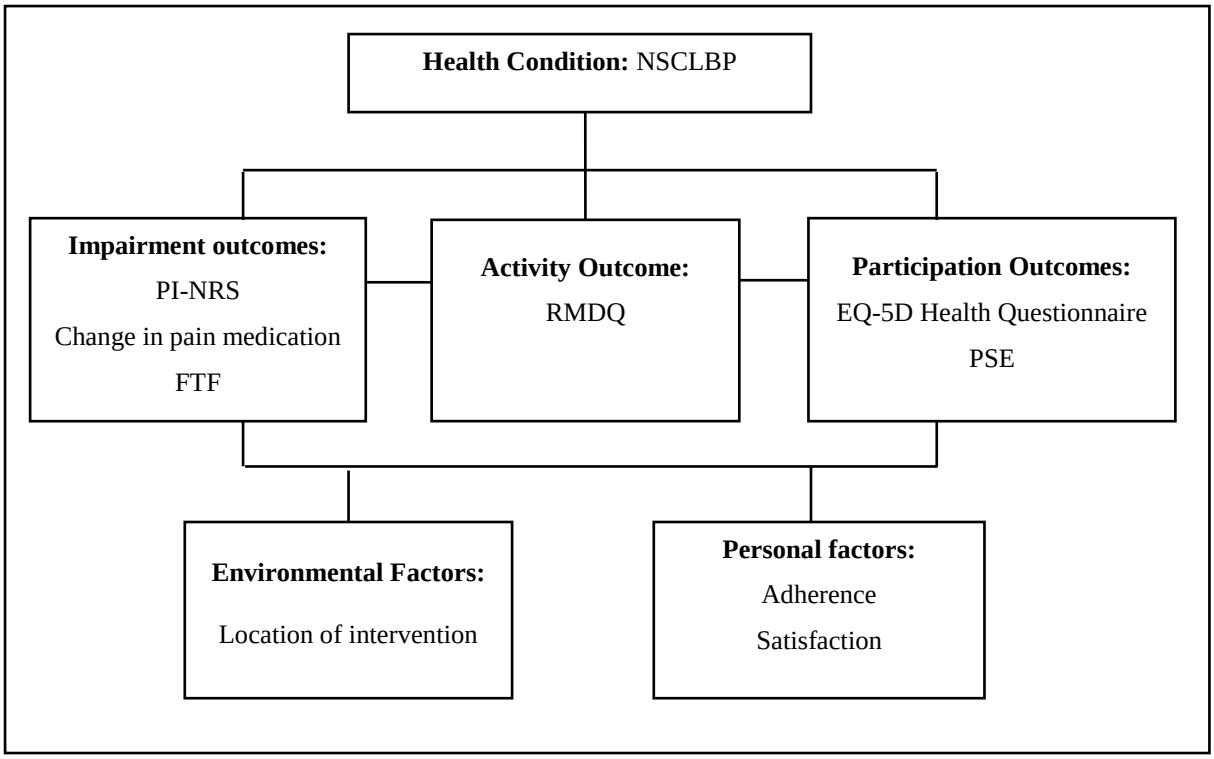


Figure 1: ICF domains used to categorise the outcome measures[7,95]

The change in pain medication outcome would normally fall under the environmental domain. It has, however, been placed under the impairment domain, as this study was primarily interested in pain management.

In analysing clinical trial data, establishing the statistical significance and confidence intervals of treatment responses is a pivotal step. However, because statistical significance reflects both the magnitude and variability of the treatment effect as well as the sample size, a statistically significant improvement may reflect a benefit that is clinically meaningless.[209] Depending on the outcome, clinical importance can be assessed by patients, clinicians, and representatives of society at large. For chronic pain, most measures of treatment response involve patient reported outcomes (PROs)[211] in which the patient is the most important judge of whether changes are important or meaningful.[209] There are situations, such as when comparing groups within a trial, where it is important to determine what magnitude of changes over time or differences between groups should be considered clinically important.[212] It is important to recognise that criteria for clinically important change in individuals cannot be directly applied to the evaluation of clinically important group differences.[209]

There is no ‘objective’ method for assessing pain and therefore self-report questionnaires provide the gold standard in the assessment of pain and its characteristics.[213]

The choice of appropriate outcome measures should be influenced by the study objectives and design, as well as the properties of the particular measure within the context of CLBP.[214] Williams et al[215] recommend including cut-offs on outcome measures in the inclusion/exclusion criteria so that a more disabled population is recruited and there is room for measuring improvement. Measuring outcomes across multiple domains is essential for an adequate understanding of chronic pain and the effects of interventions to treat pain.[216]

The Chapman et al review[214] recommends, firstly, that when selecting the appropriate outcome measures for clinical or research purposes, domains that best measure what is most important to patients must be considered. Secondly, the review identifies the domains of greatest importance in measuring treatment success for CLBP as pain, function and quality of life.

Table 5 lists the standardised outcome measures used in this study and includes references to the literature to support the reliability, validity and responsiveness of these outcome measures. It is evident from Table 5 that all the outcome measures chosen were valid and reliable tests, and that these measures have been used in LBP studies.

Table 5: The standardised outcome measures including reliability, validity and responsiveness data.

Outcome assessed	Outcome measure	Reliability	Validity	Responsiveness
Pain intensity	BPI	In the BPI User's guide the test-retest reliability for 'worst' pain was reported to be .93 in cancer patients, whereas the 'average' pain was .78.[217] Radbruch et al 1999[218] found the reliability for pain intensity to be .98 in the German version of the BPI in 109 outpatients attending a pain clinic. In 203 patients after total hip replacement, the reliability was .80.[219] The reliability was found to be .89 for pain severity in 120 arthritic patients and 131 LBP patients.[220] The reliability of the BPI in 440 patients with chronic intractable pain was reported to have an ICC of .85 for pain intensity.[221]	The validity of the BPI was tested on a group of 120 arthritic patients and 131 LBP patients and was found to be .77 when tested against the SF-36 pain questionnaire.[220] The BPI was tested on 440 patients with chronic intractable pain. Correlations between the BPI pain intensity and RMDQ was r=.4(P<.01).[221]	The responsiveness of the BPI has been shown in 203 patients with osteoarthritis one year after THR with a minimum value of 1.57 for pain severity.[219]
ROM	FTF	The reliability of the FTF test in 32 patients with LBP was reported to have an ICC=.99.[222]	The FTF was validated on 65 patients with LBP. Correlations between the FTF and RMDQ, r =.63 (P<.001).[223]	The FTF test has been found to be responsive after a functional restoration programme, with the effect size .87.[222]
Function	RMDQ	The reliability of the RMDQ in 77 LBP patients was reported to be r=.81.[224] The reliability in 20 LBP patients was reported as r= .91.[225] The reliability of the Dutch version was tested on 30 patients with LBP, ICC =.91.[226]	The validity of the RMDQ was tested on a group of 153 patients with LBP, r=.87 when tested against the Back Pain Functional Scale.[227] The validity of the RMDQ has been reported in 309 low back injury patients when tested against the SF-12, r= .8 and the SF-36, r=.8.[228] The French version was validated on 58 patients with CLBP and correlated against the Quebec Back Pain Disability Score, r=0.713.[229]	The RMDQ has been found to be responsive when tested on 155 patients with LBP, effect size .8.[230] The RMDQ was responsive in 81 LBP patients. The effect size in the improved group was reported to be 2.02.[231]

Outcome assessed	Outcome measure	Reliability	Validity	Responsiveness
Health-related quality of life	EQ-5D	The reliability has been reported on 82 osteoarthritic patients, ICC=.7.[232] The reliability of the Xhosa version of the EQ-5D was found on 144 general population with the ICC= .66 for the VAS component of the questionnaire.[233]	Validation of the EQ-5D was found in a study on 14 736 general population. The concurrent validity between the EQ-5D and the SF-6D (derived from the SF-36) was r=.7 (p<.001).[234] The concurrent validity found in a sample of 547 US population was r=.55 when the VAS component was measured against the physical component of the SF-12.[235] (Johnson 1997). The validity of the EQ-5D index found in a group of 37 LBP patients was r= .58 and r=.67 and r=.64 when tested against the BPI intensity and interference scores and the Oswestry Disability Index.[236]	The EQ-5D has been found to be responsive to change in 466 RA patients making up the samples of four cohort studies. The effect size ranged between .59 and .34 for the different groups.[237]
	PSE	The reliability has been reported in 348 chronic pain patients, ICC=.9.[238] The reliability has been tested on 145 chronic pain patients, r=.73 (p<0.001).[239] (Nicholas 2007).	PSEQ has been validated in a sample of 105 LBP patients against measures of activity –Self Efficacy Scale.[240] *	PSEQ has been has been found to be responsive in a sample of 145 chronic pain patients over nine months.[241] **

* The r-value is not included in the article

** The effect size is not included in the article

2.5.1 Impairment Outcomes

a) Pain Intensity Numeric Rating Scale (PI-NRS)

The first component of the Brief Pain Inventory questionnaire (BPI) assesses the primary pain symptom, whereas the second component assesses the effect of the pain symptom on functioning.[221] The questionnaire presents the participant with four dimensions of pain intensity, each to be rated on an 11-point linear scale ranging from "no pain" (scored as 0) to "pain as bad as you can imagine" (scored as 10). These dimensions assess the worst, the least and the average pain experienced over the previous 24 hours, along with the current level of pain, in that order. The scores on these four dimensions are totalled or averaged to provide a mean pain intensity score.[236] The first component was the only one used in this study, given that function was assessed using the RMDQ. The validity, reliability and responsiveness of the BPI is shown in Table 5.

The recent review by Chapman et al[214] identified eleven outcome measures used in CLBP studies. The five most common measures to assess pain were the PI-NRS, BPI, Pain Disability Index (PDI), McGill Pain Questionnaire (MPQ) and the Visual Analogue Scale (VAS). Among these, only the BPI has been validated in a Clow back pain population. In addition, the PI-NRS and VAS have been found to be responsive in the treatment of CLBP. There are no studies establishing the validity of PI-NRS and VAS, although they are often considered the 'gold standard' for pain.[214]

A PI-NRS like that used in the first component of the BPI is a measure of perceived pain intensity, as answered by the participant on a particular day, to compare the outcome of an intervention. Childs et al[10] looked at the responsiveness of the PI-NRS specifically in patients with LBP and found that the majority of patients had clinically meaningful improvement after both 1 and 4 weeks of rehabilitation. The authors suggest that clinicians can be confident that a 2-point change on the PI-NRS represents a clinically meaningful change.[10,242] The Chapman et al review[214] recommends using both the VAS and the PI-NRS to measure pain because of their ease of administration and responsiveness. Both these pain measures were accordingly used in the current study for these reasons.

Pengel et al[230] conducted a cohort study of 155 participants with LBP to determine the responsiveness of pain, disability and physical impairment outcomes. The findings from their study suggest that more emphasis should be placed on changes in pain and disability scores than on changes in physical impairments.

b) Change in medication

Medication use is common amongst back pain sufferers. Nonetheless, medication use is a complicated outcome measure and thus not recommended unless the specific study question is focused on this domain.[214] The current study included medication use as an outcome, as the study was primarily interested in measuring pain and the effects of the intervention on the participants' pain levels.

In a study by Sherman et al,[243] comparing yoga, exercise and a self-care book for NSCLBP, the use of medication was a secondary outcome measure. Medication use, which was similar among groups at baseline, decreased most sharply in the yoga group. Only 21% of participants in the yoga group reported medication use during the week before the follow-up measurements at the 26-week interview, compared with 50% in the exercise group and 59% in the group that had used the self-care book.

Williams et al[215] similarly reported a change in medication use from baseline to the end of their 16-week intervention, and the three month follow-up as a percentage change, as was found in the Sherman[243] study. Upon completion of the 16-week intervention, 88% of the participants in the yoga group reported that they had decreased or even stopped their medication compared to 35% in the control group. At the three-month follow-up, both groups reported further decreases in pain medication usage, but the yoga group continued to report significantly greater reductions than the control group.[215]

In a study by Brinkhaus et al,[244] looking at the effects of acupuncture on NSCLBP, the authors asked the participants of the study to record in a diary the number of days on which they had experienced pain and the days on which they had taken pain medication, during an eight-week intervention. Analgesic medication use was documented at the baseline assessment. Kendrick et al,[245] in contrast, looked at the role of radiography in primary care patients with LBP of at least six weeks duration and found no change in medication use between a group of patients who received lumbar spine radiography and usual care (consisting of attendance at primary and secondary care facilities, physical therapies or complimentary therapies), versus usual care without radiography.

For a range of commonly used back pain outcome measures, a 30% change from baseline has been suggested to represent a clinically meaningful improvement when comparing before and after measures for individual patients.[242]

c) Fingertip-to-floor test

Improvement in the flexibility of the spine and the hips is the goal of many programmes of exercise therapy in musculoskeletal conditions like CLBP.[222] The FTF test is an inexpensive, safe, quick and easy test to measure the mobility of both the whole spine and the pelvis in the overall motion of bending forward. Perret et al[222] concluded, after doing an experimental, correlational study, that the FTF test has excellent validity, reliability and responsiveness, and that it can be used in clinical practice and therapeutic trials Table 5. Specifically, Perret et al[222] found that, after a functional restoration programme including many daily exercises for flexibility, the FTF test has very good sensitivity to change, higher than that of the Schöber test. This test, in contrast, measures lumbar flexion. This test is performed with the subject standing erect; marks are made on the skin at the lumbar-sacral junction and 10 centimetres above the first mark.[238] The subject is asked to bend forward and the distance between the first and second mark is measured. The most common functional outcome measures cited in the literature for evaluating the effectiveness of treatment for CLBP are the Oswestry Disability Index ODI, RMDQ and ROM.[214] The FTF would be considered a physical test of ROM of the spine and pelvis.

The validity over time of the FTF test and the straight leg raise test (SLR) was investigated by Ekedahl et al.[223] The authors found the FTF test to have good validity in patients with acute/sub-acute LBP, and especially in those with radicular pain. The change in FTF over the first month was a valid predictor of the change in self-reported disability over one year.[223] This finding differs from earlier research, which found that the flexibility of the spine of patients with LBP did not correlate with disability.[246]

2.5.2 Functional Outcomes

a) The Roland Morris Disability Questionnaire (RMDQ)

Developed by Roland Morris (1983),[225] the RMDQ is a condition-specific functional status measure. The RMDQ is a self-report questionnaire developed from the Sickness Impact Profile to cover a range of routine functional activities, which may be affected secondary to LBP.[225] Its ease of use makes it suitable for following up on the progress of individual patients in clinical settings and for combining with other measures of function (e.g. psychological or work disability) in research settings.[247] In a recent systematic review by Chapman et al,[214] eighteen functional outcome measures were identified in CLBP studies. One of the most commonly cited measures, along with the ODQ, was the RMDQ. Both

measures have been validated, tested successfully for reliability, and found to be responsive in a CLBP population. Table 5 shows the reliability, validity and the responsiveness of the RMDQ.

A study comparing the ability of different tests to detect clinically important changes in function from the patient's perspective in a LBP population concluded that the RMDQ is the preferred measurement instrument[248] compared to the ODQ in terms of its accuracy in responses found when measuring function over time.[248] The RMDQ is more responsive for LBP patients with no leg pain, however, than in patients with leg pain.[249] Further, the RMDQ was shown to be sensitive to changes over a 4 to 6 week time period[8] and the most sensitive to changes over a 3 to 6 month time span when compared to similar measures.[9,249,250]

The magnitude of detectable change (MDC) is associated with measurement error and represents the minimum amount of change required between two scores to indicate whether a true change has taken place. Investigators report that the MDC necessary at the 90% confidence interval level is 4-5 RMDQ points,[8] for scores falling across the entire range of the scale.[9] MDC appears to depend on the value of the RMDQ scores being compared. However, the MDC does not address whether the change is an important functional change for the subject. The minimal clinically important difference (MCID) is defined as an estimate of the minimal change score, which is indicative of a change in function that is important to the patient.[11] Binkley[11] reports a MCID of 5 RMDQ points for initial scores falling across the 24-point scale and this appears to be a sensitive estimate of change in a population of subjects, whose initial RMDQ scores fall close to the mid-range.[251] Investigators recognize that the amount of change reflecting a clinically important change may differ for subjects whose initial scores fall at the extremes of the scale.[9] To maximize sensitivity and specificity to change at the extremes of the scale, different estimates of MCID have been reported. Stratford et al,[251] for instance, identified a MCID of 1-2 RMDQ points for individual subjects with initial RMDQ scores falling between 0 and 8, and a MCID of 7-8 RMDQ points for initial RMDQ scores falling between 17 and 24.[9] These scores were determined in acute and sub-acute LPB populations and it is unclear if similar estimates of MDC or MCID would apply in chronic LBP populations. Others found the minimum clinically worthwhile effect to be 2.5-5 RMDQ points, which has been derived from people who have had NSLBP for at least six weeks.[231]

Given these estimates of the MDC and the MCID, which could show a meaningful change,[49] a minimum score of 4 RMDQ points at baseline was required in the current study, in order for the participants to be included.

There are numerous disability questionnaires that could be used to measure function in LBP studies. Fritz et al[252] compared the modified ODQ to the Quebec Back Pain Disability Scale (QUE). The modified ODQ showed higher levels of test-retest reliability and responsiveness than the QUE. The MCID, defined as the amount of change that best distinguishes between patients who have improved and those who are remaining stable, was approximately 6 points for the modified ODQ and approximately 15 points for the QUE. Although there are other disability questionnaires that are reliable and responsive, Chapman et al[214] recommend using the ODQ and RMDQ to measure function in CLBP.

2.5.3 Participation Outcomes

a) EQ-5D Health Questionnaire

One of the most widely used measures of health related quality of life (HRQoL) is the EQ-5D.[253] The EQ-5D is a standardized measure of health status developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal (EuroQol Group 1990). The EuroQol Group is a network of international multidisciplinary researchers devoted to the measurement of health status, who have been meeting annually since its inception in 1987. Although there are many HRQoL instruments, such as the SF-36,[254] the EQ-5D is a short instrument, making it suitable to use together with other self-report outcomes. The EQ-5D questionnaire[255] comprises two elements: a health state classification and a visual analogue scale (VAS). The health index includes a description of the respondent's own health with regard to five domains of function: mobility, self-care, usual activities (work, study, housework, family or leisure), pain/discomfort and anxiety/depression. Each dimension is sub-divided into three categories, indicating no problem, a moderate problem or an extreme problem.[255] Any health state can be converted to a single summary "index score" by using sets of utility values derived from samples of the population. The health index scores of individuals of various populations have demonstrated that the majority of problems were reported in the pain/discomfort domain, whereas the fewest problems were reported with self-care.[235] The extremes of the VAS are the "worst imaginable" and "best imaginable" health states, represented as the scale end points of 0 and 100, respectively. The VAS records the individual subject's self-evaluated health, whereas

the index score, being derived from population weights, can be regarded as the social valuation of a health state.[236]

The validity and reliability of the EQ-5D have been found acceptable in Europe among different populations and patient groups (Table 5).[256,257] The EQ-5D health measure has been translated into different African languages,[258] and the reliability and validity of these has also been proven.[233] The EQ-5D is available in many language versions, which seems to make it suitable for studies done among both high and low income populations.[259]

Whynes et al[236] compared the responsiveness of the EQ-5D health related quality of life instrument in assessing LBP and found the EQ-5D index to be less responsive than instruments specific to pain measurement, namely the BPI and the ODQ. However, the EQ-5D is capable of indicating clinically important changes in patients with LBP.[236] An explanation of this might be that the EQ-5D instrument assesses five types of health problems, one of which is pain, whereas the BPI only assesses pain. The pairings of the EQ-5D with the BPI or a disability questionnaire like the RMDQ have been advocated for some time,[260] and they have appeared together in earlier LBP studies.[214]

b) Pain Self-Efficacy (PSE)

The pain self-efficacy questionnaire (PSEQ), developed by Nicholas[261] in 1989, consists of 10 questions about the patient's confidence in carrying out various normal activities despite the pain. There are seven response options, ranging from 0 (not at all confident) to 6 (very confident). All 10 questions include mention of performing the activities despite their pain (e.g. "I can gradually increase my activity level, despite the pain"). The total score ranges from 0 to 60 points with higher scores indicating higher perceived pain self-efficacy beliefs. The PSEQ has been used in a number of different clinical settings and in different countries.[239] The questionnaire has also been included in a battery of scales for use with a sample of CLBP patients selected for a randomized trial of cognitive-behavioural pain management.[154] The PSEQ has been tested for reliability, validity and responsiveness (see Table 5).

Bandura[262] proposed that "efficacy expectations determine how much effort people will expend and how long they will persist in the face of obstacles and aversive experiences". In the study of pain, efficacy expectations (or 'self-efficacy' beliefs) have been used to explain a range of behaviours and aspects of pain experience.[239] Self-efficacy is a personal belief about how successfully one can cope with difficult situations. Nicholas[239] looked at the importance

of taking the context of pain into account in the assessment of self-efficacy beliefs in pain populations. The author suggests that including the questions on the person's confidence to perform a particular task despite their pain is useful in helping to improve the assessment of people experiencing chronic pain, before and after treatment.[239]

2.5.4 Personal Outcomes

a) Adherence

Physiotherapy is primarily concerned with the rehabilitation of people following injury. It has been estimated that physiotherapists in Australia spend 40% of their professional time treating patients with LBP.[263] Given the increasing prevalence of LBP and the high chances of suffering from back pain, as well as the fact that recurrence of LBP is estimated to be as high as 85%,[264] establishing the efficacy and benefits of treatment is paramount. The efficacy of therapeutic exercise can only be established when patients comply with the exercise regimen being studied.[194] The development of methods for improving patient's compliance requires insight into factors that are related to non-compliance in physical therapy.[194]

Given the incidence of recurrent LBP, investing in convenient, accessible routine exercise could help to incorporate the management of LBP into a patient's everyday life.

b) Patient satisfaction

Patient satisfaction is an important outcomes issue, especially among managed care companies and with regard to quality control assessment.[265] These instruments yield important information about the quality of the health care service as perceived by the patient. A patient's perceptions of the quality of care delivered to them can be assessed by the following: acceptance of care; perception of the technical competency of the health care provider; perceptions of the setting where the care was provided; and perception of the effectiveness of the health care provider.[57]

There is no universal gold standard for measuring patient satisfaction[266] and it has been suggested that a useful questionnaire should therefore explore satisfaction across multiple domains and take the clinical condition of the patients into account. The questionnaire for the current study thus included appropriate questions that related to: the cost of the intervention (if they had been charged); the facility; the knowledge of the therapist; accessibility and convenience; availability of therapist; overall benefit from attending; enjoyment of the exercise; the helpfulness and quality of the exercise instruction sheets; the information about

back care provided; and the exercise instruction and advice received to improve the participant's back condition. This same questionnaire formed the basis for research to analyse patient satisfaction with the 'Better Backs @ Austin Programme' at the Austin teaching hospital, a clinical school of the University of Melbourne, Australia.[205] A satisfaction measure must be viewed in the context in which it will be used,[57] and the Better Backs @ Austin Programme is similar to the exercise approaches used in this study and the annotated exercises for the home programme were sourced from the Austin Hospital.

An evidenced-based booklet on back care was handed to each participant at the beginning of the programme.[267] This booklet linked in with one of the questions of the Better Backs Satisfaction Questionnaire (namely, information about back care). There is strong evidence in the literature that receiving a booklet with relevant information increases patients' knowledge of their condition[147] and in turn this information, based on a bio-psycho-social model, is also recommended in primary care to shift patients' beliefs on LBP.[268] Patient expectations can be determined before undergoing an intervention; in this regard, Kalauokalani et al[207] found that patients' expectations may influence clinical outcome independently of the treatment itself.

Patients reporting high levels of satisfaction with care are more likely to be compliant with recommended treatment plans (like exercise interventions) and this may have particular relevance to the management of NSCLBP.[60] Engagement and participation have been found to be key ingredients in successful exercise programmes[269] and patients with NSCLBP prefer participating in an exercise programme that has been designed with consideration of their preferences.[12] Evidence-based medicine includes patient preferences as an important component of the model, the other two components being the clinical expertise of the therapist and research evidence.[270-272] A recent systematic review of patient satisfaction with musculoskeletal physical therapy reported that the inter-personal attributes of the therapist and the process of care are key determinants of patient satisfaction.[270]

The association between a good patient-practitioner relationship on the one hand and patient satisfaction and adherence on the other hand is well documented.[273] For patients with NSCLBP, the patient-therapist relationship is particularly relevant, as longer treatment times can be expected due to chronicity.[274] Farin et al[273] looked at a sample of 668 LBP patients and examined the association between aspects of the patient-practitioner relationship (e.g. satisfaction with care, trust in the practitioner, patient participation) with outcomes (disability, pain, quality of life and pain-related psychological impairment). The results of

this study show that the patient-practitioner relationship is significantly associated with the outcomes.

The significance of patient satisfaction is emphasized by evidence that a patient who is more satisfied with care will be more likely to adhere to treatment, benefit from their health care and lead a higher health-related quality of life.[270]

2.6 Conclusion

Based on the findings of this literature review, it appears that LBP is a common problem, with a higher prevalence among middle-aged women. NSCLBP affects a large proportion of the LBP population. Different strategies for managing LBP have been proposed, one of them being therapeutic exercise. Evidence exists that exercise is effective, but the precise form of exercise that is the most effective for this specific sub-group of back pain sufferers has not been determined. However, Pilates is a popular form of exercise that incorporates stretching and strengthening components, and thus has been found to be effective for LBP management.

The current study recruited women with NSCLBP to participate in an intervention of either supervised or non-supervised Pilates mat exercises. There are proposed advantages and disadvantages of both group classes and home programmes. Therapeutic exercise, which includes stretching and strengthening exercises, has been recommended for the treatment of this sub-group of back pain patients. The interventions used similar exercises to make comparison easier. The RMDQ, PI-NRS, PSEQ, EQ-5D and FTF outcomes measures were chosen, as they are easy to administer, and as they cover the five domains recommended to be tested in LBP studies. Patient satisfaction and adherence to the programmes were also measured, as these are important outcomes when assessing treatment effectiveness.

3. Methodology

This chapter will describe the methods followed in the study, starting with the recruitment of the participants, the instrumentation used, the conduction of the reliability and the feasibility studies, the study procedure followed, the statistical analysis performed and finally discussing the ethical issues, which needed to be considered.

3.1 Research Design

This was a randomised, true experimental study, with single blinding. Single blinding was ensured because the outcome assessor was 'blinded' to the participant group during the study. The outcome assessor administered all the tests, whereas an experienced Pilates instructor taught the Pilates classes, and an experienced physiotherapist taught the home exercises. The participants were randomly allocated to one of the two interventions for eight weeks. The supervised exercise group (SEG) participated in a Pilates mat programme, whereas the non-supervised home exercise group (HEG) participated in a similar home exercise programme.

3.2 Null Hypothesis

The following hypotheses were tested:

1. There will be no difference in pain or disability outcomes between the SEG and the HEG.
2. There will be no difference in the ranking of the function scores, as measured by the RMDQ, over different time points.
3. There will be no improvement in pain or disability outcomes from baseline to eight weeks after the start of intervention.

3.3 Participants

3.3.1 Recruitment

Thirty-eight participants with NSCLBP (first episode or recurrent), of which the current episode had lasted for more than six weeks, were recruited from local physiotherapy, chiropractic, osteopathy, and medical practices in the Cape Metropolis (Appendix A). The online social network Facebook was also used to advertise for volunteers. Advertisements included information about the study, such as eligibility for participation, location and

procedure, and such advertisements emphasized that participation was purely on a voluntary basis with no financial remuneration. Eligible participants were required to sign an informed consent document (Appendix B).

3.3.2 Sample Size Determination

Data from a previous study that had measured functional disability by means of the RMDQ[164] was used to ensure that the sample size would provide sufficient statistical power. The criterion of functional disability was selected to determine the required sample size, as this would be one of the main outcome measures for this study. The sample size for functional disability was calculated using a smallest meaningful difference of 1 point on the RMDQ, and a standard deviation of 0.5. With statistical significance accepted as $p < 0.05$, it was determined that two groups of nine, 12, and 14 participants would provide 80%, 90% and 95% statistical power for functional disability respectively. Consequently, a slightly larger number of 38 participants were recruited for this study, thus ensuring that there would still be sufficient statistical power, should some be unable to complete the study.

3.3.3 Inclusion and Exclusion Criteria

a) Inclusion criteria

Women often suffer from LBP and form a large group of NSCLBP patients. Participants were thus eligible for the study if they were females between 20 and 55 years, who had experienced LBP for longer than six weeks at the time of recruitment, and whose LBP had been categorized as NSCLBP.[73] Such pain had to originate from the back, more specifically in an area bounded by the 12th thoracic vertebra and the 12th ribs superiorly, the gluteal folds inferiorly and the contours of the trunk laterally.[62,275] Alternatively, it had to be recurring LBP of sufficient intensity to restrict functional activity in some manner. Participants were screened telephonically and required to obtain a score of 'moderate' or 'greater' on the questions relating to 'pain/discomfort' and answer that they had 'some problems' or were 'unable to perform' their 'usual activities' in the EQ-5D; adapted from Macedo et al's[40] study. Alternatively, they had to score 4 or more on the RMDQ. Any form of back treatment, whether with a therapist registered with the Health Professionals Council of South Africa (HPCSA) or the Allied Health Professionals Council of South Africa (AHPCSA), must have been completed two weeks prior to participating in the study, and their back assessment (Appendix C) had to confirm that they were not experiencing a new episode with acute symptoms at the onset of the study.

b) Exclusion criteria

All participants were screened to identify those who might be unsuitable for exercise management of their LBP; the screening was done by means of a Back Screening Questionnaire (Appendix C) and the Patient Activity Readiness Questionnaire (PAR-Q)[1] (Appendix D). If exercise management was unsuitable, the participant was referred on to a medical practitioner or therapist of their choice for further management. Participants were excluded from the study if they presented with one or more of the following: known or suspected serious spinal pathology; previous spinal surgery; signs and symptoms of a recent episode of acute disc pathology, with or without leg pain; leg pain with evidence of nerve root compromise; rheumatic or metabolic disease; a co-morbid health condition preventing active participation in an exercise programme; pregnancy; inability to understand spoken English; inability to commit to an eight-week intervention programme or previous participation in a Pilates programme or participation in other regular therapeutic back exercise programme in the last three months.

3.3.4 Sampling Method – Randomisation and Allocation

An independent auditor produced a computer generated sequence to allocate the participants randomly to either the SEG or HEG. Each participant was allocated a code number that would link all their personal information with the data obtained. This number was not disclosed to the outcome assessor until all the data analyses had been completed. The independent auditor was responsible for compiling a list of participants' details and the group to which they had been allocated. Given the nature of the study, it was not possible for the exercise instructors or the participants to be blinded to the interventions.

3.4 Instrumentation

3.4.1 Screening Tools

a) Back Screening Questionnaire

This questionnaire screened participants for neural compromise and/or serious spinal pathology using the diagnostic triage (Appendix C).[13] The questionnaire consisted of a subjective and an objective assessment.[276]

b) Participant Activity Readiness Questionnaire (PAR-Q)

The PAR-Q screens participants for contraindications to exercise as listed in the ACSM guidelines for exercise[1] (Appendix D).

3.4.2 Outcome Measurement

The outcomes were measured at baseline, four weeks, eight weeks and 12 weeks.

a) Impairment outcomes

Pain Intensity Numeric Rating Scale (PI-NRS) from the Brief Pain Inventory (BPI)

Severity of the back pain before, during and after the exercise programme was measured using the PI-NRS from the BPI (Appendix E). Participants were asked to rate their pain "at its worst", "at its least", "average", "right now" on a scale from 0-10 (with 0 being no pain and 10 being the most pain). The mean of these scores was calculated to be the pain severity score. The BPI was first validated in patients with cancer pain, but its validity has now been demonstrated in multiple types of chronic non-cancer pain.[277, 220] The PI-NRS has been found to be responsive in measurements for LBP.[278]

Pain medication usage

At the initial screening assessment, and before starting the Pilates intervention, participants were asked whether they were currently taking any pain relieving medication, and, if so, whether this was prescription or non-prescription medication. Throughout the programme, participants were asked to record all pain medication use in their logbooks (Appendix F and Appendix G). Changes from the baseline consumption of medication were evaluated at eight weeks and at 12 weeks.

Fingertip-to-floor (FTF) Test

The FTF test was used to evaluate the mobility of both the spine and the pelvis in the overall motion of bending forward. The participants were asked to stand erect on the hard floor with shoes removed and feet together. They were then asked to bend forward as far as possible, with the knees straight, and the arms and fingers fully extended. The vertical distance between the tip of the middle finger and the floor was measured with a supple tape measure and expressed in centimetres (Figure 2). The FTF test has been shown to be valid, reliable and responsive in CLBP.[222]

Figure 2: Fingertip-to-floor test

b) Functional outcomes

The Roland Morris Disability Questionnaire (RMDQ)

The RMDQ, developed by Roland Morris[241] in 1983 (Appendix H), is a reliable, sensitive and condition-specific measure of disability in LBP.[247] It consists of twenty-four statements, each of which refers to a particular limitation that people have experienced as a result of back pain, e.g. walking, bending over, and dressing. Participants answer yes or no to each statement, depending on whether it is relevant that day. Each positive answer is worth one point, and all positive answers are tallied up at the end; total scores range from 0 (no disability) to 24 (severely disabled). Stratford[213] suggests that the minimum clinically important change in scores is 1-2 points for patients with little disability, whereas Roland recommends that a change in 2-3 points on the RMDQ should be considered the minimum clinically important change.[51] Given estimates of the MDC and the MCID, and the fact that these could show a meaningful change as a result of the intervention,[49] it was decided that a minimum score of four RMDQ points at baseline would be required in the current study, in order for the participants to be included in the programme.

c) Participation outcomes

Health Questionnaire (EQ-5D)

Health status was measured using the EQ-5D Health Related Quality of Life Questionnaire (Appendix I), which is reliable and valid for CLBP.[213] Participants were asked to answer whether they experienced none, some or extreme problems in the domains of mobility, self-care, usual activities, pain/discomfort and anxiety and depression and normal daily activities. An index score was calculated using the York A1 scoring chart that converts the sequence of

scores in the five dimensions of the EQ-5D questionnaire into a single score. (e. g. a full health score on the chart would be 1.1.1.1.1= 1).[255,279] The York A1 tariff set has been derived from a survey of the UK population (*n* = 3337), which used the time trade-off valuation method to estimate preference weights for a subset of 45 EQ-5D health states.[280] The EQ-5D also includes a visual analogue scale (VAS) which is rated from 0-Worst imaginable health to 100-Best imaginable health.

Pain Self-Efficacy Questionnaire (PSEQ)

The participants' confidence in coping with and managing their back pain problem was measured using the PSEQ (Appendix J). Participants were asked to rate how confident they felt about performing ten listed activities by selecting a number from 0 ("not at all confident") to 6 ("completely confident"). Total scores may range from 0 to 60, with higher scores indicating stronger self-efficacy beliefs. This questionnaire was developed by Nicholas,[239]and it has been shown to be reliable and valid for CLBP.[239]

d) Personal outcomes

Adherence

SEG participants were asked to record the number of classes attended in a logbook (Appendix F). Similarly, HEG participants also completed a daily logbook (Appendix G), indicating whether they had done, or had not done, or had partially done the exercises, and if the latter, for how long (in minutes). All participants were also asked to record their LBP on a PI-NRS (Appendix K) before and after each exercise session and to rate their perceived exertion (RPE) after each exercise session[281] (Appendix L). The RPE was not an outcome measure, but it was used to assess how the participants were coping with the exercise intensity. They were also asked to record any co-interventions or treatments received, any new exercise they had done, and any pain medication taken during the eight-week intervention and during the study (12 weeks). The participants handed the logbook in at the last testing session at 12 weeks.

Participant satisfaction

The participants' satisfaction with the exercise programme was measured by means of a questionnaire adapted from the Austin Hospital Patient Satisfaction Questionnaire, which had been developed as part of an evidence-based back rehabilitation programme (Better Backs@ Austin, Austin Hospital, Melbourne, Australia).[205] This questionnaire (Appendix M) was

completed immediately after the eight-week intervention. The patient satisfaction questionnaire included a question on cost. There was no cost involved in the study, but the question was nonetheless included, as one would normally pay for supervised classes. This gave us more information about the affordability of the supervised programme

e) Open-ended questions

At the completion of the study, the participants were asked to make open-ended comments on their experience of the intervention. These comments have been included at the end of the results section.

3.4.3 Interventions

a) Supervised Exercise Programme

The SEG received instructions for a Pilates mat exercise regime formulated from the Body Control Pilates Education Basic and Intermediate Matwork Manuals 2009[282,283] (Appendix N). The programme was designed to challenge the participants progressively. Fourteen exercises from SPINE (Specific Prescription INcorporating Evidence p< 0.001® PILATES) exercise sheets used in the Austin Hospital 'Better Backs @Austin' Programme[127] were included in this Pilates mat programme (Appendix O). The numbers of repetitions of these exercises was increased at weeks three and six within the classes, as would be typical in a Pilates class. Each participant was expected to attend these classes twice a week for a forty-five minute class, over an eight-week period. They were allowed to continue participating in any exercise regimen that they were already involved in before joining this study, but not if it was a specific back programme; and were discouraged from starting any new exercise during the study. The design of the mat programme, with its warm-ups and gradual progressions enabled a participant to safely pick up with exercises again in the next session if missing a class could not be avoided. The classes and the preceding individual session that prepared the participant for these classes were taught by two experienced Pilates instructors. These two instructors familiarised themselves with the Pilates mat regimen taught over the eight weeks, during two two-hourly workshops. These same instructors were briefed to look out for any new flare-up of symptoms experienced by a participant; when this happened, they had to stop the exercise immediately and refer the participant to the principal investigator, a physiotherapist, for further management.

b) Home Exercise Programme

The HEG received a home exercise programme that included the same fourteen exercises from SPINE,[127] which were included in the Pilates mat regimen. These exercises include mobility and low spinal load endurance type strengthening exercises.[57] Each participant was instructed to complete the exercises three times a week for thirty minutes over an eight-week period. The duration of Pilates exercise completed by both the SEG and the HEG equated to ninety minutes per week. They were given the 'Better Backs @ Austin' laminated information sheets, which included pictures and a short descriptions of the exercises (Appendix O). The number of repetitions was progressively increased at week three and week six. Ten repetitions made up a set, and the exercises were progressed by sets.[284] A hand-out of the exercise progressions was given to the participants before starting the home programme (Appendix P). Recommendations for the frequency, intensity, time (duration) and type of exercises were based on the FITT principle.[5] Each participant received an email from the independent auditor at the end of week two, reminding them to increase the repetitions from week three onwards, and again at the end of week five, reminding them to increase the repetitions from week six onwards. The participants were allowed to continue doing any exercises that they were already doing before joining this study, but were discouraged from starting any new exercise regimen during the study. The home exercises were taught by an experienced physiotherapist. Any new flare-up of symptoms during the period of the study needed to be reported to the principal investigator, the exercises stopped if necessary and treatment with either the physiotherapist or an appropriate medical practitioner of their choice encouraged, before further participation was allowed. Adherence to the home exercises was self-monitored using a logbook.[40]

The SPINE exercises included in both the SEG and the HEG have been validated in a South African population, in a previous study.[57] The Pilates mat exercises used in the classes have been taken from the Body Control Pilates Matwork Manuals.[282,283]

3.5 Procedure

Before embarking on the current study, ethical approval was granted by the Human Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town.

A Pilot study was conducted; this included a reliability study and a feasibility study. Reliability refers to how consistent a measurement is. A measurement is said to be reliable or consistent, if the measurement can produce similar results when used again in similar

circumstances. A common way of assessing the reliability of observations is to use inter-rater reliability.[285] This involves comparing the ratings of two or more observers and checking for agreement in their measurements.

In the current study, the anthropometric measurements and the FTF measurements were tested, and both the inter-rater and intra-rater reliability was established for these measurements. Thereafter, a feasibility study was done in preparation for the final study; this included a small-scale version, or trial run, of the major study.[286]

Based on the findings of the pilot study, changes were made to the measurement instruments and the implementation of the intervention, as well as to the exercises in the programme.

3.5.1 Reliability Study

The reliability study was done before the final study, to test the accuracy of taking the skin-fold measurements and to test the accuracy of taking the FTF measurements. The two observers were the investigator and a biokineticist with 10 years' experience in taking skin-fold measurements and FTF measurements for flexibility studies. Four participants were examined by both observers on two occasions on day one, day two and day four, thus giving a total of 12 pairs of measurements (Table 6). Four females were measured. A time gap of an hour was allowed between the first observer taking the skin-fold measurements and the second observer taking the same measurements, to allow for the skin to return to its normal, resting position.

Table 6: Participants in the anthropometric reliability study (n=4)

Number	Gender	Age
1	female	26
2	female	28
3	female	38
4	female	40

The intra-class correlation (ICC) for absolute agreement between the two observers was high ($r=.912$, $p<.001$). The intra-rater reliability was determined by measuring the four participants on two days with one day in between. The ICC for absolute agreement was ($r=.995$, $p<.001$) (Figure 3).

These results indicate that there was a high intra- and inter-rater reliability for taking the skin-fold measurements. There were eight measurements taken on four participants. The percentage body fat measurements, calculated from the skin-fold measurements, were plotted on the scatterplot (Figure 3).

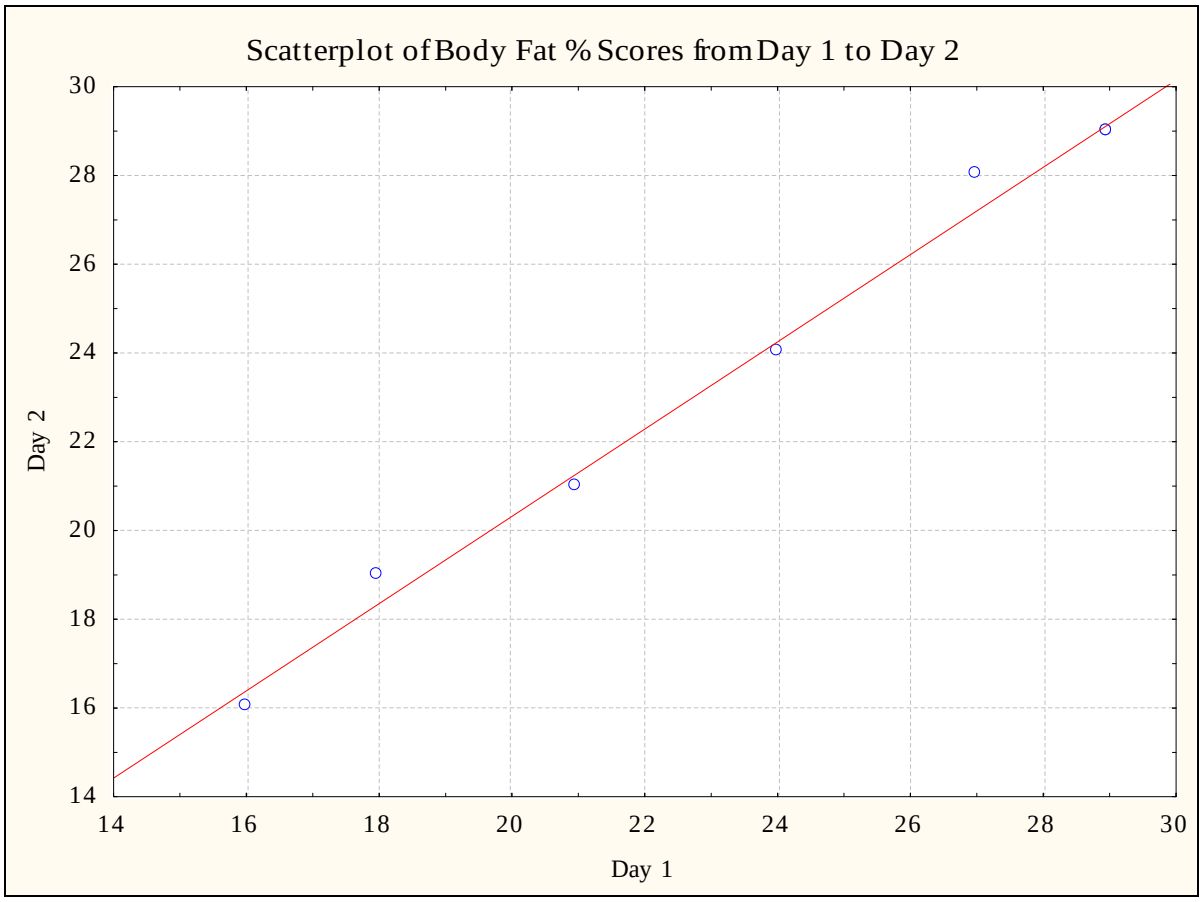


Figure 3: Relationship between body fat % and time (n=4)

Two of the original participants from the anthropometric reliability study were able to touch the floor in the FTF test (Table 7) and consequently an additional two participants were recruited. The FTF measurements were taken on Day 1 and Day 2 by both the investigator and the biokineticist. Only one measurement was taken by each observer on both days.

Table 7: Participants in the FTF reliability study (n=4)

Number	Gender	Age	Back pain (VAS)
1	female	26	7/10
2	female	28	1/10
3	female	32	5/10
4	female	41	1/10

The inter-rater reliability of the FTF test was (rho=. 987, p<.001) and between Day 1 and Day 2 (r=.869 p=.002). It was thus concluded that the anthropometric measures and FTF measures were reliable.

3.5.2 Feasibility Study

Four participants (Table 8) were recruited for the eight-week pilot study. Two of the participants took part in the supervised programme, while the other two participated in the home programme. The back-screening questionnaire was used by the investigator to assess the participants before allocating them into either the SEG or the HEG. The screening questions from the EQ-5D were included, i.e. how their LBP affected their 'usual activities', and what their 'pain/discomfort' levels were.

The feasibility study replicated the main study programme in that the individual sessions, the classes and the testing sessions were held at the Centre; the same venue that all the participants would be assessed and taught the exercises. Having a trial run of the intervention programme with fewer participants enabled the investigator to determine if the intervention was practical and feasible, and how long it would take for the study participants to complete the self-report questionnaires. The duration and the intensity of the classes, as well as the fourteen home exercises were instructed in the same way that they would be taught to the participants in the main study.

Table 8: Participants in the feasibility study (n=4)

Number	Gender	Age	Back pain
1	female	26	7/10
2	female	40	9/10
3	female	41	2/10
4	female	45	4/10

3.5.3 Changes to the Measurement Instrument

From the pilot study, it emerged that the outcome measures worked well, as did the supervised exercise classes, but the home intervention was found to be too strenuous. The exercise repetitions given to the HEG at the start of the programme were thus decreased from the original 10 to five repetitions, based on the feedback from the participants. The frequency of the home-based exercises was also decreased from four times a week to three times a week.[40] In addition, the following change was made to the home-based exercises: The participants were asked to lie on a half-inflated ball, which was placed between the shoulder blades, to help release tight muscles in the mid-back and inter-scapular region, before starting the warm-up.

All four participants (two in the SEG and two in the HEG), completed the eight-week Pilates programmes and showed improvements in pain and function measurements from baseline, at four weeks and at eight weeks.

There were no other problems detected, and the project was accordingly started as per the protocol.

3.5.4 Study Procedure

The participants for the study were made up of a combination of volunteers who had responded to the recruitment advert. The volunteers had previously attended physiotherapy at the Centre, responded to the Facebook advert, or had been referred by medical practitioners who treat LBP. The principal investigator screened the volunteers telephonically and if they met the inclusion criteria, they were invited to attend a familiarisation session at the Centre, a multi-disciplinary centre in Vredehoek, Cape Town. The volunteers were also sent the consent form to read before attending the familiarisation session. During this session, all participants attended a standard briefing regarding testing procedures and the intervention

programmes, and they received a hand-out of the study programme (Figure 4). The programme outlined the timeframe of the testing procedure and the timing of the individual sessions and baseline tests at baseline, four, eight and 12 weeks. A consent form was signed and body composition measurements, a PAR-Q and a Back Screening Questionnaire (which includes a subjective and objective assessment) were completed. An independent auditor generated a random sequence on the computer and used this to allocate the participants to the SEG or the HEG. The individual sessions with either the Pilates instructor or the physiotherapist were booked by the auditor. The SEG attended one individual session and the HEG two individual sessions at the Centre one week prior to starting the exercise programmes. The timeline of the study is summarised in Figure 4:

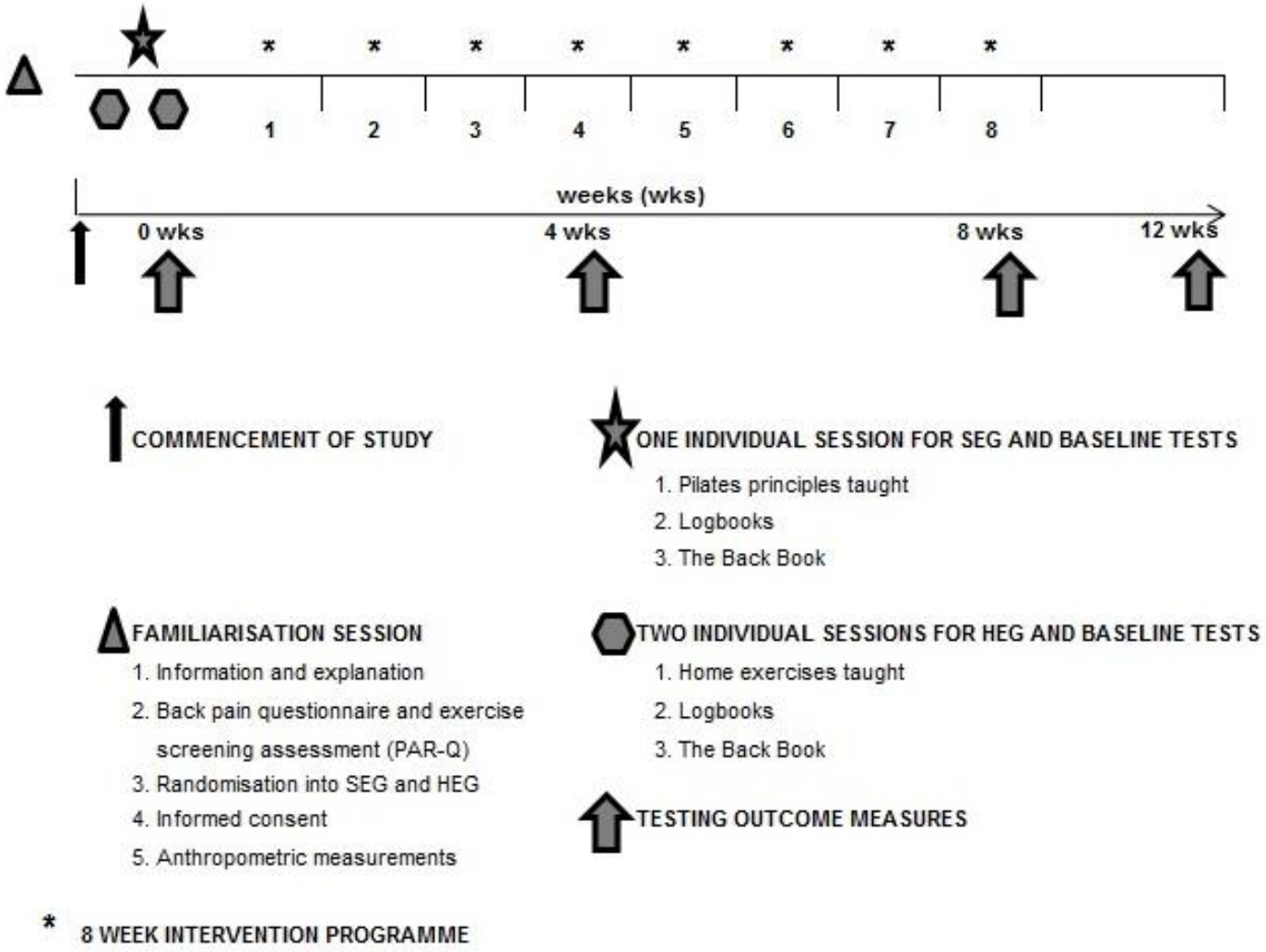


Figure 4: Schematic presentation of the study's timeline

a) Familiarisation session

Informed Consent

All participants signed the informed consent form prior to their involvement in the research study (Appendix B). Questions relating to the study were directed to the primary investigator.

Participant Activity Readiness Questionnaire

To screen for contraindications to exercise, each participant completed a PAR-Q, as listed in the ACSM guidelines for exercise[1] (Appendix D).

Back Screening Questionnaire

Participants completed a questionnaire to obtain demographic and back pain data (which included their current medication), and to screen for neural compromise and/or serious spinal pathology (Appendix C).

Outcome Measures

Self-report questionnaires were completed to determine baseline measurements and the FTF test was demonstrated and measurements taken (Figure 2). Participation in any other exercise was recorded.

Anthropometric Measurements

Body composition was measured on all participants (Appendix Q). Body mass was recorded in kilograms using a calibrated weighing scale (Adam, MOW-160M model). Stature was recorded in centimetres using a stadiometer (Adam, MOW-160M model), whilst the waist girth was measured in centimetres using a tape measure. Body fat was estimated using the sum of seven skin-folds, (triceps, chest, sub-scapular, mid-axillary, supra-iliac, thigh and abdomen).[287] These skin-fold measurements were recorded using a calibrated spring caliper. The estimated body fat was then expressed as a percentage of the total body mass.[288] Body Mass Index (BMI) was calculated as per the formula described by Armstrong et al.[1] These descriptive anthropometric results were used to compare the SEG and HEG at baseline. A high BMI has been associated with increased risk of chronic pain in the low back.[289]

b) Individual sessions

The Supervised Exercise Group (SEG)

The basic principles of Pilates were taught at the one-hour individual session. The participants were shown how to recruit their deep abdominal muscles using a variety of

facilitation strategies, which included pelvic floor recruitment and visual imagery, verbal cueing and demonstration. Participants received a copy of *The Back Book* by Roland,[267] which covers back care advice (Appendix R), an exercise logbook and a schedule of the Pilates classes for the eight-week programme. The classes were held regularly at 18:30 on a Tuesday and Thursday, and at 08:00 on a Wednesday and Friday. The participants were divided into two groups, nine in the one group and 10 in the other, depending on their class time preference. All classes started with a five minute warm up, followed by the schedule of exercises for that week (Appendix N), which included the fourteen spine exercises given to the HEG (Appendix O).

The Home Exercise Group (HEG)

The basic principles of Pilates were taught and applied whilst teaching the fourteen home exercises at the first one-hour individual session. The participants were shown how to recruit their deep abdominal muscles using a variety of facilitation strategies, which included pelvic floor recruitment and visual imagery, verbal cueing and demonstration – the same material that had been taught to the SEG. The incorporation of the Pilates principles of breathing control and neutral spinal alignment was taught and encouraged during all exercises. At the second session, the participant was asked to demonstrate the home exercises they had learnt at the first session, and their technique was corrected if necessary. The participants were given home exercise sheets, (including pictures and simple instructions), an exercise logbook, a copy of *The Back Book* and a big ball to use for their exercises.

3.6. Statistical Analysis and Data Management

Statistica Software (StatSoft, Inc. 2011. STATISTICA, Data Analysis Software System, Version 7. www.statsoft.com) was used to analyse the data.

The Shapiro Wilks test was used to test for normality. Numeric normally distributed data were analysed using parametric statistics and non-normal, ordinal or categorical data were analysed with non-parametric tests. Descriptive statistics (means, standard deviations, medians, ranges and frequencies) were used to describe the data.

The Chi-squared test was used to test whether there were associations between the SEG and HEG groups with demographic factors or with precipitating factors for back pain. To establish whether changes in medication were larger within the SEG or HEG group over the eight and 12-week time periods, the Fisher's exact test was used, as some cell sizes were smaller than five.

Various tests were used to establish if there was a difference between the two groups at different time points (i.e. between the two groups) and whether the scores were different between each of the time points (within each group). For parametric data, a repeated measures ANOVA was done to test the group, time and group*time effect. When a difference was found, a post-hoc Tukey test was done to establish where the difference lay. For non-parametric data, a Mann-Whitney U test was done, and to compare the rankings of the scores of each group at each time point, the Friedman's ANOVA was used to see if the rankings of the whole group (SEG and HEG) had changed over time.

Statistical significance was set at $p < 0.05$.

3.6.1 Ethical Considerations

Prior to embarking on this study, the proposal was submitted to the Human Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town, for ethical clearance. This study adhered to the ethical principles outlined in the Declaration of Helsinki (Seoul version, 2008). Once ethical approval had been granted (HREC REF 479/2012), participants were requested to give written informed consent for the study. The purpose, testing procedures and possible risks and benefits of the study were explained to the participants, who had the right to withdraw from the study at any time (Appendix B). All data was kept strictly confidential. This was achieved by using a coding system, whereby each participant's personal information was linked to a code. The document containing participant's codes and personal information was held, by an independent auditor, in a locked filing cabinet, for the duration of the study. Further, participants will not be identified in any publications associated with this study. The trial has been registered with the Pan African Clinical Trial Registry: (PACTR201211000443397).

a) Risks to participants

Participants were screened before the study began to determine their suitability for exercise management of their LBP. If any risks were determined during this screening process, they were referred to a medical practitioner of their choice for further assessment.

There are no risks associated with taking body composition measurements, but whilst taking skin-fold thickness measurements, the participant may have felt slight and short-lived discomfort due to the use of the calipers. To minimise the slight risk of their LBP worsening while bending forward in the FTF test, participants were asked to warm up by walking for three-minutes before the test; they only performed the test once at each testing session, and

they were asked to stop bending forward if their LBP worsened. To decrease the risk of the exercises worsening their low back symptoms, the participants were taught how to perform the exercises correctly, and the exercise load was slowly increased. The participants were instructed to perform the ball exercises on a non-slip surface. If the participant's LBP worsened, and their pain prevented them from performing the exercises, they were asked to stop the exercise programme. The investigator assessed their symptoms and treated the participant using alternate physiotherapy methods if appropriate, or referred the participant to a medical practitioner of their choice for further management. The participant then resumed the exercise programme once the LBP was back to baseline measurements, and decreased the number of repetitions to the same as that, which was being done one week before stopping the home exercise programme. In the current study, one participant had a rescue hands-on treatment after an emotional shock and was able to resume with the home programme a week later, albeit at a lower level.

b) Benefits to participants

All participants were given a copy of *The Back Book*[267](Appendix R), which included advice on back care and managing back pain. The HEG were also invited to attend Pilates classes for eight weeks after the study, and the SEG received the home exercise sheets with pictures and basic instructions. There was no remuneration for their participation in the study. The participants were informed that they would receive their body composition measurements and the final results of the study.

4. Results

This chapter will describe the results of the study, starting with a flowchart of the participants, and then describe the demographic details of the two groups and the baseline outcome scores. The two groups are compared with regard to their demographic and baseline characteristics, and finally the two groups are compared with regard to the outcome measures at four, eight and twelve weeks.

4.1 Flow Chart of the Study

As can be seen in Figure 5, of the 54 participants screened, 43 were eligible for inclusion; these were randomly allocated to the two exercise groups (SEG and HEG). Five participants (three from the SEG and two from the HEG) dropped out of the study after randomisation but before initiation of the intervention; ultimately, 38 participants completed the full study. One participant in the HEG experienced deterioration in her condition due to emotional stress following the sickness of a loved one. As per protocol and ethical obligations, she was then given one additional hands on physiotherapy treatment and her programme was adjusted to restart her programme at a lower level.

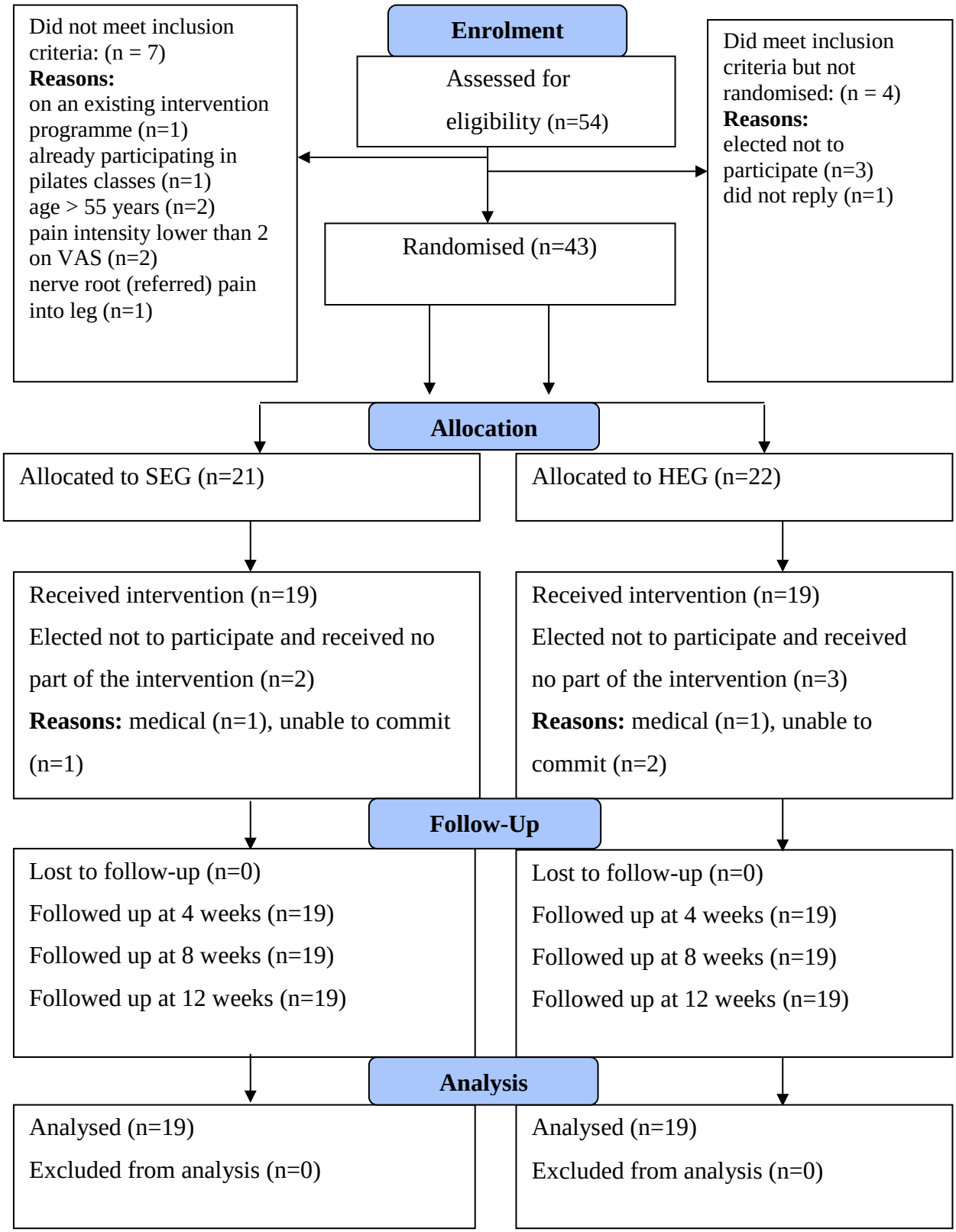


Figure 5: Flow chart of recruitment, intervention and follow-up

4.2 Demographic Characteristics of the Sample

As per the inclusion criteria, all participants were female. The mean age of the participants was 38.0 years (SD=9.26, range=22-54). The ages of both groups were normally distributed (SEG Shapiro-Wilk W=.902, p=.052; HEG Shapiro-Wilk W=.924, p=.137) and the t-test indicated that there was no significant difference (t=-0.346, p=0.31) between the mean ages of the two groups (SEG 34.16, SD=9.22 and HEG 35.21, SD=9.53). All participants had attained a school leaving certificate, and the majority, 34, had attained a post-school qualification. There was no association between higher education qualifications and group (p=.290) (Table 9).

Table 9: Post-school qualifications (n=38)

	Yes	No	Totals
SEG	16	3	19
	84.2%	15.8%	
HEG	18	1	19
	94.7%	5.3%	
Totals	34	4	38

Pearson Chi-square=1.118, df=1, p=0.290

Table 10 lists the occupations of the participants. There was no association with group membership and being self-employed or in formal employment (p=0.800).

Table 10: Employment status of participants (n=38)

	Self-employed	Formal employment	Retired	Homemaker	Totals
SEG	6	10	1	2	19
	31.6%	52.6%	5.3%	10.5%	
HEG	6	12	0	1	19
	31.6%	63.2%	0.0%	5.3%	
Totals	12	22	1	3	38

Pearson Chi Square = 0.064, df=1, p=0.800

The majority of the participants were drawn from nearby suburbs. There was no association (p=0.319) between area of residence and group (Table 11). The nearby suburbs were within a ten kilometre radius of the Centre, and the more distant suburbs were up to a 50 kilometre radius.

Table 11: Place of residence (n=38)

	Nearby suburb	More distant suburbs	Totals
SEG	13	6	19
	68.4%	31.6%	
HEG	10	9	19
	52.6%	47.4%	
Totals	23	15	38

Pearson Chi Square=0.991, df=1, p=0.319

Thus the SEG and HEG groups were equivalent with regard to demographic factors.

4.3 Anthropometric Characteristics – Body Mass Index

The mean body mass index (BMI) for the SEG was higher than that of the HEG at baseline (Table 12) but this was not significantly so.

Table 12: BMI of SEG and HEG (n=38)

	Mean – SEG	Mean – HEG	t value	df	p- value	S.D. SEG	S.D. HEG
BMI (kg/m^2)	25.36	22.73	1.81	36	0.079	5.55	3.06

t-value = 1.18, df = 36, p= 0. 079

4.4 Medical History of Back Pain

4.4.1 Precipitating Factors

Precipitating factors (i.e. the reasons why participants were experiencing NSCLBP) were post-coded into four categories: Trauma included post whiplash injuries or falls; pregnancy implied onset or exacerbation of LBP during pregnancy or post pregnancy; other referred to an emotional reason like stress, or stiffness through lack of exercise, or too much exercise or weight gain and occupational factors included strenuous workload, working position, and lifting of heavy objects at work. In three of the subjects, the initial cause appears to have been trauma but the back pain was exacerbated by pregnancy; consequently, trauma – rather than pregnancy – was recorded as the primary precipitating factor. From Table 13, it can be seen that trauma was the most common precipitating factor, followed by occupational and other factors.

Table 13: Primary precipitating factors associated with back pain (n=38)

	Trauma	Occupational	Other	Pregnancy	Totals
SEG	9	5	4	1	19
%	47.4	26.3	21.1	5.3	
HEG	7	6	6	0	19
%	36.9	31.6	31.6	0.0	
Totals	16	11	10	1	38

Pearson Chi-square= 1.741, df=3, p=0.628

There was no significant association between the SEG and HEG groups and precipitating factors for back pain (p=0.628).

4.4.2 Length of Time with Pain

Participants reported having experienced back pain for periods of time ranging from as short as 0.2 years to a maximum of 33 years. The time since onset was not normally distributed in either group (SEG: Shapiro-Wilk W=.813, p=.002; HEG: Shapiro-Wilk W=.864, p=.012). The median and quartile scores are depicted in Figure 6. The Mann-Whitney U test indicated that the ranking of the time since onset was significantly different between the two groups (z=-2.19, p=029) with the SEG having a shorter duration since onset of pain.

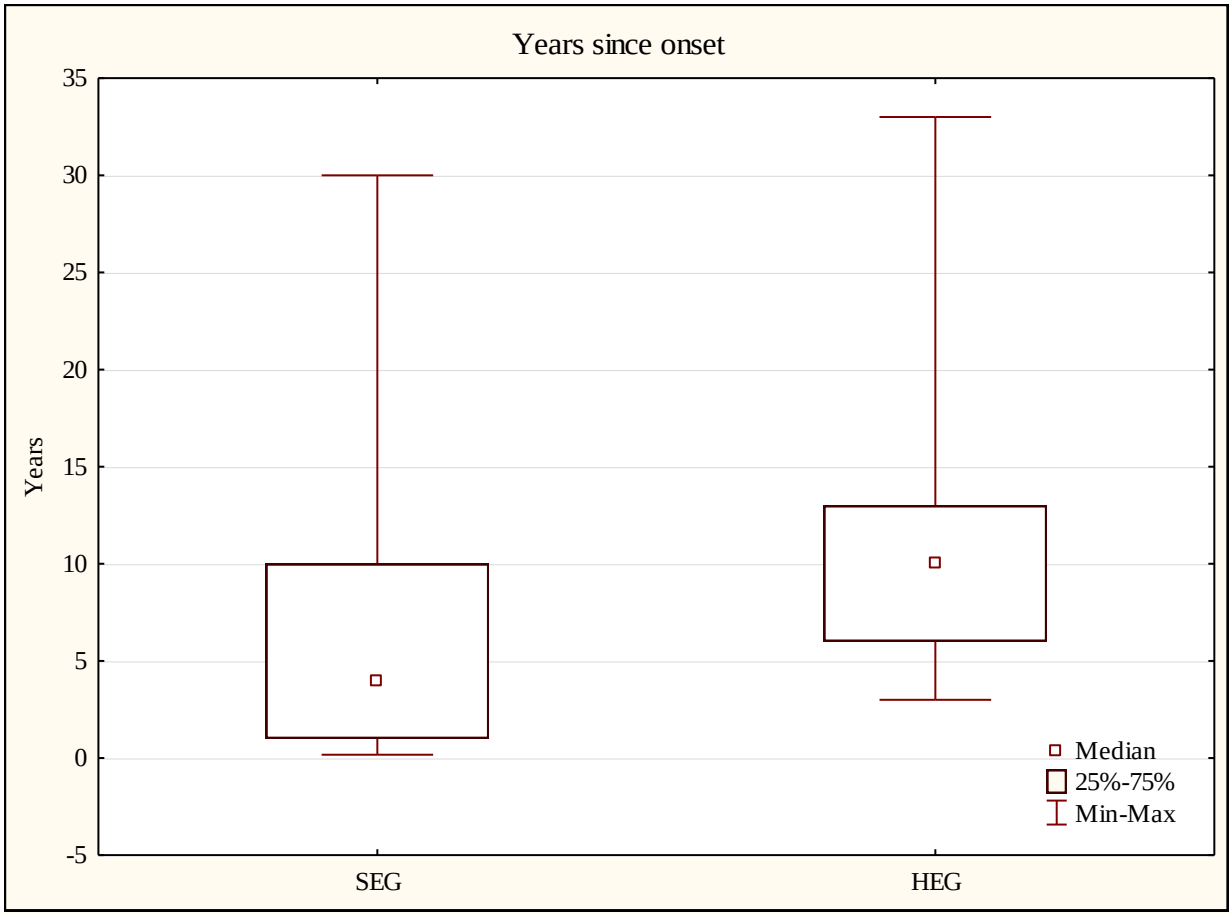


Figure 6: Box plot of years since onset of back pain (n=38)

4.5 Description of the Measures

4.5.1 Impairment Outcomes

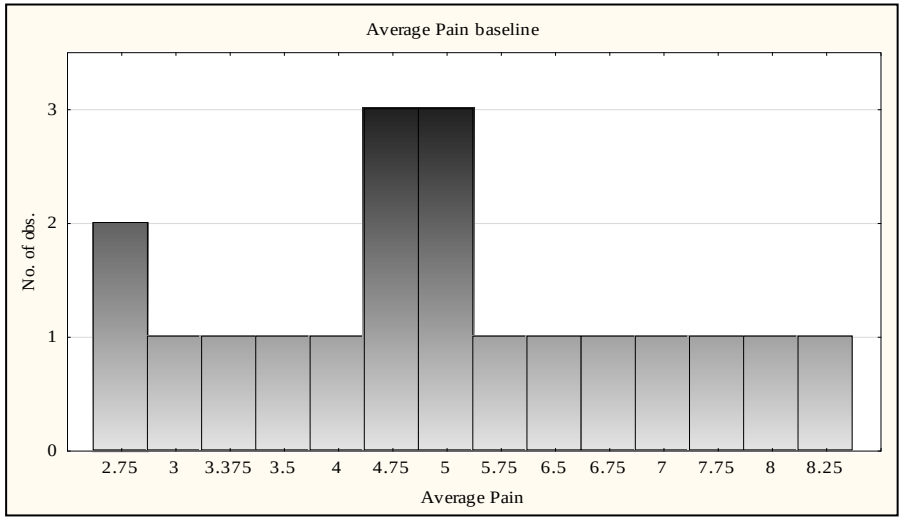
a) Pain

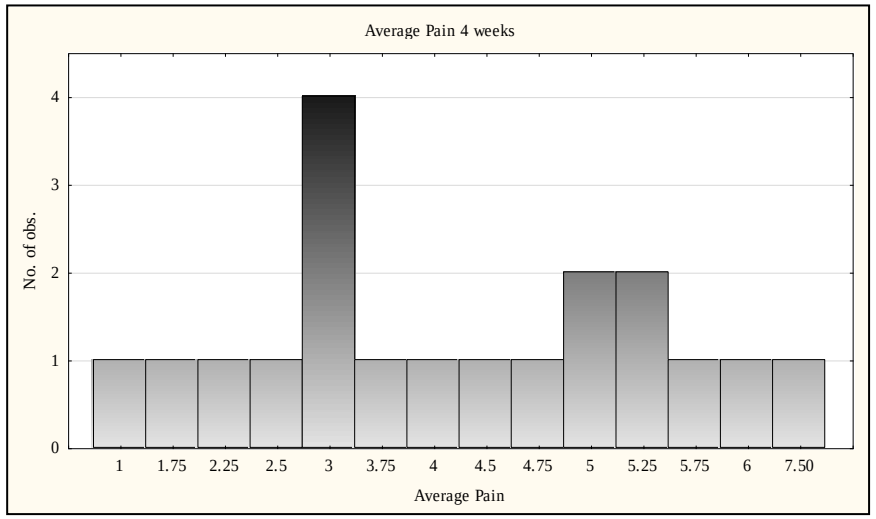
Almost all the subjects (37) reported a five or more as the level of worst pain at baseline; there was a steady increase in the number of participants who reported a score lower than two over the period of the intervention and by eight weeks, 22 participants had a score of four or less. At follow-up at 12 weeks, this had decreased to 15 reporting a level of four or less (Table 14). The lower the score on the PI-NRS, the better the result.

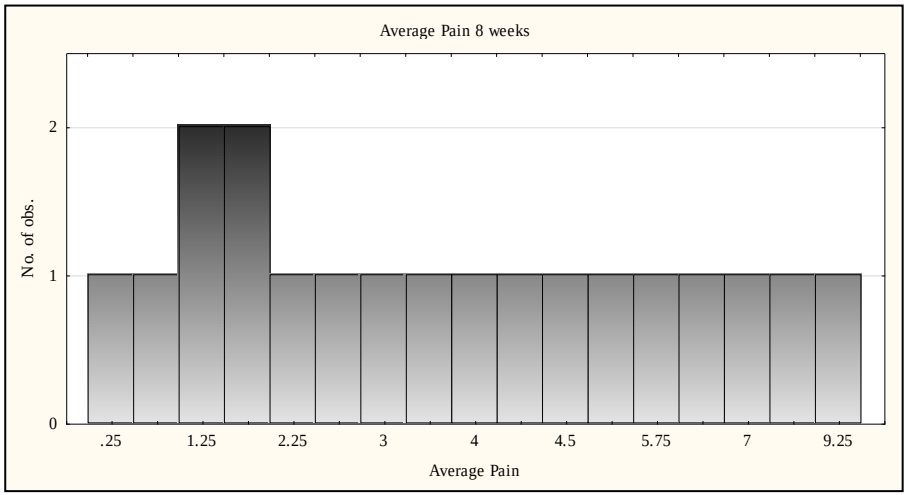
Table 14: Frequency of responses to BPI – worst pain question

Worst Pain		Baseline	4 weeks	8 weeks	12 weeks
SEG					
No pain	**0**			1	
	1			1	
	2		1		4
	3		1	4	3
	4	1	4	7	2
	5	1	3	1	1
	6	3	4	2	5
	7	6	3		3
	8	5	2	1	1
	9	2	1	2	
Worst pain	**10**	1			
HEG					
No pain	**0**				1
	1			1	1
	2			3	
	3		3	4	1
	4		1	1	3
	5	2	4	1	6
	6	1	1	3	
	7	7	6	1	1
	8	2	3	4	5
	8.5	1			
	9	5	1		1
Worst pain	**10**	1		1	

As per the inclusion criteria, all subjects reported a 2.75 or greater score on the average pain section of the PI-NRS at baseline (Figure 7 and Figure 8). Note that the x-axes average pain scores differ in range.







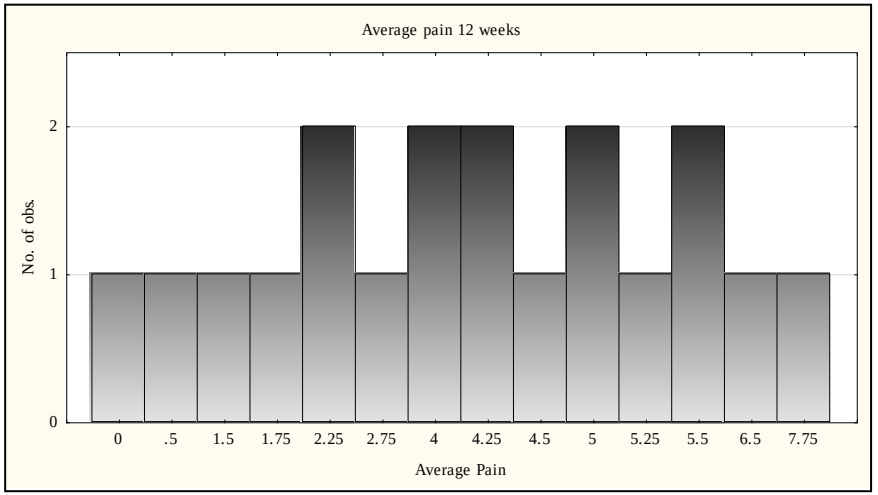


Figure 7: Frequency histograms of average pain intensity in the SEG (n=19)

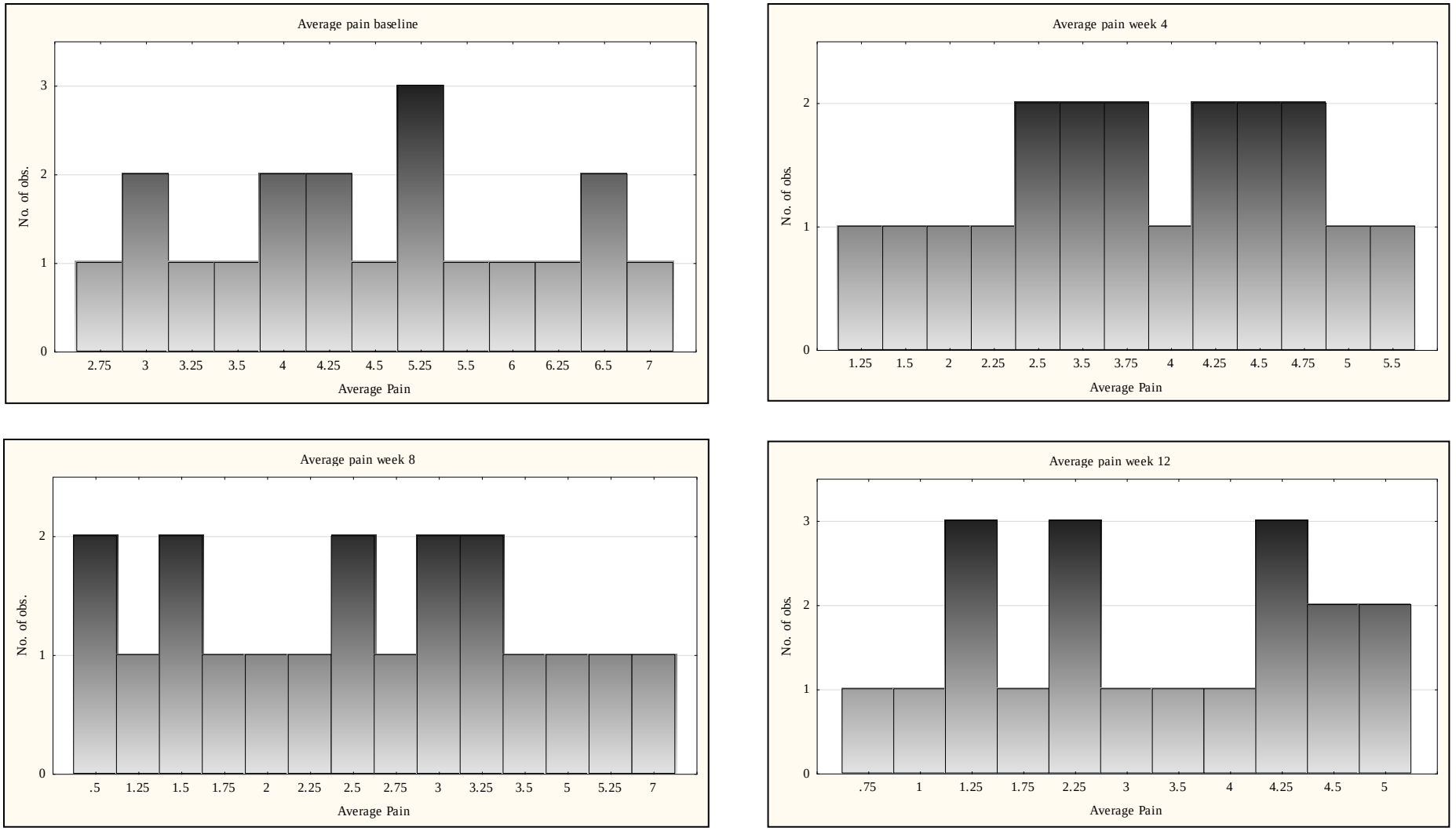


Figure 8: Frequency histograms of average pain intensity in the HEG (n=19)

b) Medication use

There was a decrease in the number of participants taking non-steroidal anti-inflammatories (NSAIDs), pain medication and anti-depressives by the end of the eight-week programme, in both the SEG and HEG. Not all the improvements in consumption of NSAIDs, pain medication and anti-depressives were maintained at 12 weeks (i.e. a month after the 8-week intervention had ended) although there was still an improvement at 12 weeks when compared to the original baseline measures (Table 15). Note that some were taking more than one type of medication.

Table 15: Types of medications used by the participants at baseline, at 8 weeks and at 12 weeks (n=38)

	NSAIDs	%	Pain Medication	%	Anti-Depressives	%	Total
SEG							
Baseline	10	52.63	6	31.58	4	21.05	20
8 weeks	0	0.00	1	5.26	3	15.79	4
12 weeks	4	21.05	1	5.26	2	10.53	7
HEG							
Baseline	11	57.89	6	31.58	3	15.79	20
8 weeks	2	10.53	3	15.79	2	10.53	7
12 weeks	3	15.79	0	0.00	3	15.79	6

After the eight-week programme, there was a 73.7% decrease in the number of participants taking medication in the SEG and a 36.8% decrease in the HEG respectively. The biggest decrease in the consumption of medication was seen between 0 and 8 weeks in the SEG, whereas the biggest decrease in consumption was seen between 0 and 12 weeks in the HEG.

The Fisher's exact test indicated that there was no association between the two groups over time in terms of the reduction in medication (p=0.725).

c) Fingertip-to-floor test

The mean distance from the floor was 13.6cms (SD=14.2) in the SEG at baseline and this decreased at each time period, apart from between eight and twelve weeks (Table 16). In the

HEG the baseline difference was 11.5cms (SD=12.9) and this continued to decrease at each time point (Table 17).

Table 16: Mean FTF scores for the SEG (n=19)

	No	Mean (cm)	Min distance to floor (cm)	Max distance to floor (cm)	SD
Baseline	19	13.6	0	55.0	14.2
4 weeks	19	7.3	0	23.0	6.6
8 weeks	19	4.5	0	24.0	6.5
12 weeks	19	5.5	0	22.0	6.8

Table 17: Mean FTF scores for the HEG (n=19)

	No	Mean (cm)	Min distance to floor (cm)	Max distance to floor (cm)	SD
Baseline	19	11.5	0	56.0	12.9
4 weeks	19	11.1	0	51.0	14.0
8 weeks	19	7.6	0	53.0	12.3
12 weeks	19	6.6	0	35.0	8.7

4.5.2 Functional Outcomes

a) Roland Morris 24-item Questionnaire

As can be seen in Figure 9 and Figure 10, the items on the RMDQ reported by most respondents as causing problems were heavy jobs around the house and changing position to get comfortable. Every item (apart from heavy jobs in the case of the HEG) showed a decrease in the number of respondents identifying these activities as painful, and a clear trend of decreasing frequency of responses with each subsequent time period. The number of participants reporting problems with each item at baseline (SEG1), 4 weeks (SEG2), 8 weeks (SEG3) and 12 weeks (SEG4) are indicated in the figures. As per the inclusion criteria, all participants had to score 4 or more on the RMDQ at baseline.

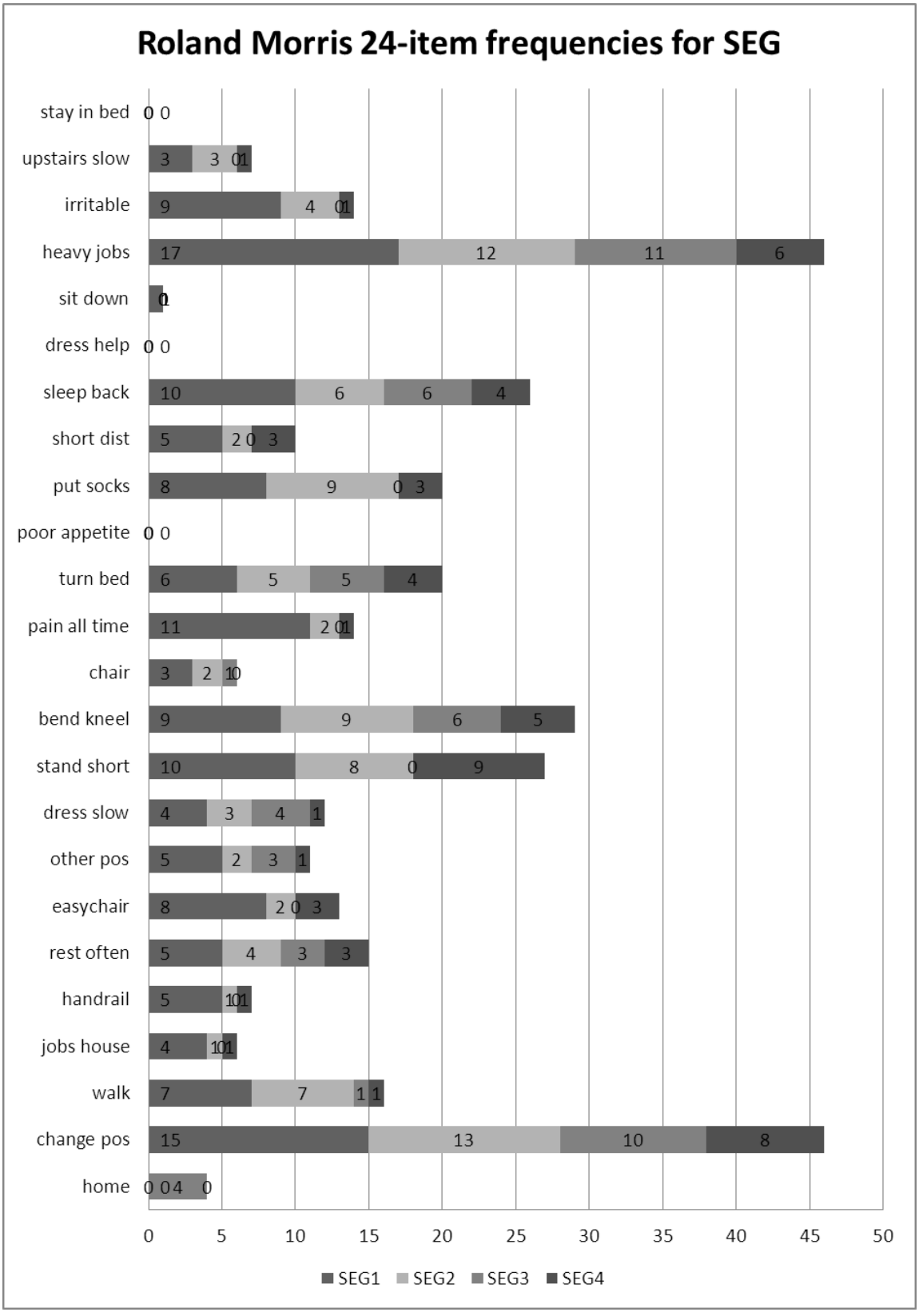


Figure 9: Frequencies of responses to the Roland Morris Questionnaire items by the SEG (n=19)

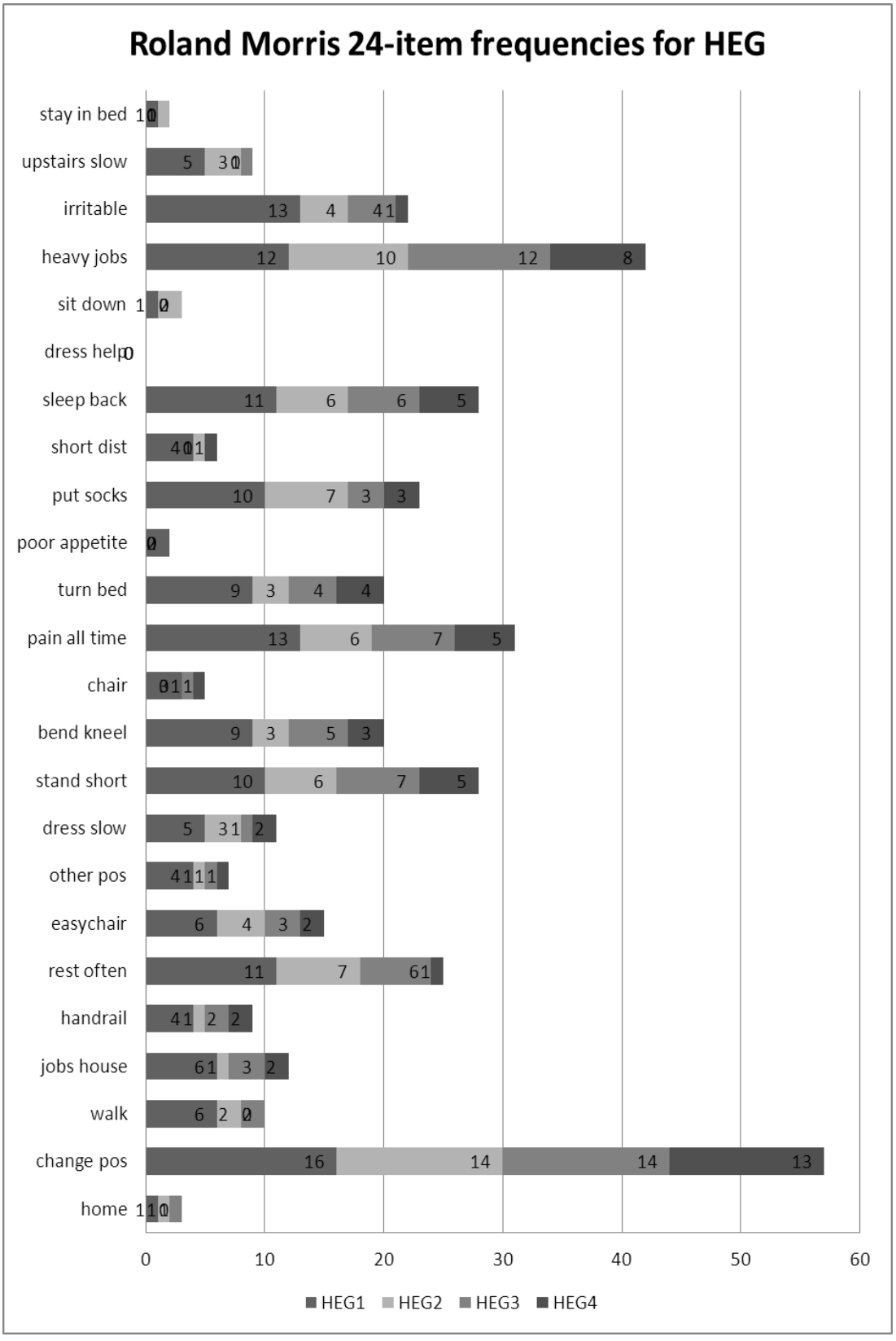


Figure 10: Frequencies of responses to the Roland Morris Questionnaire items by the HEG (n=19)

4.5.3 Participation Outcomes

a) EQ-5D Domains

The domains that were most affected at baseline were 'Usual Activities' (with only one participant reporting no problems) and 'Pain/Discomfort' (with none of the participants experiencing no problems) (Table 18). The domain that had been least affected at baseline was 'Self-Care', with 30 reporting no problems. No reported changes were found in the responses to the 'Anxiety/Depression' question over the time periods.

Table 18: Frequency of responses to the EQ-5D domains (n=38)

		Baseline	4 weeks	8 weeks	12 weeks
Mobility					
SEG	No problems	9	16	18	16
	Some problems	10	3	1	3
HEG	No problems	11	15	16	17
	Some problems	8	4	3	2
Self-care					
SEG	No problems	14	19	19	19
	Some problems	5			
HEG	No problems	16	17	18	19
	Some problems	3	2	1	
Usual activities					
SEG	No problems	1	8	13	14
	Some problems	17	11	6	5
	Extreme problems	1			
HEG	No problems	4	11	10	11
	Some problems	15	8	9	8
Pain/discomfort					
SEG	No problems		1	6	5
	Some problems	16	18	13	14
	Extreme problems	3			
HEG	No problems		3	4	3
	Some problems	13	15	14	15
	Extreme problems	6	1	1	1
Anxiety/depression					
SEG	No problems	7	10	11	8
	Some problems	11	8	7	10
	Extreme problems	1	1	1	1
HEG	No problems	11	12	10	11
	Some problems	7	6	9	7
	Extreme problems	1	1		1

However, there was a consistent improvement in responses to the mobility, self-care, usual activities, pain and discomfort questions; by 12 weeks, the number reporting no problems had increased in every domain, apart from the area of anxiety/depression. The most noticeable improvements were seen in the usual activities question, in that the majority of participants had some problems with usual activities at baseline, but reported no problems by week eight.

b) EQ-5D Health Index

The mean health index scores show an improvement from weeks four in both groups (Note that 1= full health) (Table 19, Table 20).

Table 19: Mean health index scores for the SEG (n=19)

	No	Mean	Min	Max	SD
Baseline	19	0.54	-0.08	0.80	0.24
4 weeks	19	0.72	0.26	1.00	0.14
8 weeks	19	0.79	0.26	1.00	0.18
12 weeks	19	0.75	0.19	1.00	0.17

Table 20: Mean health index scores for the HEG (n=19)

	No	Mean	Min	Max	SD
Baseline	19	0.52	-0.02	0.76	0.29
4 weeks	19	0.71	0.09	1.00	0.23
8 weeks	19	0.74	0.09	1.00	0.20
12 weeks	19	0.72	0.19	1.00	0.20

c) EQ-5D VAS

In the SEG, the mean VAS scores were 65.0 (SD=13.8) at baseline, and this increased at each time period, apart from at twelve weeks (Table 21). In the HEG, the mean baseline score was 62.1 (SD=15.8), and this increased at each time period apart from between weeks four and eight (Table 22).

Table 21: Mean VAS scores for the SEG (n=19)

	No	Mean	Min	Max	SD
Baseline	19	65.0	40.0	85.0	13.8
4 weeks	19	69.5	50.0	85.0	11.4
8 weeks	19	75.8	50.0	95.0	11.2
12 weeks	19	69.7	35.0	90.0	17.6

Table 22: Mean VAS scores for the HEG (n=19)

	No	Mean	Min	Max	SD
Baseline	19	62.1	30.0	90.0	15.8
4 weeks	19	69.7	45.0	90.0	10.6
8 weeks	19	66.3	20.0	95.0	19.7
12 weeks	19	72.9	50.0	90.0	10.2

At baseline, 19 participants in the SEG rated their general health on the VAS as below 70%. By eight weeks, 28 participants rated their general health as 70% or more, a result that was maintained at 12 weeks (see Figure 11 and Figure 12 for the SEG and HEG results respectively. Note that the X axis differs across the different time points.)

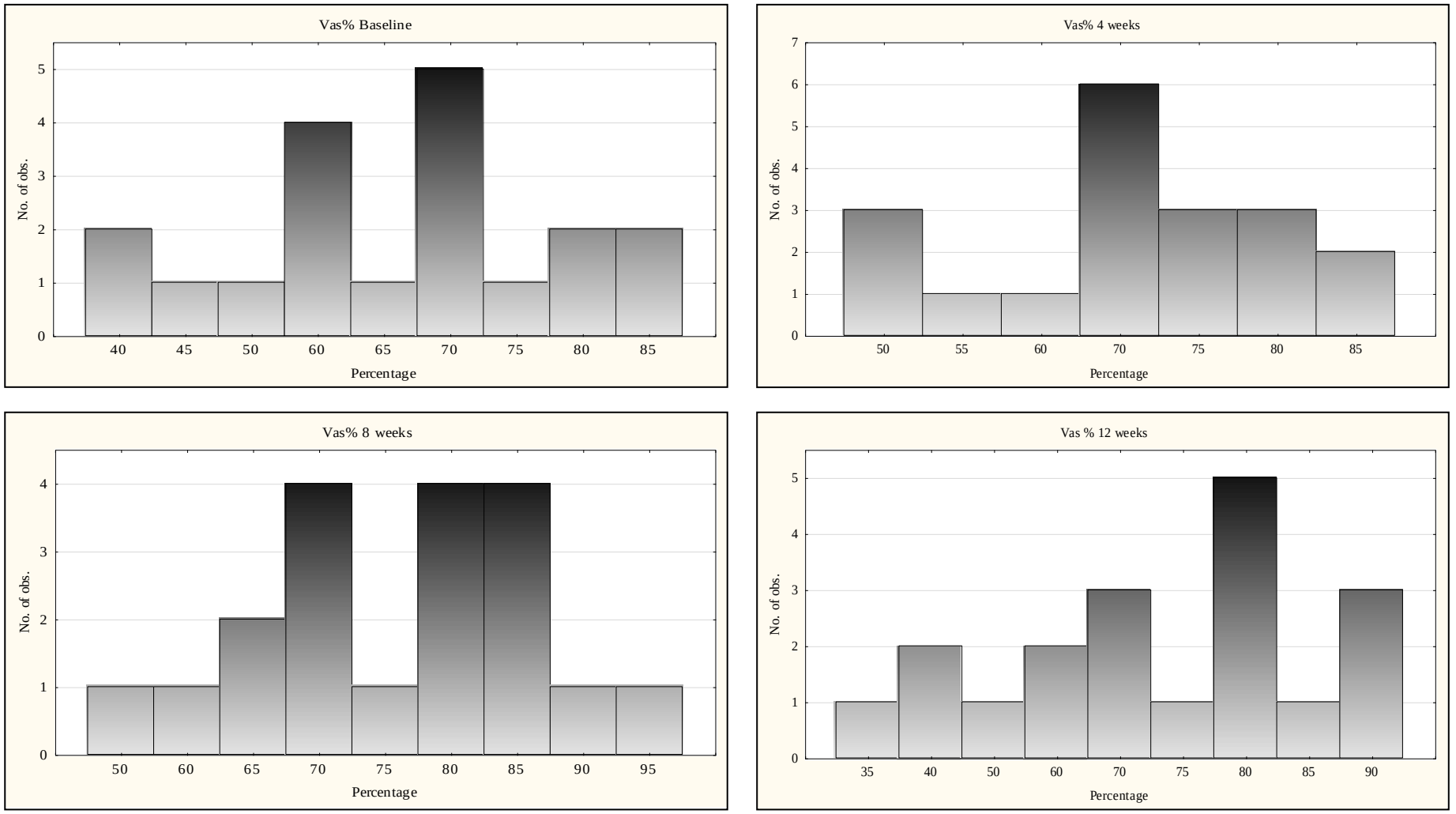


Figure 11: Frequency histograms of the VAS in the SEG (n=19)

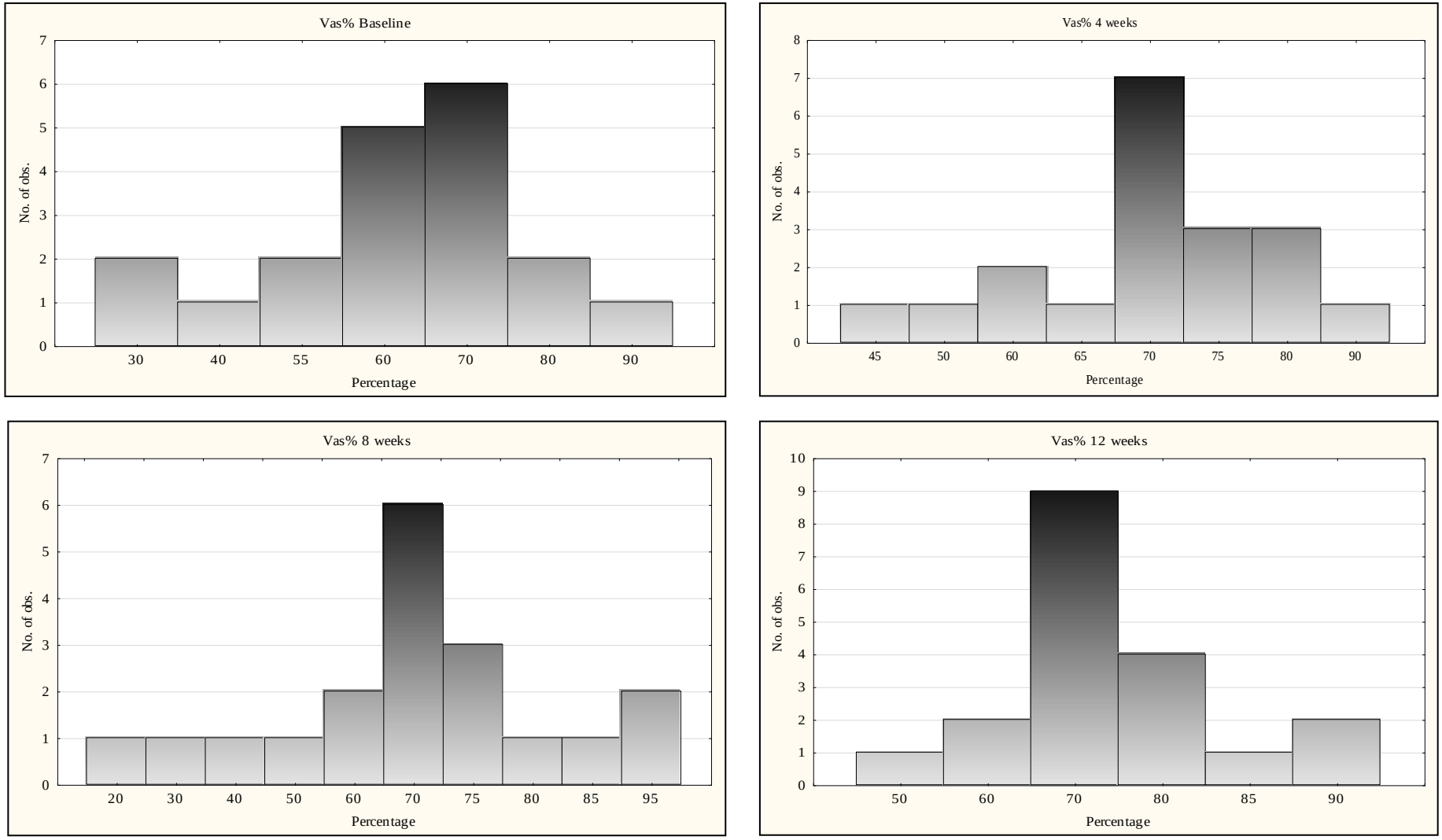


Figure 12: Frequency histograms of the VAS in the HEG (n=19)

d) PSEQ

Overall on the 10 questions asked in the PSEQ, an increased number of participants scored six (completely confident), from baseline to eight weeks. Most notably, the scores in the questions relating to socialising, work and becoming more active showed higher confidence scores at eight weeks (Table 23). A general improvement in confidence scores was seen throughout the intervention (0-12 weeks) (Appendix S).

Table 23: Frequency of the responses to the PSE questions

	Item on PSE questionnaire		0	1	2	3	4	5	6
1	**I can enjoy things, despite the pain**	SEG baseline		1		1	8	1	**1**
		8 weeks					3	5	**11**
		HEG baseline		1	1	2	9	5	**1**
		8 weeks				1	4	5	**9**
2	**I can do most of the household chores, despite the pain**	SEG baseline			2	2	8	6	**1**
		8 weeks			1	1	2	5	**10**
		HEG baseline			2	3	5	8	**1**
		8 weeks				3	3	6	**7**
3	**I can socialize with my friends or family as often as I used to, despite the pain**	SEG baseline		1	1	2	6	5	**4**
		8 weeks					3	4	**12**
		HEG baseline			2	1	7	5	**4**
		8 weeks				1	3	4	**11**
4	**I can cope with my pain in most situations**	SEG baseline					4	8	**7**
		8 weeks				1	3	6	**9**
		HEG baseline	1	1	4	6	5	2	
		8 weeks				5	7	7	
5	**I can do some form of work, despite the pain**	SEG baseline			1	1	7	6	**4**
		8 weeks				1	1	4	**13**
		HEG baseline			1	3	2	7	**6**
		8 weeks					2	3	**14**
6	**I can still do many things I enjoy doing, such as hobbies or leisure, despite the pain**	SEG baseline		1	1	3	7	7	
		8 weeks				2	4	4	**9**
		HEG baseline		1	2	5	6	3	**2**
		8 weeks				1	3	11	**4**

	Item on PSE questionnaire		0	1	2	3	4	5	6
7	**I can cope with my pain without medication**	SEG baseline			4	1	9	5	
		8 weeks					3	10	**6**
		HEG baseline	1	3	3	2	3	5	**2**
		8 weeks		1	3		2	4	**9**
8	**I can still accomplish most of my goals in life, despite the pain**	SEG Baseline	1	1		2	6	5	**4**
		8 weeks			1		2	6	**10**
		HEG Baseline			2	2	3	9	**3**
		8 weeks		1			1	7	**10**
9	**I can live a normal lifestyle, despite the pain**	SEG Baseline			3	2	5	8	**1**
		8 weeks		1			2	6	**10**
		HEG Baseline			2	2	3	9	**3**
		8 weeks		1			1	7	**10**
10	**I can gradually become more active, despite the pain**	SEG Baseline		1	1	3	3	6	**5**
		8 weeks				1		4	**14**
		HEG Baseline		1	2	1	2	10	**3**
		8 weeks			1	1	1	5	**11**

4.6 Comparison of Baseline Outcome Measures

All the outcome measures were compared at baseline. The function scores, EQ-Index, PSE scores and the distance from FTF were not normally distributed and in those cases, the Mann-Whitney U test was used. There were no significant differences found in any of the measures between the two groups.

Table 24 includes the means and the medians and standard deviations and ranges of all measures. The Shapiro Wilks test was used on numerical data. The function scores, EQ-Index, PSE scores and the distance from FTF were not normally distributed and in those cases, the Mann-Whitney U test was used. There were no significant differences found in any of the measures between the two groups.

Table 24: Comparison of all measures at baseline (n=38)

Most severe pain	**Mean**	**SD**	**SW**	**p**			**t-test**	**p**
SEG	7.21	1.44	0.946	0.339			-0.858	0.397
HEG	7.61	1.40	0.918	0.103				
Average pain	**Mean**	**SD**	**SW**	**p**			**t-test**	**p**
SEG	4.74	1.33	0.958	0.539			-0.893	0.378
HEG	5.19	1.77	0.935	0.217				
FTF	**Mean**	**SD**	**SW**	**p**	**Median**	**Range**	**z value**	**p**
SEG	13.63	14.18	0.822	0.002	11	0-55	0.132	0.895
HEG	11.53	12.92	0.746	0.000	12	0-56		
Roland-Morris					**Median**	**Range**	**MW-U**	**p**
SEG					7	4-13	-0.409	0.680
HEG					9	4-21		
EQ-5D Index score	**Mean**	**SD**	**SW**		**Median**	**Range**	**MW-U**	**p**
SEG	0.54	0.24	0.832	0.003	0.62	-0.077-0.796	-0.264	0.792
HEG	0.52	0.29	0.768	0.000	0.66	-.0016 -0.760		
EQ-5D VAS	**Mean**	**SD**	**SW**				**t-test**	**p**
SEG	65.00	13.84	0.933	0.199			0.602	0.551
HEG	62.11	15.75	0.915	0.091				
PSE					**Median**	**Range**	**MW-U**	**p**
SEG					43	15-54	0.307	0.759
HEG					43	24-55		

4.7 Change in Pain Intensity over Time and between Groups

As the baseline scores of the most severe pain and the average pain were normally distributed, Figure 13 plots the results of the repeated measures ANOVA, which was used to examine the effect of group, of time and of their interaction.

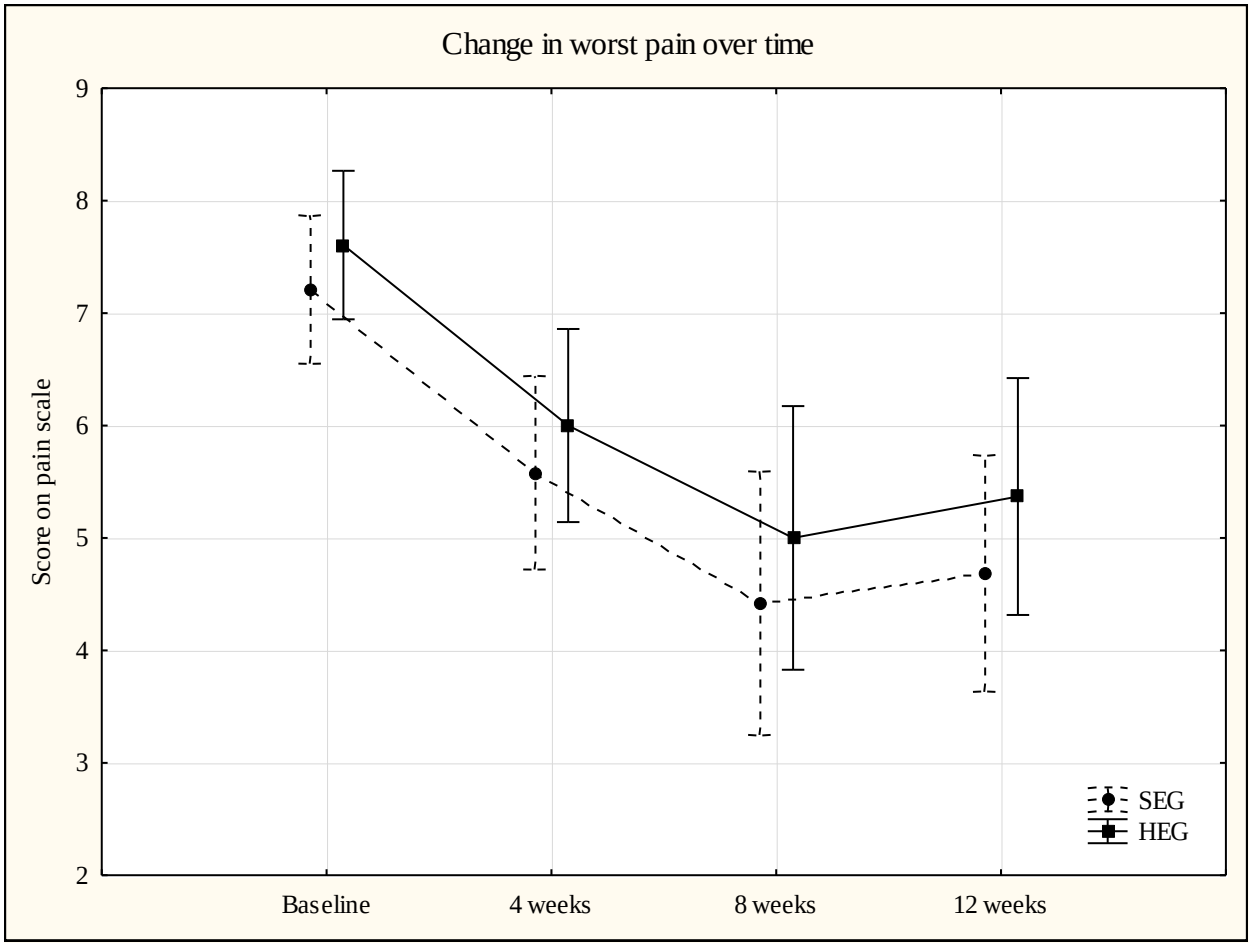


Figure 13: Worst pain and group over time (n=38)

Table 25: Repeated measures ANOVA of the effect of group, of time and of their interaction (n=38)

	SS	Degrees of Freedom	MS	F	p
Intercept	4997	1	4997	514.3	***0.000***
Group	10	1	10	1.1	0.311
Error	350	36	10		
Time	165	3	55	23.0	***0.000***
Time*group	1	3	0	0.1	0.974
Error	258	108	2		

There was no significant difference between the two groups with regard to the most severe pain scores (p=.311) nor was there a significant effect of group/time interaction (p=.974)

(Table 25). However, the effect of time was significant (p<.001), and thus a post hoc Tukey test was undertaken to see where the differences lay. The baseline measures were significantly different from the other later measures in both groups (Table 26). However, there was no further significant improvement in either group.

Table 26: Post hoc analysis of most severe pain over time (n=38)

Group	Time	Baseline	4 weeks	8 weeks	12 weeks
SEG	**Mean**	7.2	5.6	4.4	4.7
	Baseline		***0.032***	***0.000***	***0.000***
	4 weeks			0.300	0.633
	8 weeks				1.000
HEG	**Mean**	7.6	6.0	5.0	5.4
	Baseline		***0.037***	***0.000***	***0.001***
	4 weeks			0.492	0.912
	8 weeks				0.996

Mean and p-values are given

The average pain scores are plotted in Figure 14.

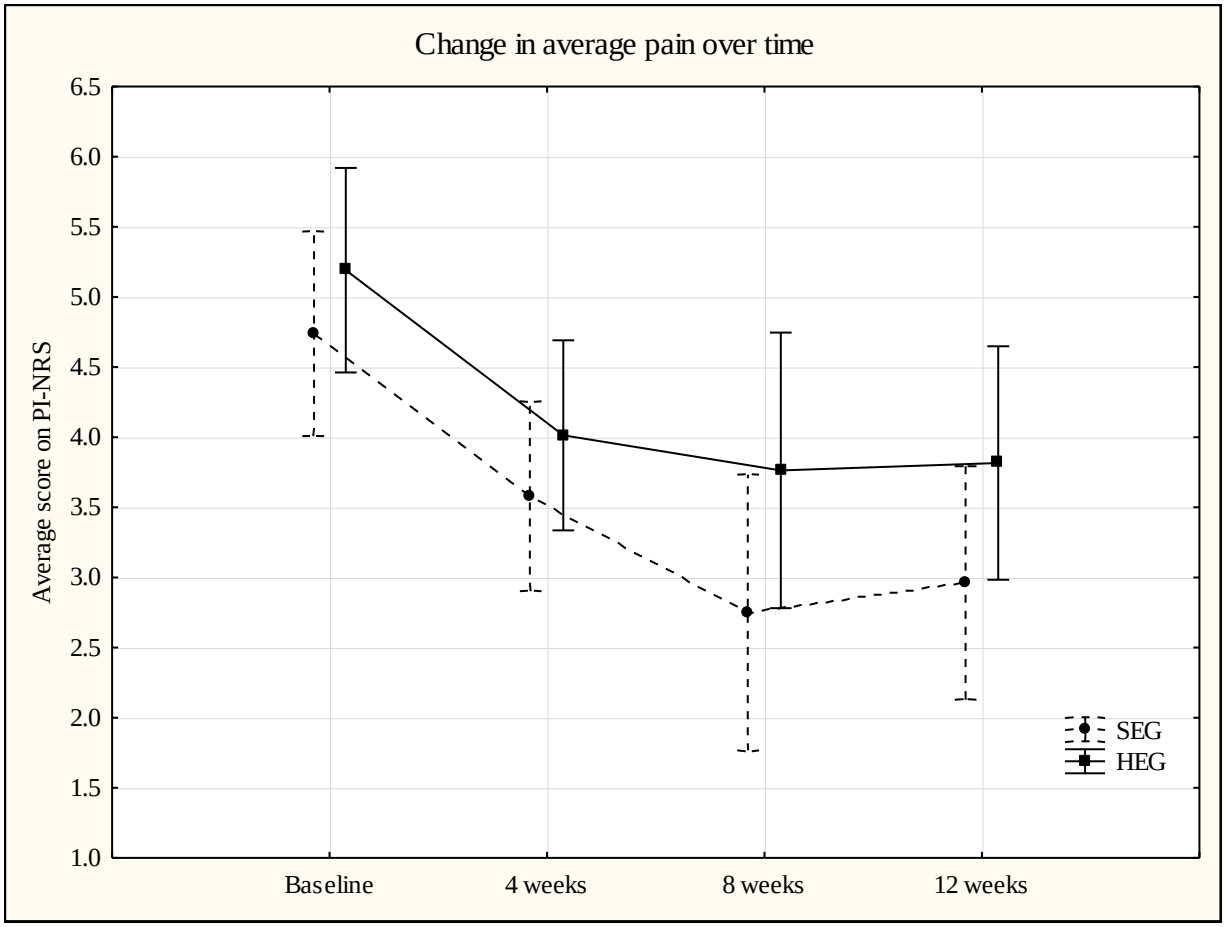


Figure 14: Average score on PI-NRS and group over time (n=38)

There was no significant difference in average pain scores over time between the two groups (p=.155), nor was there a significant effect of group/time interaction (p=.581) (Table 27). However, the effect of time was significant (p<.001), and thus a Tukey post hoc test was undertaken to see where the differences lay. The baseline measure was significantly different from the other later measures in both groups (Table 28). However, there was no further significant improvement in either group.

Table 27: Repeated measures ANOVA of the effect of group, of time and of their interaction

	SS	Degrees of Freedom	MS	F	p
Intercept	2254	1	2254	263.0	***0.000***
Group	18	1	18	2.1	0.155
Error	309	36	9		
Time	69	3	23	18.8	***0.000***
Time*group	2	3	1	0.7	0.581
Error	132	108	1		

Table 28: Post hoc analysis of average pain over time

Group	Time	Baseline	4 weeks	8 weeks	12 weeks
SEG	**Mean**	4.7	3.6	2.8	3.0
	Baseline		***0.034***	***0.000***	***0.000***
	4 weeks			0.297	0.671
	8 weeks				0.999
HEG	**Mean**	5.2	4.0	3.8	3.8
	Baseline		***0.029***	***0.003***	***0.005***
	4 weeks			0.997	0.999
	8 weeks				1.000

Mean and p-values are given

4.8 Change in Fingertip-to-Floor over Time and between Groups

Figure 15 shows that the distance from fingertips-to-floor decreased over time, with a slight increase at 12 weeks. However there was no difference between the two groups at the different time points: ($F(3, 108)=1.293$, $p=.280$)

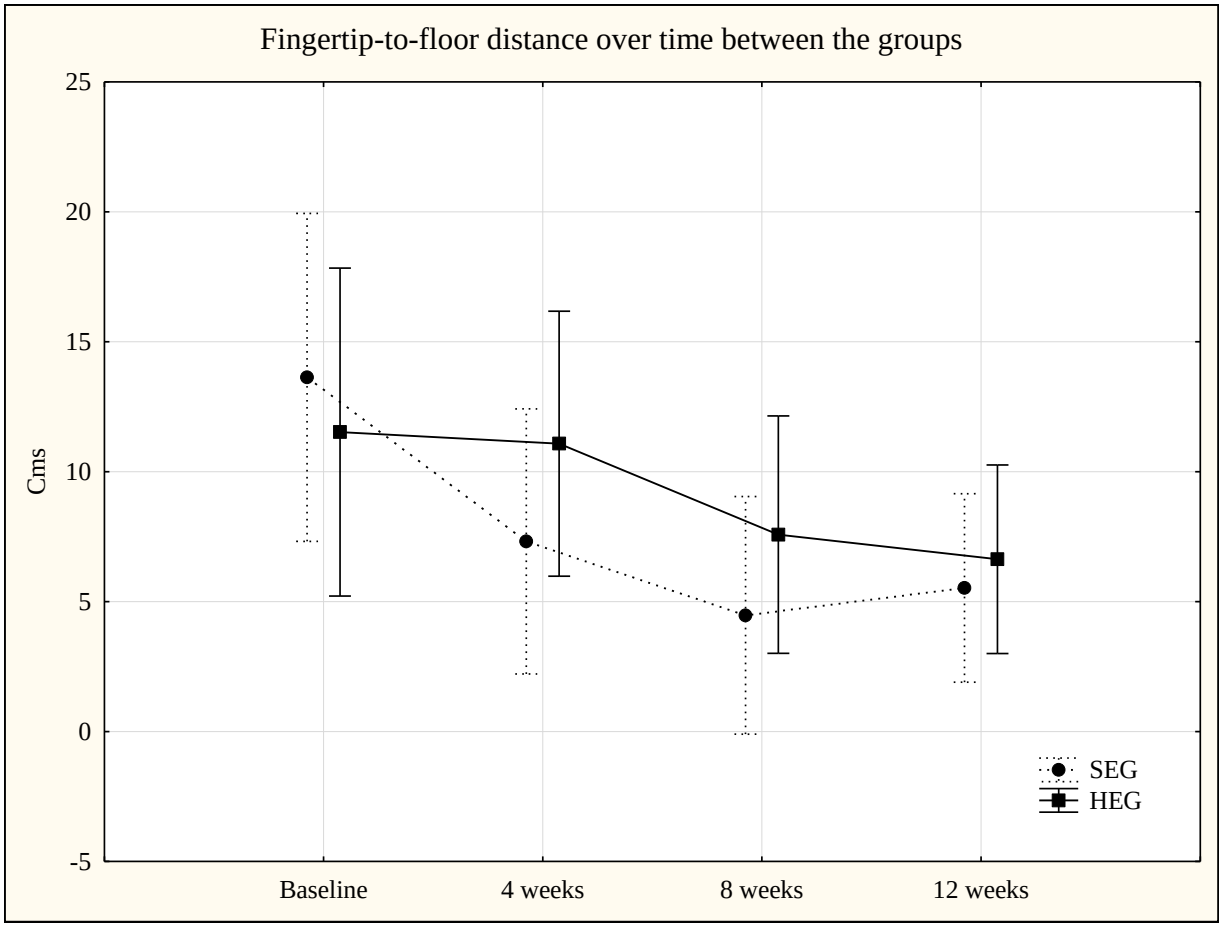


Figure 15: Distance in the fingertips-to-floor test over time for the SEG and HEG (n=38)

4.9 Change in Function over Time

The RMDQ yields ordinal data and consequently was analysed using non-parametric statistics. The Mann-Whitney U test was used to compare the scores over the various time periods. Table 29 demonstrates that there was no significant difference between the ranking of the two groups at any point in time.

Table 29: Comparison of the RMDQ scores between the two groups at each time point (n=38)

	Rank Sum SEG	Rank Sum HEG	U	Z	p-value
Baseline	356	385	166	-0.41	0.680
4 weeks	397.5	343.5	153.5	0.79	0.429
8 weeks	335	406	145	-1.04	0.299
12 weeks	363	378	173	-0.21	0.835

As there was no difference between the scores of the two groups at each time period, the Friedman ANOVA was used to compare the rank ordering of the scores of both groups combined. A significant difference was found between the scores (ANOVA Chi Square (n = 38, df = 3) = 68.79, p >.001). The average ranks at the different time periods are shown in Table 30. (Note that, the higher the average rank, the higher the Roland Morris Score and, consequently, the more functional problems reported).

Table 30: Comparison of the results of the Friedman ANOVA, of the Roland Morris Scores, at the four time periods (n=38)

	Average – Rank	Sum of – Ranks
Baseline	3.76	143
4 Weeks	2.62	100
8 Weeks	2.11	80
12 Weeks	1.51	58

Figure 16 shows how the median scores decreased over time; a post hoc sign test indicated that there were significant differences between each time point. Table 31 indicates the significant differences between each of the time periods.

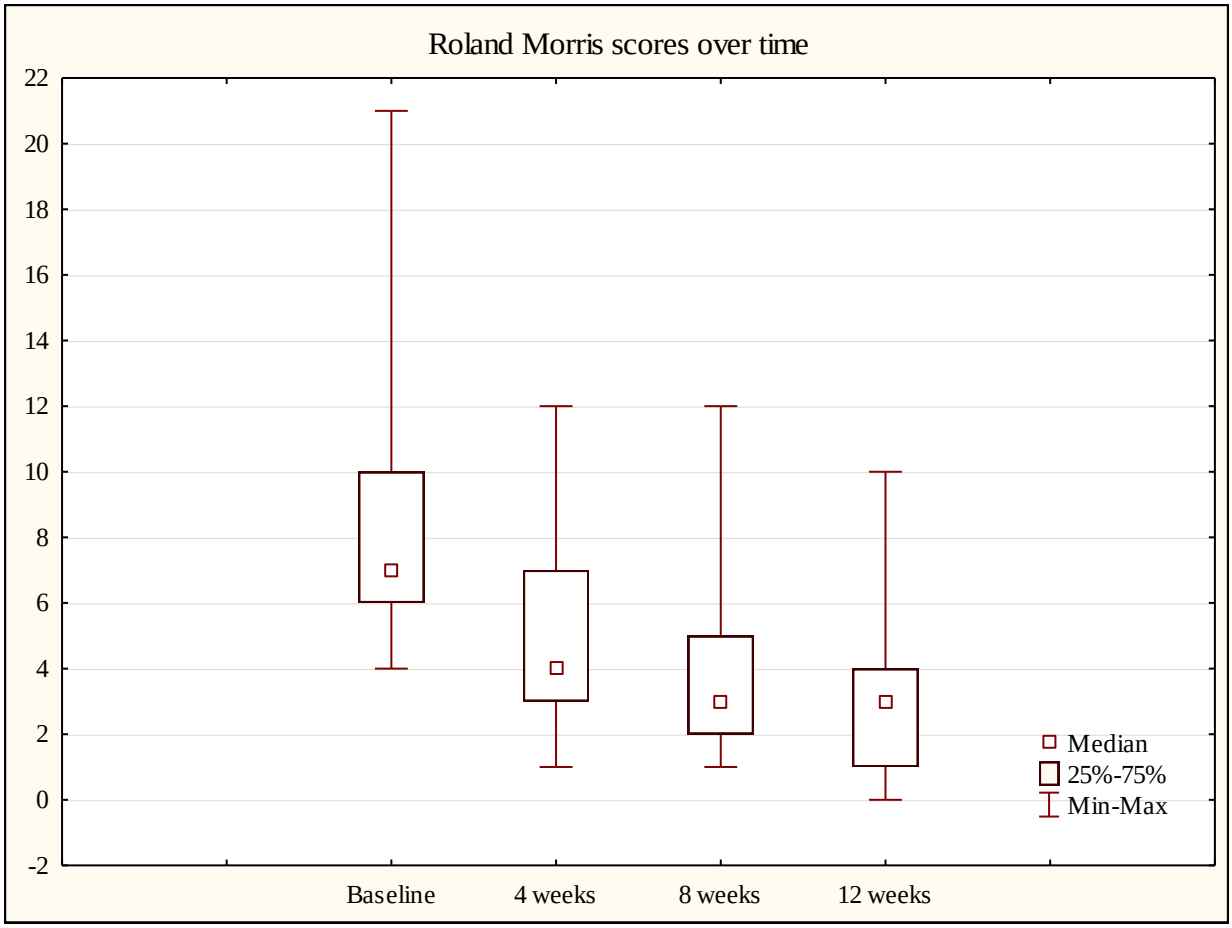


Figure 16: Roland Morris scores over time (n=38)

Table 31: Results of the sign test of Roland Morris scores at the four time periods (n=38)

	No.	Percent	Z	p-value
Baseline/4 weeks	35	5.7	5.071	***0.000***
Baseline/8 weeks	36	8.3	4.833	***0.000***
Baseline/12 weeks	37	2.7	5.590	***0.000***
4 weeks/8 weeks	29	24.1	2.600	***0.009***
4 weeks/12 weeks	33	12.1	4.178	***0.000***
8 weeks/12 weeks	27	77.8	2.694	***0.007***

4.10 Change in EQ-5D Index over Time

The scores of the EQ-5D index score are plotted in Figure 17.

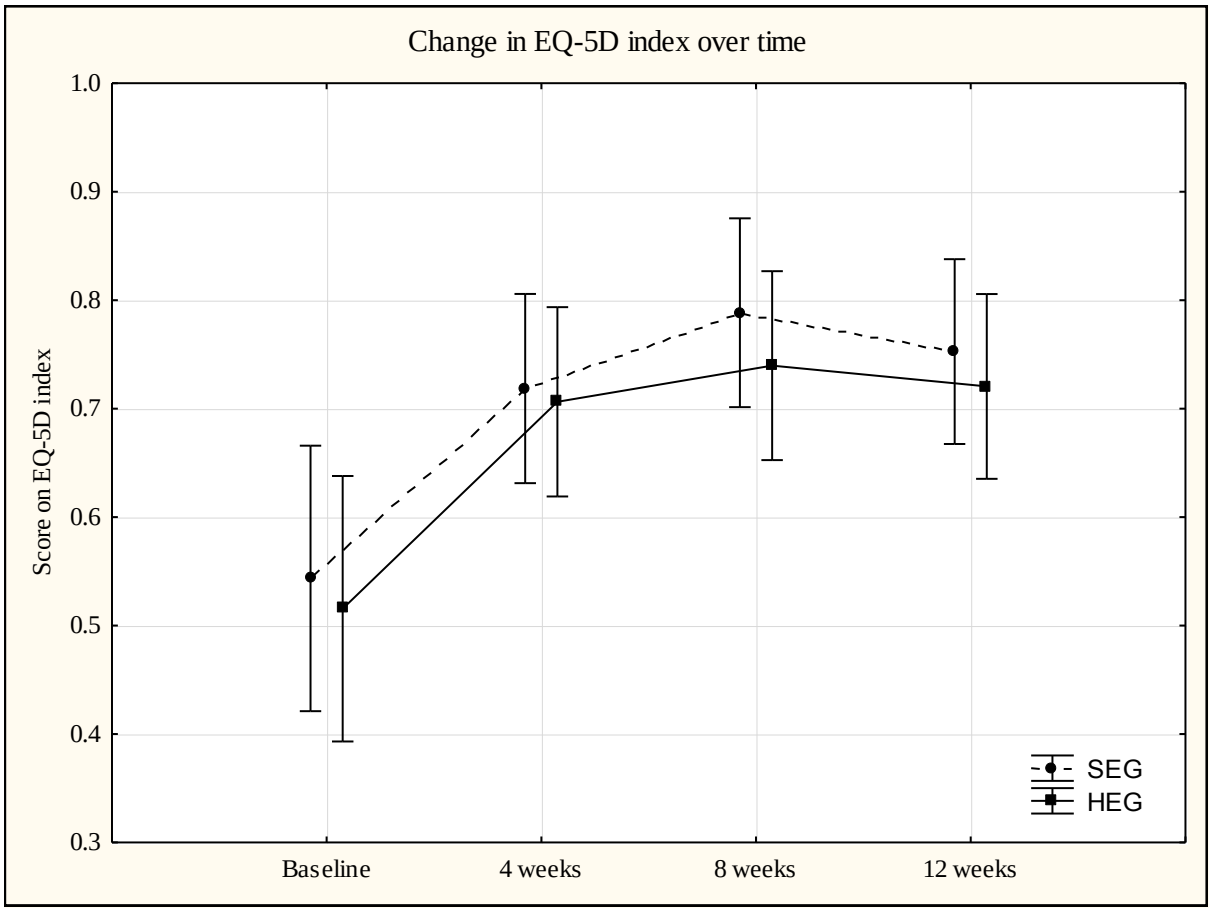


Figure 17: EQ-5D index and group over time (n=38)

There was no significant difference between the two groups, (p=.568) nor was there a significant effect of group/time interaction (p=.963) (Table 32). However, the effect of time was significant (p<.001), and thus a Tukey post hoc test was undertaken to see where the differences lay (Table 33). The baseline measure was significantly different from the other later measures in both groups. The highest score was seen at the week eight time period, in both groups.

Table 32: Repeated measures ANOVA of the effect of group, of time and of their interaction

	SS	Degrees. of Freedom	MS	F	p
Intercept	71	1	71	682.6	***0.000***
group	0	1	0	0.3	0.568
Error	4	36	0		
Time	1	3	0	18.9	***0.000***
Time*group	0	3	0	0.1	0.963
Error	2	108	0		

Table 33: Post hoc analysis of the EQ-5D index over time (n=38)

Group		Baseline	4 weeks	8 weeks	12 weeks
	Mean	0.54	0.72	0.79	0.75
SEG	**Baseline**		***0.012***	***0.000***	***0.001***
	4 weeks			0.842	0.997
	8 weeks				0.996
HEG	**Mean**	0.52	0.71	0.74	0.72
	Baseline		***0.004***	***0.000***	***0.002***
	4 weeks			0.997	1.000
	8 weeks				1.000

Mean and p-values are given

4.11 Change in EQ-5D VAS over Time

The scores of the EQ-5D VAS are plotted in Figure 18.

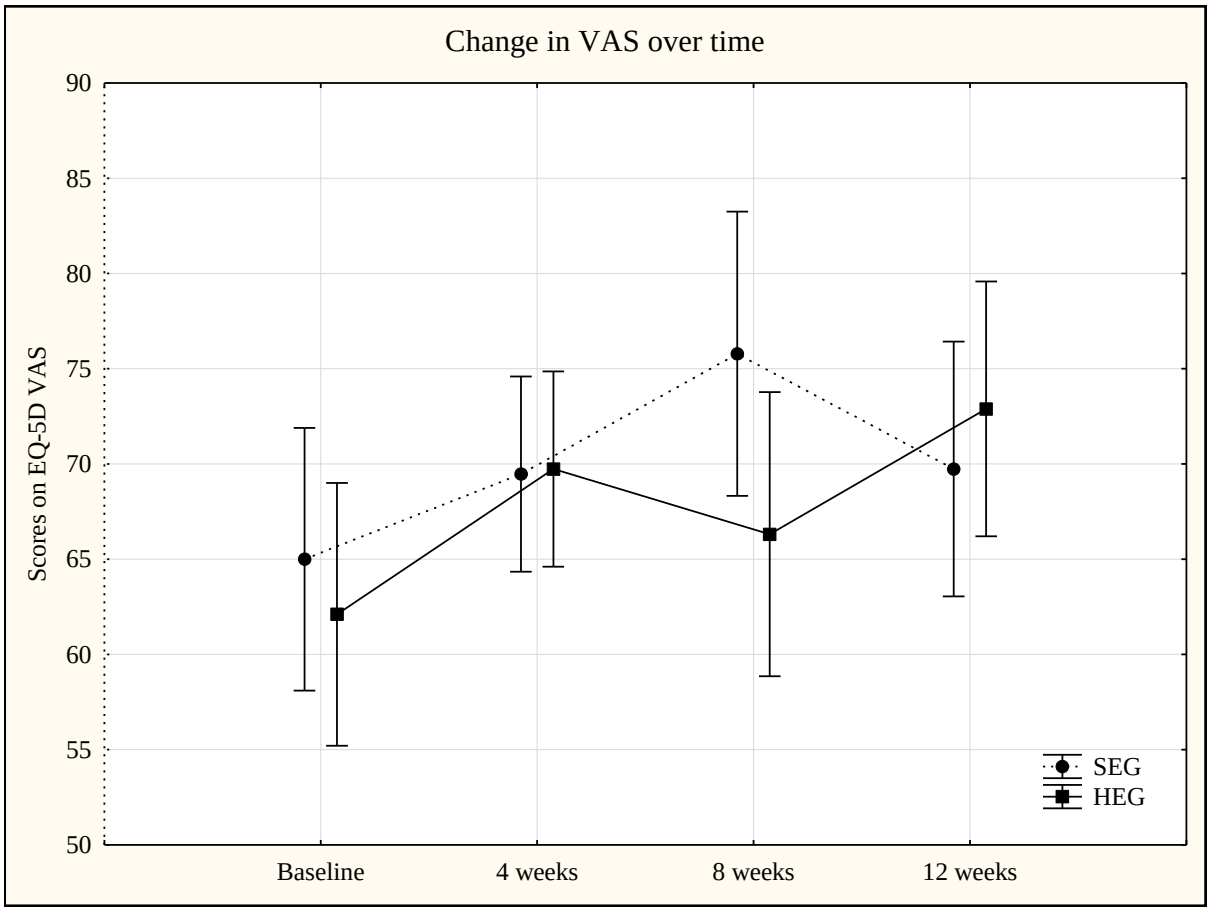


Figure 18: EQ-5D VAS over time (n=38)

There was no significant difference between the two groups, (p=.519), or significant effect of group/time interaction (p=.077) (Table 34). However, the effect of time was significant (p=.007), and thus a Tukey post hoc test was undertaken to see where the differences lay (Table 35). The highest score was seen at the week eight time period in the SEG and the week 12 time period in the HEG. The baseline measures were significantly different to the eight-week score in the SEG and the 12-week score in the HEG.

Table 34: Repeated measures ANOVA of the effect of group, of time and of their interaction (n=38)

	SS	Degrees of Freedom	MS	F	p
Intercept	721190	1	721190	1611.9	***0.000***
group	190	1	190	0.4	0.519
Error	16107	36	447		
Time	1503	3	501	4.2	***0.007***
Time*group	837	3	279	2.3	0.077
Error	12872	108	119		

Table 35: Post hoc analysis of the EQ-5D VAS over time (n=38)

Group		Baseline	4 weeks	8 weeks	12 weeks
SEG	**Mean**	65.0	69.5	75.8	69.7
	Baseline		0.910	***0.056***	0.882
	4 weeks			0.632	1.000
	8 weeks				0.682
HEG	**Mean**	62.1	69.7	66.3	72.9
	Baseline		0.39	0.934	***0.057***
	4 weeks			0.978	0.986
	8 weeks				0.583

The mean and the p-values are given

4.12 Change in Pain Self-Efficacy over Time

The PSE yields ordinal data and consequently was analysed using non-parametric statistics. The Mann-Whitney U test was used to compare the scores over the time periods. Table 36 demonstrates that there was no significant difference between the two groups at any time point.

Table 36: Comparison of the PSE scores at the four time periods (n=38)

	Rank Sum SEG	Rank Sum HEG	U	p -value	Z
Baseline	382	360	170	0.759	0.30
4 weeks	405	336	146	0.320	0.99
8 weeks	393	348	158	0.520	0.64
12 weeks	390	352	162	0.589	0.54

As there was no difference between the scores of the two groups at each time period, the Friedman ANOVA was used to compare the rank ordering of the scores of both groups combined (ANOVA Chi Square (n = 38, df = 3) = 65.84, p = .000). The average ranks at the different time periods are shown in Table 37. (Note that the higher the average rank, the higher the Pain Self-Efficacy Score and consequently the more confidence reported).

Table 37: Comparison of the PSE scores at the four time periods (n=38)

	Average Rank	Sum of Ranks
Baseline	1.16	44
4 weeks	2.49	95
8 weeks	3.05	116
12 weeks	3.30	126

4.13 Adherence

As the percentage attendances were normally distributed (Figure 19), (Shapiro-Wilk W=.912, p=.080 for the SEG and Shapiro-Wilk W=.931, p=.184 for the HEG), a t-test was used: this indicated that there was no difference in adherence between the two groups (Table 38).

Table 38: Comparison of adherence between the two groups (n=38)

	Mean – SEG	Mean – HEG	S.D.-SEG	S.D.-HEG	t-value	df	p
% Adherence	75.3	71.3	14.7	23.2	0.64	36	0.52

Forty two percent of the SEG were up to 80% compliant, and 47% of the HEG were up to 70% compliant with their respective programmes (Table 39).

Table 39: Difference in % adherence between the SEG and the HEG (n=38)

Adherence	SEG	Percent	Cumulative percentage	HEG	Percent	Cumulative percentage
10-20	0	0.0	0.0	0	0.0	0.0
21-30	0	0.0	0.0	2	10.5	10.5
31-40	0	0.0	0.0	0	0.0	10.5
41-50	2	10.5	10.5	1	5.3	15.8
51-60	1	5.3	15.8	3	15.8	31.6
61-70	4	21.1	36.8	3	15.8	47.4
71-80	1	5.3	42.1	3	15.8	63.2
81-90	9	47.4	89.5	1	5.3	68.4
91-100	2	10.5	100.0	6	31.6	100.0

4.14 Patient Satisfaction

As the data were normally distributed, (Shapiro-Wilk W=.931, p=.182 for the SEG and Shapiro-Wilk W=.943, p=.301 for the HEG), a t-test was used: this indicated that there was a significant difference in patient satisfaction between the two groups, with the SEG reporting better satisfaction (Table 40). (As the variances were different p=.011, a t-test with separate variance estimates was used.)

Table 40: Comparison of patient satisfaction between the two groups (n=38)

	Mean – SEG	Mean – HEG	S.D.-SEG	S.D.-HEG	t-value	df	p
% satisfaction	91.6	83.7	6.3	11.7	2.576	27.54	0.02

4.15 Relationship between Adherence and Change in Function

The relationship between change in function as measured by the RMDQ and compliance are indicated in Figure 19.

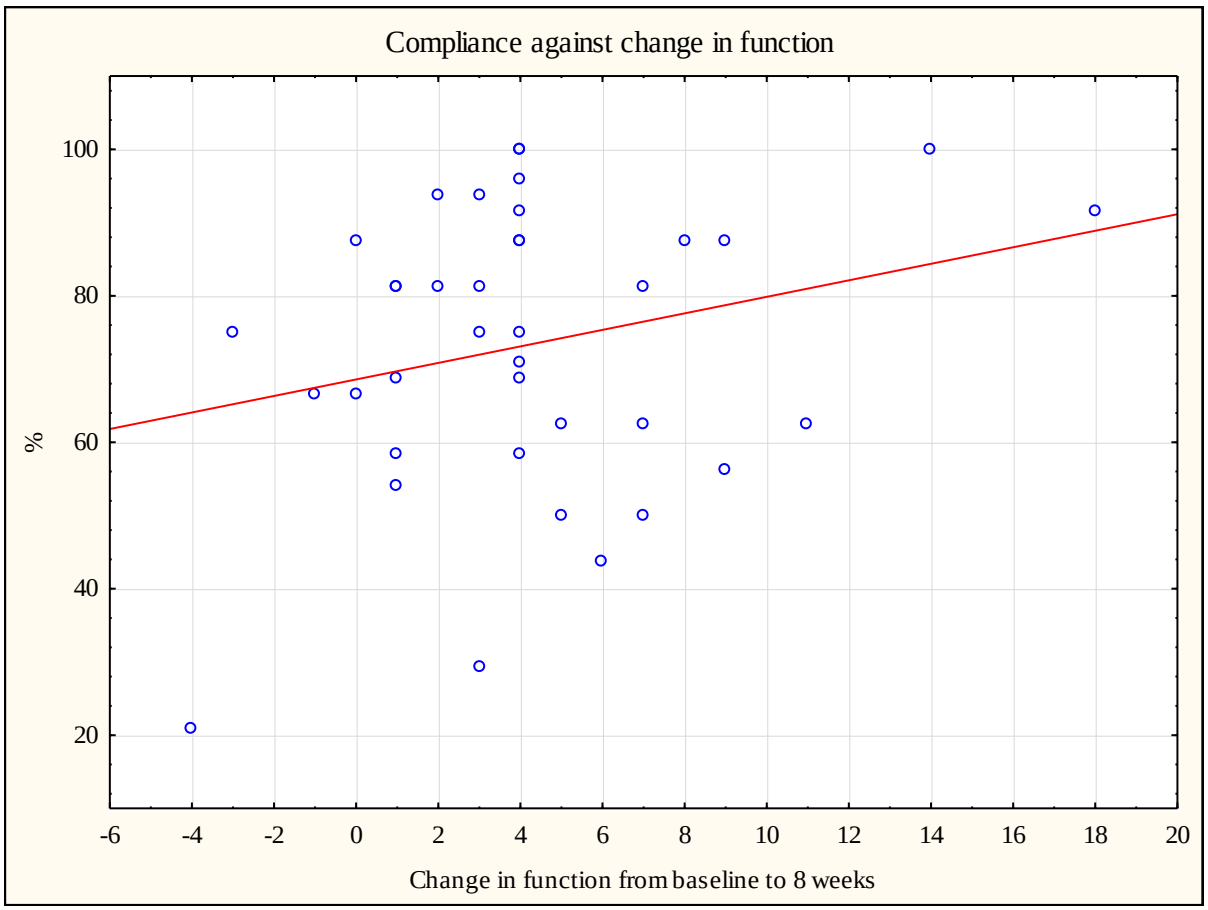


Figure 19: Relationship between % compliance and change in function (n=38)

There was no correlation between the change in function from baseline to eight weeks in compliance (r=.25, p=132) or satisfaction (r=.211, p=205).

4.16 Relationship between Change in Pain Intensity and Years since Onset of Pain

The relationship between change in pain, as measured by the PI-NRS, and years since onset of pain are indicated in Figure 20.

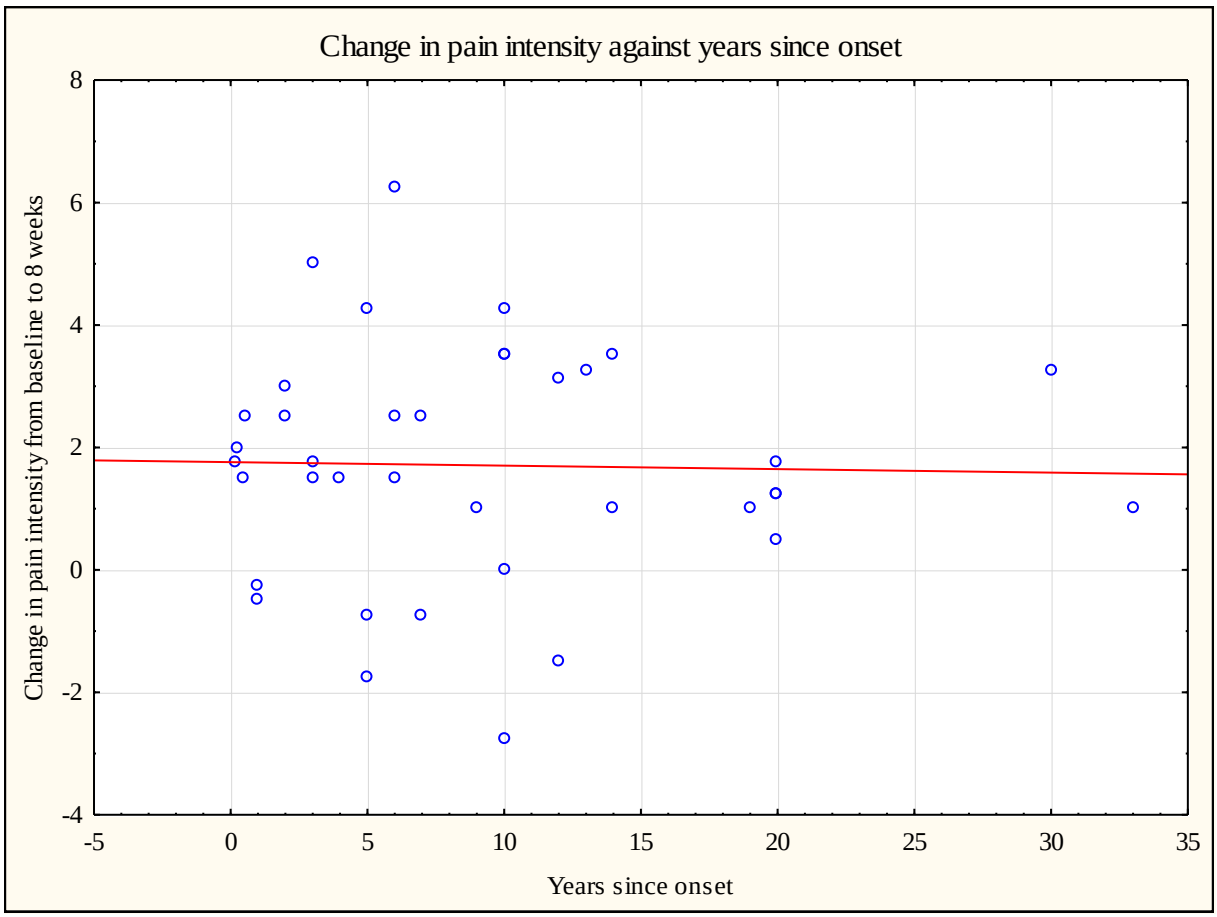


Figure 20: Relationship between change in pain intensity and years since onset of pain (n=38)

There was no significant correlation between intensity of pain and years since onset of pain (r=.024, p=.886).

4.17 Responses to Open-ended Questions requesting Comments

Table 41 and Table 42 highlight the responses to the open ended request for comments written down by 34 participants after completing the study. Nineteen participants commented on improvements in their mobility and posture, 21 participants reported a decrease in their pain, and 17 participants commented on improvements in their strength and/or ROM (flexibility). Twenty-five participants expressed a positive change in their perceptions, cognition and/or emotions, and 11 participants reported on the educational assistance they had gained from participating. Five participants made a comment relating to the service provider, and 23 reported being satisfied with the intervention.

A particularly positive and significant comment was received from participant 11 who reported:

"I no longer experience pain after experiencing high levels of pain for years. I have realised that I don't have to stay in bed and remain immobile whenever my pain is bad. My core strength and flexibility has improved. The low back programme also helped by upper back stiffness. My digestion as well as menstrual cramps improved. I felt my physical, emotional and general health states improved."

Table 41: SEG participants' comments after completion of the study, at 12 weeks

	Improvements in Mobility/ Posture	**Pain decreased**	**Strength/ ROM**	**Cognitive change, or change in Perceptions/ Emotion**	**Education**	**Satisfied with Service Provider**	**Satisfied with Intervention**
20: I liked the 'safe' space created. My mobility and pain improved and I found *The Back Book* to be very useful.	✓	✓			✓	✓	
21: Pain was always reduced after the class compared to the level of pain beforehand. Although my average pain did not decrease during the programme, my body has responded and I look forward to continuing to implement what I have learnt in my daily life. The use of good imagery helped, as the instructor was excellent.	✓	✓		✓	✓	✓	
22: This exercise programme has given me emotional confidence that I can and must exercise and move my back. I am no longer petrified to make my LBP worse. I love exercising again.	✓			✓	✓		✓

23: My pain and stiffness improved hugely, especially during the last 2 weeks of the programme. The Pilates exercises taught me how to contract my core muscles effectively to support my back. This is the first time I felt this since my pregnancy 2 years ago.		✓	✓		✓		✓
25: With the improvement in my strength, my confidence improved and I was less hesitant to do certain movements. Although I did not find the exercises strenuous, there were improvements in my strength confidence and pain levels.	✓	✓	✓	✓			✓
28: Overall my pain is less and the idea of having to slow down and isolate movements whilst exercising seemed to work for me. My initial perception of change and success from exercise was about a physical change, needing to look better. The interesting change came during the study when I 'felt' better than I looked.	✓	✓		✓			✓
29: I was motivated by the feelings of increased strength in my stomach muscles and arms. It was surprising how much stronger I felt after doing exercises that did not feel very strenuous. It was a good way to unwind at the end of a day and to help relax my muscles. I stopped having to think about how I have to move (e.g. bend over) as the pain improved, but after stopping the exercises, I became more conscious of my back when moving.	✓	✓	✓	✓			✓
30: Pilates is essential to maintain my back and neck pain. Although I still get pain when I bend, I have the confidence to do most things, as I know it will not make my back condition worse.	✓			✓			✓
31: My back ROM improved during the programme, so I felt the difference when I had to stop the exercises (at the end of the intervention). My awareness of how to move during my normal daily activities has improved.	✓		✓	✓			✓
33: The changes in my back pain and in my self-belief have been phenomenal, from feeling completely helpless to being able to perform my day to day tasks with confidence. I am also able to perform new tasks which I would have avoided for fear of hurting my back. I have learnt skills to manage my back pain.	✓	✓		✓	✓		
34: My back pain is less but I think the remaining pain comes from the emotional side, which needs to be addressed. I now believe in Pilates.		✓		✓			✓

35: My running improved with far less stitches. My body awareness and posture improved and my LBP definitely improved. As my core strength improved, my back and neck pain improved. Previous massages did not give me the improvements which Pilates gave me overall. *The Back Book* was helpful to show me what to do to avoid injuring my back.	✓	✓	✓	✓	✓		✓
36: I feel more certain of the fact that my back pain originates from my desk job (computer work). I experience improved mobility and range of movement, which transferred into my normal daily activities such as turning in bed and reversing a car. My spinal awareness and support improved as well as my shoulder stability and wrist strength.	✓		✓	✓	✓		
37: With a 70% improvement in my back pain on the programme, I feel it was hugely beneficial. The instructors were warm, friendly, encouraging and patient which contributed to the excellence of the programme.		✓				✓	✓
39: I am filled with hope and positivity after discussing my back problems, and with this nurturing support, I believe my future looks promising and I am more confident that there is a solution to my low back pain.				✓		✓	
40: I felt a huge improvement by the end of the programme. It made me realize how weak my back had been and that there are many options besides medication to help my back pain. My pain did not worsen after stopping the exercises – this reinforced the improvement to me		✓	✓				✓
42: I believe my posture improved, I feel stronger and I feel I have less stress.	✓	✓		✓			

Table 42: HEG participants' comments after completion of the study, at 12 weeks

1: No change was seen in my back condition; however I think that my back requires a different treatment approach. I would have liked more one-on-one sessions to clarify the exercises.							✓
3: I have a better perception of my back pain after having being introduced to Pilates exercise. I have seen improvement in terms of my pain levels and how I perceive my back pain. My back pain flare-ups have reduced during the programme and my back feels stronger than before the study. I can manage my pain better.		✓	✓	✓			✓
4: The exercises improved my body awareness and made me realise how efficient the movement can be when the correct muscles are used. I felt secure in dealing closely with a passionate therapist. I feel that a home programme should rather be twice a week instead of 3x week.	✓			✓		✓	✓
5: I had less pain when performing the exercises after doing them for a few weeks. My core feels stronger.		✓	✓				
6: I have gained confidence to tackle certain physical tasks with less fear. Improvements in my back pain and health made me realise I need to take time out from my busy schedule.	✓	✓		✓			
7: When I started, I was quite nervous and skeptical as I had gone through so much pain and tried just about everything to ease the pain and nothing had worked. The knowledge that I have gained and the exercises I have learnt have given me a new lease on life. I am able to do so much more and be so much more flexible now.	✓		✓	✓	✓		✓
8: I found it difficult to incorporate a home programme into my daily life and I think I could benefit from attending regular classes. The little exercises that I did made me feel more flexible.			✓				✓
9: I feel empowered, as I have learnt techniques to assist my back, like stretching and relaxation exercises. As a result, I have a heightening sense of awareness of my body. I felt it necessary to do exercises such as the ones given in the programme after having a child 4 months ago. I am almost pain free and it has made me realise that I need to be more careful to do exercises to support my back, as I don't get this from the other (competitive) exercise in which I participate.		✓		✓	✓		✓

11: I no longer experience pain after experiencing high levels of pain for years. I have realised that I don't have to stay in bed and remain immobile whenever my pain is bad. My core strength and flexibility have improved. The low back programme also helped by upper back stiffness. My digestion as well as menstrual cramps improved. I felt my physical, emotional and general health states improved.	✓	✓	✓	✓			✓
12: The exercises helped me maintain my flexibility. My running felt easier and my stride loosened up. I am more relaxed when I run. I feel more secure when doing activities in my daily life and when exercising. My perception of pain and management thereof has improved.	✓	✓	✓	✓			
13: I felt more confident that I would not hurt my back after strengthening with the exercises. I felt stronger and my LBP improved. With a small child, I found a home programme more convenient.		✓	✓	✓			✓
16: Exercise helped me to manage my stress. My approach to exercise and movement has been changed through being taught how to use specific muscles more effectively. *The Back Book* educated me on useful tips for work. After stopping exercise, I felt my body stiffen up.			✓	✓	✓		
17: I have more confidence to manage my own back. The exercises helped my back pain and I want to continue doing some form of exercise. The programme has changed my outlook and understanding about my low back pain, and has helped me to manage it more effectively.		✓		✓	✓		✓
18: The clicking and pain in my back has disappeared. I have learnt how to contract my core muscles more effectively for the first time.		✓	✓		✓		
41: There has been improvement in my strength and posture. I missed the exercise during the time-off period.	✓		✓				✓
43: I gained both physical and mental benefits from this experience. The exercises helped me to relax after a stressful day. My movements are more free and spontaneous and I do not have to think how to move. I will continue with the exercises without a doubt.	✓		✓	✓			✓

The results of the study indicate that the HEG and the SEG were equivalent and that there was no difference in their response to the respective interventions for any of the measures. However, despite all participants having a chronic low back condition, both groups showed significant improvements in pain and function and improvements in all parameters during the course of the interventions. Adherence was equally high across the groups and the SEG were significantly more satisfied with the intervention.

5. Discussion

5.1 Introduction

Exercise is widely used in the rehabilitation of patients with NSCLBP,[26] however, judging from existing RCTs and systematic reviews, no consensus exists as to the most effective programme design.[43] The current study compared a supervised Pilates mat programme with a similar non-supervised home-based programme for patients who had experienced NSCLBP for longer than six weeks.

Apart from the SEG reporting greater satisfaction, there were no significant differences found between the two groups at any point in time. It can be concluded that both interventions were equivalent in their impact. In contrast, significant improvements in the primary outcomes, pain and function, and the secondary outcomes, health-related disability, were found in both groups over the course of the two programmes. There were also improvements in the other secondary outcomes, i.e. medication consumption, FTF and PSE, thus highlighting a general pattern of improvement in all outcomes. Although causality was not proved, as there was no control group that did not receive treatment, the fact that all the participants had a history of NSCLBP might indicate support for the use of both supervised and non-supervised Pilates mat exercises in the treatment of NSCLBP.

This chapter begins with a description of the demographic characteristics of the two groups, followed by a discussion of the major findings of the study and a presentation of the results pertaining to the primary outcome measures, namely, pain and function. The responses to the individual tests will then be described, as well as the effects of withdrawing the exercise. Thereafter, the strengths and limitations of the study will be discussed, conclusions given and recommendations made for further research.

5.2 Demographic Data

The participant groups in this study were all females and, moreover, came from a high socio-economic group, with all participants having a fairly high level of education and being employed; they were all recruited from the surrounding residential areas. The participants were also motivated individuals who had volunteered to participate in the study after replying to the study advert, or they had been referred by medical practitioners/therapists. These results can therefore be generalized as pertaining to a similar group of NSCLBP patients, all

of whom had experienced LBP for longer than six weeks. However, the results should be applied with caution, as the participants were not typical of all patients with NSCLBP, many of whom would be of a different age group and drawn from a wider range of socio-economic backgrounds.

The demographic characteristics of the participants in the two groups were well matched after randomization. The mean BMI for both the SEG and the HEG was high (falling within the 'overweight' category in the SEG and the upper limit of the 'normal range' in the HEG).[290] This is similar to other NSCLBP studies, where individuals with LBP also had higher BMI scores.[63,289] A high BMI (equal to or greater than 25kg/m^2) is considered overweight and has been found to be a strong predictor of success ($p<.001$) for patients with NSCLBP to benefit from Pilates-based exercise.[183]

The years since onset of LBP varied greatly between individuals (0.2 – 33 years), highlighting the chronic, episodic nature of the condition.[24,75,76] The SEG demonstrated a significantly shorter duration since onset of LBP, compared to the HEG. However, the duration since onset of LBP did not have a noticeable effect on the results in the current study; this is different to the published literature, where patients with a duration of three years or more at baseline took significantly longer to improve in their pain, disability and psychological scores than did those with shorter duration LBP.[78] The most common precipitating factor of LBP was previous trauma, followed by occupational and other reasons; this is supported by Richmond[291] who highlights the multi-factorial etiology of LBP, to which precipitating factors such as occupational and previous trauma contribute.

The validity of the results is strengthened by the fact that there were no dropouts during the course of the study. The current study participants were made up of a select, motivated group, and for this group, the published literature suggests that Pilates-type exercises are a reasonable exercise alternative.[128]

5.3 Major Findings

The current study found no between-group differences in the outcomes measures, although within-group differences were found. These differences could largely be attributed to the programmes being very similar and comparable, only differing in the supervision component. Other published studies have compared supervised programmes with home programmes, but have not kept them similar,[126] or they have compared heterogeneous exercise types, both supervised and home-based.[128,292]

The significant differences found in the primary outcome measures, suggest that Pilates exercise (whether supervised or non-supervised) does make a positive difference over an eight-week period to participants' health status. These findings are in keeping with the Liddle et al[43] review, where both experimental and control groups were given supervised exercise programmes of variable content, and both groups achieved positive results.

During the course of the interventions, there was an improvement in both pain intensity and function; interestingly, there was a greater change in function, despite the pain. This is similar to the results found in the MacIntyre[178]study, which found minimal improvements in pain but nonetheless significant improvements in function after a 12-week Pilates mat work programme was included in the normal exercise and physiotherapy (if needed) routine. Authors of NSCLBP papers have highlighted the importance of improving functional activities, despite pain.[144] Previous reviews about the efficacy of Pilates in relieving pain and improving function in patients with NSCLBP are inconclusive.[53,54,186-188] The participant groups analysed were reported to be heterogeneous, which made comparisons between studies difficult.[185]

Across the board, the participants improved on all the outcome measures. This finding suggests that both the supervised and the non-supervised programmes were progressed adequately to allow physical and cognitive adaptations to occur, thus bringing about positive change in all outcomes. The patterns of improvement in the various outcomes demonstrated an earlier improvement for the SEG at eight weeks (the end of the exercise intervention), and a later improvement for the HEG at 12 weeks (four weeks post completion of the intervention). The adherence to the programmes was similar; however, the SEG reported significantly greater satisfaction with their programme. This finding is different to that of a recent systematic review, which reported that those patients, who were more satisfied with the musculoskeletal physical treatment, were also more compliant to the treatment.[270] Why the participants on the home exercise intervention were as compliant as the participants on the supervised exercise intervention in the current study, is considered later in this discussion.

This study found improvements in the outcomes on an exercise only intervention; this differs from Nicholas et al's[154] study, which found that there were significant improvements in NSCLBP outcomes when psychological treatment was combined with physiotherapy treatment compared with physiotherapy treatment alone.[154] It must be stressed, however, that this study, while being a randomised control trial to compare the two methods, was in fact a

pre-experimental study with regard to both groups combined, and thus the interventions cannot be said to have caused the improvement.

5.4 Primary Outcome Measures

Pain and function outcomes demonstrated a similar pattern of improvement, with function improving more than pain, which is a common finding in the literature.[32,138,178]

Pain intensity decreased steadily in both the SEG and the HEG between baseline and eight weeks (the duration of the interventions), with the maximum improvement in 'worst' pain on the PI-NRS at eight weeks. The same pattern was found for the 'average' pain scores. The baseline pain scores ('worst' and 'average' pain) were significantly different to the measurements taken at weeks four, eight and 12, in both groups, thus indicating improvements in pain intensity over the intervention period. The PI-NRS is responsive in detecting and reflecting improvement in pain intensity over time.[221] The 'worst' pain scores showed the biggest improvement between baseline and four weeks, with a 1.5/10 point difference on the PI-NRS, in both groups, indicating a rapid analgesic effect soon after starting the exercise. At the end of the eight-week intervention, the 'worst' pain scores had dropped 3/10 points on the PI-NRS in the SEG and 2.5/10 points in the HEG, and the 'average' pain scores had dropped 2/10 points in the SEG and 1.75/10 points in the HEG respectively, thus representing a clinically meaningful change in pain.[10] Wajswelner et al's[45] study found significant within-group improvements in the 'average' pain measurements using the PI-NRS over time (from baseline to 24 weeks), whereas Rydeard et al[164] and Miyamoto et al[180] found significant between-group improvements in 'average pain', as shown by a decrease in the points on the PI-NRS, which were clinically meaningful.

Function improved in both study groups, although the difference between the groups was not significant.

Rydeard et al[164] compared a specialist Pilates programme with a control group and found significant between-group differences, as did MacIntyre,[178] when comparing Pilates versus non-specific exercise as part of a physiotherapy rehabilitation programme. Marshall et al's[292] study compared specific Pilates trunk exercises and stationary cycling for eight weeks and found significant between-group differences in disability and self-rated pain scores after training.

The major difference to the current study is that the exercise types and sometimes the exercise durations compared in these studies were heterogeneous, whereas the exercise type and duration was kept similar in the current study.

In the current study, the within-group differences in function were significant at four, eight and 12 weeks when compared to baseline measurements. A significant improvement in the RMDQ scores (4 points) was evident from baseline to eight weeks, in both the SEG and the HEG. A change of two to five points on the RMDQ is equal to a moderate improvement in function,[293] which is indicative of a clinically meaningful change. This suggests that the improvements in function, as seen in the current study, are both statistically significant and clinically important.

Improvements in pain intensity and function scores were clearly shown by the results of the PI-NRS (0-10) and the 24-item RMDQ. The responsiveness, reliability and validity of these two outcome measures have been tested. The Chapman et al review[214] highlights how often the PI-NRS and RMDQ have been used to assess outcomes in LBP studies, and highly recommends their inclusion to assess pain and disability. It has also been recommended that more emphasis should be placed on pain and disability scores than on physical impairment in LBP studies and in clinical practice.[230] Exercise therapy has been shown to be effective in decreasing pain and improving function in populations with NSCLBP.[138] The results of this study are similar to the findings of eight RCTs and two cohort studies that found improvements in functional ability and decreases in pain levels[85] by incorporating trunk strengthening into a plan of care. Pilates-based exercise has similarities with spinal stabilization exercises[169] in that it emphasizes facilitation techniques, such as verbal cuing and imagery, to encourage skeletal alignment and breathing; moreover, the Pilates exercises are performed in different functional positions. Incorporating these exercises into a therapeutic exercise programme may thus help the transfer of these gains to everyday movement and functional activities, as demonstrated by the current trial.

Function improved in both groups, as did pain intensity, although pain was still present. However, since pain and disability are suggested to have a weak relationship,[294] the aim of the interventions was to improve the activity level of the patients, regardless of persistent symptoms, and to change the patients' attitudes and beliefs regarding their ability to move.[138] The change in their attitudes and beliefs can be seen in the participants' responses to the open-ended questions (Section 4.17). The effects of the exercise programmes could have been due to the reversal of physical weaknesses targeted by the corresponding exercise

modality, as well as the changes in perception of pain and disability.[295] In the current study, the length of pain duration varied from six weeks to 33 years. It is probable that the limited change in pain response in the patients who had longer standing pain was due to the more complex central pain mechanisms that develop over time.

The improvements in pain and function in the supervised group are supported by a qualitative study by Slade et al[12] and a meta-analysis by Hayden et al,[29] which looked at the intervention characteristics that might improve the exercise outcomes in NSCLBP; those studies concluded that supervision, individualisation and strategies to increase adherence would improve pain and activity. However, the improvements in the primary outcomes found in the non-supervised group are surprising, seeing that the evidence to support the use of home exercises for NSCLBP is inconclusive.[201]

The results of the present trial show that both a supervised and a non-supervised Pilates intervention resulted in similar improvements in the primary outcomes of pain and disability, as well as in the secondary outcomes of health-related disability and analgesic consumption, at short-term follow-up. This is different to earlier studies, which found that supervised physical training, which was adjusted to meet each patient's needs, was significantly more favourable than home training.[126,158] The current interventions differed from earlier studies in that no individual tailoring of the exercise programmes was included despite the fact that similar improvements in the primary outcomes in both the SEG and the HEG were seen.

5.5 Responses to Individual Tests

The responses to the various tests are described below within the ICF domains. In the parameters measured, within-group differences were found, but no between-group differences.

5.5.1 Impairment Outcomes

a) Pain

There were consistent improvements in pain intensity, which reached a plateau by week eight in both groups. This finding is supported by Rydeard et al's[164] study, which also found significant improvements in pain intensity in the group that participated in the specialised Pilates exercise programme. These findings are in keeping with the principle of exercise-induced analgesia.[114]

b) Change in medication

The majority of the participants were taking pain medications (either pain killers or NSAIDs) at the beginning of the study, and the decrease in their use of these medications by the end of the eight-week intervention highlights the analgesic effects of exercise. The use of anti-depressive medication did not decrease by the end of the intervention; however, this study design did not explore whether the anti-depressant medication usage was related to the onset of the NSCLBP.

c) FTF

The FTF test was the only physical outcome measure taken. The distance of the fingertips from the floor decreased uniformly in both groups, indicating an improvement in mobility of the lumbar spine and pelvis, specifically in the movement of bending forward.

5.5.2 Functional Outcomes

a) Function

Function improved steadily in both groups throughout the study, although the improvement in scores reached a plateau at eight weeks in the SEG, and continued to improve until the 12-week measurement in the HEG. The marked improvement in scores in the RMDQ at eight weeks in the supervised group was evident, and it can be attributed to the structured programme.[129]

5.5.3 Participation Outcomes

a) EQ-5D Health Questionnaire

There was a consistent improvement in the health-related quality of life measurement, as could be seen in the results of the EQ-5D domains, the EQ-5D health index and the EQ-5D VAS from baseline to 12 weeks, in both groups. The results of the EQ-5D health questionnaire showed improvements in both health and perception of health from four weeks (i.e. early on in the intervention) and continued to improve throughout the period of the exercise programme.

Most noticeable were the improvements in the ‘pain/discomfort’, ‘usual activities’ and ‘mobility’ domains, which parallels the improvements in pain intensity and function scores. The scores in the anxiety/depression domain did not change over time, which is not

surprising though, seeing that the interventions did not specifically address this aspect of health.

The EQ-5D is capable of indicating clinically important changes.[236] The lack of responsiveness of the EQ-5D has been reported in the literature; however, this was not the finding in the current trial, where early improvements in health were evident early on in the programmes.

b) PSE

The results of this study showed a constant improvement in PSE at all the time points, along with improvements in pain and function. These findings differ from those obtained by other authors who have suggested that physiotherapists may lack the necessary skills in physiotherapy-based treatments to bring about long-term changes in certain cognitive factors.[49] The improved confidence of the participants, as reflected in the results of this trial, supports the concept that more self-efficacious people may be more motivated to engage in health promoting behaviours and to adhere better to treatment recommendations.[65] The results of this trial are also supported by the use of exercise quotas,[206] which provide individuals with a sense of achievement by successfully increasing their levels of activity. Physical training that is supervised and adjusted to meet the patient's needs has been found to be significantly more favourable than a home training programme in terms of improvements in self-efficacy, pain, disability and analgesic consumption in the short term.[126] The current study, however, found these improvements to be true for both the supervised and home-based programmes.

5.5.4 Personal Factors

a) Adherence

The effectiveness of exercise for patients with NSCLBP depends on their adherence to it.[284] The adherence to both the supervised and home programmes was similar. Incomplete adherence is widely regarded as a substantial barrier to successful outcomes. Both the SEG and the HEG reached a 70% compliance level. It was surprising that the SEG was not more compliant than the HEG and that no significant difference was found between the groups, as it has been reported elsewhere in the literature that adherence to exercise prescription is usually poor and that, to improve adherence, supervision by a therapist is recommended.[200]

On the other hand, Kolt et al[198] and Frih et al[204] found high rates of compliance to a home-based programme, 68% and 88% respectively.

The high compliance levels observed in the HEG in the current study could be attributed to the use of exercise diaries, which have been reported to result in over-estimation of programme attendance.[296] However, higher education levels and self-selection of participants could also have contributed to higher motivation levels,[204] which is needed for a home-based programme. The use of written and illustrated exercise instructions[197] may also have contributed to the high compliance levels.

Provision of *The Back Book* to educate the participants about their condition during the physical therapy interventions may have contributed to the high compliance to the programmes, in both groups. Providing information during an exercise intervention has been found to be associated with adherence to self-management of chronic pain.[297]

b) Satisfaction

Satisfaction was significantly greater in the SEG, which highlights no association between compliance and satisfaction. This finding differs from the Hush et al[270] review, which reported that satisfied patients are more likely to adhere to treatment. The current study demonstrated that NSCLBP patients who received supervised Pilates exercise were most satisfied with the care received during the intervention. This finding is similar to Bronfort et al's[199] study, which found that the supervised exercise group was significantly more satisfied with treatment and trunk muscle endurance and strength than a spinal manipulation group and a home-based group. However, in the Bronfort et al[199] study, both short-term and long-term differences between groups with regard to patient pain, disability, general health status and medication use consistently favoured the supervised exercise group above the home-exercise and spinal manipulation groups, which again differs from the findings of the current study.

In the current study, the higher reported satisfaction by the SEG may be attributed to their positive relationship with the therapist[193] who was teaching the classes. The relationship between the patient and therapist, commonly known as the therapeutic alliance, is central to the therapeutic process.[192]

5.6 Effect of Withdrawal of Treatment at the 8-Week and at the 12-Week Follow-up

The pain scores (a combination of the 'worst pain' and the 'average' pain scores) worsened slightly in both groups after stopping the exercise. However, the change in points was too small to reflect a clinically meaningful change.[10] The decrease in consumption of medication was evident during the programme and remained constant between weeks eight and 12. The improved pain scores and decreased use of medication (pain control) during the intervention remained relatively constant from week eight to week 12, which reflects a behavioural change in the use of medication. Similarly, the results of the FTF measures indicated that the improvement in lumbar and pelvic ROM during the Pilates programme was maintained after stopping the exercise.

The change in function scores followed the same pattern as that of the pain scores, with a slight increase in the RMDQ scores, but not a big enough change in points to signify a clinically meaningful decrease in function. This finding suggests that the gain in function was maintained for four weeks after both the supervised and home Pilates mat exercise programmes. Other published data supports this finding, with some reporting improvement in function for six weeks[180] and others reporting improvements for up to twelve months[164] post a Pilates intervention.

The change in health scores as measured by the EQ-5D remained relatively constant between weeks eight and 12. There was a slight decrease in health scores at week 12 in the SEG, which was most noticeable in the EQ-5D VAS scores, which could be as a result of stopping the structured exercise programme at week eight and no longer having the interaction with the therapist.[193] The perceived health of the participants in the HEG, as shown by the EQ-5D VAS scores seemed to improve slightly at weeks 12, which might demonstrate a sense of control over their health.[206]

The PSE scores continued to improve (but not significantly so) between weeks eight and 12 in both groups, showing that an improvement in confidence was maintained after completion of the intervention. An improvement in self-efficacy has been reported as significantly predicting better functioning and less reported pain in the rehabilitation of LBP.[158] The confidence of the participants post the intervention remained higher than at baseline levels, highlighting the importance of including exercise in the management of NSCLBP.

The fact that all outcomes improved during the supervised and the home exercise programmes and that these improvements were maintained for four weeks post the exercise programmes, highlights the likely beneficial effects of Pilates mat exercise in the short term, in both the supervised and non-supervised forms.

5.7 Strengths and Limitations of Study

5.7.1 Strengths

This trial was a RCT, which included the concealment of the allocation of participants to the two groups and the blinding of the person responsible for taking the outcome measurements. The methodological outline followed an established guideline for carrying out clinical trials (by making use of the CONSORT statement 2010 checklist).[298] The two groups were comparable at baseline, with regard to participant characteristics that were known to influence response to treatment and response to outcome measures. Both interventions were delivered by the same experienced therapists to minimize the influence of different therapist styles. The dosage of the Pilates classes and home exercises reflects current clinical practice and the programmes that were followed are reproducible. The exercise content (which had been found to be effective for NSCLBP)[127] was kept similar for both groups, which also allowed for easier comparison of the groups. This trial included the use of an exercise model in accordance with the guidelines for clinical practice for NSCLBP patients.[25,26]

No participants dropped out of the study, which further makes the results representative of the groups studied, as analysis was done as per original assigned groups. The study thus had appropriate statistical power.

The use of reliable and validated questionnaires relevant to the study of LBP and the 70% adherence rate helps to validate the results of the current study.

The participants who volunteered to take part were motivated people. The study population was recruited from a group of women who sought care post a first-time LBP episode or a recurrent LBP episode and, other than five percent who were referred by therapists, had responded to the recruitment advert.

5.7.2 Limitations

The participants came from a higher socio-economic group, which means that the results are only generalizable to this group. Another limitation of the study is that there was no placebo

group. We know from the results that both interventions had a positive effect on pain intensity, function, medication use, ROM, health, and PSE outcomes in NSCLBP, but if there had been a placebo group, we would have been in a position to say how much of a difference each intervention had made. Future studies should consider including another group that does not participate in any Pilates exercises, but that possibly includes only the educational component. Withholding all forms of treatment from the placebo group might give rise to ethical concerns, given that both supervised Pilates exercise and home exercises improved outcomes and that there is sufficient published literature to support the use of these therapeutic interventions. However, as the beneficial effect of Pilates is still regarded as being inconclusive, based on the meta-analyses,[185] such a study may well be long overdue. Including a longer follow-up time post intervention, at least six months, would be helpful in determining which effects of the interventions were longer-term, and not just a change due to the abrupt termination of the exercises and/or the support received during the programmes. However, longer-term adherence to a programme is more difficult to achieve, and depends less on continuing input from the therapist and more on self-regulation by the individual.[206]

Unfortunately, it was not possible to blind the therapists to the treatment they were prescribing, nor was it possible to blind the participants to the exercise programme they were following. The inability to blind therapists and participants when active interventions are applied is a common challenge in physical therapy trials.[299] Using a bigger sample might have resulted in bigger differences between the groups.

No objective assessment tool, like the back screening questionnaire used at the beginning of the current study, was included at the end of the study. The inclusion of a movement test or a physical task to assess objective changes in stability and/or function before and after the interventions might have provided valuable information, which could be useful for clinical practice.

Another limitation of the study is that one of the participants received one ‘hands on’ physiotherapy treatment due to an emotional setback; however, this treatment enabled her to continue with the home programme. It was done per protocol, but this may nonetheless have affected the overall results of the HEG. However, it does emphasize the multi-factorial nature of NSCLBP and the difficulty in controlling all the variables that could be contributing to the patient’s pain.

6. Conclusion

6.1 Conclusion

The objectives of this study were to investigate the differential effect of a supervised and a non-supervised Pilates eight-week mat programme on pain intensity and function, medication use, ROM, health and PSE outcomes in NSCLBP, and to establish whether improvements would be maintained for a month after completing the programmes. Adherence to and satisfaction with the two programmes were established.

This study supports the findings of other LBP RCTs, which determined that supervised exercises performed at an intensity that improves physical abilities, delivered with the message that it is safe to function in the presence of tolerable pain intensity,[128] are associated with significant improvements in pain and disability. The findings of this study also support those LBP studies, which have used non-supervised exercises, given with adequate progressions, frequency and duration[300] and which have resulted in significant improvements in pain and function over time.

For NSCLBP, exercise therapy is recommended.[73] The results of this study indicate that both supervised and non-supervised Pilates mat exercises are associated with improving pain and function, medication use, ROM, health-related disability and PSE in participants who have been specifically screened for the presence of 'non-specific' CLBP symptoms, which had been present for longer than six weeks. The improvements in the outcomes measured indicate that the therapeutic exercise interventions used in this study could have made a positive difference.

The current findings are in keeping with the recent literature, which suggests that exercise design and good implementation are more important than the specific type of exercise,[40] and that the emphasis of a therapeutic exercise programme should be on getting patients to move safely and with confidence. There is a cost saving with group work[129] and home programmes[201] as opposed to individual supervised sessions and, given the results of this trial, both group classes and home programmes should be made more available to reach all socio-economic communities.

Pilates is a gentle exercise form, which has a two-fold effect: it can be used as a means to help overcome fear of movement and to improve confidence to move,[239] which in turn allows for the physiological gains of exercise to take effect. NSCLBP is a multi-faceted condition,

which requires a bio-psycho-social approach, with exercise forming one of the chief components. The results of the current study support the published literature documenting the efficacy of exercise in the conservative management of NSCLBP.

There are advantages to both supervised and home-based Pilates mat exercise programmes. The advantages of patients attending supervised classes allows for continued correction and feedback, while additionally developing a strong therapist-patient relationship. The therapist is able to add different exercises for stimulation and to help challenge and strengthen the patient further. Conversely, the advantages of doing specific Pilates home exercises allows for self-management of time and participation. (The participants' responses to open-ended questions highlight these different advantages in Section 4.17).

In summary, both a supervised and a non-supervised eight-week Pilates mat programme provided patients with an active pain management tool that was associated with decreased disability and decreased use of analgesic medicine, and with improved ROM, PSE and health-related quality of life scores. These outcomes were maintained in the short term (for one month post the intervention). Adherence to the programmes was similar, but the supervised group reported to be significantly more satisfied. The findings highlight the likely effectiveness of Pilates mat exercises as an active treatment approach in the rehabilitation of patients with NSCLBP who have experienced their symptoms for longer than six weeks. Additional research is required to extend these findings and to establish definitively the causal link between these interventions and the improvement obtained.

6.2 Recommendations

Pilates mat work may be beneficial, as it has been shown to be associated with improved pain measures, function, health-related disability, cognitive factors such as confidence, and physiological factors such as ROM, and it can thus be considered as suitable exercise, in both the supervised and the non-supervised form, for NSCLBP.

6.2.1 Practice

No differences were found between the two exercise approaches, supervised classes and the home programme: group work is suggested for those needing re-assurance and re-enforcement of the exercises; home programmes are suggested for those with time constraints, for those who live far away from class venues and who are unable to use transport easily, and for those who are able to self-motivate. Both the patient and the therapist

need to make a choice of which type of programme to follow to improve outcomes. Patient preference is one of the three components of evidenced-based medicine; the other two components are clinical expertise and research evidence.[271,272] Patient preference might also be the factor that influences patients to choose one exercise approach above another.

In practice, both a class and a home programme have a cost-saving effect compared to individual, supervised sessions and should be made more available to reach all socio-economic communities.[129] Although the current study included only women with NSCLBP, Pilates mat exercises may be effective for both men and women, if they choose to participate in this exercise form.

An exercise diary could help to keep the individual focussed and motivated. Keeping a record of attendance at a group or at a home session could lead to greater compliance with the exercise, and it requires a two-way commitment from both the therapist and the individual. This recording of participation allows the therapist to monitor changes in the patient's condition, and further enables the therapist to pace the programme of choice to cater specifically for the individual's needs.

Due to the episodic nature of NSCLBP, manual physiotherapy sessions may be required during a therapeutic exercise programme to assist patients during acute bouts and to assist the body to adapt to the introduction of the exercise.

6.2.2 Research

Studies should be performed on a heterogeneous group, which includes both men and women, participants from different ethnicities and socio-economic groups or a wider representation of both the urban and rural communities. The outcome of these studies could help determine the need for Pilates group classes in these settings for various socio-economic groups. The study intervention could include longer follow-up to determine the long-term effects of Pilates mat work, specifically since NSCLBP is associated with relapses and intermittent pain.

The development of a valid classification of homogeneous subsets of NSCLBP patients would allow for a complete evaluation of the relative effectiveness of conservative treatments.[28] It would also enable one to determine which sub-group of patients is most likely to benefit from the Pilates treatment.

6.2.3 Outcome measures

Relevant outcome measures were chosen specifically for this trial after reviewing numerous LBP studies and reflecting on which measures would be responsive to picking up the effects of an exercise intervention on patients suffering from NSCLBP. For this study, the outcome measures were found to be sensitive enough to pick up changes in pain intensity, function, medication use, health, ROM and PSE. The outcome measures for adherence and satisfaction gave relevant information regarding personal factors, which need to be considered when preparing a therapeutic programme and which may help to make a programme more suitable for an individual. It may also be important to target measures of health that people can identify with (such as rating of pain and heart rate, lifting a load, ergonomic assessments, or other physical tasks that relate to their function), rather than restricting assessment to disease-specific methods (such as disability questionnaires) and self-report questionnaires.[12] An objective assessment tool, like the back screening questionnaire used at the beginning of the current study, which includes a movement test or stability test or another physical task, could possibly have been included at the end of the intervention to determine objective changes in stability/strength.

6.2.4 Strategies to Improve Outcomes with Pilates Mat Exercise

A thorough assessment of the LBP condition prior to entry into a Pilates exercise programme is necessary to determine the suitability of inclusion into such a programme, and must include not only the subjective and objective assessments but also the specific goals and needs of the individual. Taking into account the patient's preferences is likely to improve adherence to a programme and thus improve the effects of the exercise on outcomes, leading to greater satisfaction and ultimately boosting adherence.

Individual sessions need to be included prior to entry into a therapeutic exercise programme. These individual sessions should include an assessment of the body type, the teaching and demonstration of the principles of Pilates, and the correction of movements, which provides a foundation from which the patient can progress. A minimum of two individual sessions are required but the number of sessions could be more, as it will depend on the individual's ability to grasp the principles so that they can apply them to their programme of exercises, whichever form it may take.

The Pilates classes should be graded by the experienced therapist to meet the ability of the individuals within the class, by adapting the exercises and including appropriate progressions.

Such supervised classes would be suitable for individuals who like feedback, support and a set routine, and they should be structured at convenient times, in a professional, accessible environment. Conversely, a home programme would be suitable for a self-motivated individual with family responsibilities and specific time constraints (and possibly financial constraints) who understands the key principles of Pilates and who can apply these principles to their written out progressions, making use of laminated pictures of the exercises as a reminder. Including a check-up at pre-determined time intervals for those participating in a home programme could be useful to help motivate and provide support, as well as to help meet the pre-determined goals and improve patient satisfaction.

It is heartening that a simple and cost effective physical therapy intervention was associated with significant improvements in pain and functioning in NSCLBP, despite the chronic nature of the condition. Pilates would appear to be an acceptable and effective intervention, regardless of the mode of delivery. The long-term effects of such programmes need to be established, but it has been conclusively shown that they are effective in the short term.

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Appendix A: Recruitment Advert for Study

Division of Physiotherapy, Department of Health & Rehabilitation Sciences
Faculty of Health Sciences, University of Cape Town, South Africa

FEMALES WITH PERSISTENT LOW BACK PAIN NEEDED FOR A UNIVERSITY OF CAPE TOWN (UCT) RESEARCH PROJECT

For a study comparing the effects of an eight-week supervised Pilates mat programme versus a non-supervised home exercise programme on non-specific chronic low back pain.

Study outline

I am a Masters student at UCT. Although exercise has been found to be effective and safe for managing non-specific chronic low back pain, there is little information about the type of exercise that will have the most benefit for this group. The specific type of exercise needs to be explored. This study will compare the effects of Pilates or home exercises on low back pain, as these are both popular, safe forms of exercise. You will either be allocated to a group that attends Pilates group classes, or to a group that performs a home exercise programme. Pain, function, health status, adherence and satisfaction with the exercise will be measured during and after the exercise programmes. You will be required to keep a record of your exercise participation during the eight-week programmes, and for four weeks thereafter.

Those interested in participating should

- be female, between the ages of 20 and 55 years
- have experienced low back pain for longer than six weeks at recruitment
- be available to take part in an eight-week exercise programme

Benefits of participating in the study

- Individual anthropometric measurements (height, weight, BMI, body fat %)
- A Back Book with advice on management of back pain
- Feedback regarding the results of the study

APPLY BY: 20 January 2013

For further information please contact

Catherine Chemaly **021 461 2159**

Cell: 082 465 3745 **Email: cathy@healthjunction.co.za**

Appendix B: Informed Consent

Faculty of Health Sciences Divisions of Communication Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital, Observatory 7925 Tel: +27(0)21 406 6401 Fax: +27(0)21 406 6323 Internet: www.uct.ac.za

Dear Participant

Thank you for your interest in this study. I am a Masters student in the Division of Physiotherapy at the University of Cape Town. I will be conducting a study to compare the effects on low back pain of a supervised eight-week Pilates mat programme with a non-supervised home programme of similar exercises. The information from this study will be used for a Masters in Physiotherapy degree (M.Sc. Physiotherapy) from the University of Cape Town. This study has been given ethical approval by the University of Cape Town, Faculty of Health Sciences Human Research Ethics Committee (HREC ref to be inserted).

Exercise is recommended as a safe method to manage chronic low back pain, but so far there is a little information about the specific exercise approach that will have the most benefit for people with non-specific chronic low back pain. I have chosen to compare the effects of Pilates and home exercises on low back pain, as these are both popular and safe forms of exercise.

You need to have had low back pain for six weeks or longer to take part in this study. If you agree to take part, you will either be in a group that will have eight weeks of Pilates exercise classes, or you will be in a group that will be asked to do exercises at home for eight weeks. The groups will be decided by flipping a coin ("random allocation").

The study will take 12 weeks to complete. All testing and the Pilates exercise classes will take place at the Healthjunction Centre in Vredehoek.

Please take time to read this form thoroughly before signing. If you have any questions regarding this form, please feel free to ask.

The study consists of the following sessions:

Initial screening/Familiarisation session at the Healthjunction Centre:

During this session, you will be asked to complete a *physical activity readiness questionnaire* to screen for any health problems that might affect your ability to exercise safely, and a *back screening questionnaire* to find out more about the history and nature of your back pain. If any problems are identified that do not allow you to take part in this study, you will be referred to a medical practitioner of your choice for further assessment and management. Your *weight, height* and *skinfold thicknesses* will be measured to calculate your body fat percentage.

You will then be randomly allocated to either the Pilates exercise group or the home exercise group. If you have been allocated to the Pilates exercise group you will be booked for one individual Pilates session with a Pilates instructor, and if you have been allocated to the home exercise group, you will be booked for two individual sessions with a qualified Physiotherapist.

Individual sessions at the Healthjunction Centre:

These sessions will be take place in one week prior to starting the exercise programmes.

The Pilates group*:*

At the first and only individual session, you will be taught the basic principles of Pilates to prepare you for the classes. You will be asked to fill out *five questionnaires* about your pain, level of function and health status, which will take approximately 15 mins to complete. A physical test called the *fingertip-to-floor* test will be demonstrated and tested to measure your trunk flexion. The test requires you to bend forward from the waist, reaching for the floor, whilst keeping your legs straight. You will also be asked to rate your expected benefit from the Pilates programme on a scale from 1 to 5.

Sessions	**Duration**	**Venue**
Familiarisation/screening	75 mins	Healthjunction
One individual session	60 mins	Healthjunction
Eight-week programme	2 x 75mins/week	Healthjunction
Testing sessions	3 x 30mins	Healthjunction

Pilates group: time commitment for the study

The Home group:

At the first individual session, a physiotherapist will teach you the home exercises, which are similar to the exercises that will be taught in the Pilates classes. The exercises will be given to you on exercise sheets, with drawings and simple instructions to assist you to do the exercises correctly at home. You will be asked to fill out *five questionnaires* about your pain, level of function and health

status. A physical test called the *fingertip-to-floor* test will be demonstrated and tested to measure your trunk flexion. The test requires you to bend forward from the waist, reaching for the floor, whilst keeping your legs straight. You will also be asked to rate your expected benefit from the home programme on a scale from 1 to 5.At the second individual session, the home exercises will be checked to make sure that you are doing them correctly. The exercises will be revised and corrected if necessary. You will be given a physiotherapy ball to take home as some of the exercises require the use of a ball. Please make sure that you do these ball exercises on a non-slip surface at home.

Sessions	**Duration**	**Venue**
Familiarisation/screening	75 mins	Healthjunction
Two individual sessions	2 x 60 mins	Healthjunction
Eight-week programme	4 x 30 mins/week	Home
Testing sessions	3 x 30 mins	Healthjunction

Home group: time commitment for study

You will be asked to avoid taking part in any new exercise (i.e. exercise you are not doing already) besides the Pilates or home exercise programme for the duration of the study (12 weeks). You will also be given a copy of *The Back Book* with advice on back pain and back care, and an *exercise logbook*. You will be asked to record pain and perception of effort with each exercise session; and any other treatments or medication for low back pain. The logbook will be handed in at the end of the study.

The Eight-Week Exercise Intervention:

The Pilates group will be asked to attend Pilates classes twice a week for eight weeks at the Healthjunction Centre. These classes will be taught by experienced Pilates instructors. The home group will be asked to do the home exercises four times a week for half an hour. These exercises will be taught by an experienced Physiotherapist. You will be asked to record these exercise sessions in your logbook every day for the eight-week exercise programme.

Testing sessions at the Healthjunction Centre:

You will need to come to the Healthjunction Centre for four testing sessions. The first testing session will take place before the start of the exercise intervention. The next three testing sessions will be at four weeks (mid-exercise programme), eight weeks (immediately after the exercise programme), and at 12 weeks (at the end of the study). During these testing sessions, you will be asked to fill out *five questionnaires* about your pain, level of function and health status and perform a *fingertip-to-floor*

test. After the eight-week exercise programme has finished, you will also be asked to rate your satisfaction with the exercise programme that you have been given.

Benefits of participating in this study:

You will be given a copy of *The Back Book*, which includes advice on back pain and how to manage it. You will receive your body composition measurements, and a summary of the results of the study. At the end of the study, the Pilates group will be given the home exercise sheets. The home group will be invited to attend Pilates classes at the Healthjunction Centre for eight weeks. There is no remuneration for this study and you will be required to travel to testing and exercise classes at your own cost.

Potential Risks:

You will be screened before the study begins to see if you are suited to exercise management of your low back pain. If any risks are identified during the screening process, you will be referred to your medical practitioner for appropriate assessment and further management.

There are no risks associated with taking your height or weight measurements. There might be some minimal discomfort during the measurement of skinfold thickness, as the calipers may pinch your skin slightly. There is some risk of making your low back pain worse during forward bending in the *fingertip-to-floor* test. This risk will be minimised by asking you to warm-up before the test and to make sure that you stop bending forward if you feel any pain.

There is a risk that your low back pain might get worse from taking part in the Pilates or home exercise programme. This risk will be minimised by teaching you to do the exercises correctly, and by slowly increasing the exercise load. You will also be asked to make sure that all exercises that you do are pain-free. If your low back pain does get worse, the exercise programme will be stopped. I will assess and treat your low back pain using other methods of physiotherapy treatment; or I will refer you to an appropriate medical practitioner of your choice for further assessment and management.

Questions or Concerns

If at any time you have any questions about the study, please feel free to contact me or my supervisor listed below.

- **Catherine Chemaly**
  Tel number: 082 465 3745
  Email address: cathy@healthjunction.co.za
- **Professor Jennifer Jelsma**
  Physical address: Division of Physiotherapy
  School of Health and Rehabilitation

University of Cape Town
Groote Schuur Hospital
Anzio Road
Observatory 7725

Tel number: 021 406 6595

Fax number: 021 406 6323

Email address: jennifer.jelsma@uct.ac.za

You may also contact the Faculty of Health Sciences Human Research Ethics Committee if you have any ethical concerns about the study:

- **Professor Marc Blockman**

  Chairperson: Faculty of Health Sciences Human Research Ethics Committee

  Tel: 021 406 6492

  E-mail: marc.blockman@uct.ac.za

Please note that UCT does offer a no-fault insurance that will cover all participants in the event that something may go wrong. This insurance will provide prompt payment of compensation for any trial related injury according to the Association of the British Pharmaceutical Industry (ABPI) guidelines (1991). These guidelines recommend that UCT, without any legal commitment, should compensate you without you having to prove that UCT is at fault. An injury is considered trial-related if, and to the extent that, it is caused by study activities. You must notify the study investigators immediately of any 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 taking part in the study. Your right in law to claim compensation for injury where you prove negligence is not affected.

By placing your signature below, it serves as confirmation that you have had adequate time to read the consent form, that you have understood it and that you are willing to participate voluntarily in this study. You have the right to withdraw at any time with no consequences, you may ask questions at any time during the study and all the information recorded will be kept strictly confidential. You will not be identified in any publications associated with this study. Your signature is further confirmation that you are aware of the possible risks involved in this study.

_____	_____	_____
Signature of Volunteer	Name (Please Print)	Date
_____	_____	_____
Signature of Investigator	Name (Please Print)	Date

Appendix C: Back Pain Screening Questionnaire

Personal Details and Back Pain Screening

Participant Name and Code: Date:

Cell number: Tel number:

Email address: Age:

Residential address: Occupation:

Postal address: Gender:

How many weeks have you experienced low back pain?

_____

What is your back pain like now on an11 point scale where 0 indicates “no pain” and 10 indicates “worst imaginable pain”?

_____

Medical history:

_____

Surgical history:

_____

How are you managing your back pain currently?

_____

Are you attending any back exercise interventions or receiving any treatment for your back pain?

_____

Have you attended Pilates mat classes previously? Y/N If yes, how long ago?

_____

Are you currently taking any medication (prescription and non-prescription) for your back pain? Y/N If yes, name and dosage

_____

Source: Waddell G. The Back Pain Revolution[13]

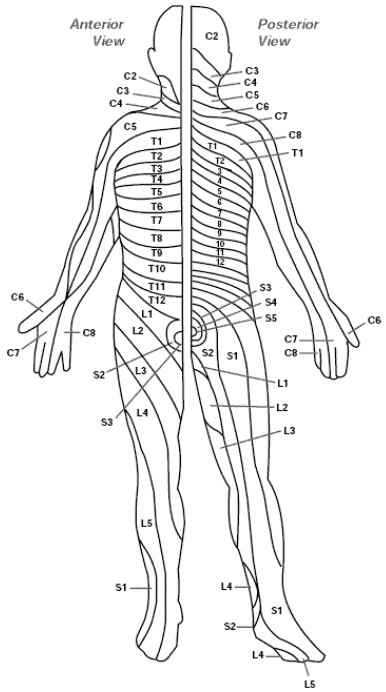
Possible serious spinal pathology:	**YES**	**NO**
Age of client <22 or >55years?		
Was there any violent trauma?		
Is the pain constant, progressive and not related to movement or posture?		
Is the pain in the thoracic area?		
Has there been long term use of corticosteroids?		
Is there any history of current or previous carcinoma?		
How is your general health?		
Any sudden weight loss without trying to lose weight?		
Intractable night pain which cannot be relieved by medication or change of position?		
Is there persisting severe restriction of lumbar flexion due to pain in back or leg?		
Has there been a sudden or gradual onset of back pain and a history of twisting, bending or lifting something heavy in the last 6 weeks?		
Any back pain with bending, lifting, coughing, sneezing or sitting in the last 6 weeks?		
Any widespread neurological signs/symptoms or dermatomal signs/symptoms? (Numbness, Pins and needles, depressed reflexes, muscle weakness)		
Difficulty with urination?		
Any faecal incontinence?		
Numbness about anus, perineum or genitals?		
Any widespread or progressive weakness in the legs or changes in gait?		
Is there marked morning stiffness, lasting more than 2 hours?		
Is there persisting limitation of spinal movement in all directions?		
Any iritis, skin rashes, colitis, urethral discharge?		
Nerve Root Pain:		
Is there pain in one leg that is worse than the back pain?		
Did the pain start in the back and progress down the leg?		
Does the pain go into the foot or toes?		

Is there weakness in the leg?		
Any numbness or pins & needles?		
Are there any signs of nerve irritation?		

Source: Petty NJ[276]

L2	Hip flexion			
L3	Knee extension		Knee jerk	
L4	Foot dorsiflexion		Knee jerk	
L5	Extension of big toe			
S1	Eversion of foot Contract buttock Knee flexion		Ankle jerk	
S2	Knee flexion Toe standing			
S3-4	Muscles of pelvic floor, bladder and genital function			

Source: Body chart reprinted from www.NeckSolutions (2005)



Appendix D: Physical Activity Readiness Questionnaire

PAR-Q

Regular exercise is growing in popularity. Being more active is very safe for most people, and for most should not pose any problem or hazard. However, some people should check with their doctor before they start becoming much more physically active. The following list of questions should be completed by anyone who is between the ages of 15 and 69, looking to increase their current activity level, or participate in a fitness testing assessment. The questionnaire helps to determine how safe it is for you.

Common sense is your best guide in answering these questions. Read the questions carefully and answer each one honestly.

Yes	No	
☐	☐	Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?
☐	☐	Do you feel pain in your chest when you do physical activity?
☐	☐	In the past month, have you had chest pain when you were not doing physical activity?
☐	☐	Do you lose your balance because of dizziness or do you ever lose consciousness?
☐	☐	Do you have a bone or joint problem that could be made worse by a change in your physical activity?
☐	☐	Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
☐	☐	Do you know of any other reason why you should not do physical activity?

If you answered YES

If you answered "yes" to one or more questions, talk with your doctor before you start becoming much more active or before you have a fitness test. Tell your doctor about the PAR-Q and which questions you answered "yes" to.

If you answered NO

If you answered "no" honestly to all of the questions, you can be reasonably sure that you can start becoming much more physically active or take part in a physical fitness appraisal – begin slowly and build up gradually. This is the safest and easiest way to go.

Things Change

Even if you answered "no" to all questions, you should delay becoming more active if you are temporarily ill with a cold or a fever, or if you are or may be pregnant. If your health changes so that you then answer "yes" to any of the above questions, tell your fitness or health professional and ask whether you should change your physical activity plan

Participants signature _____ Date_____

Source: Armstrong,[1] *ACSM's Guidelines for Exercise Testing and Prescription. 7th ed.* Baltimore: Lippincott Williams and Wilkins.

Appendix E: PI-NRS from Brief Pain Inventory Questionnaire

(Taken from the Brief Pain Inventory (BPI) questionnaire

Participant name: **Participant code:**

1. Please rate your pain by circling the one number that best describes your pain at its ***worst*** in the last week.

0	1	2	3	4	5	6	7	8	9	10
No Pain										pain as bad as you can imagine

2. Please rate your pain by circling the one number that best describes your pain at its ***least*** in the last week.

0	1	2	3	4	5	6	7	8	9	10
No Pain										pain as bad as you can imagine

3. Please rate your pain by circling the one number that best describes your pain on the ***average***

0	1	2	3	4	5	6	7	8	9	10
No Pain										pain as bad as you can imagine

4. Please rate your pain by circling the one number that tells how much pain you have ***right now***

0	1	2	3	4	5	6	7	8	9	10
No Pain										pain as bad as you can imagine

Scoring: Pain severity score = mean of items 1-4 (pain at its worst, pain at its least, average)

Appendix F: Exercise Log Book for SEG

Participant Name:

Participant Code:

PILATES GROUP

EXERCISE DIARY

Week		**Mon**	**Tue**	**Wed**	**Thurs**	**Fri**	**TOTAL**
Dates:	***Class*** ***Tick if attended***						
	Class ***X if not attended***						
	Rate your pain out of 10 before and after the class (PI-NRS)						
	Rate how you felt during the class (RPE) Scale						
Other exercise	***a. Type***						
	b. Duration						
Medication taken for LBP	***a. Name***						
	b. Dosage						
	Other treatments						

Appendix G: Exercise Log book for HEG

Participant Name:

Participant Code:

HOME GROUP

EXERCISE DIARY

Week		**Mon**	**Tue**	**Wed**	**Thurs**	**Fri**	**Sat**	**Sun**	**TOTAL**
Dates:	***Home exercises Tick if session completed***								
	X if session is missed/incomplete. (record in minutes)								
	Rate your pain on the (PI-NRS) before/ after the exercises								
	Rate how you felt during the exercises (RPE)								
Other Exercise	***a. Type***								
	b. Duration								
Medication taken for LBP	***a. Name***								
	b. Dosage								
	Other treatments								

Appendix H: Roland Morris Disability Questionnaire (RMDQ)

Participant Name: **Participant Code:**

When your back hurts, you may find it difficult to do some things you normally do.

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you today. As you read the list, think of yourself **today**. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go to the next one. Remember only tick the sentences if you are sure it describes you today.

1. I stay at home most of the time because of my back.
2. I change position frequently to try and get my back comfortable
3. I walk more slowly than usual because of my back
4. Because of my back, I am not doing any of the jobs that I usually do around the house
5. Because of my back, I use a handrail to get upstairs
6. Because of my back, I lie down to rest more often
7. Because of my back, I have to hold on to something to get out of an easy chair
8. Because of my back, I try to get other people to do things for me
9. I get dressed more slowly than usual because of my back
10. I only stand for short periods of time because of my back
11. Because of my back, I try not to bend or kneel down
12. I find it difficult to get out of a chair because of my back
13. My back is painful almost all the time
14. I find it difficult to turn over in bed because of my back
15. My appetite is not very good because of my back pain
16. I have trouble putting on my socks (or stockings) because of the pain in my back
17. I only walk short distances because of my back
18. I sleep less well on my back
19. Because of my back, I get dressed with help from someone else
20. I sit down for most of the day because of my back
21. I avoid heavy jobs around the house because of my back
22. Because of my back pain, I am more irritable and bad tempered with people than usual
23. Because of my back, I go upstairs more slowly than usual
24. I stay in bed most of the time because of my back

The score is the total number of items checked – from a minimum of 0 to a maximum of 24.

Roland M, Morris R. A study of the natural history of low back pain: Part 1. Development of a reliable and sensitive measure of disability in low back pain. Spine 1983, 8: 141-4.

Roland M, Morris R. A study of the natural history of back pain. Part 2.Development of guidelines for trials of treatments in primary care. Spine 1983, 8: 145-50.

Appendix I: EQ-5D Health Questionnaire

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 ❑

Compared with my general level of health over the past 12 months, my state of health today is:

Better ❑

Much the same ❑

Worse ❑

To help people say how good or bad their state of health is, we have drawn a scale 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.

Your own state of health

Best imaginable

Worst imaginable state of health

Participant Name: **Participant Code:**

Because all replies are anonymous, it will help us to understand your answers better if we have a little background data from everyone, as covered in the following questions.

1. Have you experienced serious illness?

	Yes	No
yourself	❑	❑
in your family	❑	❑
while caring for others	❑	❑

PLEASE TICK APPROPRIATE BOX

2. What is your age in years? ☐

3. Are you male or female?

Male	Female
❑	❑

4.

I smoke	❑
I used to smoke	❑
I have never smoked	❑

PLEASE TICK APPROPRIATE BOX

5. Do you now, or did you ever, work in

	Yes	No
health services or social welfare?	❑	❑

If so, in what capacity? .....

6. Which of the following best describes your main activity?

self employed	❑
in formal employment	❑
retired	❑
homemaker/domestic worker	❑
student	❑
seeking work	❑
other (please specify)	❑

PLEASE TICK APPROPRIATE BOX

7. What was the highest grade that you attained at school?.....

	Yes	No
8. Do you have a diploma or equivalent?	❑	❑

9. If you know the area/suburb in which you stay, please write it here.....

Appendix J: Pain Self-Efficacy Questionnaire (PSEQ)

Participant name: **Participant code:**

Please rate how confident you are that you can do the following things at present, despite the pain. To indicate your answer circle one of the numbers on the scale under each item, where 0 = "not at all confident" and 6 = "completely confident".

1. I can enjoy things, despite the pain.

0 1 2 3 4 5 6

Not at all Confident — Completely Confident

2. I can do most of the household chores (e.g. tidying, washing, etc) despite the pain.

0 1 2 3 4 5 6

Not at all Confident — Completely Confident

3. I can socialize with my friends or family as often as I used to, despite the pain.

0 1 2 3 4 5 6

Not at all Confident — Completely Confident

4. I can cope with my pain in most situations.

0 1 2 3 4 5 6

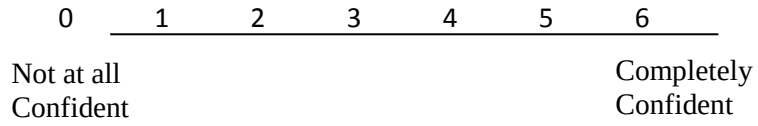
Not at all Confident — Completely Confident

5. I can do some form of work, despite the pain (work includes housework, paid or unpaid work).

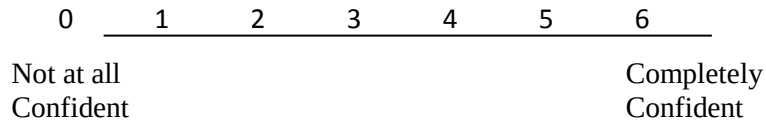
0 1 2 3 4 5 6

Not at all Confident — Completely Confident

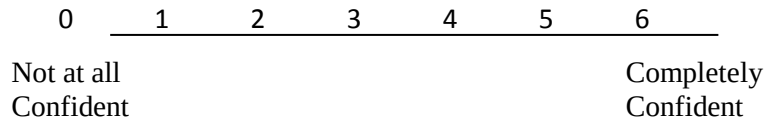
6. I can still do many of the things I enjoy doing, such as hobbies or leisure, despite pain.



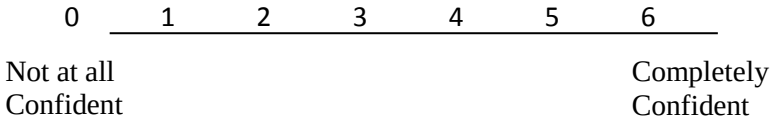
7. I can cope with my pain without medication.



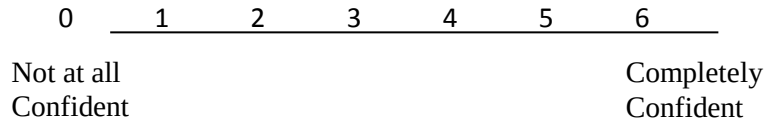
8. I can still accomplish most of my goals in life, despite the pain.



9. I can live a normal lifestyle, despite the pain.



10. I can gradually become more active, despite the pain.

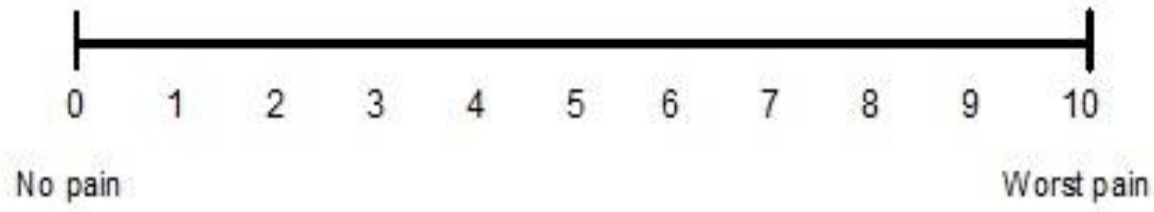


Source: Nicolas M.K.[261] Self-efficacy and chronic pain. Paper presented at the annual conference of the British Psychological Society. St Andrews, 1989

Appendix K: Numeric Rating Scale (PI-NRS)

Participant Name: **Participant Code:**

This is a pain scale that has been designed to measure your pain intensity (how strong your pain is). Please mark your **average pain intensity** by circling the number which represents your pain.



Source: © 2010 topendsport.com

Appendix L: Rating of Perceived Effort (RPE) Scale

Source: Rating scores for relative perception of effort (RPE)[281]

Participants Name: **Participants Code:**

(Please can you rate your exercise session)

Score	Description
6	
7	**Very very light**
8	
9	**Very light**
10	
11	**Fairly light**
12	
13	**Somewhat hard**
14	
15	**Hard**
16	
17	**Very hard**
18	
19	**Very very hard**
20	**Maximal exertion**

Appendix M: Participant Satisfaction Questionnaire

Pilates/Home Programme survey

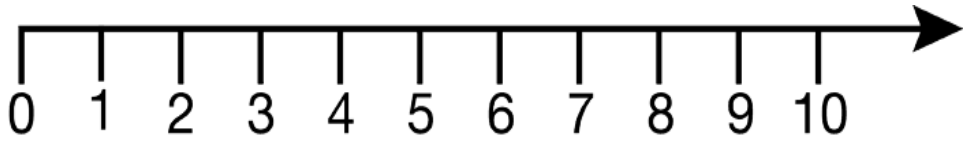
(Modified from the Better Backs @Austin Programme Survey)[205]

Participant Name: **Participant Code:**

Please place a circle round a number on the scale. 0 = "extremely dissatisfied" 10 = "extremely satisfied."

There is also space if you would like to write comments.

1. **The knowledge and expertise of the Pilates instructor/Physiotherapist** – as reflected by the educational lectures, exercise instruction, posture instruction and interaction with the patients.



Comments

2. **The accessibility and convenience of the Pilates/Home Programme** – for example the venue, parking, times of classes.

   a. Transport to Healthjunction Centre: Do you come by car / bus / train /other. …….

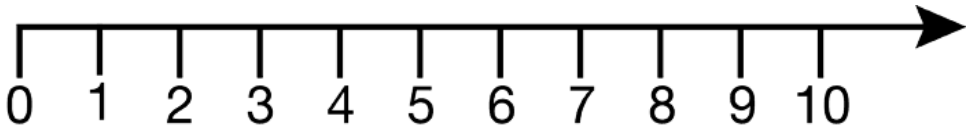
   b. Healthjunction Venue/Home Venue: Is parking a problem to you? Yes/No

If yes, state why:

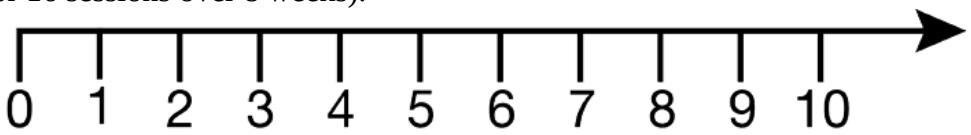
   c. Time of class/Home exercise

Comments

Rate the overall convenience to you of the exercise programme.

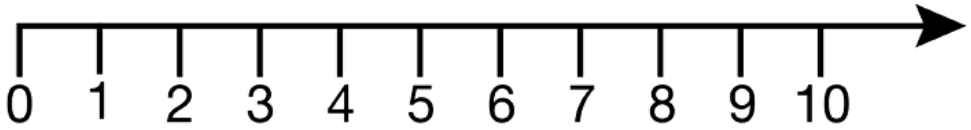


3. **Cost of Pilates/Home Programme**
(Rate your satisfaction of this service valued at about R1080 in the private health sector for 16 sessions over 8 weeks).



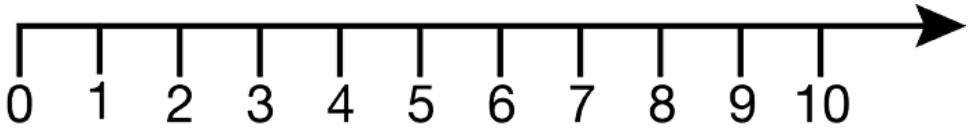
Comments

4. **Gymnasium Facilities/Home facilities** (For example the size of room, lighting, cleanliness, space, exercise equipment, etc.)



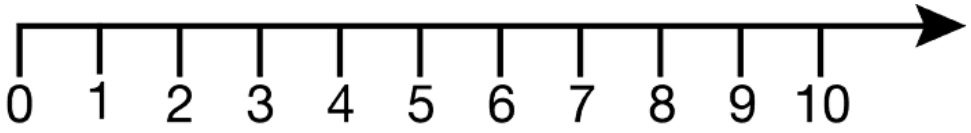
Comments

5. **Availability of the Physiotherapist** during the exercise programme.



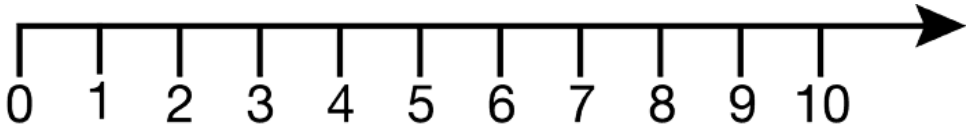
Comments

6. **Exercise sheets** (with specific instructions and drawings) – to remind you how to do the exercises at home.



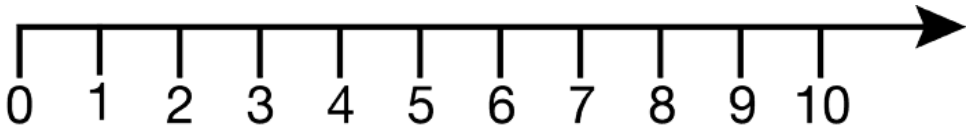
Comments

7. **Enjoyment** aspect of participation in the Pilates/ Home Programme (e.g. music, relaxation, camaraderie/ being together with other people with back problems).



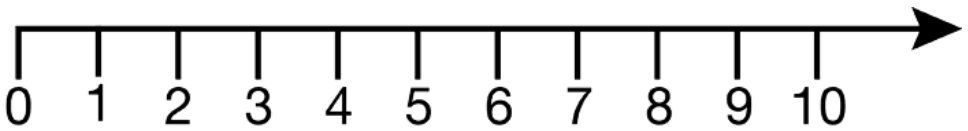
Comments

8. **The overall benefit from attending the Pilates/Home Programme** – both the information about back care and the exercise instruction and advice aimed to improve your back condition.



Comments

9. **Comparison to other approaches for back treatment** – Please compare the Pilates/Home Programme to other approaches to back treatment e.g. individual physiotherapy, chiropractic, other exercise sessions, and rate your satisfaction with this programme.



Comments

Appendix N: Pilates eight-week Mat Programme

Week One	Week Two	Week Three	Week Four
chin tucks Compass shoulder drops x5 rib cage closure (RCC) x5 pillow squeeze (PS) x5	chin tucks compass shoulder drops x5 rib cage closure x5 pillow squeeze x5	neck rolls pelvic clocks shoulder drops x5 rib cage closure x5	neck rolls pelvic clocks shoulder drops x5 rib cage closure x5
abdominal stability-just knee fold x5/leg spine curls x5 bridging x5 curl up (CU) x5 oblique no arm x3/side hip rolls x3/side	abdominal stability-just knee fold x5/leg spine curls x5 bridging x5 curl up x5 oblique no arm x3/side hip rolls x3/side	abdominal stability-press leg slightly away spine curls with pillow squeezex5 bridging x8 curl ups and alternating knee folds x6 oblique no arm x5/side hip rolls arms at 90 deg x3/side	abdominal stability-press leg slightly away spine curls with pillow squeezex5 bridging x8 curl ups and alternating knee folds x6 oblique no arm x5/side hip rolls arms at 90 deg x3/side
roll over big ball to stretch and breathe low back stability x3/leg low back stability more difficult x3/leg deep abdominal training-small range x5	roll over big ball to stretch and breathe low back stability x3/leg low back stability more difficult x3/leg deep abdominal training-small range x5	roll over big ball to stretch and breathe low back stability x5/leg low back stability more difficult x5/leg deep abdominal training-bigger range x5	roll over big ball to stretch and breathe low back stability x5/leg low back stability more difficult x5/leg deep abdominal training-bigger range x5
arm openings x3/side oyster x5/side	arm openings x3/side oyster x5/side	arm openings x3/side torpedo 1 x5/side	arm openings x3/side torpedo 1 x5/side
upper body strengthening x3/side upper body+chest mobility x3/side	upper body strengthening x3/side upper body+chest mobility x3/side	upper body strengthening x5/side upper body+chest mobility x5/side	upper body strengthening x5/side upper body+chest mobility x5/side
cobra prep x5	cobra prep x5	cobra prep x8	cobra prep x8
segmental mobility x3 low back stretch x3	Segmental mobility x3 low back stretch x3	segmental mobility x5 low back stretch x5	Segmental mobility x5 low back stretch x5

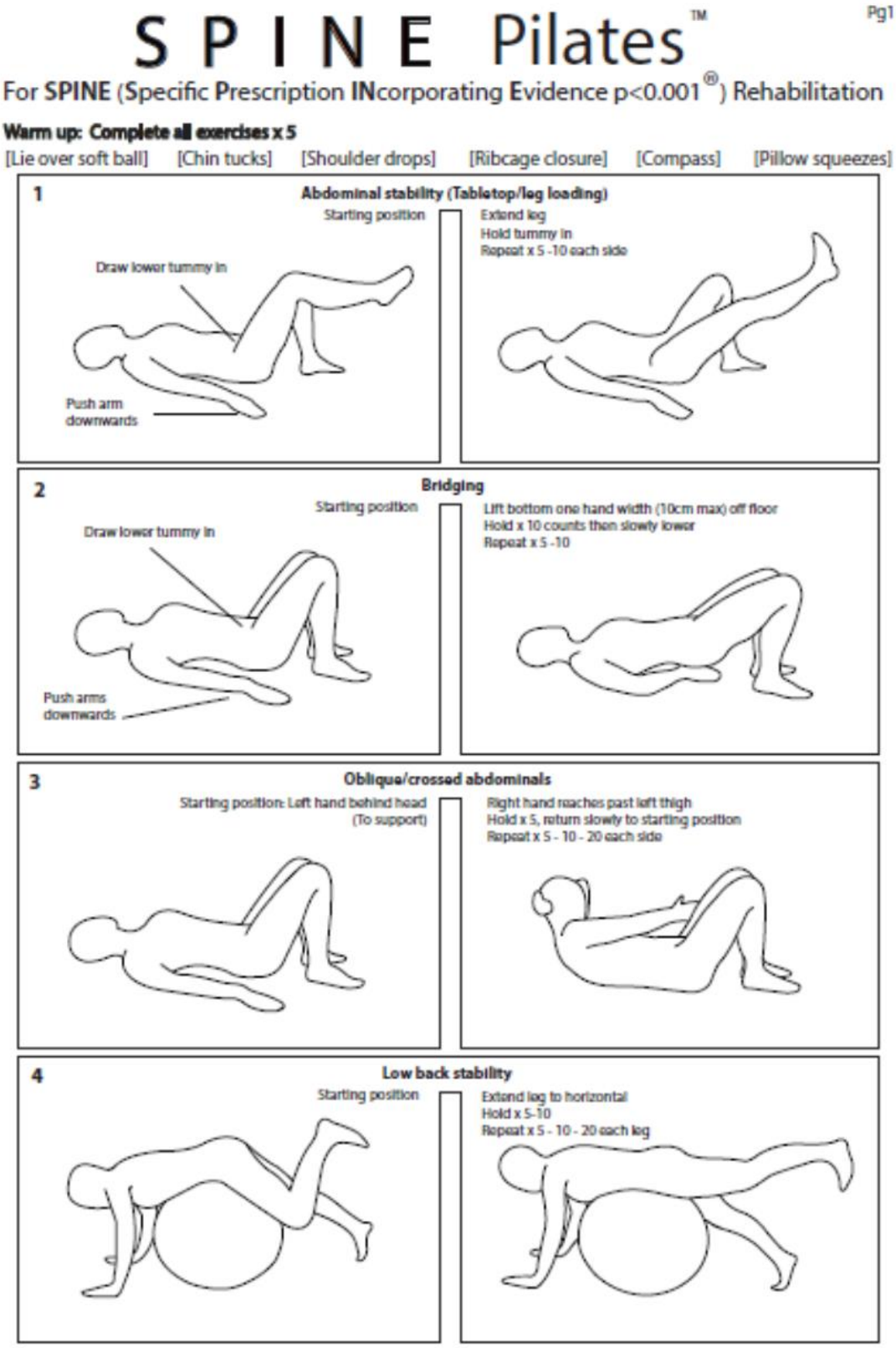
Week One	Week Two	Week Three	Week Four
seated side reach x3/side	seated side reach x3/side	seated side reach x4/side	seated waist twist x4/side
leg lifts bent knee x3/leg	leg lifts bent knee x3/leg	leg lifts bent knee x5/leg	leg lifts bent knee x5/leg
leg lifts straight knee x3/leg	leg lifts straight knee x3/leg	leg lifts straight knee x5/leg	leg lifts straight knee x5/leg
praying stretch	praying stretch	praying stretch	praying stretch
sit to stand from ball x3	sit to stand from ball x3	sit to stand from ball x5	sit to stand from ball x5
lumbo-pelvic stability x3/side	lumbo-pelvic stability x3/side	lumbo-pelvic stability x5/side	lumbo-pelvic stability x5/side
pilates squats with stickx5	pilates squats with stick add rises x5	pilates squat and chest expansion combo x5	pilates squat and chest expansion com x5
floating arms x5	corkscrew arms x3		standing side reach x2/side

Week Five	Week Six	Week Seven	Week Eight
neck rolls pelvic clocks shoulder drops x5	neck rolls pelvic clocks shoulder drops x5	neck rolls pelvic clocks shoulder drops x5	neck rolls pelvic clocks shoulder drops x5
abdominal stability-press leg further x8	abdominal stability-press leg further x8	abdominal stability-press leg further x10	abdominal stability-press leg further x10
spine curls with pillow squeeze+RCC x8 bridging arms 90 deg x10	spine curls+PS+RCC+curl up x8 bridging arms 90 deg x10	spine curls+PS+RCC+CUx5 to hundred x2 bridging arms 90 deg x12	spine curls+PS+RCC+CU x5 to hundred 3x5 bridging arms 90 deg x12
curl up and double knee fold x5 oblique add arm x5/side hip rolls legs up x3/side	single leg stretch x5/leg oblique add arm x5/side hip rolls legs up x3/side	single leg stretch x5/leg+double leg stretcx3 oblique add arm x8/side hip rolls legs up x5/side	single leg stretch x5/leg+double leg stretchx3 oblique add arm x8/side hip rolls legs up x5/side
roll over big ball to stretch and breathe low back stability x8/leg	roll over big ball to stretch and breathe low back stability x8/leg	roll over big ball to stretch and breathe low back stability x8/leg	roll over big ball to stretch and breathe low back stability x8/leg
low back stability more difficult x8/leg deep abdominal training-bigger range x8	low back stability more difficult+opp armx5/ deep abdominal training-bigger range x8	low back stability more difficult+opp arm x5 deep abdominal training-bigger range x8	low back stability more difficult+opp arm x5 deep abdominal training-bigger range x8
chalk circles x3/side torpedo 2 x5/side	chalk circles x3/side torpedo 3 x5/side	arm openings forward and back x3/side torpedo 4x5/side	arm openings forward and back x3/side torpedo 4 x8/side
upper body strengthening x8/side upper body+chest mobility x8/side	upper body strengthening x8/side upper body+chest mobility x8/side	upper body strengthening x10/side upper body+chest mobility x10/side	side twist prep x3/side upper body strengthening x10/side upper body+chest mobility x10/side
cobra prep increased range x5	cobra prep increased range x5	cobra prep increased range x5	cobra prep increased range x5
spinal mobility x8 low back stretch x8	spinal mobility x8 low back stretch x8	spinal mobility x10 low back stretch x10	spinal mobility x10 low back stretch x10
seated bow and arrow x4/side	seated bow and arrow x4/side	spine stretch forward x5	spine stretch forward+waist twist combo x3

Week Five	Week Six	Week Seven	Week Eight
leg lifts straight knee x8/leg praying stretch sit to stand from ball x8 lumbo-pelvic stability+stride x5/side pilates squat+chest expansion com x8 standing side reach x2/side	leg lifts straight knee x8/leg praying stretch sit to stand from ball x8 lumbo-pelvic stability+stride x5/side pilates squat+chest expansion combo x8 standing side reach x2/side roll downs x3	leg lifts straight knee x8/leg praying stretch sit to stand from ball x8 lumbo-pelvic stability+stride x8/side each pilates squat+chest expansion combo x8 standing side reach x2/side roll downs x3	leg lifts straight knee x8/leg praying stretch sit to stand from ball x8 lumbo-pelvic stability+stride x8/side each pilates squat+chest expansion combo x8 standing side reach x2/side roll downs x3

Note: Standard exercises given to HEG in grey scale.

Appendix O: Pilates Home Exercises



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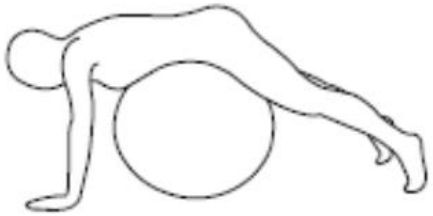
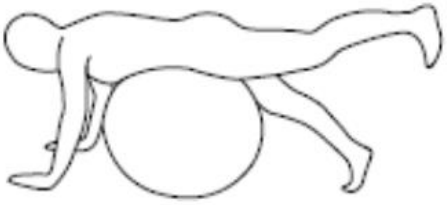
5 **Low back stability (more difficult)**

Starting position

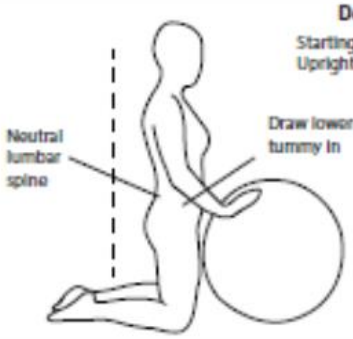


Lift leg to horizontal
Hold x 5 - 10
Repeat x 10 - 20 each leg

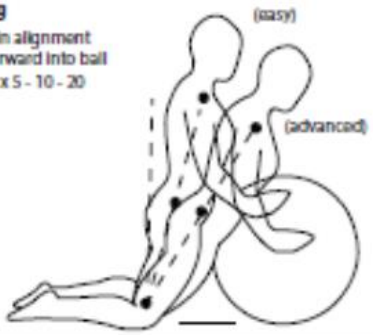


6 **Deep abdominal training**

Starting position
Upright kneeling

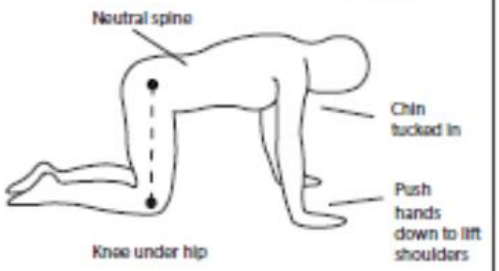


Maintain alignment
Lean forward into ball
Repeat x 5 - 10 - 20



7 **Upper body strengthening (facilitates muscular brace)**

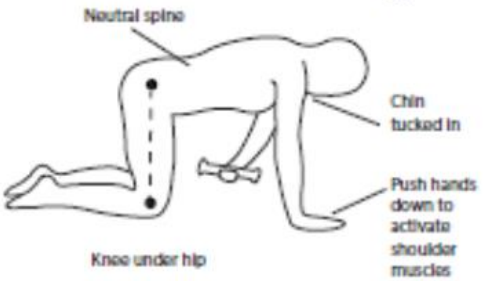
Starting position



Lift dumbell to horizontal
Hold x 5
Repeat x 5 - 10 - 20 each arm

8 **Upper body strengthening (combined with chest mobility)**

Starting position



Lift dumbell slightly above shoulder height
Rotate shoulder and chest to lift
Repeat x 5 - 10 - 20 each arm

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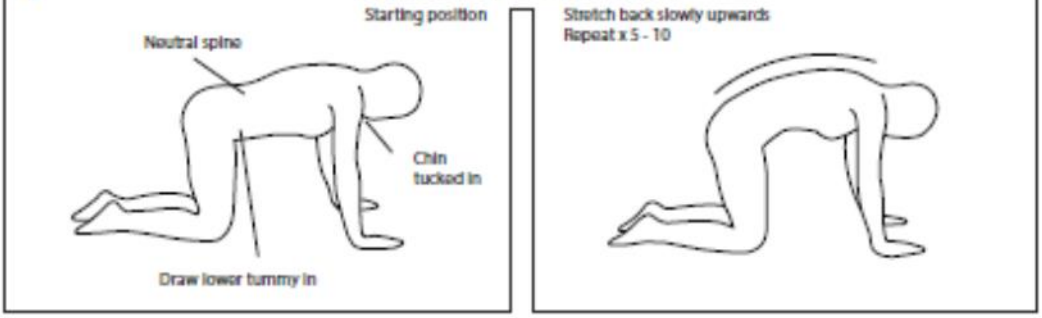
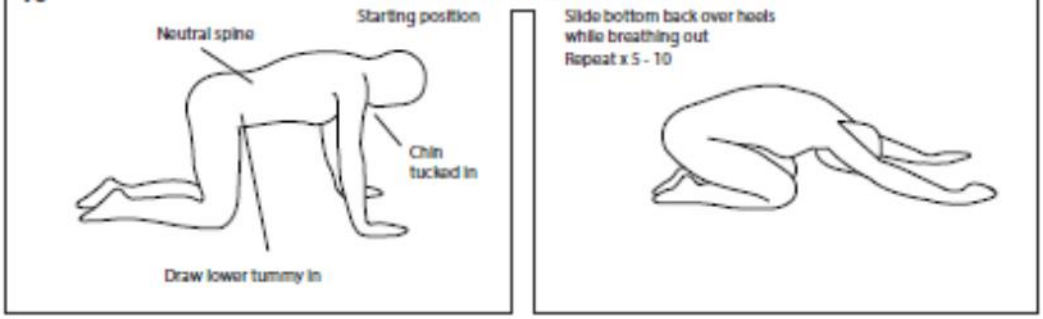
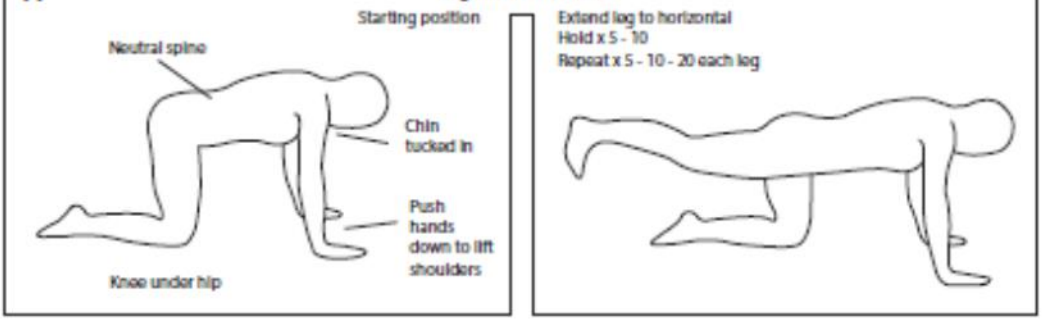
9 **Segmental spine mobility (Cat stretch)**



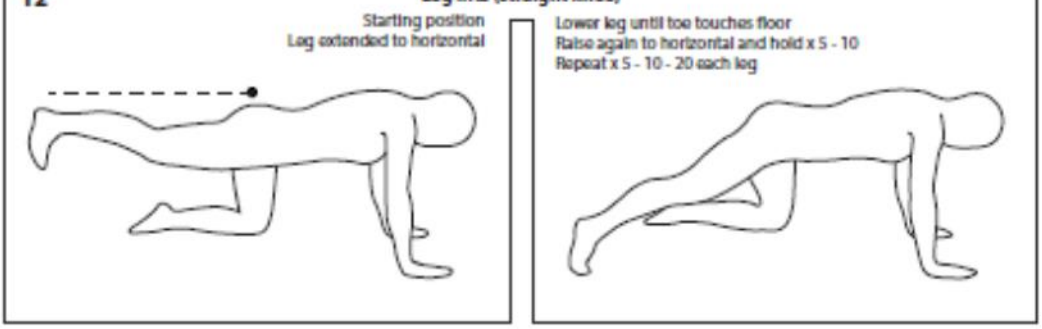
10 **Lower back stretch (Shell stretch)**



11 **Leg lifts (bent knee)**



12 **Leg lifts (straight knee)**



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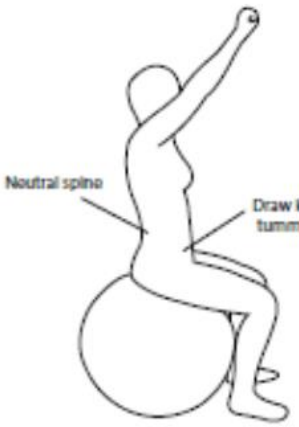
13 **Sit to stand from ball**

Starting position
Sit upright on ball, arms raised

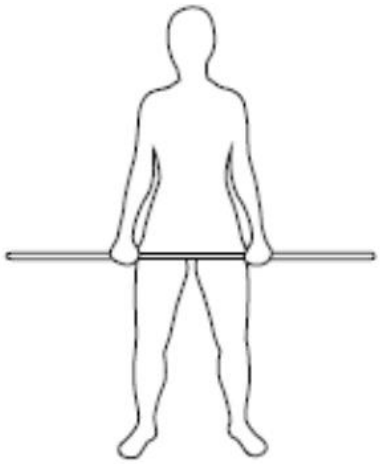


Ball height so that hips are higher than knees
e.g. average woman = 65 cm ball, tall man = 75cm ball

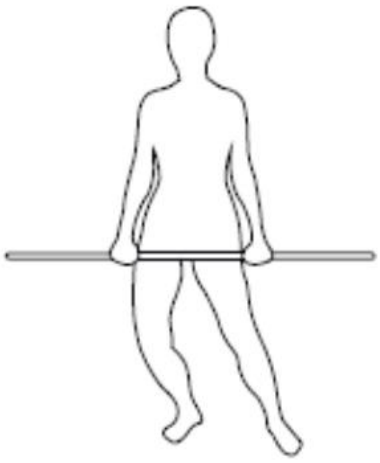
Nose over knees
Stretch arms upwards
Lift bottom 3/4 off ball
Repeat x 5 - 10

14 **Lumbo-pelvic stability**

Starting position



Transfer weight alternately to R + L
Keep pelvis level
Repeat x 5 - 10 - 20



Appendix P: Home exercises with progressions

Source: SPINE (Specific Prescription INcorporating Evidence p< 0.001®) PILATES [57]
Exercises to be done 3x/week. Warm up: Start with breathing.

[Chin tucks] [Compass] [Shoulder drops] [Ribcage closure] [Pillow squeeze]

EXERCISE DESCRIPTION (One set=10)	PROGRESSION 1 (At three weeks)	PROGRESSION 2 (At six weeks)
1: Abdominal stability Lying on back. Fold knee in to 90 degree position and extend leg slightly away whilst maintaining control of lumbo-pelvic region. Hold for 5 counts.(X 5 each leg)	X 10 – X 20 each leg	X 20 each leg Extend leg further away and back to 90 degree position
2: Bridging Lying on back, pelvic tilt and lift buttock one hands width off floor. Hold for 10 counts (X 5)	X 10	X 20
3: Oblique abdominals Lying on back hands interlaced behind the head. Curl up towards the left hip reaching the right hand past the left thigh. Hold for 5 counts and release back down. (X 5 each side)	X 10 each side	X 20 each side
4: Low back stability Lying forward over ball with one knee bent to 90 degrees. Straighten and bend the knee whilst maintaining neutral lumbar curve (X 5 each leg)	X 10 each leg	X 20 each leg
5: Low back stability Lying forward over ball with both legs straight. Lift and low one leg until toe touches the ground whilst maintaining neutral lumbar curve (X 5 each leg)	X 10 each leg	X 20 each leg
6: Deep abdominal training Kneeling in front of ball: Lean forwards into ball and back to starting position maintaining neutral lumbar spine (X 5)	X 10 – X 20	X 20 Lean further forward into ball
7: Upper body strengthening Four point kneeling. Find neutral shoulder position. Lift one arm to horizontal. Hold for 5 counts and low arm. (X 5 each arm)	X 10 each arm	X 20 each arm

8: Upper body strengthening with thoracic mobility Four point kneeling. Find neutral shoulder position. Lift one arm out to side and rotate arm across the midline rotating ribcage (X 5 each)	X 10 each arm	X 20 each arm
9: Segmental mobility Four point kneeling. Initiate movement by curling tailbone forward and curl up into a cat stretch (X5)	X 10	X 20
10: Low back stretch Low buttocks over feet with knees hip width apart. Hold the position (X 5)	X 10 – X 20	X 20 Low buttocks over feet maintaining lumbo-pelvic neutral
11: Leg lifts (bent knee) Four point kneeling. Extend one leg behind to horizontal. Hold for 5 x counts and bend knee bringing leg back to the starting position. (X 5 each leg)	X 10 each side	X 20 each side
12: Leg lifts (straight knee) Four point kneeling. Start with one leg extended behind to horizontal. Low the leg until toe touches the floor and lift the leg back to horizontal hold for 5 counts.(X 5 each leg)	X 10 each leg	X 20 each leg
13: Sit to stand Sit upright on a ball in neutral lumbar curve with arms raised. Lift bottom ¾ off ball whilst reaching arms upwards.(X 5)	X 10	X 20
14: Lumbo - pelvic stability Standing. Transfer weight alternatively from right to left, keeping pelvis level (X 5)	X 10 – X 20	X 20 including transfers in stride standing

Appendix Q: Anthropometry and Fingertip-to-floor measures

Data collection forms

Anthropometry

Participant's name: Code:

Body mass (kg's): Female:

Stature (cm's): Age:

Body Mass Index (BMI): Years of pain:

Sum of skinfolds: % Body Fat:

Lean body mass (LBM):

Skin fold measurements (mm's)	
Triceps	
Chest	
Mid-axillary	
Sub-scapular	
Supra-iliac	
Abdomen	
Thigh	
Girth measurements (cm's)	
Abdomen	

Fingertip-to-floor test measurements (cm's)

Baseline	
Week 4	
Week 8	
Week 12	

Appendix R: Back Care Advice – The Back Book

The investigator has been in contact with the publishers and they would not give permission to copy the whole book to include as an appendix. A hard copy of the book has thus been included with the proposal.

A hard copy of *The Back Book* will be handed out to all participants at their individual teaching sessions.

Source: Roland M. *The Back Book*[140]

Appendix S: Results of Pain Self-Efficacy

Pain Self-Efficacy Frequency Tables S1-S10

Table S 1: Frequency of the responses to the PSE – enjoyment question

I can enjoy things, despite the pain		Baseline	4 weeks	8 weeks	12 weeks
SEG					
Not at all confident	**0**				
	1	1			
	2				
	3	1	1		1
	4	8	3	3	1
	5	8	7	5	6
Completely confident	**6**	**1**	**8**	**11**	**11**
HEG					
Not at all confident	**0**				
	1	1			
	2	1			
	3	2		1	2
	4	9	8	4	1
	5	5	8	5	9
Completely confident	**6**	**1**	**3**	**9**	**7**

Table S 2: Frequency of the responses to the PSE – chores question

I can do most of the household chores despite the pain		Baseline	4 weeks	8 weeks	12 weeks
SEG					
Not at all confident	**0**				
	1				
	2	2		1	1
	3	2	1	1	2
	4	8	4	2	2
	5	6	7	5	8
Completely confident	**6**	**1**	**7**	**10**	**6**
HEG					
Not at all confident	**0**				
	1				
	2	2	1		1
	3	3	1	3	1
	4	5	3	3	3
	5	8	8	6	4
Completely confident	**6**	**1**	**6**	**7**	**10**

Table S 3: Frequency of the responses to the PSE – socialize question

I can socialize with my friends or family as often as I used to, despite the pain		Baseline	4 weeks	8 weeks	12 weeks
SEG					
Not at all confident	**0**				
	1	1			
	2	1			
	3	2			1
	4	6	3	3	1
	5	5	6	4	6
Completely confident	**6**	**4**	**10**	**12**	**11**
HEG					
Not at all confident	**0**				
	1				
	2	2			
	3	1		1	1
	4	7	2	3	2
	5	5	8	4	5
Completely confident	**6**	**4**	**9**	**11**	**11**

Table S 4: Frequency of the responses to the PSE – cope with my pain question

I can cope with my pain in most situations		Baseline	4 weeks	8 weeks	12 weeks
SEG					
Not at all confident	**0**				
	1				
	2				
	3		1	1	
	4	4	3	3	2
	5	8	11	6	7
Completely confident	**6**	**7**	**4**	**9**	**10**
HEG					
Not at all confident	**0**	1			
	1	1			
	2	4	1		1
	3	6	3	5	4
	4	5	10	7	5
	5	**2**	**5**	**7**	**9**
Completely confident	**6**				

Table S 5: Frequency of the responses to the PSE – work despite pain question

I can do some form of work, despite the pain		Baseline	4 weeks	8 weeks	12 weeks
SEG					
Not at all confident	**0**				
	1				
	2	1			
	3	1		1	1
	4	7	2	1	1
	5	6	8	4	3
Completely confident	**6**	**4**	**9**	**13**	**14**
HEG					
Not at all confident	**0**				
	1				
	2	1			
	3	3	1		
	4	2	3	2	1
	5	7	3	3	5
Completely confident	**6**	**6**	**12**	**14**	**13**

Table S 6: Frequency of the responses to the PSE – hobbies question

I can still do many things I enjoy doing, such as hobbies or leisure, despite pain		Baseline	4 weeks	8 weeks	12 weeks
SEG					
Not at all confident	**0**				
	1	1			
	2	1			1
	3	3	2	2	1
	4	7	4	4	4
	5	7	5	4	3
Completely confident	**6**		**8**	**9**	**10**
HEG					
Not at all confident	**0**				
	1	1			
	2	2			
	3	5	3	1	2
	4	6	4	3	1
	5	3	8	11	10
Completely confident	**6**	**2**	**4**	**4**	**6**

Table S 7: Frequency of the responses to the PSE – cope with no medication question

I can cope with my pain without medication		Baseline	4 weeks	8 weeks	12 weeks
SEG					
Not at all confident	**0**				
	1				
	2	4			
	3	1	2		
	4	9	4	3	4
	5	5	8	10	8
Completely confident	**6**		**5**	**6**	**7**
HEG					
Not at all confident	**0**	1	1		
	1	3		1	
	2	3	3	3	3
	3	2	2		1
	4	3	3	2	4
	5	5	5	4	3
Completely confident	**6**	**2**	**5**	**9**	**8**

Table S 8: Frequency of the responses to the PSE – accomplish goals question

I can still accomplish most of my goals in life, despite the pain		Baseline	4 weeks	8 weeks	12 weeks
SEG					
Not at all confident	**0**	1			
	1	1			
	2			1	
	3	2	1		1
	4	6		2	1
	5	5	10	6	4
Completely confident	**6**	**4**	**8**	**10**	**13**
HEG					
Not at all confident	**0**				
	1			1	
	2	2			
	3	2	1		2
	4	3	3	1	2
	5	9	9	7	2
Completely confident	**6**	**3**	**6**	**10**	**13**

Table S 9: Frequency of the responses to the PSE – normal lifestyle question

I can live a normal lifestyle, despite the pain		Baseline	4 weeks	8 weeks	12 weeks
SEG					
Not at all confident	**0**				
	1			1	
	2	3			
	3	2	1		1
	4	5	2	2	2
	5	8	10	6	5
Completely confident	**6**	**1**	**6**	**10**	**11**
HEG					
Not at all confident	**0**				
	1			1	
	2	2			
	3	2	1		2
	4	3	3	1	2
	5	9	9	7	2
Completely confident	**6**	**3**	**6**	**10**	**13**

Table S 10: Frequency of the responses to the PSE – become more active question

I can gradually become more active, despite the pain		Baseline	4 weeks	8 weeks	12 weeks
SEG					
Not at all confident	**0**				
	1	1			
	2	1	1		
	3	3		1	1
	4	3	3		
	5	6	5	4	4
Completely confident	**6**	**5**	**10**	**14**	**14**
HEG					
Not at all confident	**0**				
	1	1			
	2	2		1	
	3	1	1	1	1
	4	2	3	1	2
	5	10	7	5	4
Completely confident	**6**	**3**	**8**	**11**	**12**