PSYCHOLOGICAL FACTORS AND PHYSICAL OUTCOMES IN PATIENTS WITH CHRONIC DISEASES OF LIFESTYLE

Philippa Skowno

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Division of Exercise Science and Sports Medicine
Department of Human Biology
University of Cape Town

Supervisors: Prof EW Derman
Dr C Draper
Prof DJ Stein

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ABBREVIATIONS

NCD	Non-communicable diseases[1]
CDL	Chronic diseases of lifestyle
CV	Cardiovascular
CVD	Cardiovascular disease
CR	Cardiac rehabilitation
CHD	Coronary heart disease
COPD	Chronic obstructive pulmonary disorder
CLI	Comprehensive lifestyle intervention
MLI	Multifactorial lifestyle interventions
SPD	Serious psychological distress
CD-RISC	Connor Davidson Resilience Scale
SEM	Sport and exercise medicine
SSISA	Sports Science Institute of South Africa
6MWD	Six minute walk distance
6MWT	Six minute walk test
HR	Heart rate
RHR	Resting heart rate
BP	Blood pressure
RSBP	Resting systolic blood pressure
RDBP	Resting diastolic blood pressure
SkinF	Sum of skinfolds
BF%	Percentage body fat
W/Hip	Waist to hip ratio
K10	Kessler Scale for Psychological Distress
STAI-T	Spielberger State-Trait Anxiety Inventory – Trait Version

[1]While it is more commonplace in public health literature to refer to NCDs, as is acknowledged above, they will be referred to as CDL for the remainder of the paper based on the available literature and the study context.

PTG	Post traumatic growth
T2D	Type 2 diabetes
T1	Baseline cardiovascular, functional and anthropometric data collection
T2	Cardiovascular, functional and anthropometric data collection at programme completion (twelve weeks)
T2-T1	Descriptive statistic (difference between baseline and completion data)
MRC	Medical Research Council of South Africa
HCD	Human centred design
DT	Design thinking
SPARC	See, Plan, Act, Refine, Communicate

ABSTRACT

INTRODUCTION: Chronic diseases of lifestyle (CDL) are a major cause of global morbidity and mortality. Although CDL are largely preventable and treatable through adopting and maintaining healthy lifestyle behaviours, CDL rehabilitation programmes remain an underutilised resource. Behaviour modification is thus complex, and requires a collaborative approach between psychologists and medical clinicians involved in the management of CDL. This thesis examined the role of psychological factors in the management of patients with CDL who participated in a comprehensive lifestyle intervention (CLI) programme.

METHODS: An explanatory mixed methods design was used to describe the CLI experience. These included an initial clinical audit of 308 patients commencing and completing a twelve week CLI programme to test associations of psychological, demographic, medical and diagnostic factors with physical outcomes. Two qualitative studies were subsequently conducted to further understand patient experiences of CDL and CLI programmes. The first involved interviews of 14 patients at programme commencement and completion. The second consisted of a case study of a patient participating in the programme using human centred design principles as well as ethnography.

RESULTS AND DISCUSSION: The clinical audit was the first to apply psychological questionnaires to CDL cohorts in CLI settings. Demographic factors including age and sex were associated with functional, cardiovascular and anthropometric outcomes at baseline, as well as at programme completion. Psychological factors associated with physical outcomes at baseline included higher resilience scores with higher W/Hip ratios. Furthermore, higher psychological distress scores were associated with greater changes in resting diastolic blood pressure, and higher indicators of resilience were associated with a greater reduction in W/Hip ratio following completion of the programme.

Patients' accounts of CDL and of the CLI programme generated a number of important themes. CDL-related events were often perceived as traumatic. Nonetheless, all patients reported instances of resilience prior to and during the programme through the adoption and maintenance of healthier lifestyles. Finally, patients who reported greater trauma from their illness prioritized factors relating to support and the therapeutic relationship between the patient and healthcare providers. The case study using principles of human centred design identified few barriers to the patient's progress in the programme. The investigator, biokineticist and other key personnel were able to identify and respond to her initial lack of confidence and tailor the programme to her specific health requirements.

CONCLUSION: This thesis provided novel insight into the role of psychological factors in the management of patients with CDL. It reported on the descriptive ability of questionnaires, semi-structured interviews and applied ethnographic techniques in CDL cohorts. Findings were thus able to inform clinical practice, particularly in promoting more patient-centred design and implementation of CLI programmes.

CHAPTER 1: A REVIEW OF PHYSICAL AND PSYCHOLOGICAL FACTORS IN PATIENTS UNDERTAKING INTERVENTION PROGRAMMES FOR CHRONIC DISEASES OF LIFESTYLE

1.1 INTRODUCTION

Of the 57 million global deaths in 2008, 63% were due to non-communicable diseases (NCDs)[1]. These consist of chronic diseases of lifestyle (CDL), the majority of which are preventable by modifying key risk factors such as unhealthy diet, physical inactivity, tobacco use and harmful alcohol use[1]. Examples include cardiovascular (CV) diseases, diabetes, cancer and chronic respiratory diseases[1]. Middle and low-income countries accounted for 80% of global CV and diabetes mortalities, approximately 30% of whom are under 60 years old[1].Just over a third of deaths in South Africa have been attributed to NCDs[2] and approximately half of private medical insurance members in South Africa are reported to suffer from more than one chronic disease[3].

Advances in CDL treatment result in increased financial burden to individuals and health systems[4]. A hundred million individuals in low-income countries have been pushed into poverty annually from out-of-pocket health costs of managing these diseases. If one considers the average duration of a chronic health condition to be at least twelve months[5], the magnitude of time and financial resources required for secondary prevention and other treatment interventions of CDLs is substantial, with global financial estimates nearing US $30 trillion over the next two decades[6].

Furthermore, complexities of the disease experience make it unavoidable to dismiss the challenges inherent in sustainable behaviour modification[6]. This is demonstrated by the continuing increase in global incidence of CDL despite improvements in the accessibility of comprehensive and cost effective interventions at primary and secondary level as well as increasing awareness of the inherent risks attached to certain lifestyle behaviours[7].

A valuable partnership is developing between health psychology and the prevention and management of CDL. Causal links have been established between certain psychosocial factors, such as depression, and CV disease[8]. In turn, variables such as resilience[9,10] and optimism[11,12] are reported to protect against CDL, and promote more successful physical outcomes. These so-called protective factors are increasingly incorporated into comprehensive lifestyle interventions (CLIs) for the primary and secondary prevention of CDL[13]. While the effectiveness of short-term CDL intervention programmes are being established[13], the role of psychosocial factors such as resilience, as well as CLI design factors, in behavioural and physical changes is less clear.

1.2 REVIEW AIMS

This literature review consists of different parts, representing the distinct research areas and methodologies utilised in the present PhD thesis. The chapter consequently has a number of aims.

The review commences with an overview of the use of mixed methods in health sciences research as well as a brief rationalisation of the use of mixed methods in the current thesis. The following section broadly defines CDL and describes the assessment of physical outcome measures during CLI programmes. Physical outcomes include functional capacity measured by the sit-and-reach flexibility test and the six minute walk test; anthropometric data measured by waist to hip ratio, sum of skinfolds and percentage body fat; and cardiovascular data, including resting heart rate, resting systolic and diastolic blood pressure. Moreover, key findings are outlined from CLI effectiveness studies, including the study's own CLI programme, in the secondary prevention of CDL. Psychosocial variables assessed by validated measures in the study's CLI are then described. They include resilience, psychological distress and trait anxiety, measured with the Conner Davidson Resilience Scale, the Kessler Scale for Psychological Distress, and Spielberger's State-Trait Anxiety Inventory – Trait Version, respectively. The use of these

psychosocial variables and their associated measures are additionally discussed in relation to CDL and CLI research.

The second part of the review discusses the uses, and apparent usefulness, of qualitative methods in CDL and CLI research. Specifically, it reports on the use of resilience in the abovementioned literature. It then reports on recent and seminal research regarding CDL patient experiences and expectations of CLIs and, finally, assesses the use of ethnography in developing increasingly patient-centred designs of CLIs.

1.3 DATA SOURCES AND STUDY SELECTION

A literature search was conducted using Google Scholar and PubMed databases, from August 2010 to June 2015. Search terms included ‘cardiovascular diseases’ or ‘chronic diseases’ and their related terms. In addition, the terms ‘resilience’, ‘trait anxiety’, ‘psychological distress’ as well as ‘demographic’ were used in combination with the previous terms, and in relation to ‘physical recovery’ as well as ‘physical outcomes’. Searches also included reports on the psychometric properties of all psychological questionnaires included in the study, as well as their use in medical and rehabilitation settings. Official statements and guidelines relating to exercise outcomes assessment were also accessed. Search strategies for physical outcome measures and qualitative studies, as well as ‘design thinking’ or ‘human centred design’ focused on clinical or applied settings.

The search for all terms was limited to studies published in English. Articles were individually selected for further review based on their quality of research and population focus. This was achieved through screening publication abstracts. The reference lists of relevant articles were additionally searched for related studies.

1.4 MIXED METHOD RESEARCH

The current thesis employed a mixed method approach. Researchers initially integrated qualitative and quantitative methods in a single study in the late 1950's and the method has subsequently developed and been applied in a number of research fields including healthcare services[14–16].This is commensurate with a growing call for developing and implementing a greater range of methodologies necessary to evaluate the complexities of healthcare research problems[15,16].

The aim of the study as a whole was to explore and describe the role of psychological factors in the management of patients with CDL in CLI settings. The exclusive use of quantitative or qualitative methods in addressing these aims may reveal a limited picture[14]. The authors wanted to identify potential associations between psychological and physical outcomes which would require a quantitative approach - specifically, a retrospective clinical audit. However, this description would provide only a broad overview of potential associations, not a sufficient degree of detail required in understanding the more patient-centred management of CDL. Thus, it was decided that in order to address the research aims, quantitative and qualitative research methods would be merged within an explanatory as well as a triangulation research design. Explanatory designs are variations of mixed method research consisting of foundational quantitative research requiring additional qualitative detail further into the research process[14]. This design is commonly utilised in healthcare research, often using qualitative studies as an adjunct to randomised control trials[15]. Triangulation designs allow researchers to understand multilevel systems[17]. The current overall study explores CDL and patient experiences from a macro scale of over 300 patients, to an individual case study. Thus, both designs encourage a more thorough understanding and interpretation of a research problem.

1.5 CLI PROGRAMMES IN THE SECONDARY PREVENTION OF CDL

1.5.1 Overview

While CDL morbidity and mortality have increased[6,18,19], particularly in low and middle-income countries (LMICs)[1], there is encouraging growth in low-cost, effective interventions for the prevention and management of CDL[13]. This section commences with a broad outline of the structure and physical outcome measures used in the study's own CLI. It subsequently identifies CLIs (as well as equivalent interventions) in the current literature proven to be effective at reducing CDL mortality and/ or morbidity as well as improving various health-related behaviours.

In its broadest sense, rehabilitation can be defined as a collection of synchronised interventions selected to create an optimal physical and psychosocial environment for CDL patients, in order to maintain or return to optimal functioning[20]. Through improved health-behaviours they might additionally slow or reverse the progression of CDL[20].

Though the majority of chronic disease management continues to be provided through disease specific, single interventions such as cardiac rehabilitation (CR)[13,21], there appears to be a gradual shift towards more comprehensive approaches which acknowledge the interaction between and coexistence of multiple comorbid disorders and risk factors. They are often evidence-based, patient-centred and action-focused[6], and may be referred to as multi-modal or multi-factorial interventions, and CLIs.

1.5.2 Physical outcomes evaluation in CLIs

All data in this thesis were collected from patients enrolled in a CLI programme (known as the *U Turn* programme) developed at and run from a sports and exercise medicine (SEM) clinic at the Sports Science Institute of South Africa (SSISA). This programme was a multi-disciplinary, patient-centred CLI designed to provide optimal

health care for patients with a range of established chronic diseases including cardiovascular disease, metabolic and chronic respiratory disorders. Furthermore, the programme was medically supervised and ran for 36 sessions over twelve weeks. This was followed by a further twelve week programme if indicated. The programme was designed to manage both established disease states and recognised risk factors as well as to improve the patient's functional capacity[13]. The reader is directed to Appendix A for a detailed description of the *U Turn* programme.

Outcomes evaluation is essential in assessing the effectiveness of CLIs[22]. Outcomes data collected at baseline and completion of the *U Turn* CLI programme included measures of functional capacity (six-minute walk distance, and sit-and-reach test for flexibility), cardiovascular outcomes (resting heart rate, resting systolic and diastolic blood pressure) as well as anthropometric outcomes (sum of skinfolds, percent body fat and waist to hip ratio). These were selected based on current best practice guidelines[4,6,18,19,23,24]. A number of recommendations regarding targeted outcomes are listed in Table 1.1[18], and discussed in further detail below:

Table 1.1: Guideline recommendations for patients with established CHD[18]

Smoking cessation among smokers
Regular physical activity
BMI <25 kg/m2
Waist circumference <94 cm (men) <80 cm (women)
Blood pressure <140/90 mmHg

Functional capacity: Six minute walk test

Though the definitions of functional capacity vary, we have adopted a definition that refers to an individual's ability to do physical work[25], and is closely related to cardiorespiratory fitness. Cardiorespiratory fitness is considered an important health-related variable by the ACSM as it has a significant inverse correlation to the risk of premature death, particularly due to CV disease[26].

The six minute walk test (6MWT) is a 'field' exercise test that measures the total distance walked in six minutes. It was originally designed for patients with pulmonary disorders[27], but its use has subsequently branched into cardiac and other CDL

cohorts[28–34]. It assesses functional exercise capacity at baseline as well as on completion of CLIs and the total distance walked in six minutes (6MWD) is expected to increase with increased activity and cardiorespiratory fitness [32]. The 6MWD has recognised variations according to certain patient demographic factors. In particular, there is a well-established attenuation in 6MWD with increasing age, and males are expected on average to walk further than females[23].

While other valid and reliable methods of assessing functional capacity in cardiac patients exist, the 6MWT has been consistently evaluated as an equivalent[28 30], safe, patient-friendly method, requiring minimal amounts of time and resources to use[34]. Four studies in a systematic review of the 6MWT in outpatient cardiac rehabilitation found moderate to high correlations (r = 0.56 to 0.93) with other tests for cardiorespiratory fitness[29]. Specifically, it is considered a safer alternative in cardiac rehabilitation to measuring oxygen consumption using exercise stress tests[29]. It has been tested in a variety of chronic disease populations, including stable coronary heart disease (CHD)[28]; milder heart failure[31,35], as well chronic pulmonary conditions[27]. The 6MWT also serves as a valuable predictor of CV events in ambulatory patients with coronary heart disease, and is at least equivalent to treadmill exercise capacity[28]. Beatty et al reported a 55% age adjusted increase in cardiovascular events over eight years, per standard deviation (104 meters) decrease in 6MWD[28].

A 2012 systematic review of the 6MWT in cardiac rehabilitation outcomes assessment reported evidence of its responsiveness to clinical changes, and thus its suitability as a CLI outcome measure, despite a reported learning effect of between two and eight percent with repeated tests[29]. The authors reported an average increase of 60.4 meters walked following cardiac rehabilitation, with a median effect size of 0.65 meters[29]. Other studies have, however, questioned the reliability of the 6MWT[32]. Hanson et al asserted the 6MWT was unlikely to have sufficient reliability to detect the effectiveness of a CR programme as the increases in post rehabilitation distances walked did not exceed the measurement error[32]. Other studies have reported the existence of a learning effect and its potential to contribute to measurement error, both in severe[30] as well as milder cardiac disease states[31]. The

effect tended to plateau over a few weeks, leading to a recommendation of at least three initial measurements in that time[31].

Despite its recurring use in CLIs, no formal guidelines appear to exist for the 6MWT in cardiac and other non-pulmonary cohorts[29]. The American Thoracic Society (ATS) guidelines are evidently the only official statement regarding the use of the 6MWT[36]. Authors of cardiac-based studies largely concur with ATS guidelines[37 33 28], which are summarised below in Figure 1.1.

- Stopwatch, measuring tape
- A measured strip in a hallway or corridor with as few turns as possible (not circular track)
- Standardised instructions to start and stop walking
- Only eye contact. No verbal or non-verbal encouragement (up to 30% improvement in distance possibly due to this – ref)
- No following or leading participant
- Recommended three baseline measures to account for learning effect

Figure 1.1: Current guidelines for 6MWT in cardiac rehabilitation

Flexibility

Flexibility is defined by the American College of Sport Medicine (ACSM) as the ability to move a joint through its complete range of motion[23]. It has an integral role in both athletic performance as well as in everyday activities, hence its inclusion in many comprehensive health and fitness evaluations as an additional indicator of functional capacity[23]. Musculoskeletal fitness and flexibility, measured by the sit and rise test, was found to be a significant predictor of mortality in 51-80 year-old participants. Authors recommend it's inclusion in general health examinations as it adds relevant information regarding functional capabilities and outcomes in outpatient populations[38]. The *U Turn* programme has, until January 2013, made use of the sit-and-reach test. It subsequently favours the goniometric evaluation of isolated anatomic joints. Both protocols are covered in ACSM guidelines[23]. Flexibility is expected to decrease with increasing age, and females demonstrate significantly greater flexibility than males[23].

Cardiovascular Data

The relationship between blood pressure (BP) and risk for CV events is continuous, consistent and independent of other risk factors[23]. Systolic BP increases of 20mmHg or diastolic increases of 10 mmHg doubles the risk of CV events in individuals between 40 and 70 years, throughout the BP range from 115/75 to 185/115 mmHg[39]. Resting systolic (RSBP) and diastolic BP (RDBP) tend to decrease with chronic exercise training in hypertensive individuals[40]. Physical activity additionally prevents or delays the development of hypertension in normotensive populations[18]. The same trend applies to resting heart rate (RHR)[23]. The inclusion of these CLI outcomes measures is therefore essential. The influence of age and sex on cardiovascular outcomes is consistent across most populations[23]. BP and RHR tend to increase with age, and males have higher BP and HR than females[23].

Anthropometric Data

Anthropometric data are used to assess body composition. All measures are expected to decrease during a CLI, and are specifically related to changing dietary habits and changing patterns of physical activity[23].

Measures such as sum of skinfolds (SkinF) and percentage body fat (BF%) describe the nature of the weight (lean or fat mass), and waist-hip ratios (W/Hip) the distribution of body weight (central or peripheral)[23]. Indeed, it has been hypothesised that regional distribution of adipose tissue is a more important predictor of CV risk than total body weight[18]. Obesity, particularly abdominal obesity, is central to the development of NCDs[41]. Specifically, the international diabetes federation state that central obesity is a modifiable risk factor for the development of type 2 diabetes[42].

Skinfolds arguably provide the most accurate estimates of body composition (to within approximately 3.5%) when compared with height, weight or circumference measurements[23]. It is well-established that excess body fat, particularly if centrally-located, is strongly associated with CDL. Skinfold measures assume that approximately one third of the total body fat is located subcutaneously, accounting for sex, age and ethnicity[23]. Standardised descriptions of skinfold sites (three, four or seven) and procedures appear in ACSM guidelines[23], and are recommended to be

followed as closely as possible to ensure accuracy. BF% is calculated from skinfold measurements using generalised reference tables (as in the *U Turn* CLI), or specific formulae[23].

W/Hip is a simple estimate of body fat distribution and is determined by dividing the circumference of the waist by the circumference of the hips. The risk of CDL increases with increasing W/Hip, and varies according to age and sex[23].

Age-related increases occur in all three anthropometric outcomes. Sex-related differences are consistent, with females having higher average SkinF and BF%, and males higher W/Hip[23].

1.5.3 Effectiveness studies of CR and CLIs

The following section of this chapter summarises the appropriate scientific literature evaluating the effectiveness of CR and related interventions in the secondary prevention of CDL. Studies assessing the effectiveness of programmes more comparable to CLIs, including a study of the *U Turn* CLI, are discussed separately.

Systematic reviews and meta-analyses of the effectiveness of cardiac, as well as other CDL rehabilitation have proliferated over the last ten years[43–50]. They have included investigations of interventions managing mainly, but not exclusively, cardiac[43–48] and metabolic[43,44,46,49,50] disease and related risk[43,45,46,49,50] management. Although the heterogeneity of interventions may explain some of the inconsistent results[43,44,49], there was by and large sufficient consensus on the improvement of end points such as all-cause[45,48], cardiac[43,45–47] and/ or metabolic[46] mortality[46–48] and morbidity[43,45–47] as well as related risk reduction[44–46,48–50] and quality of life[44].

A meta review of 31 sub-reviews of integrated care programmes in CDL patients reported that the majority of interventions resulted in improved quality of life in diabetic patients; improved treatment adherence in diabetic, COPD and asthma

patients; as well as decreased use of healthcare resources in diabetic, CHF and patients with chronic obstructive pulmonary disease (COPD)[44].

Janssen et al. reported that despite improvements in routine cardiac care, CHD patient participation in lifestyle modification programmes resulted in benefits over and above those of routine care. These changes included all usual cardiac markers (all-cause, cardiac mortality; cardiac readmissions and non-fatal infarctions) as well as reduced risk factors (systolic and diastolic blood pressure, total cholesterol and smoking) and improved related behaviours (exercise and dietary habits) at long-term follow-ups of approximately 34 months[45]. These findings are echoed in other reviews of patients with CHD attending multifactorial interventions (MLI)[47].

A review of MLIs in patients with established CVD as well as individuals at risk of developing CVD found reduced CVD morbidity and/or mortality several years after the intervention[46]. In addition, MLIs had favourable effects on biological risk factors (such as serum cholesterol, blood pressure, body weight, diabetes and smoking) and reduced incidence of diabetes[46]. Specific lifestyle changes seem to persist in the longer term, including improved dietary habits and increased physical activity[46]. The review highlighted potential 'success factors' for interventions, including longer duration and intensive counselling[46].

A larger systematic review and meta-analysis has confirmed that exercise-based CR was associated with a significant reduction in all-cause and cardiac mortality. In addition, there was a reduction in total serum cholesterol concentrations, serum triglyceride concentrations, systolic BP and self-reported frequency of smoking[48]. The fact that no difference existed in patient mortality between the exercise-only CR and comprehensive CR lends weight to the important role of exercise training.

Inconsistent effects evident in some of the CR and CLI evaluation studies reported here are further evaluated by Angermayr et al. They evaluated 15 CHD and seven T2D studies of MLIs in primary and secondary prevention[43]. The authors found no consistent effects for markers including blood lipids, BP and BMI when patients in

these programmes were compared to usual care. However, all cardiac event rates (clinical end-points) improved significantly[43].

Finally, there are a few notable and recent systematic reviews[49] and meta-analyses[49,50] of intervention programmes, specific to patients with T2D. Both reported that lifestyle interventions minimise the incidence of T2D in high risk patients[49], as well as minimise the risk of developing CV disease in patients withT2D. While Schellenberg et al., concluded that there was insufficient evidence of reduced all-cause mortality, without concurrent benefits to CV and microvascular outcomes in T2D patients[49], Chen et al., described a number of significant differences in physiological markers including BMI, HbA1c, systolic and diastolic BP compared to controls[50].

Considering the low representation of CLIs in the above reviews, evaluations of a number of larger-scale programmes similar in structure and objectives to CLIs are outlined below. Overall, the authors of these studies report that the interventions lead to reductions in all-cause, diabetes and CV-related mortality[51] and morbidity[51–53] as well as cardiac[51] and other chronic disease related risk factors[54]. Furthermore, improved behavioural[51–57], cardiovascular[52,55–57], anthropometric[52,55,57] and metabolic outcomes[52,55,56] are reported, compared with baseline and or control (usual care) groups.

Lifestyle 180[55] consisted of a six-week initial programme and a subsequent six-month programme incorporating stress management, nutrition and physical activity in patients previously unsuccessfully treated for one or more chronic diseases. Authors reported changes in anthropometric physiological and laboratory variables at six months compared to baseline[55]. Specific changes included weight (-6.8± 6.9 kg), waist circumference (-6.1±7.3 cm), resting heart rate (-5.3±11.5 bpm), SBP (-2.5±17.1 mmHg), DBP (-2.5±10.0 mmHg), fasting triglycerides (109±52 mg/dL), fasting cholesterol (179±38 mg/dL), blood glucose (103±29 mg/dL), insulin (13±10 microU/dL), haemoglobin A1c (HbA1c, 6±1 %), and ultra-sensitive C-reactive protein (4±6 mg/dL)[55].

The Global Secondary Prevention Strategies to Limit Event Recurrence after Myocardial Infarction (GOSPEL) Study was a multi-centre randomised controlled trial (RCT) comparing a long-term, reinforced multi-factorial educational and behavioural intervention (n=1620) versus usual care after standard CR (n=1621), following myocardial infarction (MI)[51]. One-to-one comprehensive CR sessions were held monthly for the first six months, and subsequently every 6 months for 3 years. Sessions comprised of supervised aerobic exercise, lifestyle and risk factor counselling and reinforcement of preventive interventions[51]. At three years, the intervention proved to be effective in minimising risk factors and increasing medication adherence over time as well as significantly improving lifestyle behaviours. Correspondingly, all the clinical outcomes were improved by the intervention between 21 to 36%. Compared with usual care, the intervention decreased CV mortality plus nonfatal MI and stroke (3.2% vs 4.8%; HR, 0.67; 95% CI, 0.47-0.95), cardiac death plus nonfatal MI (2.5% vs 4.0%; HR, 0.64; 95% CI, 0.43- 0.94), and nonfatal MI (1.4% vs 2.7%; HR, 0.52; 95% CI, 0.31-0.86)[51]. These preliminary findings provide further support for longer term maintenance of the gains from the initial intervention[51].

The Euroaction programme was a large-scale RCT assessing a nurse-coordinated, multidisciplinary CV disease prevention programme for 1589 patients with CHD as well as 1189 individuals at risk of developing CV disease[56]. Findings included improved diet, reduced BP in both CHD and at-risk groups completing the intervention, Furthermore, cholesterol concentrations were significantly reduced in the at-risk groups at completion of the intervention[56]. Specifically, they reported a 12.7% improvement in the intervention group in achieving total cholesterol of less than 5 mmol/L between baseline and one year[56].

A further study comprised a seven year follow-up of Finnish T2D patients who had taken part in an intensive lifestyle intervention. Specifically, 172 men and 350 women who had completed a four year active intervention period and were still free of diabetes were assessed over a further three years[53]. Intervention goals included 5% or more weight reduction, 30% or less of daily energy intake from fat, and 10% or less from saturated fats, as well as moderately intense physical activity for 30 min or

more per day[53]. Patients in the intervention group experienced a 43% reduction in diabetes risk, which was related to their success in achieving the intervention goals of weight loss, reduced intake of total and saturated fat and increased intake of dietary fibre, and increased physical activity[53].

One of the defining characteristics of CLIs is their attention to CV as well as comorbid disorders and their interactions. Villareal et al., reported that a six month lifestyle intervention significantly improved almost all obesity-related, metabolic and CHD risk factors (including waist circumference, BP, circulating inflammatory markers, oral glucose tolerance, insulin resistance, plasma glucose, triacylglycerol, and FFA concentration) simultaneously when compared to usual care, and that over the longer term, CHD risk factors were reversible in obese older adults[52]. A study for a 24-week intervention for T2D patients reported improved CV and mood outcomes, as well as a reduced BMI. There were, however, no changes in lipids or glucose levels[57].

In light of the aforementioned findings, it is noteworthy that a recent evaluation of the *U Turn* CLI programme reported significant improvements in anthropometric; cardiovascular, and metabolic outcomes, as well as functional capacity[13]. Specifically, improvements were reported in percentage body fat (29.8±6.7% vs 28.5±6.6%), waist and hip circumferences (100.2±16.2 vs 97.3±14.8 cm), resting heart rate (74.2±13.4 vs 71.4±11.9 bpm), resting systolic blood pressure (125.7±16.1 vs 120.1±13 mm Hg), total cholesterol (4.7±1.2 vs 4.3±0.9 mmol/L), LDL cholesterol (3±0.9 vs 2.7±0.8 mmol/L), triglycerides (1.4±0.7 vs 1.3±0.6 mmol/L), 6MWD (559.4±156.6 vs 652.3±193.6 m) and flexibility (12.1±11.6 vs 16.1±10.8 cm, all $p<0.05$)[13].These findings are encouraging, especially as 84% of the 210 participants had comorbid chronic diseases requiring additional considerations for exercise prescription[13]. Furthermore, the findings are commensurate with current effectiveness research, which largely supports the role of CLIs in successful behaviour change and physical outcomes[18].

Therefore, overall findings from CLI efficacy studies indicate promising improvements in functional, physiological, metabolic and some psychosocial markers of wellbeing.

1.5.4 Psychosocial Factors in CLI

A psychosocial risk factor encompasses the relationship between psychological phenomena, such as anxiety, depression, other stress-related symptomatology and pathophysiological changes[58]. Important risk factors frequently referred to in this review are trauma and traumatic events. Although clinical definitions of traumatic events are often restricted for diagnostic purposes to 'experiencing actual or threatened death or significant injury[59]', other definitions allow for the inclusion of 'extremely stressful events', defining trauma itself as 'the result of the struggle with highly stressful events'[60]. Such events and responses are often associated with deterioration in physical health[61]. In contrast, psychosocial protective factors such as resilience and optimism may positively affect adverse changes, and contribute towards accelerated recovery in ill or injured patients[9].

The scope necessary to account for all reported psychosocial associations with physical change would be exhaustive. Considering this limitation, as well as the retrospective nature of the first part of the study, the psychological factors reviewed in this chapter are limited to those measured in the *U Turn* CLI programme. They include resilience, psychological distress and trait anxiety. Each factor will be introduced individually, and discussed in the context of recent and seminal CDL and CLI outcomes literature.

1.5.4.1 Resilience

Susceptibility to mental illness following a traumatic event is not uniform. Resilience is defined as an individual's ability to 'bounce back' from adversity[62], and is demonstrated by a significant proportion of the general population[63]. Various other definitions exist, including the capacity to maintain, or regain mental health in the

face of significant adversity, such as physical illness[9]; an individual's ability to thrive under adversity[62]; and functioning above the norm despite significant stress or adversity[64]. Commonly reported factors associated with resilience include self-efficacy, self-esteem[65], internal locus of control, optimism[65], perceived control[65], mastery[9], and hardiness[66], as well as behaviours and attitudes such as active coping strategies, benefit finding and the presence of social support.

Applied resilience research examines the association between psychosocial protective factors and more successful physical health outcomes[9,65]. CDL studies consistently report associated psychosocial factors, such as hope, empowerment, acceptance of illness, determination as well as physical outcomes such as self-care, adherence with treatment recommendations, health-related quality of life, illness perception, pain perception, exercise adherence, HbA_1c and CD4 counts[9].

A recent systematic review[9] of resilience in physically ill populations included only six studies relating to cardiovascular disease, six on diabetes, and seven studies with multiple conditions, including cardiovascular disease and/or diabetes. The quality of quantitative research was rated as fair for three studies reporting multiple conditions, three 'fair' and two 'poor' studies on diabetes, and six 'fair' studies on cardiovascular disease. Most notably, there were only two quantitative studies that measured resilience directly with a resilience scale[9]. Findings regarding resilience in different disease contexts were inconsistent and reflect the heterogeneity inherent in this research.

In diabetic populations, resilience, self-efficacy and optimism have been associated with improved glycaemic control, fewer complications and reduced mortality rates[10]. Factors such as self-efficacy correlate with, and may even predict, increased physical activity, weight loss, improved diet, as well as increased self-care behaviours in patients with, or at risk of developing, type 1 or type 2 diabetes (T2D)[10]. Physical activity has also been associated with improved psychosocial characteristics, particularly self-efficacy, thus demonstrating their reciprocal interaction.

Another protective factor is optimism, which has been extensively researched within CDL cohorts[11,67,68]. It has been positively associated with resilience, and predicted success in cardiac rehabilitation patients' ability to make healthier lifestyle choices[69]. Authors used the status on a variety of patient risk factors at intake and programme completion as an indication of changing lifestyle choices. Risk factors included cholesterol levels, body fat, proportion of saturated fat in diet, activity levels, smoking status and aerobic capacity. At programme completion (18 weeks) optimists were more successful than pessimists at reducing the proportion of saturated fat in their diet, their body fat and global coronary risk to recommended levels. Moreover, they were more successful at improving their aerobic capacity than pessimists. Optimism has additionally predicted lower rates of re-hospitalisation following elective coronary artery bypass surgery[11].

While other studies have examined resilience in chronic disease, particularly cardiac, cohorts, they have not always included resilience as a predictor of health outcomes[9,70,71]. Thus, of particular interest to the current study are findings from Chan et al[65], who examined the impact of personal resilience on physical and mental outcome measures of patients with chronic heart disease enrolled in an eight-week CR programme. The study additionally examined a related construct, post traumatic growth (PTG), which involves the process of change during an individual's struggle with adversity which may result in an improved level of functioning compared to before the event[72]. The impact of personal resilience on PTG was also described. Personal resilience consisted of dispositional optimism, perceived control and self-esteem. Outcomes measures included mental and physical components of general health status, as well as a scale for post-traumatic growth. Physiological outcomes included triglycerides; total, low density lipoprotein and high density lipoprotein cholesterol; Body mass index and 6MWD for functional exercise capacity. Sample demographics reflected high variation in socio-economic status and gender (43 males and 24 females) and age (mean of 63 years, standard deviation of 8.6 years). The study controlled for programme effect as well as interaction effect of resilience and the programme[65]. The findings of the study indicated that patients who scored high in personal resilience achieved higher physical and mental measures, lower cholesterol concentrations and better performances on the 6MWD than those low in

personal resilience. Despite a weak mediating effect by the rehabilitation programme on the above relationship, personal resilience was a significant predictor of the level of post-traumatic growth[65].

Lastly, it is interesting to note that resilience has been found to potentially maximise benefits patients would derive from interventions. Preliminary findings from pilot studies in workplace settings associated improved positive adaptation with improved serum cholesterol concentrations over the 13 week intervention[73]. Moreover, a resilience building programme piloted in African-American T2D cohorts demonstrated similar changes in a range of physical and psychosocial variables[74]. They reported statistically significant improvements in diabetes empowerment and diabetes self-management, as well as physical variables including body mass index, HbA1c, total cholesterol, low-density lipoprotein cholesterol, and systolic and diastolic blood pressure[74].

Assessing Resilience

Two recent reviews have assessed resilience scales[75,76]. Windle et al evaluated 15 resilience measures and rated the Connor Davidson Resilience Scale (CD-RISC, used in the current study), The Brief Resilience Scale, and the Adult Resilience Scale, highest with respect to psychometric properties[75]. The ratings were insufficient, however, to recommend a 'gold standard' measure of the construct[75].

The CD-RISC is a 25 item self-report measure of resilience. It employs a 5-point likert scale, rating how an individual felt over the past month and is scored 0 to 100, with higher scores reflecting higher resilience. It was initially designed as a multi-dimensional measure, with a five factor structure. Factor 1 represents personal competence, high standards, and tenacity; and factor 2 measures trust in one's instincts, tolerance of negative affect, and strengthening effects of stress. Factor 3 reflects the positive acceptance of change, and secure relationships; and factor 4 and 5 represent control and spiritual influence respectively[66]. The factor structure of the original 25 item version has been queried by various authors, who proposed a uni-dimensional structure in 2, 10 and 22 item versions[77 78 79]. These versions are purportedly more efficient, capturing the core features of resilience[77].

The authors' initial analyses of the 25 item version's psychometric properties in community as well as patient populations showed sufficient internal consistency, test-retest reliability, and convergent and divergent validity[80]. They reported negative associations in resilience with neuroticism and emotion-orientated coping and positive associations with extroversion, conscientiousness and task-orientated coping. Moreover, resilience moderated the relationship between childhood maltreatment and current psychiatric symptoms[80]. Follow up reviews tallied 248 peer reviewed citations and 33 translations of the CD-RISC. Factor structure and mean scores varied between settings and populations, depending on the methodology and underlying assumptions directing research[79,80]. Initial community-based norm scores are reflected below in Table 1.2[66].

Table 1.2: Factor structure and mean scores of CD-RISC in different populations

Study group	**Group no.**	**N**	**Mean (SD)**
General population	1	577	80.4 (12.8)
Primary care	2	139	71.8 (18.4)
Psychiatric outpatients	3	43	68.0 (15.3)
GAD patients	4	24	62.4 (10.7)
PTSD patients	5 6	22 22	47.8 (19.5) 52.8 (20.4)

(GAD = generalised anxiety disorder; PTSD = post-traumatic stress disorder)[66]

Connor and Davidson[81] reported equivocal findings for demographic factors (particularly age, gender and education level), although ethnic and cultural factors seem to account for some of the variance. For example, mean scores from a US population were highest at 80, and Chinese samples were the lowest at approximately 61. Possible reasons for the discrepancy include the importance of altruism as a protective factor in Eastern cultures which are not assessed in the CD-RISC[81]. Language barriers may have additionally contributed to lower scores in South African adolescent samples (mean scores of 64.8 and SD of 18.9). Psychiatric population means varied depending on the condition, with PTSD or trauma survivors averaging between 58 and 82; depressive populations between 39 and 63; and other

diagnoses ranging from 49 to 64[81].Groups with medical conditions included US primary care samples (mean scores of 71.8), US infertile women (mean scores of 68.1 and SD of 14.3)[82]; African-American diabetic (mean scores of 83.1 and SD of 8.5)[74] and Taiwanese diabetic cohorts (mean scores of 74.9 and SD of 14.8); as well as individuals with spinal cord injuries (mean scores of 82.2 and SD of 9.4)[83]. The only study (available at the time of writing) involving CV conditions reported that low resilience in addition to chronic psychosocial stress increased the odds for hypertension[81].

Shin[71] studied resilience in Korean patients with CV disease. They developed a new resilience scale for cardiovascular cohorts, deriving seven factors and 25 items through factor analysis. They found moderate correlations between items in their scale and the subscales of the CD-RISC[71]. No other resilience measure currently purports to be exclusively developed for this cohort, and none, at the time of writing, were available in English.

Therefore, resilience a multidimensional, dynamic and developmentally appropriate construct, differing in each individual according to specific interactions between risk and protective factors (both intrapersonal and environmental) over time[62]. This, in turn, complicates the assessment of resilience[75]. Furthermore, there is a commensurate gap in clinical and applied literature on the subject of the association of resilience and CLI outcomes in patients with CDL.

1.5.4.2 Psychological Distress

Psychological distress is characterised by a perceived inability to cope effectively with one's situation or condition, a change in emotional status, perceived discomfort, communication of discomfort, and manifestations of harm[84]. The necessary criteria for serious psychological distress (SPD) includes a positive diagnosis of a twelve-month DSM-IV disorder, along with a Global Assessment of Functioning (GAF) score of less than 60[85].

A relationship has been identified between psychological distress and physical illness[84]. Australian Health Surveys between 2001 and 2008 revealed an increased prevalence in psychological distress among patients with diabetes and CV disease, but not in the general population[86]. Additionally, cardiac patients experiencing psychological distress during CR were found to be twelve times more likely to experience a subsequent event[87]. A review of diabetes and SPD concluded that SPD has a significant negative impact on diabetes outcomes. They were unable, however, to establish underlying mechanisms, nor the long-term impact of SPD on diabetes outcomes[85]. Part of this limitation may be due to the variable being conceptually ill-defined[84]. It has additionally been noted that the relationship between physical disease and psychological distress can at least be partly explained by demographics (age, gender, marital and socioeconomic status) and factors related to functional disability (evident in self-reported diagnoses of common conditions such as CV disease, stroke or diabetes, or a reported need for help with any disability) [84]. Furthermore, psychological distress and depression are not synonymous, and certain measures detailed below reportedly over-diagnose depression[88].

Measuring Psychological Distress

Screening for psychological distress originated with dimensional scales 60 years ago and favoured fully structured research diagnostic interviews during the 1980's. Among the general population sampled, interviews were accurate in terms of diagnosis but not severity. Shorter measures of non-specific psychological distress were reintroduced to address this problem and their use and development has subsequently proliferated in large scale community-based health surveys[89].

The Kessler Psychological Distress Scale (K10) is a validated surveillance tool for non-specific medium-term psychological distress (specifically, nervousness, agitation, psychological fatigue and depression[89]). It distinguishes severe and non-severe cases and demonstrates consistent levels of severity across socio-demographic subsamples[89]. The ten item (and subsequent six item) tool was designed for the US National Health Interview Survey for monitoring the prevalence rates of mental disorders[90]. It has also been included in the Australian National Survey of Mental Health and Well-Being[89]; in versions of the World Health

Organisation (WHO) Composite International Diagnostic Interview (CIDI)[91]; and in various validation studies in developing nations[90] including the South African Stress and Health (SASH) survey which formed part of the WHO's Mental Health Survey initiative[90]. High K10 scores (22 out of 50 and above) correlate well with CIDI diagnoses of anxiety and depression[84]. Scores at or under 15, and between 15 and 22 represent low and medium levels of psychological distress respectively[84]. Its use in cardiac cohorts, however, is reportedly low[88].

1.5.4.3 Trait Anxiety

State and trait anxiety are differentially defined by the intensity of an emotional state at a particular time, and by frequency at which anxiety is experienced[92], respectively. It is assumed that state anxiety should increase under stressful situations, and decline under relaxed treatment conditions. Trait anxiety is required, like personality traits, to be relatively stable over time, and thus unaffected by stress[93]. Trait anxiety is purportedly linked via negative affect to anger, depression and impairments in cardiac autonomic functioning. A study by Bleil et al., adds to a growing body of evidence that depression, anxiety, and anger may reflect a general disposition to experience negative emotions that confers risk for coronary heart disease (CHD)[94]. Underlying mechanisms are not investigated in this study, but authors postulate that tendencies toward negative emotional experiences such as depression, anxiety, and anger may reflect a more rigid physiological system, less able to respond to the environment, and, thus, susceptible to disease processes associated with dysregulated autonomic nervous system function[94].

Measuring Trait Anxiety

The State-Trait Anxiety Inventory (STAI) was based on refinements of Cattell and Scheier's (1961) state-trait distinctions[92]. The original and refined versions consist of two tests, the State version (Form Y-1) and the Trait version (Form Y-2), which are administered in that order. Both tests contain twenty items the respondent must rate on an intensity (state) and frequency (trait) scale of one to four. Nine of the items (1, 3, 6, 7, 10, 13, 14, 16, 19) which measure an absence of anxiety, are written in a form opposite to the scale[95]. They are necessary for assessing lower levels of

anxiety[92], and are reverse scored so that the higher the total score per test, the higher the state or trait (and thus total) anxiety. Scores of over 40 in American populations have been classified as clinically significant[96]. The STAI has been translated into over 30 languages and applied to a variety cultural and clinical contexts[92].

The current study has only made use of the Trait version (STAI-T). It assesses how the respondent generally feels by rating the frequency of feelings of anxiety (1 =almost never, 2 = sometimes, 3 = often, 4 = almost always)[97]. Examples of feelings include apprehension, tension, and increased autonomic nervous system activity[98]. Individuals scoring high in trait anxiety perceive more situations as threatening or dangerous than those who score lower in trait anxiety. They also tend to score higher in state anxiety[98].

The STAI has enjoyed widespread use over four decades, and sufficient evidence has accumulated of sound psychometric properties in a variety of contexts[98]. Spielberger's own validation studies for Form Y report median alpha coefficients of 0.90 and 0.93 for scores on the trait and state scales, respectively, as well as test-retest coefficients from 0.73 to 0.86 and 0.16 to 0.62 for scores on the trait and state scales, respectively[98]. Barnes et al., systematic review of research using the STAI reported only six percent of 816 studies produced their own reliability data for the STAI despite the widespread use of the measure[98]. The study found relatively stable internal consistency reliabilities for both versions in most studies. Moreover, it reported that medical studies tended to report less on psychometric properties than non-medical articles[98].

Criticisms of the STAI factor structure in the early 1980's resulted in a number of significant revisions by the authors, replacing 30% of the test items. All new items correlated more highly with their respective scales and had better content validity[93]. Four factors are now consistently extracted from the revised version, namely state anxiety present, state anxiety absent, trait anxiety present and trait anxiety absent[93].

Validity, specifically construct validity, is viewed as the most important psychometric quality[93], particularly when items are initially selected for tests. STAI-T factor structure, and potentially its validity, has been questioned by several authors[95,99]. Vigneau and Cormier proposed a model combining a general factor, namely negative affect, with anxiety and depression as specific factors. This structure is possibly due in part to the use of items of opposite polarity[95]. Once considered essential elements of test construction, particularly in an effort to reduce response bias, they are now viewed as unnecessary, and potentially problematic for factor structure of various scales[99]. Bados concludes that when considering the total STAI-T score, one may be assessing negative affect in general more than anxiety[95].

Applied STAI-T research includes a variety of constructs and settings. Of particular interest to this study was Benetti et al's use of both the CD-RISC and STAI-T. They reported that trait resilience and trait anxiety act on self-esteem via the regulation of affective experiences, which, in turn, may predict an individual's feelings of self-worth[100]. Although the findings have not yet been applied to CDL or CLI cohorts, it is encouraging to encounter research into interactions between psychosocial risk and protective factors.

Despite some of the aforementioned psychometric concerns, studies of CDL have made sufficient use of the STAI. Over two decades ago, Jenkins et al., identified several factors, including low levels of anxiety measured by the STAI-T, as significant independent predictors of the absence of cardiac symptoms, six months post-cardiac valve or cardiac artery bypass surgery[101]. In a five year prospective cohort study, psychosocial factors, including anxiety as measured by the STAI were independently associated with the occurrence of major adverse cardiac and cerebrovascular event (MACCE) after adjusting for biomedical factors and perioperative variables after cardiac surgery[96]. In addition , post-operative CHF and pre-operative trait anxiety measured by the STAI-T was found to be independently associated with mortality[102] These findings are in line with other prospective evidence indicating that individuals with depression, anxiety and related symptoms are at increased risk for clinical coronary events, even after accounting for established CV risk factors[94].

Psychosocial risk and protective factors thus play an integral role in outcomes of CLI. Key variables considered in this chapter which may contribute to less successful outcomes include psychological distress and trait anxiety. Conversely, resilience, measured by a valid and reliable tool, has been demonstrated as a useful predictor of successful outcomes of a CLI. Early detection of potentially vulnerable or resilient patients might enable clinicians to tailor the intervention more effectively to suit the psychosocial needs of the patient.

1.6 QUALITATIVE METHODOLOGIES IN CLI

As outlined in Section 1.4, this thesis adds to a growing body of medical and healthcare research employing qualitative methodologies, whether exclusively, or as an adjunct to existing quantitative techniques[103]. This has partly occurred in response to parallel advances in patient-centred healthcare delivery, as qualitative methods describe the subjective experience of individuals and patient-centred healthcare focuses on the active role individuals play in securing appropriate and effective healthcare[104]. Indeed, the use of qualitative approaches enhances the description of the patient's experience and expectations of healthcare interventions.

Resilience forms a core component of the study's qualitative investigation. It has been researched using quantitative, qualitative and mixed methods approaches[9,105]. The former has been outlined earlier in the chapter, and the latter will now be examined citing recent and seminal research within the fields of CDL and CLI.

1.6.1 Qualitative Research in CDL Cohorts

Qualitative research provides an increasingly in-depth understanding of a patient's experience of chronic disease, as well as their process of change or recovery. Such insights may highlight additional steps required for sustainable behavioural change.

1.6.1.1 Patient Experiences of CDL

Patient descriptions of the illness experience inform their expectations from CLI. A number of reviews[106] and systematic reviews[107,108] have collated patients' experience of chronic heart failure (CHF), and qualitative research has distinguished generic and disease-specific experiences of CDL[109]. Elderly patients experience CHF as debilitating and distressing. There is a great deal of uncertainty, especially at an advanced stage of illness, and inefficacy in self-care[107]. Social isolation, living in fear and losing a sense of control were included as prominent themes in a subsequent review of the topic[108]. Consequently, patients were found to employ specific strategies to manage their conditions, such as sharing their experiences with others and being flexible to changing circumstances[108].

Other conceptual categories emerging in the literature include the diagnosis and manifestations of heart failure; perceptions of day-to-day life; coping behaviours; role of others; and the concept of self which influences all other categories. Adaptation to the new sense of self is suggested to then, in turn, influence self-care behaviours[106]. Patients recovering from MIs noted difficulties in making lifestyle changes[110], and focus groups from this study called for increased long-term support and monitoring, as well as group work to enhance the sharing of experiences[110].

1.6.1.2 Patient experience of Rehabilitation/ CLI

A systematic review of patient experiences of CHF observed several factors which impacted on patients' self-care and self-management in the disease trajectory[108]. These comprised of knowledge and understanding of the disease state, as well as the nature of health service encounters. The last factor has become increasingly emphasised in the healthcare industry and related research. It incorporates access, continuity and quality of care, as well as comorbid conditions and personal relationships, and thus plays a vital role in developing and improving the delivery and use of lifestyle interventions for patients with CDL[108].

Patients diagnosed with COPD reportedly experienced anger over limitations imposed by their condition[111]. However, a systematic review of COPD patient experience of pulmonary rehabilitation (PR), reported that empowered patients take

advantage of psychosocial support and health participation, leading to positive long term impacts[111]. Leading themes emphasised the importance of including psychosocial support, health education and overall opportunities for health transitions[111]. It confirmed that by doing so, PR stimulates improved well-being and health promoting behavioural changes[111].

Research of patient experiences of CR highlights the barriers to adherence or attendance. Some factors may be cultural, as outlined in Galdas et al[112]. They reported the importance of exercise, language and communication and religion. Furthermore, factors influencing CR participation may be structural in nature. Neubeck and colleagues'[113] compiled a systematic review and meta-synthesis of CR studies using a variety of qualitative methodologies. Physical and personal barriers to CR participation were identified. Examples of physical barriers are a lack of transport or financial constraints, and personal barriers may include patients feeling embarrassment about participation, or misunderstanding the reasons for the onset of CHD or the purpose of CR.

Lastly, in response to their increased use, evaluations of a web-based disease management programme of diabetic patients revealed the need to take patients' specific needs and expectations into account before the programme commenced, and to discuss the strengths and limitations of web-based care[114]. Important considerations included the active valuing of patient's chronic needs, their sense of safety, as well as the negative impact of unmet programme expectations[114].

1.6.1.3 Qualitative Research of Resilience in CDL Cohorts

There appears to be a conspicuous gap in qualitative resilience literature in CDL cohorts which has not, as yet, been adequately addressed. This is in spite of calls for the overall development in qualitative resilience research over a decade ago[105]. There is sufficient evidence of its importance in resilience research[105]. Firstly, qualitative methods discover unnamed protective processes which create rich descriptions of resilience. Secondly, it provides contextual specificity, previously mentioned in this chapter for its importance in understanding resilience. Finally, authors emphasise lesser known and more culturally specific accounts of

resilience[105]. There are unfortunately few examples of qualitative resilience research, as the abovementioned author cites only his own work as well as the seminal work of Rutter[105,115].

Published research in this area was subsequently evaluated in a systematic review. Authors retrieved nine qualitative investigations of resilience in the physically ill, and only one using mixed methods[9]. Cohorts included patients with diabetes, cancer as well as mixed cohorts. Their findings are summarised in Table 1.3.

Table 1.3: Summary of qualitative and mixed method studies[9]

Author	Disease	Sample (n) %F	Findings
Abraido-Lanza et al. (1998)[116]*	Rheumatoid arthritis Lupus; Osteoarthritis etc.	F 100%	Qualitative data indicated optimism, hope and enhanced appreciation of life associated with thriving. Self- esteem, self-efficacy, and positive affect positively correlated with psychological well-being and thriving
Iwasaki & Bartlett (2006)[117]	Diabetes	26	Culturally bound leisure activities (art, spiritual reading) can mitigate certain stressors by promoting strength and resilience.
Beardslee (1989)[118]	Cancer	3	Cognitive appraisal, relationship, and self-understanding were key in adjustment.
Chan et al. (2006)[119]	Cancer	17	Acceptance, hope, and empowerment in participants after intervention designed to promote mastery, self- efficacy and growth.
Parry & Chesler (2005)[120]	Mixed childhood cancer	50	Meaning making and psycho-spiritual growth associated with psychosocial well-being and resilience.
Parry (2003)[121]	Mixed childhood cancer	23	Coping with uncertainties of illness led to new outlook on life and development of resilience, confidence, and optimism.
Pentz (2005)[122]	Cancer (lung, prostate, digestive)	13	Social support and spirituality-faith are important aspects of resilience in older cancer survivors.
Becker & Newson (2005)[123]	Diabetes Hypertension Cardiovascular etc.	38	Past experience with adversity shaped attitude towards illness and thriving; emphasised spirituality, determination and independence.
Haynes & Watt (2008)[124]	Rheumatoid arthritis Cardiovascular Multiple Sclerosis Hypertension	8	Spirituality, focus on future, and commitment to successful living related to better adaptation to illness.
Kralik et al. (2006)[125]	Diabetes, Chronic fatigue, Psoriatic arthritis, Others	37	Resilience was about having a strong sense of self-worth, learning from experience, developing adaptability, and connection with others.

*mixed methods

Both quantitative and qualitative studies have generated similar results, frequently identifying hardiness, social support, and optimism as factors associated with resilience, though qualitative studies often used alternative terminology such as courage, faith and commitment[9].

Moreover, a systematic review by Hefferon et al., synthesized qualitative data on PTG (a construct related to resilience described earlier) and illness related trauma. They identified a number of themes, namely 'reappraisal of life and priorities', 'trauma equals development of self', 'existential re-evaluation', and 'an awareness of the body'[72].

While the majority of qualitative studies further our understanding of the patient experience of CDL and, to some degree their experience of CLIs, there is a notable paucity of research of resilience within CLIs, as well as in the qualitative evaluation of CLIs. The latter may be addressed through a relatively novel approach to product and service evaluation and innovation, known as human centred design (HCD), or design thinking (DT), which is outlined in the following section.

1.6.1.4 The use of ethnography and human centred design in CDL and CLI contexts

The applied field of SEM has advocated the use of HCD in CLI development and management to create sustainable programmes for the prevention of CDL[6]. HCD is a process of product development that seeks to understand, and then to address the specific needs of individuals who use a particular product or service, as well the enabling infrastructure[126]. It is an inherently optimistic and experiential process that assists in translating traditional knowledge into practical, individualised, everyday solutions[127]. In healthcare contexts this process would involve additional steps to decision-making and other health-related transactions with patients. These transactions include observing, discovering, interpreting, ideating, prototyping, iterating and monitoring[6].

The use of ethnographic fieldwork techniques assists HCD researchers in gaining insight into how individuals actually use goods and services available to them[127]. Incorporating HCD into traditional healthcare research can, from a systemic level, add further depth and evidence to findings of the individual experience of healthcare services and technology[128]. While the use of similar techniques is commonplace within the applied social sciences, it is necessary to validate commercially-derived products or ideas such as HCD in use in healthcare settings[129,130].

There is a steady increase in peer-reviewed research on HCD for CLIs. Informal investigations into problem areas in the hospital experience are described by Brown[127], one of the key drivers of HCD. A co-researcher of Brown's effectively tapped into the patient experience of an emergency rooms admission by feigning an injury and experiencing it himself. He noted that this differed significantly from medical professionals' understanding of how the process worked.

Using 'quick ethnography' such as patient observations and informal interviews, specific elements of radiotherapy reportedly triggered anxiety in cancer patients by perpetuating a passive, disempowered sick role[128]. In this case, the holistic framing of the patient experience assisted in the discovery of new ways to mediate and prevent situational anxiety in patients undergoing treatment[128].

In a further study, Coulter and Ellis reviewed the evidence for related patient-focused interventions, and found that encouraging higher health literacy and a sense of ownership in their health potentially assists patients in adopting and maintaining healthier lifestyles and in meeting health targets sooner and more regularly[104].

The SPARC (See, Plan, Act, Refine, Communicate) Innovation Programme at the Mayo Clinic is a multi-disciplinary service programme based on HCD, and has reportedly begun to address complex problems facing the clinic. One of their exemplary projects included the improvement of outpatient services (such as reducing waiting time and improving provider-patient knowledge transfer) which was initiated from an observational study[131].

Furthermore, patient experiences in Japanese hospitals have been researched using principles of HCD. Ideas generated from interviews as well as observational techniques included a way-finding system for patients to use if they struggled to orientate themselves in the hospital[132].

Thus, by applying ethnographic fieldwork techniques, HCD may encourage further innovations in improving patient outcomes in CLIs. It is, however, a relatively recent application, which will require continued evaluation of its validity and reliability in

healthcare, and specifically in CLI contexts. The lack of effectiveness studies in this field may be due to the commercial origins and applications of HCD. The majority of writing on HCD healthcare innovations is published in business-sector publications. The anticipated proliferation of these and related products and services, as well as their impact on healthcare variables might emerge in more prominent literature sources in the near future.

1.7 CONCLUDING REMARKS

This literature review comprised a number of objectives. Firstly, it defined CDL, described a number of physical outcomes assessments used in CLI programmes and outlined recent and seminal effectiveness research on CLI's and other forms of CDL rehabilitation. The literature indicated that developments in CDL rehabilitation are associated with improved functional capacity as well as other physical outcomes.

Following this, psychosocial risk factors as well as psychosocial protective factors were described in relation to CDL and CLI research. Whilst substantial evidence has been reported on psychological variables and their relationship to physical health outcomes, notable gaps emerge in more specific areas such as resilience in CDL cohorts as well as CLI outcomes. Although resilience is an increasingly investigated variable in CDL patients, it has not been sufficiently studied as a predictor of successful outcomes in CLIs. Moreover, the CD-RISC has yet to be used in a CLI setting.

Furthermore, an outline was provided of the application of qualitative methodologies in CDL and CLI research, particularly relating to resilience. The commercial application of ethnographic research known as HCD was also introduced, together with a brief review of current literature regarding its application in medical settings. Qualitative and ethnographic studies of resilience are relatively numerous. However, they have not, to the authors' knowledge, been applied to CLI contexts. It was additionally concluded that insufficient research and accompanying literature exists

regarding the use of HCD in CDL cohorts. A qualitative investigation into patient experiences of CDL and CLIs will certainly add to the existing knowledge base of these topics. Furthermore, the application of HCD has much potential in guiding clinicians and designers of CLIs in the development of effective, sustainable treatment and management of CDL.

The following thesis addresses a number of deficits in CDL and CLI literature regarding the role of psychosocial risk and protective factors in CDL rehabilitation. Chapters 2 and 3 evaluate the use of questionnaires in associating psychological factors with baseline physical outcomes in CDL cohorts commencing a CLI programme, as well as the changes in outcomes at conclusion. Chapters 4 and 5 subsequently explore the use of qualitative research methods in describing contributing factors to successful CLI outcomes.

CHAPTER 2: BASELINE PSYCHOLOGICAL AND PHYSICAL VARIABLES OF PATIENTS WITH CHRONIC DISEASES OF LIFESTYLE

2.1 INTRODUCTION

To date, non-communicable diseases (NCDs) are the predominant cause of global deaths[1]. NCDs consist of chronic diseases of lifestyle (CDL), which include cardiovascular (CV), metabolic and chronic respiratory diseases[1]. This is evident in middle and low income countries such as South Africa which report over a third of NCD-related mortalities[2], and a significant proportion of patients suffering from more than one chronic disease[3].

The majority of CDLs are preventable by modifying lifestyle behaviours such as diet, physical inactivity and tobacco use[1]. There is an increasing awareness of the inherent risks attached to certain lifestyle behaviours requiring behavioural modification interventions, as well as a corresponding improvement in access to comprehensive and cost effective interventions at primary and secondary level[7]. Despite these advances, however, the continuing increase in global incidence of CDL forces us to acknowledge the complexities of these conditions as well as the challenges inherent in sustainable behaviour modification[6]. Therefore, factors, including physical, psychological and demographic variables, assessed prior to commencing of intervention in CDL patients would be important. Psychosocial risk factors, such as depression have well established associations with CV disease[8].Alternatively, variables such as resilience[9,10] and optimism[11,12] reportedly protect against CDL, and are thus associated with better health profiles. These so-called psychosocial protective factors are being progressively utilised in comprehensive lifestyle intervention (CLI) programmes for the management of CDL[13]. The short term effectiveness of CDL intervention programmes are established[13]. However, it is not directly apparent how psychosocial factors, including resilience, contribute to the changes observed in patients with CDL.

Psychosocial risk factors and psychosocial protective factors thus play an integral role in physical health variables. Psychosocial risk factors commonly include psychological distress as well as trait anxiety. A relationship has been identified between psychological distress and physical illness[84,85,133]. Cardiac patients experiencing psychological distress during CR were found to be substantially more likely to experience a subsequent event[87], and serious psychological distress (SPD) has shown a significant negative impact on diabetes outcomes[85]. Moreover, trait anxiety is purportedly linked via negative affect to anger, depression and impairments in cardiac autonomic functioning[94]. This adds to a growing body of evidence that depression, anxiety, and anger may reflect a general disposition to experience negative emotions that confer risk for coronary heart disease (CHD)[94]. Distress and anxiety might also translate into poor health profiles in patients with CDL entering CLI programmes.

Resilience, a key protective factor, is increasingly investigated in CDL cohorts. Applied resilience research examines the association between positive psychological characteristics and more successful physical health outcomes[9,65]. CDL studies consistently report associations between resilience and psychosocial and physical factors such as hope, empowerment, acceptance of illnesses and determination, self-care, adherence with treatment recommendations, health-related quality of life, illness perception, pain perception, exercise adherence, HbA1c concentrations and CD4 counts[9]. However, resilience has not been sufficiently studied in relation to physical variables on entry into CLIs. The Connor Davidson Resilience Scale (CD-RISC) is the closest to a ‘gold standard’ measure for resilience in a variety of populations. Nevertheless, it has yet to be validated in CLI settings. Early detection of potentially vulnerable or resilient patients using psychometrically sound psychological measures may enable clinicians to tailor CLI programmes more effectively to suit the individual needs of the patient.

2.2 STUDY AIMS

The following chapter describes a retrospective clinical audit of 308 patients to determine whether there was a relationship between psychosocial variables and initial physical variables measured at the start of a CLI programme. In particular, patients' responses to psychological screening questionnaires administered at the initiation of a twelve-week CLI programme were assessed. Furthermore the psychological, as well as demographic, diagnostic and medical variables were assessed in relation to physical parameters, including measurement of functional capacity, cardiovascular and anthropometric outcomes data collected at the initiation of a CLI programme.

The specific aims of this chapter are to provide descriptions of baseline demographic, diagnostic, medication, psychological and physical variables of patients attending a twelve week CLI programme.

2.3 METHODS

2.3.1 Type of study

This study is a retrospective clinical audit in the form of a cross-sectional cohort study investigating the descriptive and screening value of demographic, diagnostic, medication and psychological variables at baseline of a twelve-week CLI programme for patients with CDL.

2.3.2 Participants

Participants were patients who had been diagnosed with a CDL by a physician, and had subsequently enrolled in the *U-Turn* CLI programme at the Sport and Exercise Medicine Clinic within the Sports Science Institute of South Africa (SSISA) in

Newlands, Cape Town. Patients entered the programme either by self-referral or by referral from medical insurers or physicians. In order to qualify for admission into the programme, patients with a variety of chronic diseases including cardiovascular disease, diabetes, chronic arthritis, chronic kidney disease, cancer, chronic obstructive pulmonary disease, depression were accepted. All patients who were enrolled between 2006 and 2014 were initially included in the study sample. A total of 308 participants met the inclusion criteria for this study. Participants who had previously completed a *U-Turn* programme, as well as patients who underwent an initial assessment but who did not continue the programme, due to medical conditions where exercise was contraindicated, were excluded from the database. All psychological and physical data for the remaining patients were audited and analysed. Ethical approval for this study as well as related *U Turn* research was obtained from the Research Ethics Committee in the Faculty of Health Sciences at the University of Cape Town (HREC Ref: 332/ 2007) in accordance with the Helsinki Declaration.

2.3.3 Overview of the *U Turn* Comprehensive Lifestyle Intervention

U Turn is a CLI programme conducted over 36 sessions typically for twelve weeks. It commences with an assessment by a Sport and Exercise Medicine Physician in order to risk stratify participants and identify existing co-morbidities which may influence participation, exclude contraindications to exercise testing and training, and finally ensure safe and individualised exercise prescription for participants. The first three sessions are usually one-on-one training with a biokineticist, followed by 33 group sessions with other *U Turn* patients. Such sessions include weight and cardiovascular training and are conducted by biokineticists, and medically supervised by on-site physicians. The patients are additionally educated in nutrition, exercise and stress reduction. The reader is directed to Appendix A of this thesis for a comprehensive description of the *U Turn* CLI programme[13].

2.3.4 Measurement of baseline functional, cardiovascular and anthropometric variables

The following section provides a brief overview of functional, cardiovascular and anthropometric variables. The reader is referred to Chapter 1 of this thesis for a more detailed review of psychological and physical outcome measures as well as the measures' validation data within CLI settings[13].

Of the 308 participants included in the study, a number had missing physical data at baseline. This may have been due to orthopaedic and other health-related limitations at the time of initial assessment. Depending on the variable measured, between 283 and 305 participants had their physical data recorded at baseline. All the above data were analysed.

2.3.4.1 Functional variables

Functional capacity was assessed in all participants on entry into the programme using a six minute walk test. The sit and reach test was used to assess flexibility.

Six-minute walk test (6MWT)

The 6MWT assesses functional exercise capacity at baseline as well as on completion of CLIs and the total distance walked in six minutes (6MWD) is expected to increase with increased activity and cardiorespiratory fitness [32]. The U Turn CLI programme requires participants to walk round a 140m indoor track for six minutes, covering as much distance as possible within a predetermined range of submaximal heart rate[13,36]. Heart rate was measured using a wearable heart rate monitor and watch-type display (Polar Electro Oy, Kempele, Finland)".

Sit and reach

A standard sit and reach box of 50cm was used to assess low back and hip joint flexibility[23]. Participants sat without their shoes, feet flat against the box with legs straight. They were instructed to reach as far as possible with both hands held parallel whilst maintaining a straight leg. The most distant point reached with the

fingertips was then recorded. Three trials per participant were performed with the measurement from the best attempt recorded[13].

2.3.4.2 Cardiovascular variables

Resting heart rate (RHR), systolic (RSBP) and diastolic blood pressure (RDBP)

The participant was seated and relaxed in a chair for approximately five minutes before measurements of heart rate (HR) and blood pressure (BP) were taken. The HR was measured with a heart rate monitor belt fitted to the chest, and a wrist monitor (Polar Electro Oy, Finland). The left arm was supported at heart level and the appropriate sized cuff firmly wrapped around it just above the elbow. A stethoscope (Welch Allyn, Skaneateles Falls, New York) was then placed just below the antecubital space, over the brachial artery. The cuff was inflated to above 160mmHg and slowly released at a rate of 2-5mmHg per second. Systolic BP was taken as the point at which the first of 2 or more Korotkoff sounds was heard and the diastolic BP, the point before the disappearance of the Korotkoff sounds[23].

2.3.4.3 Anthropometric variables

Sum of skinfolds (SkinF)

Skin folds were measured using a skin fold calliper at four sites: biceps, supra-iliac, triceps and subscapular[134].

Body fat percentage (BF%)

The body fat percentage was then measured using Durnin & Womersley's four site sum of skinfolds formula[134].

Waist to hip ratio (W/Hip)

With the participant standing erect, arms at the side, feet together and abdomen relaxed, a standard inelastic tape was used to measure the widest circumference of the buttocks (hip circumference) and the horizontal measurement at the narrowest part between the umbilicus and the xiphoid process (waist circumference). The

waist-hip ratio was then calculated using the formula[23] *WHR= waist circumference (cm)/hip circumference (cm).*

2.3.5 Diagnoses and medication

Diagnoses and medications classified as psychological and/ or neurological (CNS) were screened for and subsequently included in the statistical analysis. This was in order to focus the analysis within the scope of the research aims, namely, the influence of psychological and neurological factors on physical variables.

2.3.6 Baseline psychological screening

All participants were requested to complete a number of psychological questionnaires during the initial assessment. These included the Connor-Davidson Resilience Scale (CD-RISC); the Kessler Scale for Psychological Distress (K10); and the Spielberger State-Trait Anxiety Inventory - Trait Version (STAI-T). The screening was conducted to assist in identification of psychosocial issues which may influence programme participation, as well as to determine the need for individual psychological support requirements during the intervention. Thus, individuals identified as potentially at-risk were referred for further psychological management[13].

Connor Davidson Resilience Scale (CD-RISC)

The CD-RISC is a 25 item measure of resilience, using a four point likert scale rating, and a total score of 100[66]. Higher scores reflect a higher psychological resilience. The CD-RISC has been validated in a variety of healthy and clinical populations[81]. The range of mean resilience scores in all populations range between 60 and 80[81].

Kessler Scale for Psychological Distress (K10)

The K10 consists of ten questions examining symptoms of psychological distress which the participant rates on a 1-5 likert scale of applicability[89]. A score of 22 or above indicates clinically significant psychological distress.

Spielberger State-Trait Anxiety Inventory – Trait Version (STAI-T)

The STAI-T is measures dispositional or trait anxiety, and consists of a combination of 20 positive and negative statements relating to symptoms of anxiety[93]. A score of 40 and above reflects clinically significant trait anxiety.

2.3.7 Statistical Analysis

The baseline data were entered into Excel spreadsheets by the researchers. The statistical analysis for this study was conducted by the Biostatistics Unit of the Medical Research Council of South Africa (MRC) and was generated using SAS software (SAS Institute Inc., USA).

Appropriate descriptive statistics were generated for the categorical and numerical baseline data for demographic, diagnostic, risk factor, medication, psychological, functional, cardiovascular and anthropometric variables. The psychological assessments were only available for between 144 and 147 (47% to 48%) of the 308 participants.

Dependent variables included psychosocial risk factors, reflected by K10 and STAI-T scores; psychosocial protective factors, reflected by CD-RISC scores; demographic factors including sex and age; diagnostic factors including positive diagnoses of psychological and neurological (CNS) disorders; and medical factors including psychological and CNS medications. Independent variables included functional capacity, reflected by 6MWD and flexibility; cardiovascular values including RHR, RSBP and RDBP; anthropometric values reflected by SkinF, BF% and W/Hip; and psychosocial risk and protective factors. Figure 2.1 outlines the variables and associations investigated in this study.

Independent variables	Dependent variables			
	Demographic factors	**Psych & CNS diagnoses**	**Psych & CNS medications**	**Psychological factors***
Psychological factors	x	x	x	
Physical factors	x	x	x	x
*psychological factors were investigated in a separate multiple regression model				

Figure 2.1: Summary of statistical analysis

Firstly, multiple linear regression analysis was conducted to test for associations between demographic, diagnostic, medication and physical variables at baseline. A multiple linear regression analysis was subsequently conducted to test for associations between psychological variables and physical variables at baseline. Thirdly, a multiple linear regression analysis was conducted to test for associations between demographic, diagnostic, medication and psychological outcomes at baseline[135]. For the above analysis maximum likelihood estimates, least square means (SEs) and Chi-square values (p values) were reported.

2.4 RESULTS

2.4.1. Baseline demographics, diagnostic profile and medication use

Baseline demographic profiles of participants as well as numbers of participants who completed the programme, are depicted in Table 2.1

Table 2.1: Baseline demographic characteristics of the cohort

		n	%
Sex	Male	241	78.2
	Female	67	21.8
Age*	15-51 years	77	25
	52-59 years	80	26
	60-66 years	77	25
	67-84 years	74	24
Completed Programme	Yes	239	77.6
	No	58	18.8
	Completing	11	3.6

Abbreviations:
% = percentage; n = sample size; T1 = Baseline data
*Mean age: 58.13 (11.99)

The mean age of participants in this study was 58.1 years, ±11.9 years, and the overall age range was between 15 and 84 years. 78% of the participants were male. Seventy eight percent of the cohort completed the programme, 19% did not complete the programme, and approximately 4% were still completing the programme at the time of analysis.

Table 2.2 outlines the baseline diagnostic, medication and cardiovascular risk factor profiles of all participants.

Table 2.2: Baseline diagnostic, medication and risk factor data of patients

		n	%
Diagnoses	**Cardiovascular as primary or secondary diagnosis**	277	89.9
	Cardiovascular as primary diagnosis	260	84.4
	Metabolic	146	47.4
	Orthopaedic	33	10.7
	Chronic respiratory	29	9.4
	Rheumatological	20	6.5
	Psychological	16	5.2
	Neurological	15	4.9
	Renal	10	3.3
	Immunological	6	2
	Other	47	15.3
Medications	**Any medication**	282	91.6
	Poly* medication	92	29.9
	Psychological and/or Central Nervous System	55	17.9
Risk Factors	**Hypercholesterolaemia**	201	65.3
	Sedentary lifestyle	190	61.7
	Overweight	181	58.8
	Family history of cardiovascular disease	170	55.2
	Hypertension	164	53.3
	Diabetes	75	24.4
	Smoker	42	13.6

Abbreviations:
% = percentage; n = sample size; * Participant prescribed/ taking more than 6 medications

The majority of participants in this study (84.4%) were referred with the diagnosis of cardiovascular disease (CVD), yet this increased to 89.9% when CVD was considered as either a primary or secondary diagnosis. Other common co-morbidities included metabolic (47.4%), orthopaedic (10.7%) and chronic respiratory disorders (9.4%). Only 16 participants (5.2%) were diagnosed with psychological disorders, and 15 (4.9%) with neurological disorders, and were thereafter combined to form one variable of analysis. The majority of participants (91.6%) were taking prescribed medication at baseline. Almost a third (29.9%) were taking six or more drugs concurrently, and only 17.9% were prescribed psychological or CNS related medication.

The most common risk factors for CVD identified in participants at baseline included hypercholesterolaemia (65.3%), sedentary lifestyle (61.7%), overweight (58.8%), a family history of CVD (55.2%) and hypertension (53.3%).

2.4.2 Baseline psychological scores

It was necessary to establish a record of participant's psychological data collected at intake. Table 2.3 outlines the participant data for psychological questionnaires at baseline.

Table 2.3: Baseline psychological scores

	n	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
STAI-T	146	37	9.8	20	28	35	42	65
CD-RISC	147	74	13.6	30	66	76	84	98
K10	144	17	5.5	10	13	16	21	38

n = sample size; SD = standard deviation
STAI-T = State-Trait Anxiety Inventory – Trait Version; CD-RISC = Connor Davidson Resilience Scale;
K10 = Kessler Scale for Psychological Distress;

Of the cohort, 146 completed the STAI-T, 147 completed the CD-RISC, and 144 completed the K10. Mean scores were 37 (±9.8); 74 (±13.6); and 17 (±5.5) respectively.

The following table outlines the demographic characteristics of the cohort that completed the psychological questionnaires. The total sample size for each group is slightly lower than reported in the descriptive statistics, as this table was derived from the sample included in the statistical modelling which will be presented later in the chapter (specifically, Table 2.8).

Table 2.4: Demographic characteristics of cohort completing psychological questionnaires

		CD-RISC	STAI-T	K10
		n	n	n
Sex	Male	118	117	115
	Female	27	27	27
Age groups	15-51 years	33	32	33
	52-59 years	38	38	36
	60-66 years	38	38	38
	67-84 years	36	36	35
Diagnosis	Psych/ Neuro	16	16	16
Medications	Psych/ CNS	22	22	21

Abbreviations:
n = sample size; STAI-T = State-Trait Anxiety Inventory – Trait Version; CD-RISC = Connor Davidson Resilience Scale;
K10 = Kessler Scale for Psychological Distress
Psych/Neuro = positive or negative diagnosis of psychological and/or neurological disorder
Psych/CNS = Prescribed or not prescribed psychological and/ or central nervous system medication

The proportional breakdown in sex, age groups, diagnosis and medications are similar for all questionnaires, and similar to demographic proportions represented in the larger cohort.

2.4.3 Baseline physical parameters

Likewise, it was also important to include and confirm physical parameters at baseline for the cohort. Baseline cardiovascular, functional and anthropometric parameters for participants are thus reflected in Table 2.5.

Table 2.5: Cardiovascular, functional and anthropometric parameters for participants at baseline

	n	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
6 Min Walk Distance (m)	287	554	150.6	142	455	560	630	1225
Flexibility (cm)	255	12	11.2	-20	5	10	18	52
Resting HR (bpm)	302	75	15.5	50	64	74	82	148
Resting Systolic BP (mmHg)	305	126	16.1	80	118	124	138	180
Resting Diastolic BP (mmHg)	305	78	10.2	50	70	80	84	104
Waist-Hip Ratio	299	0.9	0.1	0.7	0.9	1.0	1.0	1.17
Sum of Skinfolds (mm)	297	76	32	13	53	73	94	210
Body Fat %	283	30.5	6.6	8.9	25.6	30.5	34.6	44

Abbreviations:
n = sample size; m = meters; cm = centimetres; mm = millimetres
bpm = beats per minute; mmHg = millimetres mercury; % = percentage

Mean distance walked in six minutes at baseline was 554m (±150.6m) and mean flexibility was 12cm (±11.2cm). Cardiovascular outcomes averaged 75bpm (±15.5bpm) for RHR, 126mmHg (±16.1mmHg) for RSBP and 78mmHg (±10.2mmHg) for RDBP. Anthropometric measures included W/Hip, SkinF and BF%, and averaged 0.9 (±0.1), 76mm (±31.9mm) and 30.5% (±6.6%) at baseline respectively.

2.4.4 Associations between baseline demographic characteristics, diagnoses, medications, psychological factors and physical variables

Multiple regression analysis commenced with the identification of variables that demonstrate an association with physical variables at baseline. A variety of variables were considered to be of primary interest to the research question, namely, the psychological variables. Table 2.6 details the associations of demographic characteristics, diagnoses and medications with physical variables.

Table 2.6: Associations between demographic characteristics, diagnoses, medications and physical variables in patients with CDL

		Sex						Age**				Psych_Neuro Diag						Psych_CNS Med					
		Male		Female								Yes		No				Yes		No			
	n	Est*	SE	Est	SE	Chi	p	Est	SE	Chi	p	Est	SE	Est	SE	Chi	p	Est	SE	Est	SE	Chi	p
6MWD (m)	285	528	15.3	462	18.8	11.8	0.0006”	-28.6	3.3	68.5	<.0001”’	459	25.1	531	12.0	6.9	0.0088”	480	20.0	510	14.9	2.0	0.153
Flexi (cm)	253	11	1.4	19	1.7	19.8	<.0001”’	-0.6	0.3	4.5	0.0331’	17	2.5	13	1.1	1.4	0.2327	14	1.8	16	1.4	1.0	0.3244
RHR (bpm)	300	80	1.7	78	2.2	0.6	0.4413	-0.4	0.4	1.0	0.3172	81	2.9	76	1.4	2.8	0.0945	82	2.3	76	1.7	5.6	0.0181’
RSBP (mmHg)	303	126	1.8	125	2.2	0.3	0.6133	1.7	0.4	18.4	<.0001”’	126	3.0	125	1.4	0.1	0.788	125	2.3	126	1.8	0.0	0.869
RDBP (mmHg)	303	79	1.1	76	1.4	4.0	0.0445’	-0.1	0.2	0.2	0.6547	78	1.9	77	0.9	0.8	0.379	78	1.5	77	1.1	0.1	0.7469
W/Hip	297	1.0	0.0	0.9	0.0	99.5	<.0001”’	0.02	0.02	1.1	0.2906	0.92	0.01	0.92	0.01	0.01	0.935	0.93	0.01	0.91	0.01	2.66	0.103
SkinF (mm)	295	66	3.5	92	4.4	32.4	<.0001”’	-1.40	0.74	3.58	0.0585	74	5.8	85	2.8	3.1	0.079	79	4.7	79	3.4	0.01	0.9392
BF%	281	28.8	0.7	37.2	0.9	77.2	<.0001”’	0.3	0.1	4.2	0.0408’	32.8	1.2	33.2	0.5	0.1	0.7424	33	0.9	32.9	0.7	0.03	0.8556

Abbreviations:
n = sample size; m = meters; cm = centimetres; mm = millimetres
bpm = beats per minute; mmHg = millimetres mercury; % = percentage
6MWD = six minute walk distance; Flexi = flexibility; RHR = resting heart rate; RSBP = resting systolic blood pressure;
RDBP = resting diastolic blood pressure; W/Hip = waist to hip ratio; SkinF = sum of skinfolds; BF% = percentage body fat
Psych_Neuro_Diag = positive or negative diagnosis of psychological and/or neurological disorder
Psych_CNS_Med = Prescribed or not prescribed psychological and/ or central nervous system medication
Est = estimated mean; SE = standard error of the mean; Chi = chi squared; p = estimated probability; ‘p <0.05; “p <0.01; “’ p < 0.0001
*Likelihood Ratio Chi-Square values; **estimate is for a 5-year increase in age

Sex, age, diagnoses and medications were independently associated with baseline functional, cardiovascular and anthropometric outcomes. 6MWD in males was greater than in females, at 528m (±15.3m) versus (vs) 462m (±18.8m) ($p<0.01$). However, females were significantly more flexible ($p<0.0001$) at 19cm (±1.7cm) vs 11cm (±1.4cm). RDBP was higher in males than females, with an average of 79mmHg (±1.1mmHg) vs 76mmHg (±1.4mmHg) ($p<0.05$). W/Hip was significantly higher in males at 1.0 (±0.0) than females, at 0.9 (±0.0) ($p<0.0001$). However, females had significantly higher SkinF and BF%, with averages of 92mm (±4.4mm) vs 66mm (±3.5mm) and 37.2% (±0.9%) vs. 28.8% (±0.7%) ($p<0.0001$).

For every 5 years increase in age, 6MWD was estimated to decrease by 28.6m (±3.3m) on average ($p<0.05$), as well as a significant decrease in flexibility of 0.6cm (±0.3cm) ($p<0.0001$). Increasing age was additionally associated with a significant increase of 1.7mmHg (±0.3mmHg) in RSBP ($p<0.0001$); as well as a significant increase of 0.3% (±0.1%) in BF% ($p<0.05$).

A diagnosis of any psychological or neurological disorder was significantly associated with lower 6MWD, averaging 459m (±25.1mmHg) vs participants without such diagnoses, at 531m (±12.0m) ($p<0.01$). Lastly, participants taking any psychological or CNS medication had significantly higher RHR (82bpm; ±2.3bpm) when compared with participants not taking this medication (76bpm; ±1.7bpm) ($p<0.05$).

Table 2.7 outlines the associations between psychological and physical variables.

Table 2.7: Associations between psychological factors and physical variables in patients with CDL

		K10				STAI-T				CD-RISC			
	n	Est	SE	Chi	p	Est	SE	Chi	p	Est	SE	Chi	p
6MWD (m)	133	-5.3	2.8	3.5	0.0621	3.9	2.0	4.0	0.047’	1.7	1.1	2.5	0.1119
Flexi (cm)	125	-0.4	0.2	3.0	0.0856	0.1	0.2	0.8	0.3772	-0.1	0.1	2.0	0.1621
RHR (bpm)	142	0.1	0.4	0.02	0.8857	-0.1	0.2	0.3	0.5746	-0.2	0.1	1.5	0.216
RSBP (mmHg)	142	-0.5	0.4	1.7	0.1895	0.1	0.2	0.3	0.6151	0.01	0.1	0.01	0.9416
RDBP (mmHg)	142	-0.2	0.2	0.9	0.3456	0.1	0.2	0.5	0.4848	0.02	0.1	0.1	0.8201
W/Hip	134	-0.002	0.002	0.7	0.3882	0.001	0.001	1.22	0.2686	0.002	0.001	5.1	0.0236’
SkinF (mm)	140	-0.4	0.8	0.3	0.6089	0.6	0.5	1.7	0.1991	0.1	0.3	0.1	0.821
BF %	135	-0.01	0.1	0.01	0.9245	0.04	0.1	0.2	0.658	-0.03	0.1	0.4	0.5216

Abbreviations:
n = sample size; m = meters; cm = centimetres; mm = millimetres
bpm = beats per minute; mmHg = millimetres mercury; % = percentage
6MWD = six minute walk distance; Flexi = flexibility; RHR = resting heart rate; RSBP = resting systolic blood pressure;
RDBP = resting diastolic blood pressure; W/Hip = waist to hip ratio; SkinF = sum of skinfolds; BF% = percentage body fat
K10 = Kessler Scale for Psychological Distress; STAI-T = State-Trait Anxiety Inventory – Trait Version;
CD-RISC = Connor Davidson Resilience Scale;
Est = estimated mean; SE = standard error of the mean; Chi = chi squared
p = estimated probability ‘p <0.05; “p <0.01; “’ p < 0.0001
Negative Est refers to an inverse relationship (e.g. for every point increase in K10 score, 6MWD decreases by 5.3 m)

STAI-T scores were associated with greater baseline 6MWD of 3.9m (±2.0m) ($p<0.05$), However, the distances were considered too little to be clinically significant. Interestingly, CD-RISC scores were associated with significantly greater W/Hip of 0.002 (±0.001) ($p<0.05$). No other psychological factors were associated with significant differences in baseline functional, cardiovascular or anthropometric variables.

2.4.4 Associations between demographic characteristics, diagnoses, medications and psychological scores

Table 2.8 outlines associations between demographic characteristics, diagnostics, medications and psychological scores.

Table 2.8: Associations between baseline demographic characteristics, diagnoses, medications and psychological variables in patients with CDL

		Age**				Sex				Psych _Neuro Diagnosis				Psych_CNS Medications			
	n	Est*	SE	Chi	p	Est	SE	Chi	p	Est	SE	Chi	p	Est	SE	Chi	p
CD-RISC	145	-0.2	0.1	4.2	0.0409'	3.2	2.8	1.3	0.2557	-4.9	3.6	1.9	0.1732	-3.8	3.1	1.5	0.2207
STAI-T	144	-0.05	0.1	0.4	0.5172	-1.8	2.0	0.8	0.3785	7.1	2.6	7.3	0.0068"	3.1	2.2	1.9	0.1677
K10	142	0.03	0.04	0.5	0.474	-2.4	1.1	4.5	0.0342'	4.2	1.4	8.9	0.0029"	2.3	1.2	3.6	0.0591

Abbreviations:
n = sample size; CD-RISC = Connor Davidson Resilience Scale; STAI-T = State-Trait Anxiety Inventory – Trait Version;
K10 = Kessler Scale for Psychological Distress
Psych_Neuro_Diag = positive or negative diagnosis of psychological and/or neurological disorder
Psych_CNS_Med = Prescribed or not prescribed psychological and/ or central nervous system medication
Est = estimated mean; SE = standard error of the mean; Chi = chi squared; T1 = Baseline data
p = estimate probability 'p <0.05; "p <0.01; "' p < 0.0001*Likelihood Ratio Chi-Square values;
**Every 5 year increase in age
Negative Est refers to an inverse relationship (e.g. for every 5 year increase in age, CD RISC score decreases by 0.2 points)

There is a significant decrease in CD-RISC scores with increasing age p<0.05), however, males had significantly lower K10 scores than females (p<0.05). Additionally, positive diagnoses of psychological, cognitive or neurological disorders were associated with significantly higher K10 scores, and STAI-T scores (p<0.01).

2.4.5 Effect of missing psychological data

It was also of interest to determine the potential bias between participants who completed psychological questionnaires, and those who did not, particularly as the groups were of equivalent size. Table 2.9 shows the comparison of physical outcomes between both groups.

Table 2.9: Comparison of physical outcomes of participants who do not complete psychological questionnaires and participants who completed some or all the psychological questionnaires

	No Psychological Data		Some/ All Psychological Data		t	p
Variable	n	mean	n	mean		
6 Min Walk Distance T1 (m)	146	562	141	545	0.95	0.345
Flexibility T1 (cm)	123	13	132	11	1.52	0.129
Resting HR T1 (bpm)	152	75	150	75	0.11	0.916
Resting Systolic BP T1 (mmHg)	155	124	150	128	-2.06	0.040’
Resting Diastolic BP T1 (mmHg)	155	78	150	78	0.02	0.985
Waist-Hip Ratio T1	157	0.9	142	1.0	-1.26	0.210
Sum of Skinfolds T1 (mm)	149	71	148	82	-2.98	0.003”
Body Fat % T1	140	29.7	143	31.2	-2.00	0.047’

Abbreviations:
n = sample size; m = meters; cm = centimetres; mm = millimetres
bpm = beats per minute; mmHg = millimetres mercury; % = percentage
t = statistical test of significant differences between groups,
p = estimated probability ‘p <0.05; “p <0.01; “’ p < 0.0001

Participants who completed some or all of the psychological questionnaires had significantly higher RSBP (4 mmHg) ($p<0.05$); SkinF (11mm) ($p<0.01$) and BF% (1.5%) ($p<0.05$).

2.5 DISCUSSION

The overarching aim of this chapter was to provide a detailed description of a cohort of 308 participants entering a twelve week CLI programme, using demographic, diagnostic, medical, psychological and physical data. A further aim of this study was to determine whether specific psychological measures are associated with physical variables of interest to clinicians at the start of a CLI programme. This section commences with an outline of the study’s broad findings, followed by specific results which are discussed in relation to current research as well as to the aims of this investigation.

Descriptive characteristics

Descriptive data in this investigation were commensurate with other recent studies limited to predominantly Caucasian, male and higher socioeconomic groups[13].

Although the prevalence of CDL in females, particularly over 50 years, is estimated to be equivalent to males, their low representation has yet to be sufficiently accounted for[136]. Other CLI studies additionally reported high prevalences of comorbidities and cardiovascular risk factors in CDL cohorts[13,55]. Though the focus of the study was limited to psychological and neurological influences, it was interesting to note, firstly, that the majority of participants were on one or more medications and approximately a third were prescribed over six medications concurrently. Secondly, more participants were prescribed psychological and CNS medications than those who were officially diagnosed with psychological and CNS disorders. These observations emphasise the degree of care and individualised treatment necessary for patients with CDL.

Functional, cardiovascular and anthropometric variables were within the expected range of this patient population and in keeping with findings of current research[13]. Furthermore, there was a sizeable proportion of participants with decreased functional capacity. This was evidenced in the lower quartile of the 6MWD, and was commensurate with clinically comparable cohorts, including outpatient CR[29] as well as patients with chronic heart failure[137]. Such findings support the assessment of functional capacity using 6MWD in identifying and managing patients with poor health profiles.

Psychological test scores fell within general population norms, and were considered subclinical for both anxiety and psychological distress, using the STAI-T and K10. The mean CD-RISC scores, while to our knowledge untested in this setting, fall within published norms for general populations, and slightly higher than some clinical populations[81]. However, considering the high standard error of the scores, a number of participants were classified as clinically distressed and/ or anxious. These patients were identified in the early stages of the programme and referred for further treatment.

Specific findings

Several important findings were made in this analysis. Firstly, certain demographic data were associated with baseline functional capacity, as well as in cardiovascular

and anthropometric variables. In particular, sex was associated with significant and expected differences in all physical outcomes except RSBP and RHR. Males walked significantly further at baseline than females. They had higher RDBP, and W/Hip, however females had higher flexibility, SkinF and BF%. All of the above findings are consistent with previous literature regarding sex-based physiological differences. This includes variance in 6MWD in healthy[23,138,139] and CDL[23,137] populations; as well as cardiovascular[23,140] and anthropometric differences[23]. Additionally, increasing age was associated with significantly lower performance in 6MWD, higher RSBP and BF%. This is in line with current findings reporting decreasing functional capacity with age, as well as increasing blood pressure and anthropometric outcomes with increasing age [23,138,139].

Secondly, demographic factors were associated with baseline psychological scores. There was a significant influence of increasing age on attenuation of resilience, as evidenced by lower CD-RISC scores. This finding has equivocal support in the literature, which have documented positive, negative as well as a lack of associations[79]. Even the positive associations that have been documented are weak, and often within narrow ranges in age[81]. Furthermore, males had significantly lower K10 scores than females at baseline. This is consistent with a moderate range of research showing increased psychological distress in females compared with males[84]. While the K10 has been validated as an accurate screening tool for psychological distress in very large healthy populations as well as clinical cohorts[89–91,141], there has been only one large-scale survey conducted in Australia that specifically aimed to describe age and gender-related norms (n=8841, mean=14.5, SE=0.1)[141]. The authors documented that across all age groups males had lower mean K10 scores than females. Studies involving CDL cohorts are more limited. One study found certain demographic factors such as marital status in females with CDL influenced K10 scores, emphasising the importance of support networks for patients with CDL [84].

A third finding was that in addition to demographic factors, diagnoses of psychological and neurological disorders was associated with significant differences in baseline psychological outcomes. Positive associations were found between diagnoses of any psychological and neurological disorders and higher trait anxiety

(reflecting higher STAI-T scores) as well as higher psychological distress (reflecting higher K10 scores) at baseline. This contributes somewhat to the convergent validity of both the K10 and STAI-T within CDL cohorts, particularly as both measures are already sufficiently validated within general and clinical[94,96,102,142–144] populations[89,91,141].

Lastly, and most importantly, there were limited associations between psychological measures and physical variables, and therefore have limited value with respect to identifying patients with poorer functional capacity at the beginning of the CLI programme. There was a significant association between lower STAI-T scores and a longer distance measured in 6MWD. The above findings provide some support for the relationship between higher psychosocial and overall physical functioning, and are consistent with other studies' somewhat equivocal findings with other measures of functional capacity[144]. For example, neuroticism, measured with the STAI-T did not reflect functional capacity (VO_{2max}) in patients enrolled in a twelve week cardiac rehabilitation programme[144]. Thus, the degree the current study's findings can be extrapolated are restricted by the paucity of related research associating trait anxiety and functional capacity in CDL cohorts.

Additionally, higher baseline W/Hip were found in patients with higher CD-RISC scores. In other words, patients with higher central or visceral adipose reported a greater degree of resilience. There have been other reported associations between resilience and baseline anthropometric differences[145]. However, the study in question made use of another resilience scale, as well as representative sampling of the general population, and not patients with CDL[145]. The researchers in this study reported raised body mass index (BMI) in older British and Portuguese males was associated with different cultural factors including education levels, alcohol consumption, sedentary behaviour and previous experience of illness[145]. Due to the multidimensional nature of the construct of resilience, there may be a number of potential explanations for unanticipated associations. Males have higher average W/Hip than females, and this may have skewed data as males made up the majority of the cohort. However, gender-based differences in resilience scores were not identified in this study, and the association has equivocal support in resilience literature[79]. Another explanation involves considering a typical description of a

resilient outcome, based on Richardson's[146] theory of resiliency. It requires a distinct response to an adverse event which may or may not be adaptive[146]. Thus resilience is a form of recovery, and may not apply to this association. Bonanno et al suggested resilience and recovery may instead be distinct trajectories of response to adversity[63]. Resilience involves relatively transient disruptions in functioning, whereas recovery follows the adaptive response suggested by Richardson[63,146]. Patients at risk of developing or living with CDL may be managing daily adversities, but not to a degree promoting a return to premorbid outcomes. Resilience research additionally highlights the construct's context specific nature, and reminds us that an individual may be resilient in one sphere of life but not in another. This may prove to be a useful insight when the clinical relevance of resilience measures as indicators of performance during CLI programmes are investigated. This will be the subject of the study described in Chapter 3.

2.6 STUDY LIMITATIONS

This study has a number of limitations. As mentioned, females, as well as individuals of other race and income groups are noticeably under-represented in the cohort. Therefore, any comparisons made between participants, particularly those of a different sex, as well as the conclusions one is tempted to infer, are limited by their unequal representation.

A further limitation of the study was the number of incomplete psychological data. Only 145 participants completed the questionnaires. Possible reasons for the low completion rate include participant's refusal to complete the questionnaires, a lack of interest in completing questionnaires, or potentially due to data not being collected by CLI programme staff. Some of these participants were, however, identified as at-risk during the medical assessment. There was a clinically significant difference in all physical outcomes, barring RHR and RDBP, of participants who completed psychological questionnaires at intake compared with those who did not. The differences were statistically significant in RSBP, SkinF and BF%, and all outcomes tended to be more clinically favourable in the group who did not complete

questionnaires. This may have been due to medical or support staff inadvertently selecting participants who in their opinion required a psychological assessment, thus misunderstanding the purpose of the questionnaires. The statistical impact of this reduced and potentially biased sample on inferences made regarding the predictive ability of the questionnaires should be taken into account. Although selection or sampling bias[147] is not uncommon, particularly in clinical cohorts, it needs to be accounted for and mitigated as much as possible. Due to the study's retrospective nature, it is incumbent upon the authors of this thesis to acknowledge these and other inevitable challenges in clinical research as limitations, as well as to exercise caution when interpreting results.

2.7 CONCLUSIONS

In conclusion, this chapter described the physical and psychological characteristics of a patient cohort entering a twelve week CLI programme with data commensurate with related *U Turn* research[13,148], indicating the presence of multiple comorbidities, certain functional impairments and identified certain individuals with psychological distress and anxiety. Although higher anxiety was associated with decreased functional capacity, there were notable limitations in associating baseline physical variables in CLI programmes with scores from psychological measures in this setting. Nevertheless, demographic factors including age and sex were identified as key screening variables for participants with poorer psychological and functional profiles at baseline. The findings of this chapter lay the foundation for further investigation of screening variables and changes in physical outcomes at the completion of the CLI programme. This theme is the topic of investigation in Chapter 3.

CHAPTER 3: ARE PSYCHOLOGICAL AND DEMOGRAPHIC FACTORS ASSOCIATED WITH PHYSICAL OUTCOMES IN PATIENTS WITH CHRONIC DISEASES OF LIFESTYLE?

3.1 INTRODUCTION

There has been encouraging growth in effective interventions for the prevention and treatment of chronic diseases of lifestyle (CDL)[13]. This is in response to an increasing incidence of CDL related mortality and morbidity in both developed and developing countries[1,2]. Rehabilitation is defined in Chapter 1 as a number of synchronised interventions selected to create an optimal physical and psychosocial environment for patients with CDL, in order to return to optimal functioning[20]. Through improved health behaviours patients might additionally slow or reverse the progression of CDL[20].

In addition, previous chapters have acknowledged that a large proportion of CDL management continues to be provided by disease specific interventions such as CR. Chapter 1 outlined the shift towards more comprehensive approaches which acknowledge the interaction between the co-existence of multiple comorbid disorders and risk factors[13,21]. These interventions are often evidence-based, patient-centred and action-focused[6], and may be referred to as multi-modal or multi-factorial interventions and, most recently, comprehensive lifestyle interventions (CLIs).

Recent findings from a study of the effectiveness of the *U Turn* CLI programme reported significant improvements in anthropometric (BF% and waist and hip circumferences); physiological (RHR and RSBP); and metabolic outcomes (total cholesterol, low density lipoproteins and triglycerides) as well as functional capacity (6MWD and flexibility)[13]. These findings are encouraging, especially as 84% of the 210 participants had comorbid chronic diseases requiring additional considerations for exercise prescription[13]. Moreover, the findings are commensurate with current CLI effectiveness studies, reporting reductions in all-cause mortality[51]; diabetes related morbidity[51–53] and mortality[51], CV related morbidity[51–53] and mortality[51],

cardiac risk factors[51] and other chronic disease related risk factors[54]; improved behavioural outcomes[51–57], cardiovascular outcomes[52,55–57], anthropometric outcomes[52,55,57] and metabolic outcomes[52,55,56] compared with baseline and or control (usual care) groups. A comprehensive overview and assessment of current CLIs and other rehabilitation interventions is provided in Chapter 1 of this thesis.

Psychosocial risk factors and psychosocial protective factors, introduced in the previous chapter, play an integral role in physical health outcomes of patients, including outcomes of CLIs. Psychosocial factors have well established links with physical illness[84,85,133], cardiac events [133],diabetes outcomes[85], as well as risk for coronary heart disease (CHD)[94]. Indeed, resilience has been associated with multiple favourable psychosocial and physical outcomes in CDL cohorts[9,65].However, it has also been noted that this variable, as well as the current 'gold standard' measure thereof, have not been sufficiently investigated as a predictor of successful physical outcomes in CLI settings. Perhaps it bears reiteration that the validation of such psychometric measures can only assist in the early detection and tailored management of CDLs.

3.2 STUDY AIMS

The following chapter utilises a retrospective clinical audit of 308 patients to determine if there was a relationship between psychosocial variables measured at initiation of a CLI programme and the change in physical outcomes following the programme. In particular, patients' responses to psychological questionnaires administered at baseline of a twelve-week CLI programme were assessed. Responses were analysed in relation to physical parameters, including functional, cardiovascular and anthropometric outcomes data collected both at baseline and at completion of a CLI programme. This was undertaken to identify potential changes in physical outcomes over the duration of the programme.

The specific aim of the chapter is therefore to ascertain if the psychological variables collected at the beginning of the CLI programme are related to demographic and

medical variables; as well as functional, cardiovascular and anthropometric outcomes collected at baseline and at completion.

3.3 METHODS

3.3.1 Type of study

This study is a retrospective clinical audit in the form of a cross-sectional cohort study describing the associations between demographic, medical and psychological variables at baseline and completed functional, cardiovascular and anthropometric outcomes at completion of a twelve-week CLI programme for patients with CDL.

3.3.2 Participants

Participants were patients who had CDL and had enrolled in the *U Turn* CLI programme at the Sport and Exercise Medicine Clinic within the Sports Science Institute of South Africa (SSISA) in Newlands, Cape Town. Patients entered the programme either by self-referral or by referral from medical insurers or physicians. In order to qualify for the programme, patients with a variety of chronic diseases including cardiovascular disease, diabetes, chronic arthritis, chronic kidney disease, cancer, chronic obstructive pulmonary disease, depression were accepted. All patients who were enrolled between 2006 and 2014 were initially included in the study sample. A total of 308 participants met the inclusion criteria for this study. Participants who had previously completed a *U Turn* programme, as well as patients who underwent an initial assessment but who did not continue the programme, due to medical conditions where exercise was contraindicated, were excluded from the database. All psychological and physical data for the remaining patients were audited and analysed. Ethical approval for this study as well as related *U Turn* research was obtained from the Research Ethics Committee in the Faculty of Health Sciences at the University of Cape Town (HREC Ref: 332/ 2007) in accordance with the Helsinki Declaration.

Of the 308 participants, 239 completed the programme. Fifty seven dropped out of the programme for reasons including injury during the programme. Eleven participants were currently enrolled in the programme, but due to time constraints their completion data was not included in the statistical analysis.

3.3.3 Overview of the *U Turn* Comprehensive Lifestyle Intervention

U Turn is a CLI programme conducted over 36 sessions typically for twelve weeks. The reader is directed to Appendix A of this thesis for a comprehensive description of the *U Turn* CLI programme.

3.3.4 Measurement of baseline functional, cardiovascular, anthropometric and psychological variables

Functional, cardiovascular and anthropometric variables were measured at baseline and at programme completion. Specifically, functional measures included six minute walk distances (6MWD) and the sit-and-reach test for flexibility. Cardiovascular measurements included resting heart rate (RHR), resting systolic blood pressure (RSBP) and resting diastolic blood pressure (RDBP). Anthropometric data comprised waist to hip ratio (W/Hip), sum of skinfolds (SkinF) and percentage body fat (BF%). Psychological measures included the Connor Davidson Resilience Scale (CD-RISC), the Kessler Scale for Psychological Distress (K10) and the Spielberger State-Trait Anxiety Inventory – Trait Version (STAI-T). The reader is referred to the previous chapter, as well as Chapter 1 of this thesis for a detailed review of psychological and physical outcome measures as well as validation data within CLI settings.

Of the 308 participants included in the study, up to 108 had missing physical data either at baseline and/ or at completion. This may have been due to orthopaedic and other health-related limitations at the time of initial or final assessment. Depending on the variable measured, between 283 and 305 participants had their physical data recorded at baseline; and between 200 and 241 participants had their physical data recorded both at baseline and completion. All the above data were analysed.

3.3.5 Re-assessment after CLI Completion

All participants underwent standardised re-assessment of their functional, cardiovascular and anthropometric variables at the conclusion of the 12-week intervention.

3.3.6 Statistical Analysis

The baseline (T1) and completion (T2) data were entered into Excel spreadsheets by the authors of this thesis. The statistical analysis for this study was conducted by the Biostatistics Unit of the Medical Research Council of South Africa (MRC) and was generated using SAS software (SAS Institute Inc., USA). The reader is directed to the previous chapter for descriptive statistics of T1 data, as well as reported associations between T1 demographic, diagnostic, medical, psychological and physical variables.

Out of the total of 308 participants, 68 (22%) to 114 (37%) of the participants had missing T2 physical outcome data. Additionally, the psychological assessments were only available for about 53% of the 308 participants. The missing data pattern dictated a more complex analysis of the repeated data than simply the differences between T2 and T1. The assumption of missing at random was made for the missing physical data. For the repeated data analysis, mixed linear regression was used with maximum likelihood estimation, to incorporate all available data from T1 and T2[149]. In this analysis, although a large proportion of participants dropped out between T1 and T2, maximum likelihood borrows information from the values at T1 to project what would happen at T2. For the mixed model analysis, the long format of the data was used and the model included an interaction term for predictor multiplied by time.

Dependent and independent variables were the same as those reported in the previous chapter. The first mixed multiple model included demographic and medical predictors of change. The second mixed multiple model included psychological variables of change. For both models the F statistics with p-values were reported for

the interaction term, and least squares estimates were reported for the significant interactions.

3.4 RESULTS

3.4.1 Baseline psychological variables

Although baseline psychological data was reported in the previous chapter, it is used in this study's analysis and is also included in this chapter. Table 3.1 outlines the participant data for psychological questionnaires at baseline.

Table 3.1: Baseline psychological outcomes of patients with CDL

	n	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
STAI-T	146	37	9.8	20	28	35	42	65
CD-RISC	147	74	13.6	30	66	76	84	98
K10	144	17	5.5	10	13	16	21	38

Abbreviations:
n = sample size; SD = standard deviation
STAI-T = State-Trait Anxiety Inventory – Trait Version; CD-RISC = Connor Davidson Resilience Scale;
K10 = Kessler Scale for Psychological Distress

Less than half the total cohort completed the psychological questionnaires. 146 completed the STAI-T, 147 completed the CD-RISC, 144 completed the K10 and 145 recorded their history of significant life events. Mean scores were 37 (±9.8); 74 (±13.6); and 17 (±5.5) for the first three tests included in the statistical analysis.

3.4.2 Physical outcomes at completion and the difference in outcomes from baseline to completion

Physical parameters, including cardiovascular, functional and anthropometric measures at programme completion, as well as changes in physical parameters from baseline to completion, were included as descriptive data for this study, and are reflected in Table 3.2.

Table 3.2: Cardiovascular, functional and anthropometric parameters for participants at T1, T2 and T2-T1

	n	T1	T2	T2-T1
6MWD (m)	234	554±150.6*	653±183.6	90±95.6
Flexi (cm)	200	12±11.2	16±10.6	4±6.7
RHR (bpm)	240	75±15.5	71±11.7	-4±12.5
RSBP (mmHg)	240	126±16.1	120±13.5	-6±14.1
RDBP (mmHg)	240	78±10.2	72±8.8	-5±9
W/Hip	241	0.9±0.1	0.9±0.1	-0.01±0.04
SkinF (mm)	232	76±32	65±26.4	-7±10.3
BF %	228	30.5±6.6	28.5±6.4	-1.4±2.5

Abbreviations:
n = sample size; HR = heart rate; BP = blood pressure; m = meters; cm = centimetres; mm = millimetres
bpm = beats per minute; mmHg = millimetres mercury; % = percentage
6MWD = six minute walk distance; Flexi = flexibility; RHR = resting heart rate; RSBP = resting systolic blood pressure;
RDBP = resting diastolic blood pressure; W/Hip = waist to hip ratio; SkinF = sum of skinfolds; BF% = percentage body fat
T1 = Baseline data; T2 = Data collected at programme completion; T2-T1 = difference in measures
*mean ± standard deviation

Outcomes of functional capacity and flexibility both increased during the programme. Mean distance walked in six minutes at baseline was 554m (±150.6m) and increased by 90m (±95.6m), to 653m (±183.6m) at completion. Mean flexibility increased by 4cm (±6.7cm) from 12cm (±11.2cm) to 16cm (±10.6cm).

Cardiovascular outcomes all decreased at completion. Baseline RHR decreased by 4bpm (±12.5bpm) from an average of 75bpm (±15.5bpm) to 71bpm (±11.7bpm) at completion. RSBP and RDBP both decreased by 6mmHg and 5mmHg respectively, from 126mmHg (±16.1mmHg) and 76mmHg (±10.2mmHg), to 120mmHg (±13.5mmHg) and 72mmHg (±8.8mmHg) respectively.

Lastly, mean anthropometric measures, including W/Hip, SkinF and BF%, all decreased from baseline to completion. W/Hip decreased by 0.01 (±0.04), from 0.9 (±0.1) to 0.9 (±0.1). SkinF decreased by 7mm (±10.3mm) from 76mm (±31.9mm) to 65mm (±26.4mm), and BF% decreased by 1.4% (±2.5%), from 30.5% (±6.6%) to 28.5% (±6.4%).

3.4.3 Associations between demographic characteristics, medication use and physical outcomes of change.

Multiple regression analysis commenced with the identification of variables that demonstrate an independent association with physical outcomes at programme completion. A variety of variables were considered before those of primary interest to the research question, namely, the psychological variables. Table 3.3a outlines associations between demographic factors, medication factors and differences in physical outcomes. Table 3.3b details the association between 6MWD and sex; 6MWD and quartile age groups as well as BF% and sex.

Table 3.3a: Associations between demographic factors, medication and differences in physical outcomes in patients with CDL

			Sex		Age**		Psych_CNS Med	
	T1 n	T2 n	Chi*	p	Chi*	p	Chi*	p
6MWD (m)	287	234	6.4	0.0119’	4.4	0.0047”	1.9	NS
Flexi (cm)	255	200	1.2	NS	0.02	NS	0	NS
RHR (bpm)	302	240	0.2	NS	1.9	NS	1.0	NS
RSBP (mmHg)	305	240	3.2	NS	1.2	NS	0	NS
RDBP (mmHg)	305	240	3.2	NS	1.2	NS	0.02	NS
W/Hip	299	241	1.4	NS	1.2	NS	0.03	NS
SkinF (mm)	297	232	0.4	NS	0.1	NS	0.04	NS
BF %	283	228	8.7	0.0036”	0.6	NS	0.6	NS

Abbreviations:

n = sample size; m = meters; cm = centimetres; mm = millimetres;

bpm = beats per minute; mmHg = millimetres mercury; % = percentage

6MWD = six minute walk distance; Flexi = flexibility; RHR = resting heart rate; RSBP = resting systolic blood pressure;

RDBP = resting diastolic blood pressure; W/Hip = waist to hip ratio; SkinF = sum of skinfolds; BF% = percentage body fat

Psych_CNS_Med = Prescribed or not prescribed psychological and/ or central nervous system medication

Est = estimated mean; SE = standard error of the mean; Chi = chi squared

p = estimated probability ‘p <0.05; “p <0.01; “’ p < 0.0001

*Likelihood Ratio Chi-Square values; **Every 5 year increase in age

It is not possible to include diagnostic predictors in the multiple model due to low cell sizes

T1 = Baseline data; T2 = Data collected at programme completion

Table 3.3b: Least square estimates for selected physical outcome differences (T2-T1) for sex and age groups

	Sex						Age					
	Male		Female		Age 15-51		Age 52-59		Age 60-66		Age 67-84	
	Est	SE	Est	SE	Est	SE	Est	SE	Est	SE	Est	SE
6MWD (m)	100	6.7	58	13.3	108	13.09	88	12	70	12.7	51	13.1
BF%	1.69	0.2	0.54	0.4								

Abbreviations:
6MWD = six minute walk distance; BF% = percentage body fat
Est = estimated mean; SE = standard error of the mean

Sex was associated with significant changes in 6WMD ($p<0.05$). Males walked an average of 100m (±6.7m) further than at baseline, and females walked 58m (13.3) further.

Age was associated with significant changes in 6MWD, namely, participants in each increasing age quartile covered significantly less distance at T2 ($p<0.01$). Participants between 15 and 51 years walked an average of 108m (±13.1m) further, and the next age quartile (between 52 and 66 years) walked 88m (±12.0m) further during the 6MWT on completion of the programme. Participants between the ages of 60 and 66 walked 70m (±12.7m) further, and the oldest age category (67 to 84 years) covered an average distance of 51m (±13.1m) further than at T1 on completion.

Finally, sex was associated with significant changes in BF%. Males achieved a significantly greater reduction in BF% of 1.69% (±0.2%) at programme completion than females, who lost 0.54% (±0.4%) of their BF% by T2 ($p<0.01$). No other demographic factors and no medical factors were associated with significant changes in physical outcomes.

3.4.4 Association between psychological variables and changes in physical outcomes

Associations between psychological variables and changes in physical outcomes are described in Table 3.4.

Table 3.4: Associations between psychological variables and changes in physical outcomes (T1 &T2) in patients with CDL

		T2 n	STAI-T		K10		CD-RISC	
	T1 n		F	p	F	p	F	p
6MWD (m)	133	108	0.01	NS	0.24	NS	0.84	NS
Flexi (cm)	125	96	1.49	NS	0.15	NS	0.82	NS
RHR (bpm)	142	108	0.19	NS	0.26	NS	0.37	NS
RSBP (mmHg)	142	108	0.45	NS	2.2	NS	0.18	NS
RDBP (mmHg)	142	108	3.27	NS	5.77	0.018’	0	NS
W/Hip	134	108	0.01	NS	0.22	NS	0.01	NS
SkinF (mm)	140	105	0.4	NS	0.02	NS	4.04	0.0471’
BF %	135	104	1.71	NS	0	NS	7.03	0.0093”

Abbreviations:
n = sample size; m = meters; cm = centimetres; mm = millimetres; bpm = beats per minute;
mmHg = millimetres mercury; % = percentage
6MWD = six minute walk distance; Flexi = flexibility; RHR = resting heart rate; RSBP = resting systolic blood pressure; RDBP = resting diastolic blood pressure; W/Hip = waist to hip ratio; SkinF = sum of skinfolds; BF% = percentage body fat
K10 = Kessler Scale for Psychological Distress; STAI-T = State-Trait Anxiety Inventory – Trait Version; CD-RISC = Connor Davidson Resilience Scale; Est = estimated mean; SE = standard error of the mean; Chi = chi squared
p = estimated probability ‘p <0.05; “p <0.01; “’ p < 0.0001
T1 = Baseline data; T2 = Data collected at programme completion T1-T2 Differences Least Squares estimates for the multiple regression model

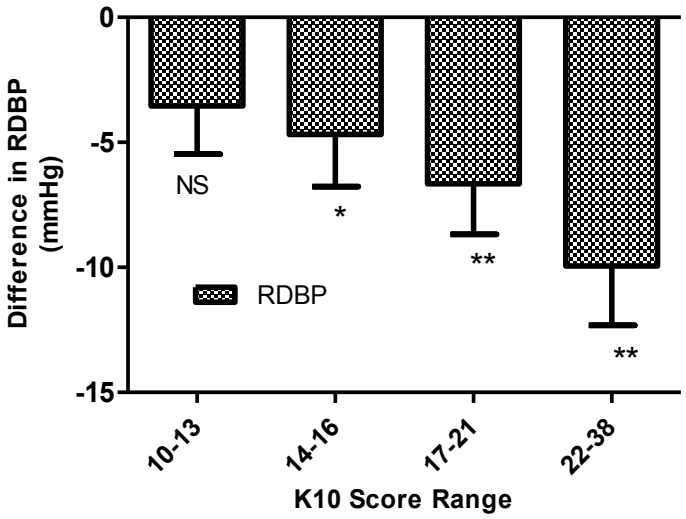
Results of the K10 were associated with significant differences in RDBP ($p<0.05$) from baseline to programme completion. The CD-RISC was associated with significant changes in BF% ($p<0.01$), and in SkinF ($p<0.05$). No other psychological factors were associated with significant changes in physical outcomes at completion.

Table 3.5 details the associations between K10 and CD-RISC quartile scores and differences in RDBP and BF% from baseline to programme completion, respectively. Figure 3.1a follows with a graphical view of the association between RDBP and K10 quartile scores, and Figure 3.1b presents the associations between BF% and CD-RISC quartile scores.

Table 3.5: RDBP and BF% least square mean differences (T2-T1) for ranges of K10 and CD-RISC in patients with CDL

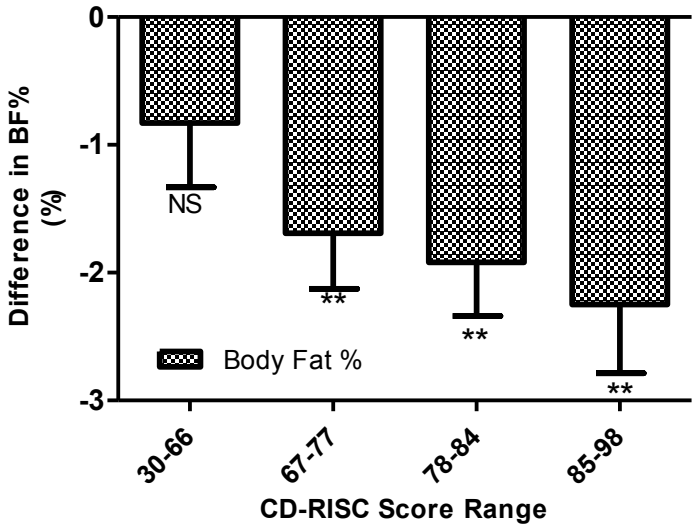
	K10 range	n	T1	T2	LSM Diff*	SE	F	p
RDBP	10-13	44	78.9	75.4	-3.54	1.93	3.37	NS
	14-16	34	79.6	74.9	-4.68	2.09	5.01	0.028’
	17-21	29	76.6	69.9	-6.66	2.02	10.87	0.001’
	22-38	33	76.2	66.3	-9.94	2.38	17.41	0.0001”
	CD-RISC range							
BF %	30-66	37	31.5	30.7	-0.83	0.501	2.73	NS
	66-76	38	31.5	29.8	-1.69	0.436	14.99	0.0002’
	76-84	42	30.4	28.5	-1.92	0.419	21.08	0.0001”
	84-98	30	32.1	29.9	-2.25	0.535	17.7	0.0001”

Abbreviations:
n = sample size
mmHg = millimetres mercury; % = percentage; RDBP = resting diastolic blood pressure; BF% = percentage body fat
K10 = Kessler Scale for Psychological Distress; CD-RISC = Connor Davidson Resilience Scale
Est = estimated mean; SE = standard error of the mean; Chi = chi squared
p = estimated probability; ‘p <0.05; “p <0.01; NS = not significant
T1 = Baseline data; T2 = Data collected at programme completion
* Differences Least Squares estimates for the multiple regression model



Abbreviations:
K10 = Kessler Scale for Psychological Distress;
RDBP = resting diastolic blood pressure; mmHg = millimetres mercury
T1 = Baseline data; T2 = Data collected at programme completion
p = estimated probability; *p <0.05; **p <0.01; NS = not significant

Figure 3.1a: K10 and difference in RDBP



Abbreviations:
% = percentage
BF% = percentage body fat
CD-RISC = Connor Davidson Resilience Scale
T1 = Baseline data; T2 = Data collected at programme completion
p = estimated probability; *p <0.05; **p <0.01; NS = not significant

Figure 3.1b: CD-RISC and difference in BF%

Table 3.5 shows that increasing K10 and CD-RISC scores are associated with statistically larger differences in RDBP and BF%, respectively. This linear increasing trend is significant. The trend commences with a small decrease in RDBP of 3.54mmHg (±1.93mmHg), from 78.9mmHg to 75.4mmHg at a K10 score between 10 and 13. At the next quartile, 14 to 16, there is a larger decrease of 4.68mmHg (±2.09mmHg), from 79.6mmHg to 74.9mmHg between T1 and T2 ($p<0.05$). The third and fourth quartile scores of 17 to 21 and 22 to 38 were associated with even larger decreases of 6.66mmHg (±2.02mmHg), from 76.6mmHg to 69.9mmHg ($p<0.01$) and a 9.94mmHg (±2.38mmHg) decrease, from 76.2mmHg to 66.3mmHg in RDBP respectively ($p<0.01$).

A similar trend occurred with BF% and increasing quartile scores of the CD-RISC. Between CD-RISC scores of 30 and 66 there is no significant associations with changes to BF% at T2, with mean decreases of 0.83% (±0.50%), from 31.5% to 30.7%. There are, however, significant decreases in BF% in the following three quartiles of CD-RISC scores ($p<0.01$). At 66 to 76, there is a significant decrease of 1.69% (±0.44%), from 31.5% to 29.8%; and at 76 to 84 the decrease rises to 1.92%

(±0.42%), from 30.4% to 28.5% ($p<0.01$). Finally, at 84 to 98 the increase rises to 2.25% (±0.54%), from 32.1% to 29.9% ($p<0.01$).

3.5 DISCUSSION

The primary aim of this study was to analyse associations between demographic, medical, psychological variables and changes in functional, cardiovascular and anthropometric outcomes following completion of a CLI programme. General and specific findings from the analyses follow.

General Findings

Changes in functional, cardiovascular and anthropometric variables over the twelve week programme were commensurate with findings from other U Turn research[13], as well as other lifestyle intervention research[55]. Specifically, investigators at Cleveland Clinic measured changes in cardiovascular, anthropometric, and metabolic variables in participants with chronic conditions during a six week intensive CLI programme, and after a 30 week follow up[55]. A finding of the Cleveland research was that changes occurred in cardiovascular parameters at six weeks, which were equivalent to the findings reported in the current study at completion of the programme. However, RSBP and RDBP in the Cleveland study was attenuated by approximately 50% after 30 weeks[55]. Furthermore, anthropometric measures including waist circumference, weight, and BMI continued to attenuate over the 30 weeks post intervention, thus advocating longer term management and follow up of cases after the completion of intensive CLI programmes[55].

Specific findings

The most important finding of the study was that there were few associations between psychological test scores used in the study and differences in physical outcomes of change over time. Nearly all statistical analyses were non-significant.

Indeed, there is a notable paucity of research on associations between psychological variables and changes in physical outcomes during lifestyle interventions. This is

echoed by Vizza et al[150]. Although they reported clinically meaningful improvements in psychosocial variables (including depression and perceived stress) after a year-long CLI programme, they were unable to associate any changes in psychosocial variables with changes in physical variables (including BMI, RDBP, metabolic variables and physical fitness)[150]. This highlights the contestability of claims that the modification of psychosocial risk factors is causally related to improvements in clinical outcomes of patients with CDL. These factors, as well as the evident range in intervention duration and structure reiterates calls for more standardisation of research into all potential mechanisms which may elucidate the current findings[150].

Two associations were identified between psychological variables and physical outcomes of change. Firstly, greater psychological distress demonstrated by higher baseline K10 scores were associated with greater decreases in RDBP. In other words, the greater the reported distress at the start of the programme, the greater the observed improvements in RDBP over time. This is not an uncommon finding, as greater disability, in this case, cardiovascular and functional disability, is often associated with a greater treatment effect[151].

Secondly, it was found that higher resilience, reflected in higher baseline CD-RISC scores, was associated with greater decreases in BF% at programme completion. While this illustrates another association between resilience and anthropometric factors, higher resilience scores on this occasion were associated with an expected decrease in BF% over the programme. At the time of writing, no studies appear to have included W/Hip, SkinF or BF% as outcomes of change during any CDL interventions. Chan et al's CR study found patients with high personal resilience experienced significantly greater improvements in total cholesterol and LDL cholesterol[65]. Interestingly, 6MWD was included as a physical outcome, and was found to be significantly improved in patients with higher personal resilience[65]. The latter finding lends tentative support toward an association between resilience and improved functional capacity during an intervention in CDL populations. Whether any improvements in physical parameters were due to psychological factors, by a programme effect, or indeed a combination, has yet to be established in our study. This finding, along with the association between RDBP and K10 scores could

additionally reflect a broader trend relating to disease or distress severity and increased treatment effects identified in behavioural medicine interventions[152,153 154].

Lastly, demographic factors, which have demonstrated associations with baseline measures (see Chapter 2) showed fewer associations with physical outcomes of change. There were three significant associations. Firstly, increasing age was associated with attenuated improvement in 6MWD. Furthermore, males achieved greater improvements in 6MWD, as well as greater reductions in BF% than females. As before, these are well established findings which are commensurate with current research[23].

3.6 STUDY LIMITATIONS

Undoubtedly the study's reduced sample size leads to false negatives. Though selection or sampling bias is not uncommon, particularly in clinical cohorts, it needs to be accounted for and mitigated as much as possible[147]. Due to the study's retrospective nature, it is incumbent upon the authors of this thesis to acknowledge the limitation and to exercise caution when interpreting results relating to the psychological variables. This additionally applies to physical outcomes of change over time, considering missing data at completion.

The lack of associations between baseline variables may additionally be due to the influence of the actual intervention, which was not factored into the statistical analysis. Chan et al's study of personal resilience during an eight week CR programme accounted for a programme effect as well as interaction effects between resilience and the programme. Despite a weak mediating effect of the programme, they were able to demonstrate a significant predictive effect of resilience on post-traumatic growth[65].

Finally, it is important to note that effect sizes in behavioural medicine are reportedly equivalent to those based on psychological predictors[153]. Thus, they appear smaller

than they potentially are and therefore require statistical techniques beyond coefficients to increase the scope of their clinical interpretation of results[153].

3.7 CONCLUSION

In conclusion, the results of this study suggest that changes in functional capacity due to participation in a CLI programme cannot be predicted by certain psychological parameters (including resilience, psychological distress, and trait anxiety) at initiation of the programme. Exceptions to this finding were that increasing psychological distress was associated with attenuated decreases in RDBP, and increasing resilience was associated with further reductions in BF% by completion of the programme. Notable limitations to the study included high participant dropout rates as well as incomplete data. Nevertheless, the study plays an important role in supporting the call for more individualised treatment of patients within this complex disease group. It is acknowledged that group means do not take individual variations into account, and that there is a corresponding need in current research to emphasise and examine these variations using clinical observations and qualitative methodologies. This is the topic of investigation in the following chapter.

CHAPTER 4: USE OF QUALITATIVE METHODS TO DESCRIBE PATIENT EXPERIENCES OF A COMPREHENSIVE LIFESTYLE INTERVENTION PROGRAMME

4.1 INTRODUCTION

The magnitude of the burden of chronic diseases of lifestyle (CDL), detailed in Chapter 1 of this thesis, continues to amplify despite the increased availability of a range of primary and secondary level interventions. Moreover, lifestyle behaviour modification is sufficiently complex that at least part of the increasing global incidence of CDL is accounted for. Chapter 1 reviewed the development of comprehensive lifestyle interventions (CLI) as potentially effective secondary treatment for CDLs. It was also acknowledged that psychosocial risk factors and protective factors play an invaluable role in influencing the success of behaviour modification. The validity and reliability of a number of psychosocial measures were reviewed within the CDL context, and Chapters 2 and 3 reported that physical outcomes of a CLI programme may be associated with a range of factors, including psychosocial measures, but more commonly through demographic characteristics such as age and sex. It is possible that the role of psychosocial factors in CLI programme outcomes might be more effectively explored using detailed, subjective accounts of the CLI programme experience in addition to standardised questionnaires.

Quantitative research methodology has historically dominated scientific enquiry in the health sciences. Although it is able to account for much observed phenomena, it is often less able to provide a comprehensive understanding of them[155]. Healthcare practice and research deals with humans: participants who are generally more complex than those in the natural sciences. Moreover, there are numerous questions about human interaction which health professionals may require answers to, and experimental and quantitative methods are less well suited to answer these questions[156].

Qualitative research aims to help us understand naturally occurring social phenomena, emphasising meaning, experience, and views of all the participants[156]. Subjective accounts of such phenomena promote a range of ways of understanding the world, emphasising the experiences of the participants under investigation along with their world view, rather than that of the researcher's[157]. This fundamental shift in perspective enables qualitative research to describe aspects of complex behaviours, attitudes, and interactions which quantitative methods cannot[156]. Qualitative description is, in fact, an essential element of research, particularly in new areas of investigation[156]. Researchers in medicine and healthcare therefore increasingly employ qualitative research methods, often as an adjunct to existing quantitative studies[103].

Lastly, context is considered to be vital in qualitative research. In the case of resilience research, for instance, social and cultural factors determine what we define as risk and protective factors, or what a good or bad outcome is, making resilience a socially and culturally biased construct[105]. Considering subjective, relative views of resilience and other constructs is therefore essential to provide a more complete account of their nature and relationship with physical health. Moreover, they highlight differences between popular and personal accounts of health and mental health, which may be complex and often contradictory in nature[156].

Patient experiences of CDL[106–108] and CLIs[108,111] have been documented using qualitative techniques, as well as research relating to cardiac rehabilitation (CR) and CLI programme adherence[112–114]. These studies, as well as recent[9] and seminal[105,115] resilience research within the fields of CDL and CLIs is described in detail in Chapter 2 of this thesis.

4.2 STUDY AIMS

This chapter aims to identify and describe the various factors influencing the physical and psychological outcomes of 14 patients with CDL completing a twelve week CLI

programme. Specifically, it aims to describe the role of psychosocial protective factors, such as resilience, in the CDL and CLI experience.

4.3 METHODS

4.3.1 Study Design

The following chapter details a qualitative study undertaken with a cohort of 14 participants with chronic diseases of lifestyle at the commencement and the completion of a twelve week CLI programme using semi-structured interviews. The section below outlines the use and usefulness of such methodologies in creating more detailed descriptions of how patients experience their illness, their understanding of resilience, as well as the role CLI programmes may have in promoting changes in their physical wellbeing.

4.3.2 Theoretical Framework

The theoretical framework underlying this investigation combines social phenomenology with critical realism.

Schutz's social phenomenology is a theory of social action[158]. It explores the subjective experience within the everyday life of individuals[158] and understands the meaning they generate from that experience[159]. The theory relies on the postulates of logical consistency, subjective interpretation and adequacy[158]. *Logical consistency* requires well planned methods as well as a transparent analytic process to ensure rigour[158]. *Subjective interpretation* accounts for research context, and links reported themes to actual extracts of participant responses, increasing both face validity and credibility of findings[158]. *Adequacy* also ensures credibility and relevance of findings in the real world[158]. Phenomenology has been adopted for this investigation because it allows for a more inductive style of inquiry. The foundation of the research is, however, based on pre-existing knowledge of human physiology, as well as

established psychological theories, particularly relating to resilience. A more deductive approach must, therefore, be supported within the theoretical framework.

Scientific realism asserts that the best theories generate knowledge of both observable and unobservable aspects of the world through true descriptions of objects[160]. Bhaskar developed a variant of social realism, known as critical realism. It acknowledges the structural role of such truths, but acknowledges that human subjects, including the researcher, can never gain a completely accurate picture of the social world[161]. The purpose of critical realism is therefore to recognise not only the reality of the natural world but also the events and discourses of the social world[162]. Certain truths, such as those regarding physiological and disease outcomes, must be acknowledged in this investigation. However, the perceived meaning and importance of those outcomes, as well as other subjective experiences must also be considered.

These two theoretical positions have thus formed the backdrop to this investigation, and to this thesis. However incompatible they may seem, they reflect a more recent trend in scientific research which acknowledges the multifaceted and complex nature of knowledge and enquiry, particularly within the social sciences.

Issues of Rigour

Qualitative research has been historically criticised for a lack of scientific rigour, evident in anecdotal, subjective evidence, researcher bias and lower transferability[163]. Indeed, studies with inferior design and reporting may result in inappropriate application of qualitative methods within health care research[164]. However, some of the most heavily criticised aspects can be argued to be their most effective, accessing parts of research phenomena which traditional empirical methods cannot. Nevertheless, it is incumbent upon the researcher to give a thorough account of the collection, analysis and reporting of qualitative data. In fact, a more detailed description of methods allows for better transferability. This refers primarily to external validity, allowing other researchers to do similar studies. Generalisations, on the other hand, are exclusive to quantitative methodologies, and within a qualitative study are to be made by the reader, and not the authors[165].

Detailed discussions of these and other important considerations feature later in the chapter.

4.3.3 Study Setting

U Turn is a CLI programme conducted over 36 sessions typically for twelve weeks. The reader is directed to Appendix A of this thesis for a detailed description of the *U Turn* CLI programme[13].

4.3.4 Interview Participants

Participants were identified and recruited from a cohort of CDL patients commencing the *U Turn* CLI programme between 2013 and the end of 2014. Any patient included in the programme referral criteria were included in the study, though the majority were referred to by staff, and referred to themselves as 'cardiac patients'. Only patients who had previously completed a *U Turn* programme were excluded from the study.

The principal investigator was alerted by the clinic when a new patient had enrolled in the programme, and the patient was subsequently contacted, per telephone, by the investigator. Most patients were made aware of the study and that they may be contacted if they agreed. As the investigator was not based at the clinic, she may not have been made aware of all new intakes, but found the recruitment process to be largely successful, with the majority of recruitments established at first contact.

Convenience sampling was thus deemed the most suitable sampling strategy for this investigation, based on the availability of new intakes into the CLI programme and referral from clinic biokineticists and doctors. Purposive sampling strategies may have provided a richer description of the cohort and are used regularly in CDL research[109,125]. However, the study would have required a significantly longer time frame to access participants with specific demographic, health and psychosocial profiles. It is believed that the participants recruited for this study represent both a

'typical' common health and demographic profile for the clinic concerned, and includes a number of cases outside the norm for comparison. An overview of cohort characteristics is detailed in Table 4.1.

Table 4.1: Characteristics of cohort

Age (2014)	**>60 years** **<61 years**	5 9
Sex	**Male: Female**	10:4
Race	**White** **Coloured**	12 2
Employment	**Full time** **Part time** **Retired**	8 (all self but 1) 1 4
Referral to *U Turn*	**Fedhealth Medical Scheme** **Cardiologist/ other**	6 7
Primary diagnosis	**Cardiovascular disease** **Metabolic disorders**	13 1
Interviews completed	**Interview 1** **Interview 2**	14 (in person) 11 (in person) 2 (written)
Activities since U Turn	**Completed programme then own gym** **Completed more programmes** **Did not complete, but did some exercise**	4 7 2
Social support	**Married** **Single** **Divorced**	9 3 2

Fourteen individuals consented to being interviewed at the approximate commencement of the programme. At completion, of the 14 initially interviewed, eleven were available for recorded interviews. Two requested they submit written responses due to the inconvenience of returning to the study site, and one who did not complete the programme did not respond to requests for a follow-up interview. Of the eleven interviewed in person, two participants had dropped out of the programme due to health complications, with one reporting that he/ she intended resuming the programme at the time of his/ her second interview.

Demographic characteristics reflect similar trends to the cohorts from which the participants were selected, as reported in previous chapters, as well as in other *U Turn* studies[13].

Timing of interviews varied. Although some participants were interviewed before their first assessment, the majority had already commenced either one-to-one sessions or group classes. The estimated average timing for the initial interview was during the participants' second or third week after the physician's assessment. The second interviews were held any time from the last few weeks of a participant's programme to six months thereafter.

4.3.5 Procedures

Semi-structured interviews

While not the only valuable tool for qualitative data collection, interviews were selected over other data collection methods for a number of reasons. Questionnaires, for instance, tend to be less flexible, and do not allow for individually tailored follow-up questions, or a less formal exchange of ideas which has potential to yield valuable insights. The semi-structured nature of the interviews consisted of open-ended questions within a flexible structure in order to define a specific area of inquiry, as well as diverge to another area if necessary[166,167]. This flexible structure was chosen over more in-depth techniques because of time and resource-related restrictions. It was important that the technique balance both structure and flexibility, necessary for both deductive and inductive analytical processes to operate, respectively. It was decided that semi-structured interviews sufficiently fulfilled these criteria, and have specifically been found to assist in identifying potentially modifiable factors for improving healthcare[164]. Naturalistic records, though valuable sources of interviewer-free data, require a great deal of time to transcribe and analyse, and have thus been restricted to the case study documented in the final chapter, where a variety of ethnographic techniques was employed[167].

Interview process

The study intended to gain a better understanding of the psychological and structural factors associated with CLI outcomes from the patient's perspective.

The study was briefly introduced to patients by a physician or a biokineticist during their initial assessment. The interview process was explained in a follow up phone

conversation by the interviewer after interest had been indicated by the participant. Once participants had received an overview of the study's objectives and requirements, they gave their written, informed consent before the commencement of the first interview.

Interviews took place in a consulting room at the Sports and Exercise Medicine Clinic, and were recorded using a digital voice recorder[168]. They were conducted by the principal researcher, a registered counselling psychologist, and lasted between 15 and 50 minutes. The interviewer requested permission from participants at the conclusion of the first interview to participate in a follow-up interview if it were deemed necessary. All participants agreed to participate in a subsequent interview. The guide questions for both interviews are detailed in Figure 4.1.

Interview 1:

- When was the last time you remember feeling your (psychological, physical, spiritual) best?
- What happened since then?
- Detail the events that brought you to the U Turn Programme
- Were you referred by Fedhealth? (if not mentioned)
- What are your expectations of the programme? What do you hope will be achieved?
- (If already commenced)What are your impressions so far of the programme?
- What personal qualities may assist you in successfully completing this programme?
- How would you define the term resilience?
- How does it apply to your life?
- Is there any potential benefit to what has happened to you?
- What aspects of your recovery are within your control? (or not)

Interview 2:

- How long since you completed/ dropped out of the first U Turn Programme?
- What have you done since then to manage your physical health?

Completed Programme

- What aspects of the programme did you find helped or hindered your progress?
- What aspects of your everyday life (work, relationships) helped or hindered your progress?
- What personal qualities may have assisted in or perhaps prevented your progress?
- Were your initial expectations of the programme met? If so/ not, how?

Both Completed and Dropped out

- Other definitions of resilience include maintaining functioning through difficult times instead of a distinct "bouncing back" or recovery. Which describes your experience of resilience and why?

Figure 4.1: Interview framework

Interview recordings commenced at the formal commencement of the interview, and typically did not include a great deal of preamble or informal conversation. The recordings were transcribed. Transcriptions are a verbatim account of all verbal and some non-verbal (e.g. coughs, laughter, long pauses) utterances[169]. It was important to retain the fidelity of the participants' responses, therefore details included punctuation which would be important to meaning of the data[169]. The dependability or accuracy of recordings were ensured by subsequent play backs as well as revisions of transcript extracts by a senior qualitative researcher and co-supervisor of the thesis[169].

4.3.6 Ethical Considerations

Ethical approval for this study as well as related *U Turn* research was obtained from the Research Ethics Committee in the Faculty of Health Sciences at the University of Cape Town (HREC Ref: 332/ 2007) in accordance with the Helsinki Declaration. Additional approval was awarded in February 2013 and November 2014 for the qualitative interviews as an addendum to the overall coverage. Participants gave their written, informed consent after a number of mandatory conditions were met, namely, the exact nature of the study was explained to the patient's satisfaction; the qualifications of the interviewer were clarified; and a full account of how confidentiality would be maintained through the management of files and the use of pseudonyms in reports. They were additionally made aware of their right to withdraw from the study for any reason without penalty, and that they had access to appropriate psychosocial resources if requested or noted during the interviewing process. The information sheet, consent forms and relevant authorisation letters from both interviews are included in Appendices C and D of this thesis.

4.4 DATA ANALYSIS

Interview data in this thesis has been analysed using thematic analysis. It is a user-friendly and intuitive method of identifying and selecting central themes and patterns

in the data[169]. It is flexible and can be adapted into numerous research designs irrespective of the researcher's theoretical background[170]. This is particularly useful for the current study, which makes use of both inductive and deductive research strategies. Some aspects of enquiry, such as psychological resilience, were compared with existing theory and were investigated using predetermined, semi-structured questions. Nevertheless, it was on the whole considered a relatively new area of research and thus much of the interview questions and the analysis was kept open-ended to allow for the evolution and identification of new themes[169]. It is therefore considered a sufficiently adaptable tool for this study's data analysis.

Thematic analysis identifies basic features of the data that interests the researcher[169]. This is achieved through coding, a process of extracting the most basic, yet meaningful segments of raw data from a data set[169]. The current study made use of QSR NVivo 10 data coding software[171]. Coding of the interview data was guided in part by the semi-structured questions. This assisted in the initial categorisation of data, as illustrated in Table 4.1. Following the coding process, themes were identified. Themes relate important aspects of data to the study's research question[169]. They occur relatively frequently within the data set and carry some degree of meaning[169]. For example, resilience was coded in the current data set. This categorised the data on resilience, but only through further analysis, were themes identified within the topic[123].

Preliminary thematic analysis commenced with the broad categorisation of codes. Codes were listed and defined, as well as linked to and differentiated from other codes. For instance, the code 'support_group_empathy' was found to be consistent in content in most responses, identified across the data set and distinct from another code named 'support_group_perspective'. The latter code was additionally found to be less consistent in response content, less frequent across the data set, and too distinct from other support related codes. It was subsequently discarded. The former code was later consolidated into the subtheme, 'support', which formed part of the theme, 'components of resilience', a psychosocial protective factor. Themes were initially identified in a distinct analysis for each data set, namely the initial and subsequent interviews. Once all themes were identified for both sets we were able to identify themes common to both set.

Conventionally, interview data sets consist mainly of participant responses. While this format characterised much of the study's data collection and analysis, it was deemed equally important to review participant responses within the context of the interview itself. The investigator's questions as well as the conversation that resulted between the investigator and the participants were thus included in the analysis process before the final confirmation of themes from participant responses. A number of case examples follow.

If viewed in isolation of the conversational context, the theme of problematic environmental factors may have been assigned to the following responses of Participant 14. However an exchange between the participant and the interviewer shifted the emphasis of the conversation toward to his increasing self-awareness. The conversational context of the participant's response alerted the investigator to another potential theme, namely, initiating changes.

014 I don't want to keep the class waiting, you know, I wouldn't want to be late and keep everybody else waiting. That again stresses one out. Because it's not fair keeping other people waiting.

PI We don't want it to be another source of stress

014 Ja, I must think of that too. I must think of that

PI Well, as much as humanly possible. As you say, daily stresses happen, and we cope with them as best we can

014 Thank you, you've alerted me to something there, which is quite important. Because I do stress. I don't like keeping other people waiting. And I know there are five or six people plus

PI And you will do everything humanly possible... not to do that, because you are aware of it

014 Yes

PI ...and that is all the stressing that is needed

014 Okay. Okay. Because even today, today was only the second time, I realised, on a Friday the traffic's even bad

PI Oh, oh all the time

014 Oy, yoy yoy, I mean, cars coming like this, bumper to bumper. I thought, "why did you bother to go to work if you're coming home already?"

PI [chuckle] it's Friday?

014 Ja!

PI Absolutely, ja.

014 So that was a bother. And I thought I would be late. I wasn't late. But, you know, you get round things. [Physician] said, oh we've got heart monitors here. Then, I noticed on

Wednesday, the one guy had a heart monitor when he arrived. I went straight out somewhere and bought one.

PI Okay

014 So that I've got it, it's on... I don't have to go through that. That's two minutes saved

PI Okay

014 You know, if I run late for whatever reason, or the traffic

PI At least one step's taken care of

014 One step's taken care of

PI Okay. Alright, so discipline's high. What

014 Very important to me, and that stresses me. But I also realised today... that they do follow. That's why he sent a programme, for two to three weeks, he realised very quickly. And I'm going to, I'm going to try and not stress and, you know, if I am a few minutes late... I can pick up. Because, you know, I am reasonably fit, I can walk fast, I can cycle fast

PI Ja

014 And I think they've seen already that if I lost a couple of minutes on the bike it's not going to be the end of the world. I could catch up with the class.

PI Ja

014 I don't intend to do that, but it's psychologically, it's

PI Yeah, it gives you a bit of leeway

014 If it happens

PI It's okay

014 It's okay. Because it's not the end of the world, it's not the end of the class. I won't put them out. I will do a little shorter on the bicycle, then I'll carry on with them

PI Ja. No, that's good to bear in mind

014 So I figured that out today for myself

Participant 14 responded to the interviewer's reflection regarding sources of stress which may interfere with his recovery process. The participant began to recall previous strategies and to develop new strategies to reduce stress when coming to classes. In particular, to create as little disruption to his fellow participants as possible if he was late. In addition, he was able to put the disruption and potential stress into better perspective, stating, "...it's not the end of the world, it's not the end of the class". Interestingly, the interview had served as a space to review and potentially revise coping mechanisms during the CLI programme.

Participant 1 reported experiencing some difficulties in maintaining changes in weight and fitness levels after completing the first programme. The interviewer's questions and reflections were conveyed in a fairly consistent manner. This may

have influenced his responses, shifting them from more problem focused statements about having, “fallen off the wagon” to solution focused ideas around recruiting exercise peer groups.

PI And the experience of improvement... does that in itself... build a new story for you? “Okay, I’ve improved here, or here already, so I know how to do it... let’s just do that again”

001 Improvement in my mental?

PI In your health... mental, mentally, health-wise

001 Yes, I have, I have fallen off the wagon I would say, as regards to, you know, the commitment I had to this. ‘Cos you kind of think, “well, you know, everybody says how good it looks”, and... you know, the changes in me and so on. But then... you tend to say, ”well, okay, I’m done now, I can go back to my ways”

PI Hmm

001 Um... obviously... because you’re more... healthy and so on, you feel that little bit younger as well, and try go back to the ways. So... you have to

PI And when you’ve been back to the ways? How does one go back to where... the preferred self?

001 That’s when you think, “wow... I used to be able to cycle this area... no problem, and now I’m struggling”, so that’s when it’s a kick to say

PI It’s a bit of a reminder, to get back on it

001 Ja. Or when you put a shirt on and suddenly go, “oh... this is a bit tighter than it used to be.” So little things like that would remind me

PI Okay, and then done fairly soon, after the

001 That I would...

PI ...so one doesn’t leave... leave it as long as you did before, in the past. You’re noticing sooner, now, when things are changing

001 Yes... ja

PI So you can respond to them... quicker

001 Correct. Ja

PI And you know how to respond to them because you have responded to them successfully so

001 Yes, exactly

PI ...so doing that is not as big a deal as

001 Yes. And even with that, if it’s not the programme, I can always say to somebody, you know, “why don’t we go cycling... this weekend, or something, or cycle in the morning”

PI So those opportunities

001 Again, it’s like recruiting someone with you, so again, a support structure

PI Because that’s been such an important part here,

001 Yes

Participant 12 mentioned a useful coping mechanism early in his first interview that was quickly identified and developed in the conversation that followed. From describing his symptoms of panic in some detail his shift in emphasis towards coping was supported by the interviewer and thickened by the interaction.

PI Okay. And so you go through a... is it... would you describe it as panic? Or anxiety?
012 It is, it is
PI Or once you've interpreted it as something serious
012 Yes, I mean I'll stop at something... I'm quite a deeply spiritual person, I will stop and I will pray and pray and pray until I feel like, okay, it's calmed down... you know, things seem to be...managing
PI What do you find that you generally do while you pray?
012 Um...
PI What sort of state do you go into when you, when you pray at that moment
012 It does tend to give me a sense of calmness
PI Okay
012 It does seem to bring a sense of calm, you know
PI That you're accessing help
012 I'm accessing help, ja
PI Ja, so it means that... Is there anything physical that changes, while you're praying? In terms of breathing, or heart rate or
012 It does help, ja. I mean I do feel at times that... just to shut everything out of my mind... television, people talking to me, everything. Just to shut them away for a few moments, to shut myself away
PI Ja
012 ...until it feels like the crisis is over
PI Ja
012 ....and, and , and then I can
PI Okay
012 ....I can sort of engage again a little bit
PI What a useful strategy that you've found
012 Useful, oh, ja

The influence of conversational contexts may not always be immediately apparent. However, underlying processes often occur in research interviews which may be unanticipated. If managed appropriately, these processes may have a positive impact on the relationship between interviewer and interviewee, promoting more detailed and authentic accounts. Participant 4 demonstrated particular courage in

disclosing a great deal about her experiences. This was accompanied by an understandable need for interviewer feedback and reciprocation. The interviewer was able to provide this with frank, but measured amounts of self-disclosure, particularly in relation to parenting and their degree of life experience.

PI Uh, no, I'm not there yet

004 No

PI No, this is the thing, as you say, of being a psychologist is... We do our very best... to imagine what it would be like

004 Ja, well I think you've got the training to do that. Hmm, ja.

PI So everything that you talk about, and the parental thing, that, you know a younger person particularly would... wonder about and go, "goodness, you know, maybe she's worrying a bit much", but no! [laugh]

004 Have you got kids?

PI No I don't even have kids, but I, I've been a teacher, and I have nieces and nephews and it's building

004 Yes

PI That sense of, you can start to feel the sense of... how much a little being is going to mean to you...

004 I know!

PI ...means!

004 I never knew...

PI So I can just put it up to that sort of level over there and then and I can imagine how...

004 Ja

PI ..this is your primary thought.

The above extracts illustrate how certain participant responses required further analysis within the context of the conversation that gave rise to them. This essential component of qualitative research serves as a useful reminder of the researcher's role as a research tool. This topic is examined in greater depth in Section 4.7.

Following the preliminary thematic analysis, a thematic framework was constructed in which to consolidate similar themes and distinguish some from others. The themes identified in the data set were categorised as: programme-related factors; professional and programme-related problems; psychosocial protective factors (components of resilience and examples of resilience); and lastly psychosocial risk factors. The themes and their categories are listed in Figure 4.2 below:

1. Programme-related factors Atmosphere Programme results Structure and facilities **2. Professional and programme-related Problems** Administrative/ technical problems Professional incompetency **3. Psychosocial protective factors** a. Components of resilience Perceived self-efficacy Benefit finding Support	3b. Examples of resilience General examples of resilience Increasing awareness Initiating changes Maintaining changes **4. Psychosocial risk factors** Responses to CDL

Figure 4.2: Data set themes

Finally, participant responses were described as resilient or as less resilient based on a number of theory-derived criteria, including: the ability to find benefit in adversity, demonstrating self-efficacy, and identifying sufficient support networks. Clinical observations further contributed to the distinction, identifying individuals who, according to the researcher, made suitable progress in their physical health status. Of the 14 participants interviewed, five were classified as demonstrating typically resilient responses. Four were described as mixed responses, as they experienced some complications, as well as some progress. The remaining participants' responses to CDL and the programme were classified as less resilient as they experienced multiple complications, with few obvious improvements in health at the time of the second interview.

4.5 FINDINGS

Participants identified a number of factors which they believed were influential in facilitating or impeding potential improvements in health. Programme-related factors included the overall atmosphere of care and support, as well as the presence of noticeable results. Conversely, the importance of professional and ethical conduct by

health practitioners (in the programme and in general) was highlighted, as well as a number of technical issues which may have been perceived as sufficiently frustrating to interfere with progress. Several psychosocial factors were introduced by the interviewer for discussion, such as resilience and related qualities, while others were identified by the participants, including increased self-awareness and prioritisation of physical health.

4.5.1 Programme-related factors

Atmosphere

The majority of participants believed the programme and the Sports Science Institute housing the clinic had a positive influence on their progress. They noted and appreciated that staff members often knew their names, were welcoming and friendly, and that this contributed to a sense of belonging. Participant 4 found this particularly reassuring and important:

> And, and you know? But, ja... the whole place. Even the, the staff who... let you in. There's a particular woman at the gate, who knows me and the kids. They're all so friendly, you kind of wait for it to change, you know, sort of... well, how? Have they been very well trained these folk [chuckling] because, you feel as though you're coming to something that you belong to. And that you could ask any *one* of them... for assistance if you were in trouble. [Participant 4, T2]

Another surprisingly appreciated aspect of the programme's environment was the use of humour. Several participants commented on how it personalised the treatment process and enhanced positive engagement.

> And... It's got a lovely cheerful attitude, there's a lot of humour, um... And sometimes it's gentle teasing humour, but there's a kind of give and take there. But there again, I think that the people involved are sensitive enough to know. [Participant 2, T2]

Programme results

Participants became increasingly motivated during the programme as they began noticing early changes in physical and/ or mental wellbeing. Improvements were often experienced as quite tangible during and after the programme.

And also when it's caused me to get my clothes changed, that's concrete difference, evidence that it works! [Participant 1, T2]

Well, and my partner, wife says that I'm much more alive. That I was slow… I thought it was aging... But it was actually… cardiac I think. And um, so I've got more… energy. I feel better… more alive. My… curiosity is coming back. [Participant 2, T1]

Yes and suddenly you feel full of vigour for going, you know? [Participant 10, T1]

Structure and facilities

Some participants included the programme's structure and the facilities as aspects of the programme that contributed toward making necessary health changes. The layout of the institute and gym facilities, as well as the access to health professionals and educational material were some of the examples provided.

4.5.2 Professional and Programme-related Problems

A number of professional and programme-related factors were identified as potential impediments to participants' progress, as described below.

Professional incompetency

Several participants reported experiencing dissatisfaction with the healthcare provided by at least one professional, either currently, or in the past. Reasons included unethical conduct or the failure to diagnose and treat certain complications. That said, the professionals concerned were not directly involved with the clinic, or the *U Turn* programme. A few participants suffered significant setbacks from drug side effects. All of these had the potential to impede participants' progression towards healthier outcomes, and even adhering to the programme itself, as experienced by Participant 12. He dropped out of the programme because of severe

side effects from his anticoagulant medication, leading to an overall sense of helplessness and demotivation.

The feeling is, you know, how does anybody actually know what is going on with this heart of mine? Is it improving or isn't it? You know? [Participant 12, T1]

Participant 4 relayed an unpleasant interaction with her cardiologist:

Um, had an appalling... doctor who said I didn't deserve the heart I had because I was so fat. Um, because I apparently had the heart of a 35 year old and I'm 54. Um, because there is no narrowing, there's no cholesterol issues, he says, nothing. Um, but... he cleared me for that, discharged me, and now I've just been panicking ever since then. Never saw him again, refused to consult with him. [Participant 4, T1]

And Participant 8 communicated her unease with the ability of previous biokineticists in managing certain patient populations:

But I just get the feeling like, well it's an hour of trying to get you fit, and moving on. I mean there were often times when... I just felt like they...y, you... they want you to do exercises, but they actually have no concept for how to do them for somebody who is overweight. [Participant 8, T1]

A number of participants had complicated presenting problems at entry to the programme, and communicated their lack of faith in their doctors' ability to correctly manage their conditions:

Ja, and then I mean, I... you know, I, I was saying, well you know... to myself, um...maybe I the wrong advice from my cardiologist. Maybe he should have said to me, don't go carry on with your walking, start doing a short, gentle walk, uh, on the level, and gradually increase and see how you go. But he did say I was a new, um, exceptional case, uh... my case mystified him. [Participant 10, T1]

Administrative/ logistical problems

A few participants found the timing of the programme to be too intensive. They reasoned that three times a week, at over 90 minutes a session, took significant time away from other commitments. The times that were offered, 8.00 am or 2.00 pm on Mondays, Wednesdays and Fridays, were also considered to be inadequate and problematic from a commuter's perspective.

U Screen is an online component particular to the *U Turn* programme. It consists of assessments, graphical feedback of outcomes and educational modules, which are emailed to patients every day to complete and submit. Participants have expressed frustration with this component of the programme for a number of reasons. Some participants experienced 'teething' problems with the software and were required to recomplete and resubmit assessments on several occasions.

I've tried to do it, and I can't get in, so I come in here and I sit with [programme staff member] and I see, they're, sort of [tapping finger on table], "[Participant 4].... you haven't filled it in" and it's just *another* thing to do. [Participant 4, T2]

Many participants, although being at least partially computer literate, still struggled with accessing and completing the forms from tablets and mobile phones and requested for paper versions.

Others simply found the educational modules to be unnecessary and time consuming, as they felt they knew enough about the topics covered and did not need to complete the modules.

4.5.3 Psychosocial protective factors

Psychosocial protective factors of successful physical outcomes form the core findings of this chapter. They centre on the construct of resilience. The following section details participant responses to questions focusing on the components of resilience, namely: perceived self-efficacy; benefit finding; social support; and the participants' own past and more recent accounts of resilience, particularly in relation to their CDL.

4.5.3.1 Components of resilience

Perceived self-efficacy

Perceived self-efficacy is the belief in one's ability to attain a specific goal[172]. It was examined by asking participants how much of the recovery process they believed was in their control. The majority of participants believed they possessed the ability to control their lives and their health. Those who believed they were not in control of many aspects still acknowledged the potential role they might play in overcoming adversities they faced.

I think about ninety f... I think the greater part of it is in my control
Correct, because, um... I made the decision to, to get up at six o' clock in the morning to be here at, at seven, or half past five. I make the decision to come three times a week. [Participant 6, T1]

Um, I believe that, it's mostly in the universe's control, but by… But, the genetic expression can be influenced by mind. [Participant 2, T1]

Benefit finding

An obvious demonstration of optimism is finding benefit in adverse circumstances. Only two participants believed that there was no benefit to being diagnosed with a CDL. The majority regarded it as a second chance rather than a direct benefit, but believed it would help them in future to make better lifestyle choices.

Um, the benefit, I would think is where it gives you time to re-evaluate your life, and... are you, are you on the right track, are you... you know if life had to come to an end right now would you have done everything you wanted to do? [Participant 3, T1]

I believe so. Because... if number one, if this did not happen, uh, I would have just gone on my merry little... on, on my, the same lifestyle... You know, eating habits. And, for once... this really brings it closer to home, this, you know, listen, you've got to eat more healthily, and... And be aware that, uh... not everything that you do contributes to your health. [Participant 6, T1]

But I, you know, if that's the... slap in the face I needed... then good [laugh] You know in a way I'm glad it happened. And I think... like I said to you just now, if my foot hadn't happened, and I hadn't... I probably would still be on the same treadmill... of denial. [Participant 8, T1]

Support

Support refers to the presence of relationships inside and outside of the programme perceived by the participant to be important to their psychological and or physical wellbeing. The majority of participants reported having supportive relationships and

recognised the positive impact they had on their health. Spouses, other family members, friends and even community members were included as potentially valuable sources of support.

I think that the older you get, and... when your circle of friends are more or less the same age, or colleagues doing the same thing. Um, we're always looking at ways and means of learning from each other, and everybody has weight problems, has fitness problems, tried this, tried that. [Participant 6, T1]

A number of participants, however, described the difficulties of not having access to supportive relationships during adverse life events.

Family is very, very important. And, and I did have… you know I had to speak, I had to get in touch with my family back in Ireland, and England, and Canada. Em, because in a way I felt at the time, after the… like I said, the stent and the fall, and on that medication, like I say I wanted to move back. They wanted to come over and then *take* me back, sort of thing, you know... Like my nieces and nephew. [Participant 1, T1]

I think I've had very little, but I also think I've learnt to live with that. In that… I've learnt… that I can relate with people. I, I love relating with people. Um… But there are very few people who understand me. [Participant 2, T1]

I often wish they [my parents] were here because my father would've, been very instrumental in... taking care of me. [Participant 4, T1]

Many participants identified sources of support within the programme, particularly from staff members.

They are concerned when they need to be, and they're encouraging when they need to be. And that suits me... very well. So I've ascribed a *lot* of my improvement to this programme. If I hadn't done this programme, I don't know where I'd be mentally. [Participant 4, T2]

So, they do give an incredible feeling of safety... to me, I don't know about the other people, but to me. Um, and they're caring and they... I suppose they get sick of hearing all the stories. But I can at least say, "I'm feeling nervous" or, "I feel giddy" or ,"I feel funny" and I know if I fall over... they're going to be there. [Participant 4, T2]

Here were people constantly asking you, “are you okay?” uh, “what’s your, uh, blood pressure? What’s the heart beat?” etcetera, etcetera. That was very comfortable that you in a, sorry... that you’re in good hands. [Participant 7, T2]

And I said, “you know, for the first time actually I feel excited about a process, because there’s support. So, willing to push, listen to my issues, but... and I think it’s being listened to. I don’t think at the other side I felt listened to. You know, with my foot, I’d say, “oh, it’s painful”, I kind of got the feeling they thought I was just being paranoid. [Participant 8, T1]

Others included fellow *U Turn* patients as part of their support network, connected by their shared experiences of CDL.

But eh, it did, it was better, um, to have people around you that could encourage you and also you could encourage them as well [Participant 1, T2].

Almost a family, but also the people here that like... one particular person... I think he’s 82 now. But, you know he’s had... I don’t know, two, three heart attacks, a couple of bypasses... several stents, cancer, and he’s still going. So for someone like me, it’s a case of, “my back’s feels sore, so what?” [Participant 1, T2]

The positive aspect is that they’re all in the same boat, so you don’t feel you’re alone. Um, and I have connected with one woman there who’s had a bad time. She’s an older lady and we phone each other out of the class. And I love the guys. I didn’t in the beginning, I felt intimidated by them, but they’re all actually very nice. So, ja, no there’s definitely, the sense of comradery is huge. [Participant 4, T2]

4.5.3.2 Examples of resilience

The following section organises participants’ experiences of resilience into several themes, namely: general examples of resilience; initial responses to CDL; changes in attitude and self-awareness; changes in health behaviours; and maintenance of health behaviours during and after the programme.

General examples of resilience

Most participants recalled a time in their lives when they believed they were resilient. Some identified their current health challenges as evidence of resilience.

So I think I was resilient in the sense that, if, if, if again, if this is the right…em… tense or, or, the right way to use it. To say, "if these guys aren't interested in trying to make me better, I need to make the effort". So, you know, even though I felt, you know, terrible, I'd go out, get up in the morning, check my blood pressure, "it's okay", and I'd go cycling. I'd get in the pool and do my exercising, even with five or six ribs broken, just for resistance training. And I thought, "I'm not going to… let this thing that has, sort of, happened to me, bring me *further* down. In other words, I think I was feeling quite low…so, I kind of thought, "I'm going to float back to the top again". [Participant 1, T1]

Others believed they were more resilient in some circumstances than in others, highlighting the context specific nature of this construct.

Um... would I describe myself as resilient? A year ago, before November a year ago? [construction sounds] Completely. Went and adopted two kids, brought them up. Going to school, doing all the things, completely coping. Businesses, other business. I think the other business was a catalyst for the heart attack, by the way. But I do that, I just go gung-ho into things, and yes, I would describe myself as resilient. Resilient now? Fifty percent less so. [Participant 4, T1]

And... this is where I almost feel schizophrenic... but I'm not... just make sure you know that [laugh]. Is that... to my patients it would appear that I have *tonnes* of resilience.
But I think my 'bounce-ability' is not that great... to be honest. Um... depends on... the stuff that... You know, some issues I can bounce back from easier than others. [Participant 8, T1]

Increasing awareness

Participants with more resilient responses to CDL emphasised an increased awareness and prioritising of their physical and their mental wellbeing

You know, eating habits. And, for once... this really brings it closer to home, this, you know, listen, you've got to eat more healthily, and... ...and be aware that, uh... not everything that you do contributes to your health. I'm being much more focussed on, on, sort of, certain things in life. [Participant 6, T1]

But, uh.... Ja, for me, uh... it's been useful... in that it has obviously made me more aware of my *lack* of physical condition. And, uh... what I never... gave... any *real* thought to... is the condition of my heart. [Participant 7, T2]

I've had the warning and I must take note of it. Why did it happen? I think partially hereditary, but I *do* know... that it's because of my stress levels, which are exceedingly high.
...but, just seems to be, I think it's almost burnout, because I've not been taking any holidays or taking breaks. [Participant 14, T1]

Initiating changes

Although a few participants struggled between motivated, empowered periods and times in their lives when they were more fearful and disempowered, most reported feeling more optimistic and motivated to make necessary health related changes by the time they were referred to the programme. Reported changes included: dietary and often weight loss; smoking cessation; actively coping with the trauma caused by their disease; initiating or resuming exercise routines; managing stress levels; and re-evaluating lifestyle priorities.

...I mean I can answer that question on that side of it, for the cardiac side of it, and that is: My life changed in the sense that…I went back to church…I changed my eating habits… I exercised every day. 'Cos I really thought it was the end, I really thought. There was no support after that stent. [Participant 1, T1]

I'm handling stress better. I'm less frustrated… by… um, let's say I'm handling my frustration, um, it is frustration… objective frustration, when you can't do what you want to do, because you have to do other things. [Participant 2, T1]

Yes, yes. And I kind of do feel it's, career-wise, life-wise, lifestyle-wise maybe it's reached a crossroads. That is also nagging me a bit to examine that. Should I be going on at the pace that I'm going on, and... should I be changing things? Is it time to relinquish... part of what we do? In order, as you say, that we can carry on doing it for longer? [Participant 14, T1]

Maintaining changes

Participants reported varying degrees of confidence in their ability to maintain changes initiated or resumed during the programme over the long term. Some were confident in resuming their active lifestyles, while others recognised potential difficulties in maintaining the changes. For instance, Participant 10 had to decrease previous intensity of the activity and Participant 4 needed to accept that that other health complications need to be addressed before physical activity could become a priority.

4.5.4 Psychosocial Risk Factors

Participants were asked whether they believed any personal history, relationships or qualities may have hindered their ability to improve their health during the programme. A number of participants responded with accounts of premorbid and or current psychosocial difficulties. Overall, one theme was identified which dealt primarily with participants' problematic responses to their CDL.

Responses to CDL

There were varied reactions by participants to their respective health challenges. For some, the decline in physical condition came as a shock, highlighting a disconnect between perceived and actual health status.

> Correct. I thought, you know, "I'm a fit, healthy guy, and I exercise a lot, and I'm looking after my health, I don't smoke... And here I'm getting a heart transplant. What's that about?" [Laughs]. [Participant 3, T1]

> I don't wanna be a sick cow, you know, sick old cow, you know I wanna just move around and say well, like, "let's start, and let's motivate and let's get going and let's get better!" You know? I would love to be back, you know, to where I was. [Participant 11, T1]

> I know, but I couldn't bring... The only, the only adverse thing was that I couldn't bring myself to actually say, "you had a heart attack". And I still don't even like saying it now. [Participant 14, T1]

Many participants responded pessimistically to their initial CDL event and diagnosis. For a few, this included blaming themselves for their poor health:

> Ja! And, and this has made me think, "you know what, you are 54, you've buggered around for thirty something years, or forty years, since I've been overweight, taking chances." I mean, some of the weight is, medically... caused, and the other is completely self-induced. I eat too much, I drink too much, I smoke 40 cigarettes a day. Um... and used to eat every second day to try and control it. So ... I've done all that damage [3 sec pause] Now you've got to a point where you're going to have to [3 sec pause] live with what you've got, and get *it* to be the best... functioning body. Which I've never done to my poor body. Because I've always had so many things wrong with it, it's like, "oh for god's sake something else" [Participant 4, T1]

Others experienced a significant loss in confidence, particularly in their bodies. These reactions often resulted in a sense of helplessness and decreased motivation to make necessary health changes:

It has, I've lost confidence... in my body. [Participant 9, T1]

So, it's my first... feeling of being in a health problem, of having a health problem, and thinking, "I'm now scared if I have a heart attack or something!" You know? Can I push myself? I don't know. [Participant 9, T1]

And that... that knocked me... confidence-wise. Um... I was scared to do anything. I went for a little walk in Kirstenbosch and slowly went up some steps. Felt... felt I was tired. [Participant 10, T1]

I am so lacking in confidence in myself I find it even difficult - I went to the shop with my wife earlier today, uh, because I'm not even driving anymore, I'm *that* uncomfortable you know. And, um... I was in the shop for as long as I could make it but then I, then I just got to a place where, I just couldn't take it anymore and I had to go back to the car
...I don't recognise this body at all right now
Um... ja. This is definitely the most traumatic event I've had to deal with. [Participant 12, T1]

Premorbid psychosocial difficulties included lifelong narratives of trauma, low self-esteem and anxiety. Not all accounts, however, were indicative of poor CLI outcomes. Of the six participants who were identified, three reported achieving successful physical outcomes by the end of the programme and three others experienced continued difficulties in initiating and or maintaining health changes.
Current psychosocial stressors involved work; difficult relationships; co-morbid conditions and drug side effects complicating the treatment process; family commitments; and problems related to retirement.

4.6 DISCUSSION

This component of the thesis investigated patients' experiences of a CLI programme and the influence of specific personal factors, as well as programme-related factors had on their ability to improve their physical and mental wellbeing. Semi-structured

interviews conducted before and after the programme allowed for current theory to be expanded upon, particularly resilience research in CDL populations, as well as for the introduction of new themes through open-ended questions. Three key findings follow, along with considerations of their clinical relevance in CLI and CDL populations.

The investigation's principal finding concerned the majority of participants' ability to recollect and report instances of resilience when coping with adverse life events and particularly in managing their chronic health problems. This is evidenced in their readiness to find benefits in adverse events; their degree of perceived control over their condition; the constructive ways they responded to their diagnosis; as well as the positive lifestyle changes they were able to initiate and maintain.

Benefit finding is considered a potential correlate of resilience[9,65,173–175] and of posttraumatic growth[60,72,176,177]. While some participants took some time to identify a specific benefit, nearly all had the initial response that there must be one. Perceived self-efficacy is a related concept and is associated with successful outcomes in patients with CDL[9], particularly in patients with diabetes[9,10,178]. Some participants felt responsible for their current state of ill-health. On the other hand, the modifiable nature of CDL presented some participants with the opportunity of playing an active role in their own recovery. Those who identified themselves as resilient and self-efficacious also reported managing to adopt and often maintain healthy lifestyle behaviours. This is in line with previously published data by de Sousa Pinto et al. [111], who reported more empowered patients with COPD were better able to take advantage of psychosocial support and health participation in pulmonary rehabilitation programmes[111].

Another important finding was that nearly all participants experienced at least a moderate degree of trauma at the time of their initial diagnosis. This occurred in individuals with varying CDL, premorbid health, and degree of self-reported resilience. Furthermore, the impact of earlier psychosocial difficulties, rather than the events themselves, was considered. Participants who readily reported past psychosocial difficulties often complained of having current problems and co-morbid conditions which complicated their treatment process. While not all participants

experienced a major cardiac event, most reported that their lives and confidence in their bodies had been significantly altered by the diagnosis. Similar accounts can be found in related qualitative research[106–111], and are described in greater detail in the first chapter of this thesis. Two definitions of resilience were explored in the second interview. The first was the more widely accepted definition of "bouncing back"[62] after an initial reaction to an adverse event and the second emphasised the maintenance of functionality during adversity[9,64]. The former allows for an initial period of trauma before consolidation and recovery commences[146], and was more readily adopted by participants. It is therefore important to include any initial traumatic reaction to the total description of a resilient response, as well as any instances of resilience from other contexts which may assist the patient later on.

Lastly, participants emphasised the importance of having access to support, both from relationships outside the programme as well as from their medical practitioners. This is common to resilience research[62,63,66,75,105,146], particularly in CDL contexts[9,10,74,178,179]. Professional competence and ethical behaviour were identified as a concern for all medical interactions, however the degree of support and care experienced by participants during the *U Turn* programme highlighted the positive impact CLIs can have on mental and physical health outcomes. In particular, the clinic and the SSISA staff were described as caring and professional, and the overall atmosphere as motivating and good natured. While a few participants evaluated as particularly resilient found this aspect less important to their progress, the majority believed it was essential. Specifically, programmes may be able to provide additional emotional support and attention for patients identified as vulnerable or less resilient. Patients identified as resilient may benefit from other forms of support which enhance the recovery process in more concrete ways. It is possible that observations like this will assist CLI programmes in gaining recognition for being individually tailored and patient-centred[6,180].

4.7 ROLE OF RESEARCHER

It is of paramount importance that researchers acknowledge and account for their role as a research instrument in qualitative methodologies. Indeed, researcher reflexivity is essential in all aspects of qualitative investigations[167]. The following section considers the influence that I, the study's primary investigator and interviewer had on the process of interviewing and interpretation of respondent data. Moreover, contextual limitations on the research process are discussed.

Interviewers are required to maintain an awareness of the influence of their own values and personal biases in the questions they include and those they omit, as well as in how they interpret and report participants' responses[166]. For example, it was important that I safeguard against an inappropriate degree of directedness during the interview process, which is often evident in the frequency of leading questions[166]. It was a commonplace challenge to balance the directed, deductive nature of some of the interview questions with a more open-ended enquiry. I found that my experience in postmodern psychotherapies encouraged participants to be the expert in the interview and thus determine much of the interview content.

The use of transcripts may influence the quality of interpretations. The inclusion of certain transcript extracts over others when demonstrating a particular theme may have been subject to researcher bias. This may have occurred when choosing which participant's responses to include in the discussion of themes. Participant 4 had a high proportion of responses included in the study's discussion. This reflected the degree of self-disclosure and introspection she demonstrated during the interview process. However, there were occasions where her responses were substituted with another participant's in an effort to represent the experiences of the whole cohort.

While every effort was made to ensure the fidelity of participant responses through the verbatim transcription of audio recordings, this process is subject to researcher bias. The following extract may demonstrate the possibility of response manipulation, using punctuation, to produce meaning that may not be there. A response from Participant 8, regarding CDL events as a second chance to improve her health, included a number pauses. As they were transcribed and reported as, "...", they may

have been interpreted by some readers as hesitant. It may have been more effective to omit the pauses, or transcribe them as commas to lessen the possibility of readers interpreting their response as less certain than it was originally intended by the participant. In addition, I may have inadvertently interpreted her reported experiences in such a manner which was not aligned with the participant's meaning. This was commonplace in this study as many responses reported both the experience of resilience as well as trauma or CDL in the participant's life. My task was to extract the dominant message from the response, which often indicated whether the participant believed they had more or less control over their responses to their CDL. This ultimate meaning may have on some occasions been prone to misinterpretation.

Indeed, my intentionality required constant monitoring. This was particularly important in a study utilising deductive interviewing strategies. The selection of background literature influences the collection and interpretation of qualitative studies. However the relatively recent nature of resilience research, particularly in the health care sector, meant that all available literature was accessed to gain adequate understanding of the topic.

Another important, yet often neglected consideration discussed in the analysis section of this chapter, is the interactional nature of the interview[167]. While creating a more detailed context of the interview data, it also requires the interviewer to reflect on what data was co-created between interviewer and participant[167]. I am a counselling psychologist, adept at asking questions, but usually as a therapeutic means to an end. Although the interviews functioned for the most part as data gathering, the influence of my profession could not be overlooked. The actual impact would be difficult to determine, however, it is possible conversations were unwittingly steered towards potentially therapeutic ends, and thus influencing the participant's responses accordingly. It should also be noted that participants' expectations of being interviewed by a counselling psychologist may have restricted or perhaps encouraged the disclosure of more personal information.

The power dynamic between qualitative researcher and participant should always be accounted for, particularly in medical contexts, where privileged access to

information and the potential for exploitation of participants is high. For example, it is likely that a proportion of the participants may have felt pressured into volunteering for the interview component of the research, as well as disclose more than usual because I was often mistakenly presumed to be a member of the programme's medical team. Though I took pains to rectify this misunderstanding, it may have influenced aspects of the recruitment process as well as the quality of information. As previously stated, my professional background encouraged close associations with medical practitioners. Thus there was a clear power differential between myself and patients, as well as with a few junior biokineticists. I received extensive professional training in identifying and working with countertransference which is common to this research approach. The inevitable and necessary relationship which developed between myself and participants needed to be unburdened of any personal bias or identification during the interview process, as well as the analysis phase. What remains undoubtedly carries aspects of my own personal narrative, but with the concerted intention of conveying the participant's experience as authentically as possible.

Lastly, contextual constraints and limits on the research process require due consideration. Though the SEM clinic environment was largely conducive to clinical research, a number of factors pertaining to recruitment of participants may have influenced the quality of data collection. Data collection was limited by patient intake into the *U Turn* programme, which was infrequent at times. Delays in intake and participant recruitment created a number of delays in research deadlines. Although the effect of this possible tension is difficult to determine, it was important to bear in mind. In addition, staff may have inadvertently used the recruitment stage as more of a referral system, often only remembering to introduce the study to patients who had mentioned psychological problems early in the intake process. This may have created a bias in the cohort who contributed to this investigation.

4.8 CONCLUSION

Chronic disease events and diagnoses are undoubtedly traumatic, and require a significant degree of resilience to overcome. However, this study argued that the degree of trauma and necessary resilience in patients with CDL can be better assessed using qualitative assessments, as the perceived importance of those events and factors must be equally accounted for.

The previous chapters concluded that standardised psychological questionnaires have a limited role in screening for such factors within this cohort. Using semi-structured interviews, this chapter focused the description of CDL patients' perceptions of and responses to their illness, as well as to their recovery process. By providing a more flexible and individualised investigative approach it was able to yield clinically relevant psychosocial insights of patients with this complex condition.

Ideally such assessments should be conducted by a qualified psychologist who is trained to observe and illicit relevant patient information, as well as to guide the intervention process more effectively. It is hoped that such techniques be included in the assessment of patients with CDL, which in turn, will further the development of patient-centred interventions in these and other disease cohorts.

CHAPTER 5: A PATIENT'S EXPERIENCE OF A COMPREHENSIVE LIFESTYLE INTERVENTION PROGRAMME USING HUMAN CENTRED DESIGN

5.1 INTRODUCTION

The current thesis presents a multifaceted description of patient-centred management strategies for chronic diseases of lifestyle (CDL). Using large clinical audits as well as qualitative methods, it incorporates scope as well as finer detail in order to create a comprehensive overview of the topic. Nevertheless, generating genuinely relevant insights and recommendations for clinicians may require further consideration.

The previous chapter highlighted the invaluable role patients play in guiding research and clinical practice in the sustainable management of CDL. Specifically, it was argued that *how* the patient perceives professional care during a comprehensive lifestyle intervention (CLI) programme enhances or possibly detracts from them reaching their anticipated health outcomes. Patients identified as more resilient emphasised the benefits of their circumstances and their own self-efficacy. They were less concerned with the support provided by personnel in the programme, and focused on other programme related factors. The converse was found in more traumatised patients who were vulnerable to related psychosocial risk factors.

Case study methodology is valuable for health science research because of its flexibility and rigour, encouraging the development of theory, the evaluation of programmes, and the development of interventions[181]. A pilot case study was therefore conducted, employing ethnography as well as elements of human centred design (HCD) to apply and test these findings within a CLI programme. The objectives were to demonstrate how employing HCD on a case by case basis might assist clinicians in assessing the ability of the programme and the staff to adapt to a variety of cases and patients, thus ensuring that they are indeed patient centred. HCD is a recent development in exploring and conceptualising design and service-related challenges[182]. It is an optimistic approach to research, focusing on the ways

individuals interact with products and services, and the infrastructure that enables them[126]. Empathy for the user or participant is crucial to investigators understanding the experience as they do. Following a growing trend in action-oriented research, this approach has been commercialised and applied in a variety of settings in an effort to promote the development of sustainable, tailored interventions and products[126,182]. Healthcare settings are among those increasingly applying HCD strategies[128,131,132], heading calls by global health authorities for creative, human (and patient) centred approaches to the world's most challenging health problems[6,183]. Although the literature review of this thesis details the use and usefulness of HCD strategies within the healthcare sector, it bears mentioning that no published studies have been found at the time of writing that apply HCD strategies within CLI settings.

5.2 STUDY AIMS

The following case study describes a single participant's experience of a twelve-week CLI programme for patients with CDL using principles of HCD. It specifically aims to detail personal as well as professional aspects of the programme that assisted the participant in achieving desired physical outcomes during the latter stages of the programme.

5.3 METHODS

5.3.1 Study design

Overview

The research design consisted of a single case study employing ethnographic techniques and informed by principles of HCD. Techniques included participant

observation and semi-structured interviewing to describe the experiences of an individual participant, Megan[2], during her first CLI programme. The observations and interactions were made by a counselling psychologist and doctoral student. Thematic analysis was utilised to identify and consolidate recurrent and pertinent themes from the transcriptions and field notes. As prescribed in HCD, relevant insights from earlier analysed data were fed back to the participant and clinic staff later on in a reflexive process in order to better understand the participant's specific needs[126]. 'Patient experience' in this context has been defined as all interactions with professional staff during the programme that may have influenced the patient's perceptions[128]. The study applied the first two phases of HCD. It utilised all aspects of the *inspiration phase*, as well as part of the process of problem solving known as *ideation*[126]. The former phase covers data collection and the latter, analysis and discussion sections of the chapter.

Ethnographic Fieldwork and HCD

Ethnographic research has been used in medical settings for over fifty years. It consists of several methods of data collection and analyses, principally through participant observation. This is a lengthy process of participation in and/or observation of a naturally occurring event *in situ*[129,130]. The degree to which the researcher participates in the events he or she is observing depends upon the nature of the research taking place. Patient confidentiality and professional scope of practice traditionally delineates the extent to which an investigator can intervene within exploratory healthcare research.

HCD emphasises the participant role of the investigator in exploring design challenges, as well as co-creating sustainable services and products with the participants themselves[128,184]. The importance of including users in the development and implementation of design solutions is an intuitive yet relatively innovative strategy which ensures users actually desire and therefore use the products and services designed for them[183]. Indeed, it is already acknowledged that conducting ethnographic research within medical contexts can inspire reflection and opportunities to feedback not only to participants, but to the health care professionals

[2] pseudonym

involved in the case[130]. As explored in detail in Chapter 1, HCD's basic principles promote the development of appropriately scaled and tested programmes for primary and secondary prevention of CDL[6].

5.3.2 Theoretical framework

As in the previous chapter, this study combined social phenomenology and critical realism as overarching theoretical frameworks. This was done in an effort to maintain theoretical continuity within the qualitative research of this thesis. For further elucidation on the nature and use of these theories, the reader is directed to the methods section of Chapter 4.

Furthermore, the study has included insights from HCD. It is also considered an integrated approach, and combines aspects of social phenomenology and critical realism[126,158,161]. Like social phenomenology, HCD places emphasis on the subjective experience of the participant, as well as their context[158,182]. There is additionally an inductive generation of insights and solutions in HCD[126,182]. Nevertheless, critical realism is included as the generation of real world solutions requires acknowledging the impact of social and environmental structures[161].

In order to consider and apply important facets of HCD in this case study, data collection and analysis were guided implicitly by a specific procedural framework, displayed below in Table 5.1. The reader is advised to refer to the table while reading subsequent sections of the chapter.

HCD – PROCEDURAL FRAMEWORK		
Inspiration Phase	**D Analogous inspiration**	**Ideation Phase: Synthesis**
1 Choose design challenge	Brainstorm analogous experiences	**1 Capture your learnings**
Collect thoughts	Make arrangements	Download your learnings
Define what you know		Share inspiring stories
Define what you don't know	**3 Build your Interview Guide**	
Review constraints or barriers	Identify objects	**2 Search for meaning**
	Brainstorm questions	Cluster related information
2 Plan your research methods	Organise your questions	Find themes
	Word questions strategically	Turn themes into insight
A Learn from people	Conversation starters	statements
Define your audience	Confirm your plans	Revisit your challenge
Extremes and mainstreams	Assign roles	Refine insight statements
Plan logistics		
Recruitment tools	**4 Additional research methods**	**3 Create "how might we" questions**
Create a trusted atmosphere	Personal diaries, photo essays, customer journey, card	Frame insights as questions
B Learn from experts	sorts, concept provocations	Select top 3
Expert interview		
Plan for the conversation	**5 Capture your learnings**	**Ideation Phase: Prototyping**
Secondary research	Take time to regroup	**1 Generate Ideas**
	Share your impressions	**2 Select Promising Ideas**
C Immerse yourself in context	Illustrate new ideas	**3 Determine What to Prototype**
Plan your observations		**4 Make Your Prototype**
Capture what you see		**5 Test & Get Feedback**
Reflect on what you've observed		**6 Integrate Feedback & Iterate**
		Implementation Phase

Figure 5.1: Human centred design – procedural framework

5.3.3 Study setting

The study took place in the Sport and Exercise Medicine Clinic within the Sports Science Institute of South Africa (SSISA) in Newlands, Cape Town. Interviews were conducted in the board room of the clinic, and observations were made in a variety of locations, including consulting rooms, common spaces of the clinic and SSISA, as well as the SSISA gym. *U Turn* is the twelve week CLI programme the participant was enrolled in, and operated at the clinic. It is described in detail in Appendix A of this thesis.

5.3.4 Study participant

Prior to recruitment, it was envisaged that the participant reflect the demographic and medical characteristics of a more 'typical' patient with CDL[184]. However, upon further reflection a patient was identified who met some 'typical' CDL criteria, but who would additionally serve as a revelatory case. In such cases, specific

differences in participants' demographic characteristics and medical history might elucidate the generation of new insights and subsequent instances of tailored treatment during the programme[184].

The participant, Megan, is a Caucasian female who was in her mid-30's at the time of her first programme. Megan was unmarried and was a professional working full time in the city centre, and living near to her workplace. She has a genetic syndrome that affects connective tissue[3], often leading to hyper-flexibility, heart valve as well as eye problems. She was diagnosed before puberty, and had experienced a number of traumatic injuries including aortic dissection and subsequent replacement. Moreover, she had suffered from a number of spinal problems which hampered movement and involvement in physical activities. As a result of decreasing functionality, she was almost completely sedentary, although she used public transport which included a small amount of walking in her daily commute.

5.3.5 Procedures

Data collection strategies were numerous, and included a number of semi-structured interviews with the participant as well as key informants such as doctors and biokineticists. Additionally, the participant was observed during formal activities, including medical consultations, assessments and individual classes; as well as informal activities before and after classes. Furthermore, Megan granted the researcher access to documentation of her medical history. Such a variety of data sources enabled the investigator to immerse herself in the subjective world of the participant, and thus generate the required empathy to ideate appropriate changes.

Recruitment to study

Megan was initially approached by her physician, who was the principal supervisor of the study. He explained the basic objectives of the research, and that I, the primary investigator, would contact her if she showed an interest in participating. She agreed to be contacted, and was contacted a day later. Although she seemed interested and

[3] Including the name of the syndrome may compromise anonymity

willing enough to be involved, she expressed concern about her validity as a case study for CDL patients, emphasising that she was “anything but typical”. I explained to her that the actual objectives of the study were to explore the ability of the programme and the staff to adapt to a variety of cases and patients, and that she would therefore be a very suitable candidate. I estimated how much of her time was expected to be required, and she gave verbal consent to participate. We arranged to meet the following week at her second assessment where I would observe the assessment and interview her for approximately 20 minutes after the session. I discussed other aspects of the study with her at the first interview and obtained her signed consent after reading out the information sheet to her (included in Appendix C of this thesis).

Patient records

All investigations in this thesis were granted ethical clearance to access patient records as well as to discuss cases with the relevant health professionals. I was not present at Megan’s initial physician’s assessment, which included her stress ECG assessment. I therefore made use of records as well as her physician’s account of it to add to my data. As I was not familiar with the genetic syndrome she was affected by, I consulted relevant websites, publications, as well as her patient records for detail on the injuries sustained and related procedures she had undergone.

Observations

I joined Megan in the assessment room and was able to observe and interact with her and her biokineticist, asking questions but also making casual conversation and building rapport with her and with the staff. I was additionally able to join her one-on-one sessions in the gym, taking rough notes on a clipboard. Observation sessions lasted as long as the class, which were an hour. All field notes were subsequently typed out.

Semi structured interviews

All four observation sessions were followed by a 20 to 30 minute interview. They were conducted in the first, second, eighth and eleventh week of the programme. I usually had a rough estimation of the questions I would like to ask her by the end of the observation or by the preceding day, but discussions in the interviews were

invariably less structured and followed themes that seemed pertinent to both Megan and me. Interviews were recorded using a visible digital recorder. Most interviews were followed by an unscheduled debriefing conversation where some of the issues raised in the interview were discussed a little further, but were not recorded and served more of a therapeutic value. I created verbatim transcriptions of all interviews with Megan.

Key interviews

Although a number of informal conversations took place between various staff members of the clinic and myself, one interview was prearranged with all of the biokineticists in the practice, and was semi-structured and recorded. It covered the purpose of HCD in the *U Turn* programme and a number of aspects about the case study that I wished to obtain their input and perspectives. I made rough notes during the interview, and developed more detailed notes afterwards.

5.3.6 Ethical considerations

Ethical approval for this case study as well as related *U Turn* research was obtained from the Human Research Ethics Committee in the Faculty of Health Sciences at the University of Cape Town (HREC Ref: 332/ 2007) in accordance with the Helsinki Declaration. Additional approval was awarded in February 2013 and November 2014 for the qualitative interviews and observations as an addendum to the overall coverage. The participant gave her signed, informed consent after a number of mandatory conditions were met, namely, the exact nature of the study was explained to her to her satisfaction; the qualifications of the interviewer were clarified; and a full account of how confidentiality would be maintained through the management of files and the use of pseudonyms in reports. For example, we decided not to disclose the name of her genetic condition, as well as her name, occupation and place of residence. She was additionally made aware of her right to withdraw from the study for any reason without prejudice or penalty, and that she would have access to appropriate psychosocial resources if requested or noted during the programme by the interviewer or by clinic staff. The information sheet and consent forms are included in the appendices of this thesis.

5.4 DATA ANALYSIS

Thematic analyses, as well as a number of analytical components of HCD, were used in this investigation. The former technique was described in Chapter 4 of this thesis. Analysis began early in the case study during formal note taking after observation sessions and interviews, where general and more specific impressions were recorded and themes were identified which guided subsequent data collection.

The analysis stage of HCD research is known as ideation and has two phases, namely synthesis and prototyping. The synthesis phase is closely comparable with thematic analysis techniques, where meaning is sought from collected data, which is subsequently clustered into related groups and searched for relevant themes. HCD goes further than thematic analysis by converting themes into statements and then questions which begin to address the initial design challenge. Prototyping then initiates the production of products and services which are fed back to the user or participant in an iterative process until an appropriate solution is co-created[126]. Time constraints restricted prototyping to a more informal process of reflecting and delivering feedback to both Megan and her relevant health providers.

5.5 FINDINGS AND DISCUSSION

A number of factors were identified as contributing to Megan's experience of the CLI programme. They have been categorised as environmental factors, physical and psychological variables, as well as factors relating to programme staff, the investigator and the creation and assessment of programme-related goals. Each factor, as well as its potential impact, is reported as and when it occurred during the programme as well as the relevant stage of the HCD process. The aim of this section is to highlight changes that were observed and reported in Megan's experience of the programme, and the observed variations in her own contribution towards her improved health outcomes.

5.5.1 Physical factors

Megan's medical history accounts for much of her experiences of her body throughout her life, and particularly during the programme. Physical factors identified in the study included those related to her genetic syndrome, as well as other factors which may or may not have been related to it.

5.5.1.1 Syndrome related factors

The syndrome Megan inherited played a significant role in shaping her identity as a "special case". She was concerned for some time whether she would be a suitable candidate for the study, despite my reassurances that the purpose of the study was to identify a patient who may require the programme to be tailored to their needs more so than the 'typical' CDL patient.

Accordingly, she saw herself as different to others - that she was more vulnerable to illness or injury and, most importantly, that the syndrome was "too big" for her to manage on her own.

I'm not *at all* equipped to deal with [3 sec pause] my illness... at all. [Interview 1]

5.5.1.2 Other physical factors

Megan's overall functional capacity, or base level fitness, was significantly below average for her age. She reported a number of syndrome-related and unrelated injuries including scoliosis which have prevented her from engaging in physical activities and which impacted on her confidence in initiating exercise.

I think it's also. No, it does seem so, it seems so silly that I'm actually here, because I should be able to start exercising on my own... *But*, I totally appreciate that I've reached the point, um, where I'm almost am too nervous... to start [Interview 2]

5.5.2 Psychological factors

5.5.2.1 Risk factors

Several psychological factors affecting her experience of and progress in the programme were related to her genetic syndrome, particularly the trauma and incapacitation she has endured because of complications related to it.

Hence... because even with... I've had two major operations now, actually no, more, but two major heart related operations... The down time... during and after those two is [3 sec pause] a lot. [Interview 3]

Uh, the... because of the back injury, that was quite... intense, because it was incredibly painful, and my spine was apparently exposed slightly [in breath]. So, and it hasn't entirely healed properly. So, that was... sort of... I had to be on my back for... I think, I can't remember how long it was, but I had to be flat on my back for a number of weeks [Interview 1]

But, ja. I do have a psychologist, and I do, I *had* a psychiatrist. After the first operation I went into a major depression... because it was such a shock [Interview 1]

Describing the traumatic nature of her health complications often led to a sense of helplessness, followed by dysphoria and tearfulness.

So... I get tired of hearing my own drama [tearful] [Interview 1]

Ja, it's like... what are you going to do? It's not like....Uh... gracious! [3 sec pause] The... first heart operation I had was a *huge*... trauma. [3 sec pause, inhale – exhale] And [3 sec pause] yeah, it just... it is what it is [Interview 1]

Furthermore, Megan believed the reason she developed some of her complications was due to her own negligence and inability to look after herself adequately.

Well, for a long time I didn't go and see all the specialists, and as a result I had a ruptured aortic aneurism which required emergency surgery to replace my aortic valve and part of my heart [Interview 2]

Well, yes, I mean it could have been caught earlier [Interview 2]

Lifelong physical difficulties eroded Megan's sense of self confidence in her body as well as her identity as 'an exerciser'. This was reported by herself as well as the biokineticists, one of whom believed Megan had "zero confidence in her body".

I like the fact that... 'Cos I've never really been a gym person, so I've never done this type of thing before [Interview 2]

I also don't want to be one of those ones that it becomes a born-again Christian, that's starts converting other people [to start exercising]... I don't think that's cool [Interview 2]

Megan spoke frequently about her propensity for boredom and an inability to sustain exercise programmes, especially if her efforts were interrupted by other commitments, by injury or simply when a specific programme came to an end. She

attributed boredom to not feeling adequately challenged by the activities, and recognised the necessity to identify these periods during the programme and address them proactively. By the final interview, 29 sessions into the 36 session programme, she expressed only a few lingering doubts about not being able to continue the process and the progress she recognised she had made, on her own:

...but then again, this could... there is a concern that if I take this, going forward after the programme that I might not keep this up. [Interview 4]

5.5.2.2 Protective factors

In conjunction with the resilience she demonstrated as the programme progressed, Megan identified a number of other personal qualities early on which she believed would assist her during the programme. She included stoicism.

My, particularly my family, they say I'm stoic. And if I say something's a little bit sore, then generally I should be put on morphine because it's incredibly sore. Personally, I don't think that's true... that... but, but I do think I have a high tolerance of pain [Inhale]... But, that's also... What are you going to do about it? If you have pain, you have pain... you know. There's only so much that you can actually do. [Interview 1]

She believed that she committed to achieving specific goals once she had established a solid routine.

But [inhale]... I am definitely a person, when I get into a routine then I will do it. So... I did get into a routine in swimming. [Interview 2]

Furthermore, Megan described herself as bossy, preferring to use her own judgement as opposed to being told what to do. While the latter description initially applied to work contexts, she was increasingly able to make use of them during the programme to determine her own goals.

5.5.3 Environmental factors

Overall, challenging aspects of Megan's everyday environment included commuting, work related stress as well as interruptions due to illness.

She expressed moderate frustration at the inconvenience of commuting to and from the CBD, where she worked and lived, and the clinic. It was important to her to use public transport more often than not, despite owning a motor car. Consequently, the time and distances required her to wake, to arrive at and to leave work at an earlier time. This resulted in sleep disruption, increased fatigue, as well as an overall increase in distress from coping with the unpredictable nature of public transport.

For the moment, ja. I'm feeling exhausted, 'cos...[inhale] I don't know, it has been a very tough week... So, the trains particularly, the buses... the public transport was atrocious... And... just getting into the timing of starting early, getting here [Interview 2]

Work-related stressors dominated the environmental factors affecting her participation and progress in the programme. She described her job as enjoyable and even inspiring at times, but often highly stressful, especially when she needed to rely on other colleagues' contributions towards completing various projects. She recognised the role that this source of stress played in her declining physical and mental health.

Work is an absolute bitch at the moment. So... but I think I've reached the point in this *whole* other drama... I reached the point where... it's not helping me. Last year... I just worked. [3 sec pause] I did a *major* relook at... 2014. Realised that I got pissed off at a hell of a lot of stuff, and nothing changed! The only thing that changed was that I was getting crosser and crosser and more stressed and more blob-like. [Interview 1]

However, as detailed in later findings, she became increasingly able to prioritise her health goals during the programme and to curb negative and unhealthy reactions to uncontrollable events. One of the first major positive changes she identified was to not allow herself to be held up by work commitments instead of leaving at her new time to get to the clinic:

But... that... from, at three o' clock, [sound of a bell], I go. That's it. No matter what. That has been a huge change. [Interview 4]

It has to be a concerted effort. Always. Of deciding what the priorities are and then acting on them. [Interview 4]

Other notable disruptions to her progress occurred due to a three week respiratory tract infection. Despite feeling frustrated at her attenuating fitness and strength, she had started viewing it as a necessary reminder to continue to prioritise her health goals, develop her base level fitness, and to attend to potential 'boredom' which

arose in response to her frustration. Near the end of the programme, her resilience had developed enough that she in fact interpreted the disruption as a potential benefit to her long term progress:

And if I leave this programme... thinking I've built up all of this [indicates body], you know, wonderfulness, and you know, and nothing's happened during it. And then, I go off and... I get sick... with a cold or with 'flu or whatever. ...It's good that it's happened *within* the programme because I *know*... that my fitness will come back relatively quickly, that the exercises that I'm doing are valuable, etc. etc. [Interview 4]

5.5.4 Expectations and goals

Much of the conversations I had with Megan and with the biokineticist addressed the development and assessment of health related goals. I initiated some of the conversations after realising that Megan displayed a significant lack of confidence in assessing her capacity for physical activity. The discussions were thus introduced to begin addressing this potential setback.

5.5.4.1 Programme expectations and goals

Both Megan and the head biokineticist reported that she had initially sought advice from the head physician of the programme upon the recommendation by her orthopaedic surgeon that she improve her fitness levels.

I went to visit my orthopaedic surgeon because my back issue was sort of flared up again, or possibly was a weak head... was literally. So I went to visit him again, to see if anything had changed, and he said, "we need to get you as fit and as", um... "as fit and as healthy as possible". That's, and that's literally the first time that somebodies actually said what I could possibly do to me. So, now I'm doing it [tearful]. [Interview 1]

Her primary goal on entering the programme was to have access to an all-in-one physician who could advise her on all aspects of her physical wellbeing. Secondary, but no less important, was the goal of improving her base level fitness and becoming strong enough to manage everyday as well as syndrome-related stressors:

[Pause] No, I'd say the *most* important thing is to get *fit*... and *then* learn how to make it sustainable [Interview 2]

Yes. And that's not only from a physical and health point of view, it's also from a mental point of view. Because I will... I think it will come down to... feeling strong...to be able to know... that... I *can* [Interview 2]

During the programme it was suggested by her biokineticist that she try swimming once a week as a cardiovascular fitness session in the programme. She was initially hesitant, but had reported enjoying swimming as a teenager and agreed to add it to the programme. She had recently realised, however, that her lack of base level fitness meant that she could not swim the length of the pool. This was initially very discouraging, but she decided to add it her goals as she hoped she would still enjoy the activity after the programme ended.

Her progress through the CLI programme was evident in her longer term fitness goals. It was essential to her that she be able to continue most of the process on her own, but that she have access to staff at the clinic on a regular basis to keep track of her.

But I mean, but you do know that I would like to continue [wry smile and pause] I'm hoping that I actually mean that for real and that it will happen... and work doesn't become a major issue. But I would like to continue after the, what is it, twelve weeks?... But I do want to be able to come back... to ensure that... what I *am* doing is still appropriate, or can be pushed, or whatever.....
Because... I... Ja [3 sec pause] yeah, that's what I want. Somebody to tell me that I'm doing it okay [Interview 2]

5.5.4.2 Assessing progress

As previously discussed, one of Megan's goals was to improve her cardiovascular fitness for swimming. It was discovered early on that she could gauge her levels of exertion best when swimming by using her rate of breathing. Moreover, she could easily quantify the progress she made in the pool. As we developed the idea that she be her own judge of her physical abilities, she was encouraged to focus on activities she enjoyed and that she could assess her own. Although perceived effort was apparently less straightforward for her to determine during strength-related exercises, she was still able to appreciate progress she made in these activities.

Yeah. *I* know that... But clearly, my heart doesn't really like it for a full length! So, it has to... improve. Not to say that I might not... Well, I definitely do want to continue after this programme... However that happens [Interview 3]

But it's *really* nice... to have the swimming, and the [strength training] ...because it's two totally different... methods of exercise. And... this one [strength training]... I can... from where I was... I have improved so much. I can see. And, the other one [swimming] is... getting there! [Laugh] [Interview 3]

Furthermore, Megan preferred a retrospective form of goals assessment, noting which goals had already been achieved, rather than emphasising what was expected

of her for the following sessions. She felt early on that the latter strategy would demotivate her if she were unable to reach the set goal.

I think it's good to, ja, it is more retrospective. Good to keep *reminded*...of what you were... not doing... we're doing. [Interview 3]

Joke that perhaps a certificate at the end would be a good way to remember achievements [Observation 3: notes]

Towards the end of the programme Megan acknowledged how quickly she recovered her fitness after a three week 'flu break, and how a potentially demotivating break served as a useful reminder to remain focused on her initial goals.

Main discussion with [Megan] on bike was about the motivation that came from realising she had lost condition[ing] after breaks in the programme. It led to musings over how short humans' memories are of what is important etc. I hinted, and M[4] agreed, that it probably helped her **stay focused** (and not become bored as previously said). [Observation 4: notes]

She additionally began to identify her own shift from reacting to stressful triggers towards making more positive, considered responses:

I'm not sure if I can answer it. But I *can* say that I was incredibly pissed off on Friday... after work. So I went for a walk. A very long walk. And I mentioned it to M, and she said, "that's so good, you are learning positive choices!" And I was like... "Oh! I have learned positive choices, which I see". So instead of, you know, smoking seven cigarettes, which I don't smoke, and, you know, drinking... whatever... I decided to go for a walk! So, perhaps, and that's walking, exercise is a way of dealing with stress? Yes? [Interview 4]

By the latter stages of the programme she was able to recognise the value of developing her base level fitness, how it contributed to her overall progress, and how it served as further motivation to reach unmet goals.

But the other thing that I have noticed... So, it's, um... just how awful I can feel. It sucks. Also, the sickness is saying, this is how awful you can feel and you have to just stop. Ja. It's showed that the exercises are actually achieving something
Ja. But a third thing after the cold was that now that I'm on three sessions this week...that getting back into the rhythm, and into the same – I don't feel awful. So, gaining that fitness level back is actually happened quite quickly. And that's also good to know!

So, so it has been... The programme itself has def, definitely been a progress, pro, and, pro, ja... a *process*, and an evolution of goals. I still haven't actually achieved my full lap of the pool... but it's not... it's not a... train smash. It really isn't. [All Interview 4]

[4] Biokineticist

Megan provided concrete evidence that she was able to judge her own progress and self-efficacy in her final interview. She believed that the programme had in fact enhanced her self-perception.

[laugh] I was a blob, I was a definite blob. I wouldn't say I was a blob now. But I did feel, yeah... I did feel incredibly like a blob... before [Interview 4]

5.5.5 Role of staff

It was important to understand how Megan perceived the care she was receiving from the clinic staff, as well as how she accessed that care and how the staff responded to her.

Megan recalled an earlier experience at the SSISA as being a good one, describing the facilities and staff as "incredibly helpful". This assessment was bolstered by her surgeon's recommendation that she do something to address her overall fitness.

That's, and that's literally the first time that somebodies actually said what I could possibly do to me. So, now I'm doing it [a little tearful] [Interview 1]

She was however, ambivalent about other healthcare professionals she has consulted over the years. She believed she was either treated as though she was helpless, or with a disregard to how traumatic the complications of her syndrome could be. Overall, it emphasised her need for a physician who could oversee more of her healthcare needs.

No, it's been a realisation that no one is... monitoring... *all* the facets... of the syndrome... other than me! [Interview 2]

So I don't know. It is too big. It's like, it's... Everybody sees me individually and nods and says, "fine, you're doing fine, come back and see me next year, ja you're doing fine" [Interview 2]

Her perception of care changed over time as she realised the objective of the programme was the tailoring of care in response to close observation of the patient's individual lifestyle needs. She initially felt uncomfortable with the degree of "fuss" made over her, but later recognised the contribution of this approach in her progress.

Well, no, it's good. It's definitely good, because that's the purpose of this programme is that it *is* about *me*. [Interview 3]

'Cos I am doing one-on-one, hey? But it's about me. So, my ankle started hurting... and I told them, then we had to change the programme. I felt that was slightly... silly... because... it's just a little ankle in comparison to all the other health issues that I have. But, you know apparently they're important too [laugh] So we changed the programme! [Interview 3]

She eventually recognised that the tailoring was necessary, especially when she considered the interconnectedness of physical health.

It's part of the process...because they know what they are doing [Interview 3]

And rather tweak, and have a longer term positive, than not tweaking, and... doing something else to something else [Interview 4]

Megan quickly developed a good rapport with the staff, particularly the two biokineticists with whom she trained. She appreciated the different benefits they each brought to her experience, noting that the degree of fun was balanced with education, and an accompanying sense of containment.

So it's... they're totally different... people. But I think... that... I don't know, it has been quite nice having them both. Because, if there are questions, I can ask, you know [Interview 4]

I was able to observe M, one of the biokineticists, throughout the programme, and noted her interpersonal skills and professional conduct from the first assessment.

Overall am noticing M's way of interacting with [Megan] is very calm and caring, and she explains all of the procedures she does and asks for feedback from [Megan] if she's experiencing any discomfort or pain. She smiles and laughs a little at [Megan]'s jokes, but generally does a noticeable job at easing any possible tension or anxiety [Megan] is experiencing during the assessment, simply with her calm tone and delivery. [Observation 1]

Megan's relationship with the biokineticists developed her perception of individualised care to the extent that she no longer considered it unnecessary to seek out additional assistance once she left the programme.

But it does seem slightly silly. But there is definitely... a... benefit. There is definitely a benefit of having somebody there because, "What? Relax your shoulders, don't do that, straighten up" prod, prod, prod. [Interview 4]

Her overall shift from a hesitant, often negative approach to fitness and physical health was evident by the final observation of her interactions with her biokineticist, as well as her relaxed and confident manner in the gym.

5.5.6 Role of the participant-observer

The final, and possibly the most important, consideration of this case study is the role that I as primary investigator played in Megan's experience of care, as well as in the process of programme tailoring through HCD. The nature of participant observation can be conceptualised as a continuum of research roles, and my role on any point of the spectrum was influenced by a number of factors within the various research contexts.

I began the research process primarily positioned as an observer, a role that was relatively straightforward to negotiate. Training for counselling psychology encourages a more passive role, and it was consistent with my own nature which is to observe before engaging with others. Moreover, the clinic environment was facilitative of academic activities. I had become a relatively familiar presence in the clinic over the past three years, and although I had not interacted a great deal with all of the staff in that time, my presence there was largely tolerated.

Sources of bias which may have influenced the recording and reporting of observation and interview data includes my professional and familial contexts. Several members of my family of origin are medical practitioners. Therefore, my familiarity with the physicians may have resulted in unintended bias or perhaps a less questioning approach when discussing participant case histories. However, my personal and professional history was equally influenced by post-modernist philosophy. This certainly contributed to the development of a healthy scepticism for hierarchies and power dynamics between health professionals, and most importantly, between practitioners and patients. In any regard, it is a tension I am familiar with, and hope to have accounted for in my observations of Megan as well as her interactions with the practitioners and myself.

My role as fellow participant in the case study developed in conjunction with the rapport between myself and Megan, as well as between myself and the clinic staff. My position as a researcher who was also a counselling psychologist did not create as much tension as I initially anticipated. Although the division of labour and hierarchy according to profession and experience was evident between the

physicians, biokineticists and administration staff, I found my own place to be relatively separate and non-descript. Staff may have seen this as being unbiased, as they were easy to talk to, and forthcoming with necessary information or even in sharing their own opinions with me.

While the contribution of the investigator toward research outcomes has become increasingly acknowledged and incorporated into healthcare research, it is relatively uncommon to intentionally intervene when examining an existing programme[130]. Nevertheless, qualitative research provides opportunities for behaviour change and improvements in wellbeing. This is reported in Kralik et al., where the use of participatory action research may have strengthened resilience in chronically ill patients through the sharing of experiences and narratives[125]. This case study has considered elements of HCD, such as identifying the limitations of a service within a specific context, and subsequently exploring and designing a solution. It wasn't my primary objective to alter Megan's experience and outcomes. Nevertheless, our interactions, as well as those with clinic staff involved exploring and addressing potential barriers to participation - which should ideally occur in patient-centred interventions.

With improving rapport came an increase in conversations regarding goal setting and assessing progress. These were echoed in subsequent conversations she had with the staff, particularly her primary biokineticist. In one of our final conversations, I decided to test the extent of her abilities to evaluate her own progress. I suggested to her that ultimately her syndrome may not be too big for her to handle. This and other possible suggestions may have extended the influence that the programme had on her resilience and self-confidence in her body into the future.

Megan	I don't think it's ever going to be... *not* big
PI	No... but *too* big
Megan	Yeah that's just semantics, ne!
PI	Well! The importance of semantics in psychology!
Megan	Okay....Ja, this is mos true.
PI	Nobody would doubt that it was big
Megan	This is true

Limits to confidentiality are highlighted in Pope's 2005 paper on ethnographic research in medical contexts. She warns that either extreme of the participant-

observation continuum may pose ethical dilemmas. For example, blending in too much as a participant may mean that the actual participant forgets you are researching them and discloses more than they usually might. It is important to also take care not to 'observe' too obviously, as this may stifle interactions[130]. Moreover, Pope recommends remaining mindful of the limits to confidentiality that exist within multidisciplinary practices, where patient information is relatively free flowing[130]. This was particularly evident when I interviewed the biokineticists working in the clinic, as most of them knew the case study and details of her medical history. Although I outlined the limits of confidentiality to Megan at the outset of the programme, I was careful not to share verbatim content of our conversations with the staff, rather relying on my own observations and insights when discussing her case.

Thus, very much in the spirit of qualitative research, I acknowledged and incorporated my dual role in the study as observer/ investigator and participant/ practitioner[184]. Reflexivity was paramount in ensuring the roles did not conflict with one another, and, if possible, in contributing meaningfully to Megan's progress.

Finally, it was essential that I move from reflexivity into action, and discuss the findings of the study with members of the clinic and others involved in the care of patients with CDL[184]. HCD allows all personnel involved to contribute to the process of inspiration and ideation. One particular example was that a minor barrier identified by Megan (but not discussed as a major factor) highlights this point. Megan commented that pedestrian access to the SSISA was restricted to the entrance gate on the side farthest from the train station. She lamented that the first barrier to her programme participation occurred so early in the process, and hoped I would feed the comment back to relevant personnel. If trained in HCD, any member of the SSISA staff would be better equipped to observe and address this scenario.

5.6 CONCLUSION

The aim of this case study was to explore and describe an individual patient's experience of a twelve week CLI programme using principles of HCD. Specifically, it

examined the role that physical, psychological, environmental factors played in her progress, as well as the contribution the staff and I made towards her reaching some of her health-related goals.

Introducing the idea of goal setting provided a useful system for Megan to negotiate the various programme-related as well as external challenges with increased confidence and resilience. Her collaborative relationship with her biokineticists encouraged her to progress through the programme with both a sense of self-efficacy and competence, as well as containment and security.

Incorporating ethnography and HCD in this case study enabled us to demonstrate that the *U Turn* programme consists of a sufficiently broad and flexible framework on which to tailor aspects to the specific needs of patients. It is hoped that the proliferation of CLI modelled programmes results in the extended and continued emphasis on patient-centred care, and possibly more sustainable treatment for CDL.

CHAPTER 6: SUMMARY, STUDY CONTRIBUTIONS, LIMITATIONS AND FUTURE RECOMMENDATIONS

6.1. INTRODUCTION

The current thesis utilised an explanatory mixed-methods research strategy to explore and describe a number of psychological factors potentially associated with physical outcomes in patients with CDL who were completing their first CLI programme. Moreover, patient experiences of CDL and CLI programmes were explored, as well as the role of psychological and programme-related factors in the management of CDL. The following chapter outlines the findings from the previous chapters and concludes with contributions, limitations as well as future recommendations of the research described.

6.2 CHAPTER SUMMARIES

6.2.1 Chapter 2

The aim of the first study was to describe a cohort of 308 patients with CDL entering a twelve week CLI programme using demographic, medical, diagnostic, functional, cardiovascular, anthropometric and psychological variables. Furthermore, it aimed to determine whether demographic, medical, diagnostic and psychological variables were associated with the aforementioned physical variables at the commencement of the programme.

Descriptive data were found to be consistent with recent and similar studies. These included a high prevalence of poor functional capacity as well as co-morbid CDL disorders. However, mean psychological scores fell within subclinical population norms.

Demographic factors, specifically sex and age were associated with numerous differences in baseline physical and psychological variables. The majority of associations with physical variables were in line with current research. However, associations with certain psychological variables were novel, particularly within CDL cohorts. Important findings included that there was decreasing resilience with increasing age and lower psychological distress scores in males compared to females. In addition, patients diagnosed with psychological or neurological disorders were more likely to have higher psychological distress and trait anxiety scores.

There were few associations between psychological factors and physical variables at the baseline assessment of patients entering the CLI programme. In particular, higher W/Hip ratios were associated with higher resilience scores. Although the latter findings lack supporting literature, it highlights the multi-dimensional and highly contextual nature of resilience and alerts clinicians to the complexities of using it as a predictive variable.

The findings described in this chapter laid the foundation for further investigation of screening variables and their association with changes in physical outcomes at the completion of the CLI programme.

6.2.2 Chapter 3

The aims of Chapter 3 were to analyse associations between demographic, medical, psychological variables and differences in functional, cardiovascular and anthropometric outcomes in 308 patients with CDL following the completion of a twelve week CLI programme. Baseline data from the previous chapter were combined with follow up assessments of the abovementioned physical variables.

Changes in physical variables over the programme were consistent with findings from other *U Turn* CLI studies, as well as with other lifestyle intervention research. However, fewer associations were noted than those documented in the previous chapter.

There were, however, two associations documented between psychological test scores and change in physical outcome parameters over the duration of the programme. Firstly, greater psychological distress demonstrated by higher baseline K10 scores were associated with greater decreases in RDBP. Secondly, higher resilience, reflected as higher baseline CD-RISC scores, was associated with greater decreases in BF% at completion of the programme. The former finding was expected, considering the well documented associations between psychological distress, cardiovascular reactivity and treatment effects. The latter finding may also be partly explained by increased treatment effect, but it is as yet unclear whether any improvements in physical parameters were due to psychological factors, a programme effect, or a combination both.

It was acknowledged that group means did not take individual variations into account, and that there was a corresponding need in current research to emphasise and examine these variations using clinical observations and qualitative methodologies.

6.2.3 Chapter 4

Chapter 4 investigated patients' experiences of a CLI programme and the influence personal factors, as well as programme-related factors had on patients' ability to improve their physical and mental wellbeing. This was accomplished with semi-structured interviews of 14 patients with CDL before and at completion of a twelve week CLI programme.

Resilient responses were demonstrated by the degree of perceived control over their condition; the constructive manner they responded to their diagnosis; as well as the positive lifestyle changes they were able to initiate during, and maintain subsequent to the programme. Benefit finding was evident in patients' perceptions of CDL as well as in their ability to play an active role in their own recovery.

Nearly all participants experienced a moderate degree of trauma at the time of their initial diagnosis. This occurred in all individuals despite varying severity of CDL,

premorbid health, or degree of self-reported resilience. Furthermore, the impact of earlier psychosocial difficulties, rather than the events themselves, was considered.

Finally, the degree of support and care experienced by participants during the *U Turn* programme highlighted the positive impact of CLIs on mental and physical health outcomes. This was especially evident in participants identified as more vulnerable to psychosocial risk factors.

Thus, providing a more flexible and individualised approach enabled the investigation to yield clinically relevant psychosocial insights with respect to patients with chronic disease.

6.2.4 Chapter 5

The aim of the case study was to explore and describe an individual's experience of a twelve week CLI programme using principles of HCD. Specifically, it examined the role that physical, psychological and environmental factors played in the progress of the patient, as well as the contribution that the staff and the investigator made towards reaching some of the patient's health-related goals.

The use of ethnographic techniques, informed by HCD identified a number of physical factors which were both typical and atypical of CDL cohorts. Trauma and accompanying helplessness contributed to a lack of self-efficacy particularly in health related matters. This was often compounded by external, work-related stressors which were identified as potential setbacks during the programme.

Nevertheless, sufficient resilience in other contexts of the patient's life became evident during interviews, and increasingly utilised throughout the programme. Potential setbacks including illness were reframed as benefits and opportunities for growth and improved health. By the concluding weeks of the programme, the patient demonstrated increased resilience, evident in improved self-efficacy and increased perceived support, particularly from clinic staff. The degree of support and individualised instruction from the attending biokineticist reduced in response to the

patient's improved confidence and self-efficacy. In addition, it is possible that the interactional style of interviewing and the use of reflection and feedback encouraged much of her active coping and benefit finding which is characteristic of resilient responses to adversity.

The programme thus demonstrated a sufficiently broad and flexible framework with which to tailor aspects to the specific needs of patients. The use of HCD assisted in the evaluation of the programme as well as in the development of a more tailored intervention for the participant. Future work facilitating the inclusion of HCD in CLI programmes might result in the improved patient-centred care, and possibly more sustainable treatment for CDL.

6.3 STUDY CONTRIBUTIONS

At the time of writing, this current thesis was the only known study to investigate associations of psychological factors with physical outcomes both at baseline and at completion of a CLI programme. The STAI-T and K10 have been assessed in CDL cohorts, but not in relation to physical outcomes in CLI programmes. Moreover, the CD-RISC has been validated in only a few CDL studies, but never in the context of a CLI programme. Of the CDL studies featuring the CD-RISC, none included CDL cohorts with multiple comorbidities.

Studies reported in this thesis support a combination of objective, generalisable as well as a subjective, context-sensitive conceptualisations of CDL and CLI effectiveness[185]. Psychological factors including resilience were, in turn, described using both quantitative and qualitative methods. Thus, the thesis investigated various psychological, physical and programme-related phenomena in their distinctive forms within each paradigm. The study as a whole benefited from the inclusion of larger sample sizes in generating useful generalisations, as well as smaller samples which add a more detailed, in-depth understanding of the topic. It is envisaged that the overall findings of this thesis using this approach will add to a growing body of

healthcare research employing mixed methods strategies[15,16], and further assist in bridging the gap between equally valuable methodologies.

Furthermore, this is the first known study to apply ethnographic and HCD principles in a CDL and/ or CLI context. It adds to a growing body of strategies employed to describe the patient experience of CDL and of CLI programmes. Indeed, the interactive nature of CLI programmes encourages the use of research methods like HCD that assess the many factors influencing a patient's mental and physical wellbeing.

The study as a whole provided evidence of the effectiveness of CLI programmes in the management of CDL. This was achieved through a number of statistically significant changes of physical outcomes at programme completion; through the subjective experiences of patients participating in the programme; as well as the observations of interactions between a patient and the programme staff.

6.4 STUDY LIMITATIONS

Sampling limitations in all four studies resulted in an overrepresentation of Caucasians and males in middle and higher income groups. This was due to the fact that CLI programmes are currently only available to a limited sector of the South African population, particularly individuals who are able to afford private sector healthcare, or who subscribe to medical aid schemes. Within that group there may have been additional bias towards individuals who make more use of lifestyle interventions over and above the recommended surgical and pharmacological treatment options. Moreover, more resilient patients may volunteer more frequently to participate in psychological research studies, particularly if they believe it may benefit their recovery process. Furthermore, potential sampling bias by clinic staff has been discussed in detail in Chapter 2. Lastly, the clinical audits described in Chapters 2 and 3 reported a notable attrition of data between the baseline assessment and the assessment at completion of the CLI programme. All of the

above biases must be considered when making any generalisations regarding the characteristics of the CDL cohort.

Other limitations included the study's single setting as well as a lack of longer term observation and follow up of cohorts. Such strategies are commonly implemented in CLI effectiveness research. However this was not the focus of the current group of studies, and future work will be targeted at investigating longer term outcomes.

There are limited reference scores in cohorts with CDL with respect to the psychological factors assessed in the current study. The importance of context in understanding psychosocial constructs including resilience have been emphasised in previous chapters and thus discourage generalisations regarding the scores in this particular population. In addition, psychosocial constructs should preferably be operationally defined in order to improve validity. This is evident when reviewing the existing variations in definition and description of resilience.

Clinical audits have been criticised in the literature for a lack of scientific rigour, and randomised control trials (RCT) continue to be regarded as the "gold standard" of evaluation of interventions. However, the use of control groups is often unethical and impractical, and RCT findings might be difficult to apply[186]. It is incumbent upon clinicians to address current gaps in research, as well as to promote continuing professional development within their specific disciplines, as mandated by The Health Professionals Council of South Africa. This is frequently achieved through conducting regular clinical audits in addition to other non-experimental methodologies to evaluate the effectiveness of patient care. Large clinical databases add to the existing knowledge base as well as promoting evidence-based, best practice in the field concerned. Clinical audits as well as other non-experimental methods of evaluation are therefore increasingly popular, as practitioners emphasise the complementary nature of their use, rather than replacing one with the other[13,186].

Lastly, although the benefits of mixed methods research have been recognised, there are some authors who argue that fundamental differences in quantitative and qualitative approaches prevents the use of both in understanding a particular topic as they may not be referring to the same constructs.

6.5 FUTURE RECOMMENDATIONS

As private and public sector healthcare costs increase, the need for more effective clinical interventions for patients with chronic disease become more exigent. This is particularly relevant in the management of CDL.

Considering the potential for confounding variables in clinical research, the selection, administration and interpretation of psychological assessments in such research contexts should ideally be supervised by a qualified psychologist. In addition, the psychometric properties of measures should be well established within relevant peer-reviewed research and, ideally, within comparable patient cohorts. Furthermore, the majority of psychological measures are subjective and therefore prone to a variety of bias, both by participants as well as those conducting the assessments. Particular care should therefore be exercised in standardising the administration, as well as the scoring and interpretation of psychological measures.

This thesis has discussed the role of qualitative methodologies as adjuncts to clinical research. Specifically, it described the use of interviews in a) identifying psychosocial risk and protective factors potentially influencing a patient's recovery and b) guiding the appropriate tailoring of CLI programmes to the individual. Moreover, interviews revealed psychosocial characteristics specific to CDL cohorts, including trauma and reduced self-efficacy. Although the goal of qualitative methods is not to create generalisable findings, the descriptions of CDL as well as the CLI experience of the patients developed our understanding of this cohort in ways that may not have been accomplished using standardised questionnaires.

Another objective of this thesis was to describe more patient-centred approaches to treating CDL. Ideally this could be achieved through individual tailoring using HCD principles, as demonstrated in the final case study. However, the practicality of such treatment strategies may be limited due to time and financial constraints. It is therefore hoped that a combination of assessment and treatment strategies be utilised in future, making greater use of HCD in everyday clinical practice from the design stages of programmes through to longer term follow up of patient outcomes. Hence, through early identification of potential barriers within a programme, as well

as the promotion of appropriate support structures, resilience can indeed be improved.

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APPENDIX A: DESCRIPTION OF THE *U TURN* CLI PROGRAMME

All data in this thesis were collected from patients enrolled in a CLI programme developed at and run from a sports and exercise medicine (SEM) clinic at the Sports Science Institute of South Africa (SSISA). The *U Turn* programme (previously known as the Chronic Disease Risk Reduction Reversal Programme) is a multi-disciplinary, patient-centred CLI designed to provide optimal health care for patients with a range of established chronic diseases including cardiovascular disease, metabolic and chronic respiratory disorders[13]. The programme is designed to manage both established disease states and recognised risk factors as well as to improve the patient's functional capacity.

The programme provides risk screening, medical assessment, supervised exercise sessions, injury prevention strategies, dietary education and psychosocial support. The exercise component involves 36 one hour sessions held three times a week, either at 7:00 am or 2:00 pm. Individualised exercise and lifestyle prescriptions are developed for patients based on findings from baseline medical, exercise and psychosocial assessments. Exercise recommendations include the intensity, duration, mode and progression of exercise. Moreover, the exercise sessions are supervised by a biokineticist as well as a sports physician, and prompt and appropriate response is available to deal with any potential emergencies during exercise sessions[13].

All patients are screened by the sports physician prior to commencing an exercise session. Screening consists of reviewing the patient's medical history as well as identifying signs and symptoms of conditions which may preclude exercise. If indicated, special investigations may be performed in order to identify conditions potentially increasing the risk of acute medical events during exercise. Patients with contraindications to exercise are not allowed to exercise. Patients participate in an array of exercise training, including aerobic fitness training, muscular strength and endurance training, flexibility training, core stability training and balance exercises. They are taught the correct techniques for each form of exercise in order to maximize benefits and prevent injuries. The principle objectives of exercise training are to improve functional capacity, reduce chronic disease related disability, improve

psychosocial wellbeing and positively alter physiologic and metabolic profiles. Patients identified during screening as requiring a dietary intervention may consult with the dieticians within the SSISA. Furthermore, psychological support is available for patients throughout the programme, especially those at risk for anxiety, depression and psychological distress[13].

Patient education is in the form of lectures and tutorials emailed to each participant on a regular basis. Moreover, medical personnel are available to discuss individual health topics with patients during exercise sessions, or through individual consultation. The topics include introductions to lifestyle and disease, chronic respiratory disease, cardiovascular disease, cancer, diabetes mellitus, hypertension, dyslipidaemia, metabolic syndrome, obesity, arthritic conditions, low back pain, osteoporosis, depression, and exercise training and monitoring.

Prior to completion, patients are reassessed by a biokineticist and a sports physician. This may be followed by a further twelve week programme if indicated[13].

APPENDIX B: CHAPTERS 2 & 3
INFORMATION SHEET AND CONSENT FORM

Derman and Schwellnus Inc
Ground Floor – Sports Medicine Suites *P.O. Box 725*
Sports Science Institute of South Africa *Rondebosch*
Boundary Road, Newlands, 7700 *7701*

Tel: 27-21-659 5644 *Fax: 27-21-659 5633* *email: dns@intekom.co.za*

EXERCISE CONSENT FORM

This rehabilitation programme will include physical exercises, educational activities and other health-related services. The levels of exercise which you will undertake will be based on your cardiovascular response to an exercise stress test. You will be given clear instructions regarding the amount and kind of regular exercise you should do. Exercise sessions may be adjusted by the exercise specialist in consultation with the exercise programme director and physician, depending on your progress.

Your pre-exercise pulse and blood pressure will be monitored. You agree to learn, monitor and record, as instructed by the staff, your own pulse rate before, during and after each exercise session.

There exists the possibility of certain changes occurring during the exercise sessions. These include abnormal blood pressure, fainting, disorders of heart beat, and in rare instances heart attacks, stroke, or death. Every effort will be made to minimize those risks by the provision of appropriate supervision during exercise. Emergency equipment and trained personnel are available to deal with unusual situations that may arise.

Participation in the rehabilitation programme may not benefit you directly in any way. The results obtained may help in evaluating in which types of activities you may engage safely in your daily life. No assurance can be given that the rehabilitation programme will increase your functional capacity although widespread experience and research have indicated that improvement is usually achieved. To gain expected benefits and promote your safely, you must give priority to regular attendance and adherence to prescribed amounts of intensity, duration frequency, progression and type of activity.

The information that is obtained during exercise testing and while participating in the rehabilitation programme will be treated as privileged and confidential. It will not be released or revealed to any person except your referring physician without your written consent. The information obtained, however, may be used for statistical analysis or scientific purpose with your right to privacy retained.

I hereby declare that I do not and will not hold the Sports Science Institute (SSI) or any of its employees liable for any injury or accident to myself, and for any damage, theft or loss of my property for whatever reason.

I, _____ (please print) acknowledge that I have read this form in its entirety or it has been read to me, and that I understand the rehabilitation programme in which I will be participating. I accept the risks, rules and regulations set forth. I consent to participate in this rehabilitation programme.

_____ _____
Signature of patient Witness

Date: _____

APPENDIX C: CHAPTERS 2 & 3 HREC APPROVAL

UNIVERSITY OF CAPE TOWN

Health Sciences Faculty
Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
e-mail: lamees.emjedi@uct.ac.za

27 July 2007

REC REF: 332/2007

Prof W Derman
Human Biology
Sports Science Institute

Dear Prof Derman

PROJECT TITLE: CLINICAL AUDIT: CHRONIC DISEASE RISK REDUCTION AND REVERSAL PROGRAMME

Thank you for your letter to the Research Ethics Committee dated 19 July 2007.

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

signature removed

A/PROF. M. BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

lemjedi

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Annual Progress Report

REC REF Number	332/2007
Title	Clinical audit: Chronic Disease Risk Reduction and Reversal Program
Principal Investigator	Prof Wayne Derman

List of documentation

Progress Report

This project is an ongoing audit of patients involved in our chronic disease risk - reversal programme. At present Tashlin Kaya an MPhil Biokinetics candidate is working with the database to determine predictors of improvement in functional capacity. The other student who is investigating this database is Phillippa Kgamma who is presently working on her PhD. This the work analysing this database is ongoing.

HREC office use only (FWA00001637; IRB00001938)

Approved ✓	This serves as notification of annual approval, including all documentation described above.		
Not approved	See attached comments.		
Type of review	Expedited ✓	Full committee	
Expiry date	30/9/2012		
Signature Chairperson of the HREC	signature removed	Date	28/9/2011

RESEARCH ETHICS COMMITTEE
30 SEP 2011
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

APPENDIX E: CHAPTER 4
INFORMATION SHEET AND CONSENT FORM

U TURN PROGRAMME
INFORMATION SHEET AND INFORMED CONSENT (INTERVIEWS)

In addition to the research currently being undertaken in the *U Turn* Programme, is the goal of understanding the role of psychological characteristics, in recovery from chronic disease. You have already agreed to complete a series of psychological questionnaires investigating various characteristics such as resilience, stress and anxiety. The study would like to better understand the role that these characteristics play in your personal experience of rehabilitation and recovery from chronic disease, and will therefore be recruiting volunteers currently completing the *U Turn* Programme to participate in interviews with the primary investigator.

The interviews will be scheduled at a time convenient to you, and will take place in a private consulting room at the clinic. The interviewer is a registered Counselling Psychologist, completing a doctoral study on the *U Turn* Programme, and is thus bound by ethical standards set out by the Health Professions Council of South Africa, as well as the University of Cape Town Human Research Ethics Committee, ensuring confidentiality and an unbiased account of your responses. The interview will last approximately 45 minutes, and will be recorded using a portable audio recording device which will be visible to you. A copy of the transcript may be reviewed by you to ensure accuracy in transcription, and to make any additional comments. The transcripts and recordings will be kept at the clinic in access controlled storage, and will only be available to the interviewer and her supervisors (see below). Reporting of data will alter or exclude any identifying information of participants, such as names or places of employment. If the interviewing process encourages you to explore any issues raised in more detail, a suitable referral to a psychologist can be arranged.

Informed Consent

I, _____ acknowledge that the exact nature of this research study has been thoroughly explained to me. I will be able to ask questions and raise concerns about the process of interviewing, and these have been discussed and answered to my satisfaction.

I am aware that participation in this component of the study is absolutely voluntary and that I am free to withdraw from the study at any time without stating a reason and without prejudice. I know that any personal information required by the researchers and derived by the interviewing process will remain strictly confidential and will only be revealed as a pseudonym in research reports.

I have carefully read this form together with the information sheet and understand the nature, purpose and procedures of this study. I agree to participate in this research project of the UCT/MRC Research Unit for Exercise and Sport Medicine.

Name of Volunteer: ……

Signature of Volunteer: ……..

Name of Investigator: ……

Signature of Investigator: ……..

Date: ……

Principal Investigator: Philippa Skowno
UCT/MRC Research Unit for Exercise and Sport Medicine.
Mobile: +27 83 302 2174
Email: skwphi001@myuct.ac.za

Supervisor: Prof Wayne Derman
UCT/MRC Research Unit for Exercise and Sport Medicine
Tel: +27 21 650 4661
Email: wayne.derman@uct.ac.za

University of Cape Town Human Research Ethics Council:
Room: E52.23 Old Main Building, Groote Schuur Hospital
Tel: +2721 406 6338
Fax: +2721 406 6411

APPENDIX F: CHAPTER 5
INFORMATION SHEET AND CONSENT FORM

Case Study
Information Sheet

In addition to the research currently being undertaken in the U Turn Programme is the goal of understanding the role of psychological characteristics, such as resilience, in recovery from chronic disease. You have already agreed to complete a series of psychological questionnaires investigating various characteristics such as resilience, stress and anxiety. The study would like to better understand the role that resilience plays in your personal experience of recovery, and will therefore be recruiting volunteers currently completing the U Turn programme to participate in interviews with, as well as observations by the primary investigator. Access to relevant medical records as well as consultation with the staff involved in your treatment is also required. The interviews will be scheduled at a time convenient to you, and will take place in a private consulting room at the clinic. The researcher is a registered Counselling Psychologist, completing a doctoral study on the U Turn Programme, and is thus bound by ethical standards set out by the Health Professions Council of South Africa, as well as the University of Cape Town Human Research Ethics Committee, ensuring confidentiality and an unbiased account of your responses. The interviews will last approximately 20 minutes, and will be recorded using a portable audio recording device which will be visible to you. Observations will be made with the aid of a phone camera and standard note taking, and you will always be made aware of the researcher's presence during observations. A copy of the transcripts and notes may be reviewed by you to ensure accuracy in transcription, and to make any additional comments. The transcripts and recordings will be kept at the clinic in access controlled storage, and will only be available to the interviewer and her supervisors (see below). Reporting of data will alter or exclude any of your identifying information, such as your name or your place of employment. If the interviewing process encourages you to explore any issues raised in more detail, a suitable referral to a psychologist will be arranged.

Informed Consent
I, _____ acknowledge that the exact nature of this research study have been thoroughly explained to me. I was able to ask questions and raise concerns about the process of interviewing and observation, and these have been discussed and answered to my satisfaction. I am aware that participation in this component of the study is absolutely voluntary and that I am free to withdraw from the study at any time without stating a reason and without prejudice. I know that any personal information required by the researchers and derived by the interviewing process will remain strictly confidential and will only be revealed as a pseudonym in research reports. I have carefully read this form together with the information sheet and understand the nature, purpose and procedures of this study. I agree to participate in this research project of the UCT/MRC Research Unit for Exercise and Sport Medicine.

Name of Volunteer: ……
Signature of Volunteer: ……..
Name of Investigator: ……
Signature of Investigator: ……..
Date: ……

Principal Investigator: Philippa Skowno
UCT/MRC Research Unit for Exercise and Sport Medicine.
Mobile: +27 83 302 2174
Email: skwphi001@myuct.ac.za

Supervisor: Prof Wayne Derman
UCT/MRC Research Unit for Exercise and Sport Medicine
Tel: +27 21 650 4661
Email: wayne.derman@uct.ac.za

University of Cape Town Human Research Ethics Council:
Room: E52.23 Old Main Building, Groote Schuur Hospital
Tel: +2721 406 6338
Fax: +2721 406 6411

APPENDIX G: CHAPTER 4 HREC APPROVAL

UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Human Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
e-mail: lamees.emjedi@uct.ac.za
Website address: http://www.health.uct.ac.za/research/humanethics/forms/

12 February 2013

HREC REF: 332/2007

Ms P Skowno
19 Belvedere Road
Rondebosch

Dear Ms Skowno

PROJECT TITLE: CHRONIC DISEASE RISK REDUCTION AND REVERSAL PROGRAMME (CDRRR): ARE PSYCHOLOGICAL MARKERS (RESILIENCE, PSYCHOLOGICAL DISTRESS AND TRI-DIMENSIONAL PERSONALITY PROFILE) PREDICTORS OF PHYSICAL RECOVERY IN PATIENTS WITH CHRONIC DISEASE?

Thank you for your letter to the Faculty of Health Sciences Human Research Ethics Committee dated 11 February 2013.

The HREC has noted and approved the changes to the informed consent form.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

signature removed

PROFESSOR MARC BLOCKMAN
CHAIRPERSON, FHS human research ethics committee

Lemjedi

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS006: Protocol Amendment

HREC office use only (FWA00001637; IRB00001938)			
☑ Approved	☑ Type of review: Expedited	☐ Full committee	
This serves as notification that all changes and documentation described below are approved.			
Signature Chairperson of the HREC	signature removed	Date	14/11/14

Note: All major amendments should include a **PI Synopsis** justifying the changes for the amendment (please see notice dated 23 April 2012)

RESEARCH ETHICS COMMITTEE
2014 -11- 04
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	04 November 2014
HREC REF Number	332/2007
Protocol title	Are psychological markers predictors of successful physical outcomes in patients with chronic disease?
Protocol number (if applicable)	
Principal Investigator	Prof EW Derman
Department / Office Internal Mail Address	MRC Research Unit for Exercise Science and Sports Medicine, Department of Human Biology

1.1 Is this a major or a minor amendment? (see FHS006hlp) Major (tick box) Minor (tick box)	☐ Major	x☐ Minor
1.2 Does this protocol receive US Federal funding?	☐ Yes	x☐ No
1.3 If the amendment is a major amendment and receives US Federal Funding, does the amendment require full committee approval?	☐ Yes	x☐ No

2. List of Proposed Amendments with Revised Version Numbers and Dates

Please itemise on the page below, all amendments with revised version numbers and dates, which need approval.
This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary.

Please refer to attached document. Only additions and no amendments to current protocol.

APPENDIX I: PSYCHOLOGICAL QUESTIONNAIRES

Should the reader wish to obtain copies of the psychological questionnaires utilised in this thesis, they are kindly directed to the following publications and websites:

Conner-Davidson Resilience Scale

http://www.cd-risc.com/#

Spielberger State-Trait Anxiety Inventory

http://www.mindgarden.com/145-state-trait-anxiety-inventory-for-adults

Kessler Distress Scale

http://www.nevdgp.org.au/files/programsupport/mentalhealth/K10_English%5B1%5D.pdf

APPENDIX J: EXTRACT FROM CASE STUDY FIELD NOTES

CASE STUDY NOTES

'POOL' SESSION	25 MAY 2015 4 PM – 4:45 PM

Met LR at reception and chatted for 5-6 minutes before M met us. She'd decided not to swim. She'd only had two sessions since being off sick with 'flu for three weeks (with one session in the pool when she was already sick which was tough – we agreed – no air to breathe!). Other topics were light hearted (I'd highlighted my hair and we joked about not getting natural highlights from the sun anymore). She also showed me her 'guns' (biceps) when I asked about general progress.

[The mood was much more relaxed and familiar between us today, despite not seeing each other for over 6 weeks (most of her programme). This extended into the gym session – LR was much more confident in her ability to operate equipment, to complete fitness tasks, looking almost nonchalant when I remarked on how easy it looked to cycle 6 min as opposed to 2 at the start. Her relationship with M is as easy going and productive. M still explains exercises (particularly the stretches, and reiterates their importance in maintaining condition)].

M arrived with fancier HR monitor after LR said she found a monitor but no strap, M said they were being washed. Resting BP a little higher, M asked her about planning – they explained to me she had a very big project at work which she was stressed about, and involved relying on others who weren't doing their bit. She also joked about her mother telling her she needs drugs (anti anxiety), and she commented that the high BP was because she wasn't on any drugs.

In the gym - They walked 2 laps, too quickly for me to walk and take notes so I stayed behind and caught up note taking during these periods. Also useful so that I didn't have to take notes while talking with them.

Bike – 5 min – I commented how easy it looked and she joked that M shouldn't hear that! Discussing her **recovery** from three weeks off, she said the last two sessions last week she had slept very well the night after, but today it was feeling a lot easier, and M agreed it usually takes a week or so to start feeling better/ normal in the gym.

Main discussion from LR on bike was about the motivation that came from realising she had lost condition after breaks in the programme. It led to musings over how short humans' memories are of what is important etc. I hinted, and LR agreed, that it probably helped her **stay focused** (and not become bored as she'd previously said).

Met them again after losing them on the lap at the 'bat mobile' – I commented that she had conquered it, and she agreed, only indicating fatigue near 6 minutes. They had been discussing, 'where to next' as she is at 27 of 36 sessions. They called her next step a progressive programme, which would include monitoring her on a weekly/ monthly basis as she worked at city based gyms on her own. They also confirmed she'd need to see WD one more time to 'sign her off' as well as complete the online module tests and physical assessments.

After another lap (M explained where they'd be after the lap!) LR was back on the bike for 5-6 minutes. Discussing **expertise** required to look after herself physically. LR said the modules were useful, but sometimes too much information – she agreed with me that she was happy to stay expert at her own profession and allow someone else (WD) to be expert in her health matters (referring to our earlier conversations about the purpose of coming to SSISA). She also agreed it was useful to know the basics, and they discussed how she would complete the modules which had been emailed to her over the first 12 weeks. She joked about expertise with an MA not meaning much, (after my story about a friend just qualifying with a PhD and feeling like a fraud) but that relatively speaking she agreed that it reminds us when explaining our stuff to others that we actually know a lot about our own fields.

After some stretching and balancing work and laughing about young runner on the track having a 'speed wobble' [they think I'm funny!] I had to leave a little earlier, but confirmed last interview with LR and expressed my enthusiasm at seeing her last assessment/ session to 'see how the story ends!' they were both happy with this.

APPENDIX K: HREC APPROVAL FOR AMENDED THESIS TITLE

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS006: Protocol Amendment

HREC office use only (FWA00001637; IRB00001938)			
☑ Approved	☑ Type of review: Expedited	☐ Full committee	
This serves as notification that all changes and documentation described below are approved.			
Signature Chairperson of the HREC	signature removed	Date	23/3/16

Note: All major amendments must include a local **PI Synopsis** justifying the changes for the amendment. Please note that incomplete amendment submissions will not be reviewed.

Comments from the HREC to the Principal Investigator:
HUMAN RESEARCH ETHICS COMMITTEE 16 MAR 2016 HEALTH SCIENCES FACULTY
Note: The approval of this protocol amendment does not grant annual approval. Please complete the FHS016 / FHS017 form for annual approval at least one month before study expiration.

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	15 March 2016
HREC REF Number	332/2007
Protocol title	Chronic disease risk reduction and reversal programme (CDRRR): Are psychological markers (resilience, psychological distress and tri-dimensional personality profile) predictors of physical recovery in patients with chronic diseases of lifestyle
Protocol number (if applicable)	
Principal Investigator	Prof EW Derman
Department / Office Internal Mail Address	Research Division of Exercise Science and Sports Medicine, Department of Human Biology, UCT

1.1 Is this a major or a minor amendment? (see FHS006hlp) Major (tick box) Minor (tick box)		X Minor
1.2 Does this protocol receive US Federal funding?		X No
1.3 If the amendment is a major amendment and receives US Federal Funding, does the amendment require full committee approval?		

2. List of Proposed Amendments with Revised Version Numbers and Dates

Please itemise on the page below, all amendments with revised version numbers and dates, which need approval. This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary.
1. Thesis/ study title CHANGED FROM: **Chronic disease risk reduction and reversal programme (CDRRR): Are psychological markers (resilience, psychological distress and tri-dimensional personality profile) predictors of physical recovery in patients with chronic diseases of lifestyle** CHANGED TO: ***Psychological factors and physical outcomes in patients with chronic diseases of lifestyle*** I decided to simplify the title, and not list psychological variables. I additionally decided to use "factors" rather than "predictors" to reflect the study's exploratory nature. Furthermore, the name of the intervention programme was deemed unnecessary to mention in the title, and was thus excluded in the final version.

3. Protocol status (tick ✓)

	Open to enrolment
	No participants have been enrolled
x	Closed to enrolment (tick ✓) Research-related activities are ongoing Research-related activities are complete, long-term follow-up only Research-related activities are complete, data analysis only

4. Proposed changes will affect: (tick ✓ all the categories that apply)

	Protocol
	Study objectives, design (including investigator's brochure, clinical activities, study length)
	Study instruments, questionnaires, interview schedules
	Sample size
	Recruitment methods
	Eligibility criteria (inclusion and exclusion criteria)
	Drug/device (composition, amount, schedule, route of administration, combination with other drugs/devices, safety information)
	Data collection/ analysis

APPENDIX L: HREC CORRESPONDENCE - STAFF INTERVIEWS

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

11 March 2016

HREC REF: 332/2007

Prof W Derman and Ms P Skowno
Exercise Science and Sports Medicine
Sports Science Institute of South Africa

Dear Prof Derman and Ms Skowno

PROJECT TITLE: CHRONIC DISEASE RISK REDUCTION AND REVERSAL PROGRAMME (CDRRR): ARE PSYCHOLOGICAL MARKERS (RESILIENCE, PSYCHOLOGICAL DISTRESS AND TRI-DIMENSIONAL PERSONALITY PROFILE) PREDICTORS OF PHYSICAL RECOVERY IN PATIENTS WITH CHRONIC DISEASES OF LIFESTYLE

Thank you for your recent correspondence with the Faculty of Health Sciences Human Research Ethics Committee (HREC).

The HREC note that data from the staff interview component of this study, conducted in 2015, never received formal ethics approval. In addition, only verbal informed consent was obtained from staff members who took part in the interviews.

The issues of serious non-compliance, namely the violation of regulations governing human research and deviations from the Human Research Ethics Committee-approved protocol, have thus been documented in the study record.

The HREC acknowledge that the study procedures involved minimal risk to the study participants; that verbal informed consent was obtained; and that individual privacy and the confidentiality of data were maintained.

The HREC cannot provide retrospective approval for data collected without ethics approval. This is in accordance with the National Health Act (NHA) (s 72(1)), which requires that proposals to conduct health research must undergo independent ethics review before the research is commenced. In addition, retrospective review and approval or clearance is not permitted according to s 1.6.9 of the NHREC guidelines for Ethics in Health Research, 2015.

However, the HREC believe that study data were collected ethically. Any use of data from this study (for example, doctoral thesis, publications, conference presentations, grant reports) must be accompanied by this letter, indicating that no formal approval was obtained for the staff interviews component of the study.

Yours sincerely

signature removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

APPENDIX M: HREC CORRESPONDENCE - ADOLESCENT PARTICIPANTS

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

11 March 2016

HREC REF: 332/2007

Prof W Derman and Ms P Skowno
Exercise Science and Sports Medicine
Sports Science Institute of South Africa

Dear Prof Derman and Ms Skowno

PROJECT TITLE: CHRONIC DISEASE RISK REDUCTION AND REVERSAL PROGRAMME (CDRRR): ARE PSYCHOLOGICAL MARKERS (RESILIENCE, PSYCHOLOGICAL DISTRESS AND TRI-DIMENSIONAL PERSONALITY PROFILE) PREDICTORS OF PHYSICAL RECOVERY IN PATIENTS WITH CHRONIC DISEASES OF LIFESTYLE

Thank you for your recent correspondence with the Faculty of Health Sciences Human Research Ethics Committee (HREC). This letter serves to clarify the HREC's position regarding the doctoral thesis examiner's queries regarding the study title; assent/consent for the retrospective record review component of the thesis; and Ministerial permission for the inclusion of adolescent data in the retrospective record review component of the thesis.

The HREC reviewed the study records, and have no evidence of a request to change the study title. The study title that the HREC approved has been included in all study correspondence.

The HREC note that the retrospective record review component of the doctoral thesis included data from adolescents. The HREC do not require assent from minors or consent from parents/legal guardians for retrospective record reviews.

In addition, with regards to the examiner's query regarding Ministerial permission, on 1 March 2012 section 71 of the National Health Act came into effect. This information was made known only on the 23 March. Subsequently, a letter from the National Health Research Ethics Council (NHREC) dated 3 April 2012 explained that the section was promulgated without its accompanying regulations. The letter from the NHREC indicated that it was trying to obtain clarity on how researchers are to meet the new requirements, especially that regarding ministerial consent. It indicated also that the NHREC was aware of the consequent conflict between the newly promulgated legal requirements and the current national research ethics guidelines. Therefore, in light of the letter from the NHREC, UCT supported the continuation of procedures and decision-making as they were implemented immediately before 1 March 2012. Therefore, HREC review and approval of a retrospective record review that included data from adolescents was considered acceptable.

The HREC are therefore satisfied that this component of the doctoral thesis adhered to ethical guidelines, and that the necessary approval was obtained for the retrospective record review component of the thesis.

Yours sincerely

signature removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE