Rehabilitation outcomes of a lifestyle intervention program for chronic disease: medical insurer referred and funded patients versus self-initiated and self-funded patients

A dissertation prepared by Fallon Hope (HPXFAL001) in partial fulfilment of the requirements for the Master of Philosophy degree in Biokinetics (MPhil Biokinetics) from the University of Cape Town

August 2012

Declaration

I, **Fallon Hope**, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Acknowledgements

- Prof Wayne Derman, thank you for your guidance, support, mentorship and most all your patience over the past two years.
- Prof Martin Schwellnus, thank you for always being willing to help when needed.
- Gaby and Yumna, thank you for all your assistance and mentoring over the past year.
- My work colleagues, for all their support and understanding during the rough times.
- To my friends and family, thank you for being supportive, understanding, and for always knowing what to say.
- Trishanta and Esme at The Medical Research Council for their statistical support throughout this study.

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List of abbreviations

CDRRRP	The Chronic Disease Risk Reduction and Reversal program
LDL	Low density Lipoprotein
HDL	High density lipoprotein
WHO	The World Health Organization
UN	United Nations
DALYs	Disability Adjusted Life Years
YLL	Years of Life Lost
YLD	Years Lived with Disability
NGO	Non profit government organization
SADHS	South African Demographic Health Survey
CVD	Cardiovascular Disease
COPD	Chronic obstructive pulmonary disease
DPAS	Diet, Physical Activity and Health Strategy
BMI	Body mass index
ACSM	American College of Sport Medicine
FH	Fedhealth funded group
SF	Self-funded and referred group
SANAS	South African National Accreditation System
ECG	Electrocardiogram
MRC	Medical Research Council of South Africa

T1	Assessment at baseline
T2	Re-assessment at completion of programme at 12 weeks (36 sessions).
NDDM	Non-insulin dependent diabetes mellitus
IDDM	Insulin dependent diabetes mellitus
BYPASS	Coronary artery bypass surgery
HR	Heart rate
BP	Blood pressure

Abstract

Background: Chronic diseases of lifestyle are typically diseases of long duration and slow progression and are the major cause of morbidity and mortality globally [1]. In 2008, 57 million people died worldwide of which 33 million deaths were due to chronic diseases [2]. The burden of chronic disease in low and middle income countries is increasing, yet the capacity for prevention and control thereof is inadequate [2]. It has been suggested that more than 50 % of global deaths can be prevented by combining cost effective national and international efforts as well as individual action to target management of well established risk factors including increasing physical activity, improvement of nutrition, decrease tobacco and alcohol use and implementation of strategies to address adverse psychosocial stress [3].

The Chronic Disease Risk Reduction and Reversal program (CDRRRP) is a lifestyle intervention programme based at the Clinical Sport and Exercise Medicine Practice that is located at the Sports Science Institute of South Africa. The programme caters for patients with established chronic disease including cardiovascular disease, diabetes mellitus, chronic respiratory disease, cancer, fibromyalgia, chronic renal disorders, myopathies, and joint degeneration. The CDRRRP involves a systematic assessment and supervised lifestyle intervention programme (including an exercise regime), focusing on increasing the functional capacity and psychological well-being of these patients. The aims of the programme is to limit the negative physiological and psychological effects of chronic disease, to reduce the risk of further pathologies and events, to stabilize or reverse further progressions of chronic disease, to improve functional and exercise capacity and overall to enhance the patients well being. While many studies have examined the impact of diet or exercise programs on risk, few have examined programs that are multidisciplinary or holistic in nature. In our study, we wanted to determine the patients who were referred and fully funded compared to those who proactively referred and funded themselves through the CDRRRP. It is assumed that all patients will show improvements in the outcome variables and decrease their risk factor levels. However, when comparing the medical insurer referred and funded group of patients to the self funded group of patients, it is hypothesised that the self funded patients will show a greater readiness to change and subsequent adaptation because they have a greater vested interest in their compliance and participation in the CDRRRP due to the fact that they financially funded themselves through the programme.

Objective: The main aims of this dissertation were 1) to review the existing literature focussing on the prevalence, associated risk factors, management and treatment interventions of chronic disease, and 2) to compare rehabilitation outcomes between a pilot group of patients referred and funded to the CDRRRP by their medical insurer, namely Fedhealth (FH) versus a self funded and referred group (SF) of patients with chronic disease, to determine if any differences exist in their outcomes achieved after completing the 12 week programme, and 3) to evaluate the effect of a chronic disease rehabilitation programme on outcomes after 12 weeks (36 sessions) for chronic disease patients.

Methods: This study analyzed if differences existed in outcomes measured between a medical insurer referred and funded group (FH) of chronic disease patients versus a self initiated and funded group (SF) of chronic disease patients after 12 weeks (36 sessions) of a chronic disease rehabilitation programme (CDRRRP). The study also examined the overall effect of the CDRRRP on patients with chronic disease. The main outcomes measured were weight, body mass index, body fat percentage, waist circumference, hip circumference, waist-to-hip ratio, resting heart rate, resting blood pressure, total cholesterol, LDL, HDL and triglyceride concentration as well as, functional capacity measured as the 6 min walk test.

Results: Two hundred and nine patients with chronic disease (176 males [86 %]; 33 females [14 %]) were admitted to the CDRRRP during the observation period. One hundred and seventy nine completed the programme. Paired t-tests were used to assess for changes from baseline to 12 weeks (36 sessions) and completion of the CDRRRP. Between the two groups of patients, namely the funder funded and referred; Fedhealth (FH) group and self funded (SF) group, no significant changes in variables were found. However, there were significant improvements found in the total group of patients from admission (T1) until completion of the 36 session programme. (T2) These differences were noted in the following parameters; total cholesterol concentration (p: 0.0015), LDL concentration (p:0.0001), resting heart rate (p:0.0001), resting systolic blood pressure (p< 0.0001), resting diastolic blood pressure (p< 0.0001), body fat percentage (p< 0.0001), sum of skin folds (p< 0.0001), waist circumference (p< 0.0001), hip circumference (p< 0.0001), waist-to-hip ratio (p< 0.0001), flexibility (p< 0.0001), six minute walk test distance (p< 0.0001), and maximum heart rate (p< 0.0001) . Thus, the programme had the overall effect of favourably altering metabolic, cardiovascular and anthropometric variables as well as improving functional capacity. **Conclusion:** This multidisciplinary lifestyle

intervention program was effective in reducing the chronic disease risk factors among patients with chronic disease. There was no difference in outcomes measured between the two groups, suggestive that there are no differences in adaptation, adherence or compliance amongst patients who are both referred and funded compared with patients who initiate and fund themselves through a chronic disease rehabilitation programme. Future studies should examine whether the changes seen after 12 weeks are increased or sustained.

CHAPTER 1

Introduction and scope of the thesis

Chronic diseases of lifestyle are a major global burden in health care. Currently, these diseases contribute to more than 60 % of all deaths worldwide [1]. More than 80 % of these deaths occur in low-income and middle-income countries [4]. It is projected that the number of deaths due to cardiovascular disease will rise from 17 million in 2008 to 25 million in 2030 [5].

There are four main categories chronic non-communicable diseases, namely cardiovascular disease, diabetes, cancer and chronic respiratory diseases. The majority of the chronic disease of lifestyle share similar risk factors including poor diet, tobacco use, lack of regular exercise and chronic psychosocial stress, and the major risk factors linked to these diseases are high blood pressure, tobacco and alcohol use, high serum cholesterol, physical inactivity and obesity [1].

Previous interventions for chronic disease designed for individual diseases including cardiac, pulmonary, stroke or orthopaedic rehabilitation, have provided favourable results. However, evidence has shown that, within South Africa, more than 50 % of medically insured members have significant co-morbidities namely, more than one simultaneous chronic disease [46,105]. This has created the need for a shift towards developing more patient-centred interventions taking into consideration that patients frequently suffer from a multitude of chronic conditions including musculoskeletal conditions.

It is well known that rehabilitation is an integral component of the care of patients with chronic disease [6]. Multi-disciplinary rehabilitation programmes reduce the impact of chronic disease on health services, communities and the individual. Patients who have access to multi-component rehabilitation services have an improved quality of life through increased functional capacity and a sense of control of their life through improved understanding of their disease and its management. The key components of the optimal chronic disease rehabilitation should include exercise, education, a dietary and nutrition component, psychosocial support and strategies to modify other risk factors.

Therefore the aim of this thesis was to investigate the effects of a chronic disease rehabilitation programme on the health and outcomes in chronic disease patients. An analysis was also conducted

to determine if a difference in rehabilitation outcomes existed between two groups from different referral and funding strategies.

CHAPTER 2

Rehabilitation outcomes of patients with chronic disease to a lifestyle intervention programme: A review of the prevalence of chronic disease and lifestyle interventions

2.1 Introduction

Chronic diseases of lifestyle are typically diseases of long duration and slow progression and are the major cause of morbidity and mortality globally [1]. The World Health Organization (WHO) has identified non-communicable disease as a leading threat to human health and development. There are four main categories chronic disease that constitute this group, namely cardiovascular disease, diabetes, cancer and chronic respiratory diseases. The majority of the chronic diseases of lifestyle share similar risk factors including poor diet, tobacco use, lack of regular exercise and chronic psychosocial stress. The major risk factors linked to these diseases are high blood pressure, tobacco and alcohol use, high cholesterol, physical inactivity and obesity.

2.2 The burden of the chronic diseases of lifestyle

Of the 57 million people deaths globally in 2008, 33 million were due to chronic diseases [2]. More than 80% of these deaths occurred in low-income and middle-income countries [4]. The burden of chronic disease in low and middle income countries is on the rise, yet the capacity for prevention and control thereof is inadequate [1;2;7]. It has been estimated that 32 million deaths from chronic disease could be averted in 10 years in countries that have a high burden of these diseases if global efforts were further widespread and more cost effective interventions endorsed and implemented [8]. It is projected that the number of deaths due to cardiovascular disease will rise from 17 million in 2008 to 25 million in 2030. Cancer deaths are also expected to increase from 7.6 million to 12 million. The total number of deaths due to chronic disease is expected to reach 55 million by 2030 [7;9]. There has been strong evidence presented by the UN General Assembly demonstrating the link between poverty, lack of

education and other social determinants to chronic diseases and their risk factors. This has created an unfavourable cycle whereby chronic disease and the associated risk factors worsen poverty which causes a further increase in chronic disease [10].

In developing countries, 48 % of all chronic disease related deaths occur in people under the age of 70 years. These figures are projected to increase from 10.8 million in 2010 to 15.4 million in 2050. In comparison, deaths from infectious disease are expected to decline by 2 % per year over the next forty years [11].

This prevalence of premature deaths has major adverse social, economic, and health outcomes for these poorer, low income countries [7;12]. Their capacity to effectively cope with a shrinking workforce and sick population is challenged and the healthcare systems and resources are placed under enormous strain.

There is also a negative effect on the individual, who struggles to be productive and healthy. This ultimately affects their earning capacity and potential, impacting on their investment and education opportunities, socioeconomic status as well as their families [11]. On a national level, chronic disease reduces life expectancy which adversely affects economic productivity ultimately depleting the workforce [13]. However, these diseases have a negative effect across all age groups. Indeed, nearly a quarter of all chronic disease related deaths are amongst those aged 60 years old and constitute substantial challenge to the economies, society, families and the sustainability of health care systems internationally. In fact, if no further action is taken to improve the global chronic disease profile, the WHO has estimated by 2020, 73 % more healthy years will be lost to chronic disease [12;14]. Different methods exist to quantify the burden of chronic disease. The mostly used method is the approach that measures the global burden of chronic disease in terms of Disability Adjusted Life Years (DALYs). This is a combination of Years of Life Lost (YLL) through premature death and Years Lived with Disability (YLD). Hence, DALY is considered of as one lost year of healthy life [15].

Global deaths can be prevented by combining cost effective national and international efforts as well as individual action to target the management of well established risk factors by increasing physical activity, improving nutrition, decreasing tobacco and alcohol use and implementing strategies to address adverse psychosocial stress [3;16]. As stated in the UN General report (2011) the knowledge

and technology already exists to tackle the onset and effects of chronic disease and it is up to global health efforts to effectively implement the proven and affordable measures and efforts [10].

Indeed, some countries have established strategies and guidelines to address chronic disease and their associated risk factors, through changes to healthcare infrastructure, new and better funding systems and improved monitoring systems and policy responses [1]. An example of this can be seen in the success of the North Karelia Project in Finland [6]. This project was launched 25 years ago to help reduce the exceptionally high coronary heart disease mortality rates in the area. With the assistance of local and national authorities as well as WHO, the project was designed and implemented to carry out interventions through community organizations and involve health services, schools, NGO's, local media and the food industry. The results of this project are evident in the reduction in nearly all risk factors associated with chronic disease, resulting in a 73 % decrease in cardiovascular mortality rates in 1995 [6].

Unfortunately, these efforts are not repeated, especially in developing countries. A more organized and collaborated movement is needed especially with changes to policies and initiated community-based efforts. Only for the second time in its history, the UN General Assembly held a high level meeting on Non-Communicable Diseases in September 2011 (the first meeting held was for HIV/AIDS in 2001) to create a greater awareness and implement a call to action towards tackling this global crisis [10]. The President of the General Assembly pledged to examine better options to improve prevention and stated "there had been too much focus on too few illnesses." The ban of smoking in restaurants and public areas in New York City was used to illustrate the effective use of public policy and strict campaign implementation in reducing both adult and teenage smoking rates [10]. Key issues that are pivotal to moving forward with chronic disease prevention and awareness are approaches that include cost effective interventions aimed at addressing risk factors, stronger surveillance and monitoring and improved access to basic health care needs. This requires investments both in time and finances but can lead to quick gains in counteracting the effects of chronic disease [6;10].

South Africa is both diverse and unique as seen in its history, economy and population [17]. In South Africa, 33 % of all deaths are due to chronic diseases [18]. Cardiovascular disease accounted for 11 %; cancer 7 %;chronic respiratory disease and diabetes were 3 % respectively and 4 % to other chronic diseases and injuries [18].

The chronic disease trends within South Africa are also affected by the HIV/AIDS epidemic and socioeconomic factors such as poverty, urbanization and industrialization [14;19]. Furthermore, the impact of these chronic diseases is compounded by the high injury rate due to violence, high crimes and traffic accidents. This complex burden of diseases places an excessive demand on the health services in South Africa, stretching it beyond its available resources. However, there has been very little recognition given to the severity of the burden of chronic diseases of lifestyle in South Africa [20].

In 2002, The South African Demographic Health Survey (SADHS) was conducted among the general South African population, and showed that 55 % and 29 % of South African women and men respectively, were overweight, nearly half of the men and women were physically inactive and 42% of men and 11% of women were smokers [20].

Nearly 60 % of all South African adults have at least one major reversible risk factor [19;21]. In 2003, the World Health survey released data indicating that data were released from a World Health survey displaying the following factors attributable to deaths in 2000, tobacco use accounted for 8-9 %, excessive body weight 7 %, alcohol use 7.1 %, physical inactivity 3.3 %; high blood pressure 9 %; high cholesterol 4.6 % and diabetes 4.3 % [22].

2.3 Chronic non-communicable diseases and risk factors.

2.3.1 The four main chronic non-communicable diseases.

The four main chronic non-communicable diseases include:

Cardiovascular Disease (CVD).

Cardiovascular disease includes both the heart and blood vessels. More than 82 % of global mortality is caused by ischemic heart disease, stroke, hypertension and congestive heart failure. Within the past ten years, CVD has become the highest cause of death worldwide [1].

Diabetes.

Diabetes is a metabolic disorder characterized by disordered regulation of blood glucose concentrations. Type 1 diabetes accounts for 5–10 % of patients with diabetes and is characterised

by pancreatic β-cell destruction usually leading to insulin deficiency [23]. Type 2 diabetes accounts for over 90 % of all diabetes and is characterized by insulin resistance and a relative insulin deficiency [24].Type 2 diabetes has important lifestyle associated risk factors that include obesity, physical inactivity, poor nutritional choices and psychosocial factors [23]. Diabetes is a major risk factor for cardiovascular disease, renal disease and blindness leading to increased morbidity and mortality [1].

Cancer.

Cancer is characterized by a rapid growth and division of abnormal cells within a part of the body. These cells have the destructive ability to outlive, metastasize or invade and spread to other parts of the body. There are over 100 different types of cancer as well as different associated risk factors. Cancer is the second highest cause of death worldwide [1]. In South Africa, lung cancer is the leading cause of cancer deaths accounting for 17 %, oesophageal cancer follows with 13 %, cervical cancer 8 %, breast cancer 8 % and liver cancer 6 % [25].

Chronic respiratory disease.

Asthma, Chronic Obstructive Pulmonary Diseases (COPD), respiratory allergies, pulmonary hypertension are the common forms of chronic respiratory diseases [1;26]. The most common of these is COPD, which includes chronic bronchitis and emphysema, and is characterized by the obstruction of airflow; it is progressive and not always reversible [26-28]. Chronic respiratory diseases account for 7 % of all deaths worldwide. [1;26].

2.3.2 The four main risk factors for chronic non-communicable diseases.

Despite the growing public awareness of chronic diseases of lifestyle, there is generally a poor understanding on how the associated risk factors contribute towards the development and progression of the disease. Many patients are uneducated regarding the effect that their lifestyle behaviour choices have on their health and the risk this places on the development and progression of chronic disease. This lack of knowledge and education makes the treatment and management of these disease challenging. Besides poor knowledge of the disease states, the development of many chronic diseases, can largely be attributed to poor lifestyle choices, which includes poor dietary factors, physical inactivity, tobacco and alcohol use and high psychosocial stress [1].

Physical inactivity.

The WHO recently reported strong evidence that physical inactivity contributed towards 80 % of heart disease, stroke, type 2 diabetes and 40 % of cancers [3]. Guthold et al[29] produced data from a survey of 51 countries which showed that 47.6 % of women and 44.7 % of men were physically inactive [29;30]. The 2002 South African Youth Risk Behaviour Survey showed a similar pattern among young people. 43 % of females and 30.5 % of males were physically inactive [30;31].

Physical activity delays the onset of illness and disease and acts directly on the cardiovascular system causing favourable changes in metabolism and body composition and weight. [1]. The health benefits of physical activity increase with an increase in physical activity frequency and intensity. The evidence has shown that the effects of exercise are, short lived. Maintaining these positive changes on health requires a long term commitment to regular consistent exercise [32]. It can be concluded that being physically inactive would be detrimental to one's health especially with respect to the development of chronic disease. In today's society people are finding their lifestyles have been adapted and modified to 'move less'. In fact, a great portion of the populations' occupation requires them to be sedentary. Worksite health promotion programmes have increased over the past decade to tackle this health issue by implementing physical activity initiatives during working hours, such as lunchtime walking groups and worksite exercise programmes and facilities. Subsequently, the WHO developed the Global Strategy on Diet, Physical Activity and Health (DPAS), to promote health awareness by creating environments that allow sustainable healthy behaviours by individuals and communities at national and global levels [33]. Together these actions will lead to a reduction in chronic disease development and deaths [3].

Poor diet.

Lifestyle choices with respect to diet are important in both primary and secondary prevention of chronic disease [22;34]. The change in nutrition and dietary intake due to globalization and urbanization has resulted in foods being more processed and high in sugars, unhealthy fats and refined carbohydrates. This has resulted in obesity related health consequences, which are on the increase, especially in developing countries [18]. Obesity is currently the fifth leading risk factor for global deaths. More than 2.8 million people die globally each year as a result of obesity. Furthermore the burden of, diabetes (44 %), ischemic heart disease (23 %) and cancers (7-41 %) is attributable to obesity [5].

The patterns in consumer consumption have been strongly influenced by the relative price changes for fresh fruits and vegetables, sugars and sweets, and carbonated drinks. A study highlighted by the WHO report 2008 showed the substantial increase in the prices of fresh fruit and vegetables between 1978-2009 and the decrease in prices for sugars, sweets and carbonated drinks. These trends together with the financial recession, has forced people to make food choices based on price and not health [35].

South African diets have also been demonstrated to be high in these foods. Learners frequently consume fast foods (38.8 %), cakes and biscuits (47.4 %), cool drinks and sweets (52 %) at least four days a week. The data also showed that urban and rural areas show similar consumer patterns [6;30].

Tobacco use.

Tobacco use is one of the most modifiable risk factors and preventable causes of death in the world. The World Health Organization (WHO) has attributed four million deaths a year to tobacco. It is estimated that by 2030 smoking will kill one in six people globally [30]. In South Africa, approximately 31 % of men aged 15 years and older smoke daily, compared to only 8 % of women [24].

Individuals who smoke expose themselves to nicotine, tobacco, tar, carbon monoxide and many other harmful chemicals. Smoking increases the risk of at least 50 medical conditions. Interventions such as counselling and pharmacological therapies can be implemented to assist with smoking cessation [22].

Psychosocial stress.

Stress is associated with destructive behaviour patterns and choices and has adverse effects on the body systems. It impacts negatively on hormonal responses, and causes abnormalities in metabolic response, inflammatory response, glucose and insulin control [22]. Anger, depression and anxiety all contribute towards increased risk of cardiovascular disease [22]. Stress is also linked to non compliance with medications and poor lifestyle choices such as dietary choices, smoking, drug addiction and sedentary behaviour [36]. Stress is a modifiable risk factor and there are tools and techniques such as learning to breathe correctly, meditation and regular exercise, which can be implemented to help reduce the affects of stress [22].

2.4 Primary, secondary and tertiary prevention of chronic disease.

Maintaining a healthy lifestyle and engaging in regular physical activity contribute towards primary and secondary prevention of chronic disease [8]. Yet, people with a chronic disease especially cardiovascular disease tend to be overweight and physically inactive [37]. Although the benefits of attending a lifestyle rehabilitation or intervention programme have been well documented, many people with chronic disease still choose to exercise insufficiently and maintain a poor weight and lifestyle. People with chronic disease who do not attend a formal lifestyle intervention programme are thought to have higher risk profiles because of their poor risk factor knowledge and poor lifestyle behaviours [36]. Strategies for disease prevention may be divided into primary, secondary, and tertiary according to the presence or absence of disease and its severity. The term 'prevention' is used with reference to efforts in promoting, protecting and sustaining good health [34]. Recently, the success of reducing chronic disease has been mostly due to secondary and tertiary prevention treatments, yet there needs to be a greater emphasis on primary prevention and better investment and endorsement of medical insurers into tertiary prevention to achieve greater reductions in chronic disease mortality [34]. All tiers of prevention contain similar principles including the use of preventative medications, lifestyle interventions, psychosocial interventions, diet and nutritional interventions, physical activity. These factors are all targeted by educational modules, behaviour interventions and policies by government to improve health of all individuals [34]. Developing a holistic healthcare system that incorporates all levels of prevention, will enable cost effective and achievable improvements in health across all populations.[34]

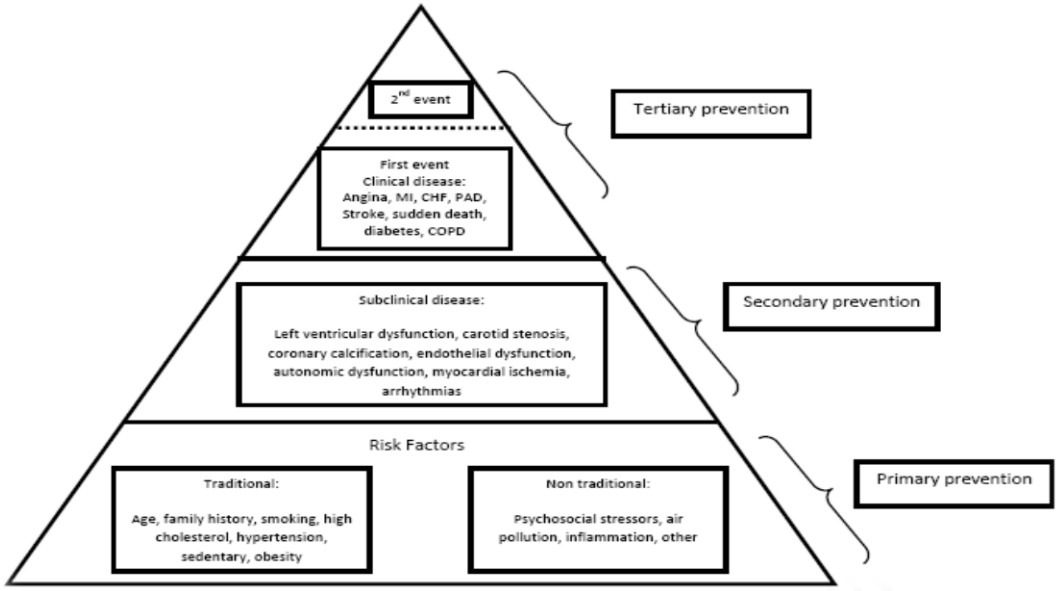

Figure 1. The prevention pyramid consisting of primary, secondary and tertiary levels of prevention

Primary prevention addresses the prevention the development of risk factors in healthy individuals. Primary prevention interventions focus on maintaining a healthy lifestyle, limiting the incidence of disease and associated risk factors and encourage activities that promote good health [34]. Examples include exercising five or more times a week, optimal dietary intake, non-use of alcohol and tobacco, and stress management. It is important this level of prevention starts at government, public policy development, town planning and within the communities.

In the United States, it is estimated that an investment of $10 per person annually in community based programs targeting physical inactivity, poor diet and smoking could save more than $16 billion in medical costs each year over 5 years [38].

Secondary prevention occurs after the identification of risk factors and/or disease. The goals are to reduce the progression of disease through early detection and early treatment [34]. Examples of interventions include the Discovery Vitality “healthy living’ initiative, the Healthy Weight programme at the Sport Science Institute of South Africa and the Greater Green Triangle (GGT) Diabetes Prevention project in Australia [39]. At this level of prevention, the patient is typically asymptomatic but requires the individual to be actively involved in monitoring and managing their associated risk factors.

For example, regular monitoring of cholesterol levels, blood pressure, cessation of smoking, weight reduction, diabetes management, psychosocial stress management and physical activity education and training [40].

Tertiary prevention is practiced after an event or established disease has occurred or has been diagnosed [41]. The goal of tertiary prevention is to improve functional capacity, minimise the effect of the disease, and prevention further complications and events through aggressive management of risk factors and physical and psychological rehabilitation [34]. Interventions within this category are directed at individuals with established disease who are considered high risk. Medically supervised programmes such as The Chronic Disease Risk Reversal and Reduction Programme at the Sport Science Institute of South Africa are designed specifically to meet the needs of these individuals. The concept of high risk is used to describe individuals with three or more risk factors present as well as established disease according to the ACSM [42]. Although only 5-10 % of the total population fall within this tier of prevention, however, it is estimated that the cost of medically treating these individuals contributes to 80 % of total medical insurers costs [43].

Thus, there is a need for interventions on all tiers [8;18]. Yet, in South Africa, the promotion of healthy lifestyles, prevention of chronic disease through early diagnosis and cost effective management of the risk factors seems not to be a high priority in relation to other infectious diseases [41]. The model for patient care, on which most developed and developing countries base their health-care facilities, are based predominantly on acute patient care and do not incorporate the patient in an active way to ensure compliance with long-term medical treatment or the necessary lifestyle modifications [44;45]. Effective management of the chronic diseases of lifestyle requires that the patient becomes an active participant in their own care and treatment.

2.5 Disease specific versus patient centred approach to chronic disease rehabilitation.

Disease centred interventions were introduced in South Africa in the 1970's with the advent of Cardiac Rehabilitation. In the 1990's, the medical aid schemes started a small but active interest in the prevention, diagnosis and treatment of specific diseases. In 2005, the Risk Equalisation Fund

study (completed in South Africa) [45,46], identified that more than half of medical aid members had one or more chronic disease and that some patients were being treated for up to eleven chronic conditions simultaneously [46;47].

The first disease centred programmes introduced were for diabetes and asthma because they were seen as tractable and measurable in terms of the effectiveness of interventions. Although cardiac conditions were more prevalent conditions cardiac programmes were seen less frequently. Jollife et al (2004) conducted a review on cardiac rehabilitation programmes, and found there was a reduction in total mortality in patients who underwent a cardiac programme by 26-31 % [48]. Similarly, benefits were also seen in COPD patients who engaged in a pulmonary rehabilitation programme. There were no improvements in pulmonary function but there were significant improvements in functional and maximal exercise performance, peripheral and respiratory muscle strength, and quality of life. However, there was a 31 % dropout rate of patients by the sixth month and 36 % by the eighteenth month [49]. This is suggestive that these patients who took part in a disease centred intervention did not adopt the necessary lifestyle and behaviour changes that would have been implemented more effectively in a multi-component chronic disease programme.

In Canada, the First Step programme [50] and study evaluated the effects of daily exercise, specifically walking, on glucose control in type 2 diabetics. The results showed an improvement in walking behaviour and biometric measurements at 16 weeks. However, the high rates of relapse by week 24 was also indicative that a stronger, more holistic intervention was needed amongst patients who present with more than one risk factor for chronic disease [50].

The TOHMS study [51] conducted in the United States, investigated the normal pharmacological interventions for the treatment of stage 1 hypertension in conjunction with a lifestyle intervention in comparison to a control group who received a placebo as well as a lifestyle intervention. Results showed continued improvements in weight up to 4 years after the intervention, physical activity increased by 86 % and improved blood pressure and blood lipid profile changes were also recorded. These results also support the role for lifestyle interventions and showed that the implementation of such programmes can be achieved in a clinical setting [51].

The Extensive Lifestyle Management Intervention (ELMI) was evaluated in Canada by Lear et al (2003)[51]. The Extensive Lifestyle Management Intervention (ELMI) was a one-year intervention designed at chronic disease risk factor control and rehabilitation. Patients with ischemic heart disease were followed after completion of a cardiac rehabilitation programme and were randomized to either ELMI or usual patient care. ELMI included exercise sessions, telephone follow-ups and risk factor and lifestyle counselling. The study concluded that a one-year multi-factorial post-cardiac rehabilitation programme intervention resulted in a modest increase in beneficial effects compared to usual care [52]. This again, provides further evidence for the need of a patient centred lifestyle intervention instead of a disease centred approach when treating patients with chronic disease.

A further study in Germany compared multidisciplinary rehabilitation versus usual care for patients with chronic low back pain showed that patients responded better to the multidisciplinary intervention. It was also mentioned that specialized back rehabilitation centres were rare and not readily available for all patients [53].

However, although the health improvements are evident from these disease centred programmes, they are not ideal for patients with multiple diseases. They are not sufficiently comprehensive and only focus on the disease at hand and do not take into consideration the patient and their existing co-morbidities. Access to these programmes is also limited as well as access to resources in terms of educated and qualified staff, facilities and availability to the larger populations who are in need of such treatment and interventions.

Today, some of the leading medical aid schemes or medical insurers have moved towards programmes addressing high-cost individuals who have multiple conditions, a more patient centred approach. The Old Mutual Healthcare Surveys in 2003 showed that 59 % of medical schemes had disease management programmes in place, and indeed have increased from 38 % in 1999. Thus, the focus is slowly shifting to the person rather than the disease [46;47]. However, better developed patient-centred approaches still need to be implemented for environments that lack appropriate resources, such as the primary health care services in the public sector of the country [19].

2.6 Interventions to address the chronic diseases of lifestyle.

"Lifestyle" is a complex concept within the framework of medicine. It refers to a way of living of individuals, families and societies and includes coping mechanisms within their physical, psychosocial and economic environments [17]. Lifestyle also reflects an individual's attitude and values as well as how they view their health. It is therefore the individual that plays an active role in determining their health through daily choices in dietary habits, physical activity, the use of tobacco, alcohol and other risky behaviours [54].

Lifestyle interventions should be used in conjunction with conventional medicine to lower the impact of chronic disease on health services through reduced re-hospitalisation and decrease reliance on other community services and treatment such as medications [55].

Such interventions include nutrition management, physical activity, stress management, sleep management, and smoking cessation. This would involve educating and coaching patients to improve personal lifestyle choices, anxiety and chronic psychosocial stress management as well as risky behaviours and habits [17].

Goble and Worcester (1999) gave a definition of chronic disease rehabilitation that includes concepts from the WHO, the United States Public Health Service and the European Society of Cardiology. They describe rehabilitation as: *'… the coordinated sum of interventions required to ensure the best physical, psychological and social conditions so that patients with chronic or post acute disease may, by their own efforts, preserve or resume optimal functioning in society and, through improved health behaviours, slow or reverse progression of disease.* [45]."

In The United States, The Lifestyle 180 programme [56] was launched at the Cleveland Clinic in 2008 aiming to tackle the burden of chronic disease by focusing on prevention of chronic disease and improved management of diagnosed chronic disease patients through implementation of a holistic set of interventions including correct nutrition, physical activity and stress management [56]. A study by Ricanati et al (2011) evaluated The Lifestyle 180 programme. The programme used class based exercise sessions and on-going follow-ups with its patients for a minimum period of 6 weeks. Results showed that engagement in such a lifestyle intervention programme had significant improvements in biometric and laboratory measurements and a reduction in prescribed medications at a 30 week

assessment [56]. Ultimately, this is the main objective of any chronic disease rehabilitation programme; to achieve reductions is chronic disease related risk factors and enable the patient to obtain a better understanding and control of their chronic condition.

A review by Blue and Black (2005) examined 17 well-controlled studies. The studies targeted physical activity and healthy eating among adults in the community, worksite and medical clinic settings. Goals were set at either weight loss or diabetes prevention and interventions consisted of a combination of educational and behaviour change strategies. Eleven of the 17 studies showed significant positive changes in physiological outcomes, physical activity and healthy eating behaviours. The outcomes were maintained during follow-up periods of up to 5 years [57;58].

Part of the challenge in treating patients with chronic disease with lifestyle intervention programmes is the maintenance of the behaviour changes that take places during the programme. According to the review by Marcus et al (2006) structured exercise programmes have dropout rates ranging from 9-87 % [57]. This is indicative of the challenges related to compliance and adherence amongst chronic disease patients seeking to initiate change and incorporate physical activity into their activities of daily living [57].

A further review by Morgan (2005) concluded that sustainability of appropriate physical activity levels are important for the maintenance of physiological benefits, and the use of follow up consultations are important to ensure physical exercise is sustained and not just used for short term goals [59].

A suggestion by Kendall & Rodgers (2007) [60] and their study concluded, that merely being offered an intervention and knowing that on-going group support is available, may assist individuals to improve their adherence to interventions. They found that a self-management group intervention failed to influence mood, thinking, social roles and self-efficacy. However the intervention tended to maintain a stable level of adjustment over the first year after an event [60].

Another aspect to consider when presenting a lifestyle intervention is the environment and medium in which the programme takes place, especially the exercise component. This has shown to impact on the success or failure in adherence to the programme and maintenance of behaviour changes after completion of the programme in treating chronic disease patients [61].A study by King et al (1992) [62] examined home-based exercise versus group based exercise. Higher adherence rates were seen in

home-based exercising participants over a two year follow-up. Participants had greater flexibility in the choice of physical activity and whether to complete it intermittently or in one single bout.

Studies by Clark et al[63] found that shorter programmes delivered by non-specialist health care professionals in non-clinical settings were least effective in reducing mortality [63;64]. This is further supported by Eakon et al (2000) who found that interventions conducted in healthcare settings and delivered by specialized healthcare providers increased physical activity over a shorter period of time [44;57]. From this evidence, it is important to understand that the medium in which the lifestyle intervention takes place, follow up appointments to help patients feel accountable and, to reinforce the positive changes they continue to make as well as the settings (clinical or home based) all impact adherence and maintenance of lifestyle changes.

Each lifestyle intervention programme incorporates different components in which patients acquire skills such as self-monitoring, goal setting and self-motivation that increase their physical activity levels and long term adherence to on-going changes. Programmes that are too short in duration possibly don't allow individuals enough time to adjust to their new changes and when they continue on their own they have not fully acquired the skills and knowledge to do so. Specialists and professionals working with chronic disease patients will also be able to provide these individuals with valuable knowledge and education about the purpose for each component as well as the appropriate environment in which this should take place. Chronic disease patients need to understand that making lifestyle behaviour changes is a process and requires time, and that there are no short cuts in rectifying poor health behaviours.

Part of the purpose completing a lifestyle intervention and assisting individuals in modifying their lifestyle behaviour to improve on their health status, is to ensure individuals don't become dependent on such programmes and interventions and must be educated about how to continue on their own after completion of their programme. This is often a transition that individuals struggle with and revert back to their old habits. It is important that as a part of these interventions, participants are encouraged to exercise on their own, within safe limitations and demonstrate their 'new' behaviours.

Research has shown that lifestyle interventions could be delivered and enhanced by new technologies such as interactive computer-mediated programs, telephone, or computer web-based forums to reduce these relapses [61]. Programmes that have used new technologies and demonstrated

improvements in health related outcome variables include an Australian study by Vale et al (2003)[65], which identified the benefits of telephone delivered, pedometer-based interventions on physical activity amongst people with cardiac disease. Results showed the method to be effective in reducing body mass index (BMI) [64;65].

The CHOICE programme by Neubeck et al[66] was also found to be effective in improving cardiac risk factors in people with cardiac disease, who had previously not attended any rehabilitation or lifestyle interventions. The programme included a one-on-one consultation and four follow up phone calls [64;66] Results showed improved risk factors including blood pressure, total cholesterol and body mass index [66].

Yet, despite all of the evidence supporting the benefits of lifestyle interventions, challenges still remain. Patients need to maintain their lifestyle changes and clinicians and health care systems need to encourage and educate patients to develop these strategies and incorporate these interventions as part of their treatment and prevention plan, and refer patients into existing programmes [61].

2.7 Barriers to lifestyle changes and adherence

The existing knowledge of barriers to chronic disease risk control is primarily from studies that have indicated the patient's financial difficulties to afford care, physician failure in appropriate clinical treatment, and insufficient self management support for patients and patient non adherence to medication [36].

In other studies, statistics showed that only 22 % of the population in America adhered to regular exercise and only 3 % adhering to healthy diet, regular physical activity, no tobacco use and maintaining normal body weight. This evidence highlights the importance of identifying and understanding these barriers to chronic disease and risk factor control [67].

There have also been gains in understanding the resistance to healthier changes from self reports by patients which highlight the same reasons of financial difficulties, poor coherence between treatment protocols and perceived health and complicated medical treatments [36].

Studies by Crossen et al investigated these barriers by looking at the perceptions of physicians. Common themes emerged as barriers to cardiovascular disease risk control [36]:

- The presence of their co-morbidities and pain
- Poor patient "motivation" to take care of themselves
- Healthcare system barriers preventing physicians from delivering care such as lack of communication with other healthcare providers and lack of financial support
- Difficulties in finding healthcare providers who provide these services, location and time
- Physicians' frustration with patients' poor motivation for maintaining good health, their resistance to treatment prescriptions and adherence
- Physician's belief that these barriers are outside of their control

By creating awareness and a better understanding of the challenges physicians face in 'convincing' patients to make healthier changes could impact positively in the treatment interventions and regimes used for patients [36].

Barriers to an active lifestyle and subsequent strategies to overcome them, were investigated by Brinks et al (2011) [67]. The following factors were identified as contributing towards low adherence rates included time and financial constraints, psychosocial factors, and physical limitations. The study suggested healthcare providers should make use of counselling strategies to assist patients in overcoming these barriers. Motivational interviewing, goal setting and identifying physical and psychosocial limitations were suggested to improve exercise and lifestyle change adherence [67].

To improve on the poor referral rate it is important to understand the barriers to appropriate care, which include issues of patient referral and enrolment in such programmes and the availability and access to chronic disease rehabilitation among women, minorities, and older individuals [36].

Table 2.1 Factors contributing to low referral, enrolment and completion of chronic disease rehabilitation programmes [68]

Factors associated with limited referral and enrolment in chronic disease rehabilitation programmes:

- Gender (females)
- Older age
- Racial/ethnic minority group
- Lack of or limited medical insurer funding
- Low socioeconomic status
- Poor level of education
- Poor health education
- Lack of perceived need for chronic disease rehabilitation
- Language
- Cultural beliefs
- Work-related factors
- Limited social support
- Healthcare system factors
- Lack of referral
- Insufficient enrolment after referral
- Strength of physicians support for chronic disease rehabilitation
- Chronic disease rehabilitation programmes
- Lack of programs in rural areas and low-income communities
- Programme operation hours
- Transportation problems

2.8 Referral into rehabilitation programmes

Although there is evidence to support the benefits of chronic disease rehabilitation programmes and interventions, the use of these programmes is still very low [69]. The referral of patients in need of a lifestyle intervention is infrequent due to various factors including financial costs, awareness of healthcare providers specializing in these interventions and the involvement and co-ordination of medical insurers and health care organizations. A major role of primary health care organizations and medical insurers is to communicate and create networks of referral services to support patients engaging in lifestyle interventions. Brief interventions implemented by general practitioners are not sufficient to achieve the necessary changes needed in high risk patients with chronic disease [70;71].

Grace et al (2011) [72] determined the optimal strategy to maximize cardiac referral, enrolment and participation. The study evaluated three referral strategies compared with usual care of “automatic” referral via discharge card or electronic record, health care provider liaison only, or a combined approach. In-patients with coronary artery disease were used as the study sample. A one-year follow

up assessed the patient's cardiac rehabilitation utilization. The study concluded that automatic referral combined with a patient discussion achieved among the highest rates of cardiac rehabilitation referral. The implementation of such strategies could ensure that more patients being treated for cardiac disease would have access to and realize the benefits of cardiac and chronic disease rehabilitation programmes [72].

Other studies have also shown the enormous impact that physician's recommendations to patients have on influencing patients' lifestyle behaviours [61]. This provides a huge window of opportunity for all physicians to provide information to their patients in making lifestyle changes and engaging in a lifestyle intervention as part of prevention and treatment for chronic disease. Unfortunately, physicians often underestimate the importance and power of their role as health behaviour change counsellors [61]. Thus part of the inconsistency in referral of patients can be explained by the physicians' endorsement of such programmes and the healthcare providers in hospitals to correctly refer patients [73]. A study by Brown et al (2009) [37] found hospital programmes had a higher referral rate than the national average. The study highlighted that increasing referrals into a cardiac rehabilitation programme is but a single factor but enrolling, adherence and completing these programmes continue to provide a major challenge to healthcare providers [68;74].

A further review by Baladay et al (2011) [68] gave insight into different models for delivery of rehabilitation as well as referral strategies into these programmes. They highlighted that patients are very often not referred to participate in a rehabilitation programme and therefore hospital based intervention programmes that have automatic referral from physicians have a much higher referral and enrolment rate [68;75].

Suaya et al (2007) [76] studies found only 14 %-35 % of myocardial infarction survivors and 31 % of coronary bypass graft surgery patients attend cardiac rehabilitation [55;76]. Referral rates were also found to be lower in women, older adults and ethnic minorities [69]. These groups are also less likely to participate in cardiac rehabilitation and more likely to die within 5 years after an initial myocardial infarction [68;76].

Suggestions to improve low referral rates and the utilization of interventions and rehabilitation programmes by Crossen et al[36] are to create patient-specific programmes (such as programmes for women, over 60's etc.), different delivery methods of the programme (e.g. Home-based or internet

based programmes), and increase the medical insurance coverage of these programmes to assist in overcoming these adherence and referral issues [36].

Therefore, there is a need for a better understanding of referral strategies and barriers to lifestyle and behaviour change. Improved methods to identify of these 'red flags' when a patient is referred and enrolled for a chronic disease rehabilitation programme are also needed [77].

In Australia, strategies and referral rates have been enhanced, with the NSW Department of Health implementing strategies such as facilitating inpatient visits by family and appropriate healthcare providers ensuring them of the benefits of rehabilitation, identifying barriers such as transport or financial constraints, follow up phone calls after a patient has been discharged again and possible home visiting services [55].

An established model that has been used in Western Australia to enhance access to chronic disease rehabilitation has had 81 % participation and completion rates for cardiac rehabilitation patients [55]. Reasons for their success has been attributed to policies that allow for recruitment into their programme without a medical referral, enabling the rehabilitation to be incorporated into the medical pathway, inpatient visits to potential patients and follow up phone calls on discharge [55].

2.9 Behaviour change

Understanding the theory of behaviour is very important in working with patients with chronic disease and their rehabilitation. Current knowledge of validated behaviour change theories provides healthcare providers with an understanding of the patient's responses, actions and challenges they face in changing behaviour. With this knowledge, healthcare providers are better able to support patients through these stages and processes [55;78;79].

To successfully achieve ideal lifestyle behaviour modifications requires individuals to make conscious decisions to change [80]. Many individuals struggle to implement new health behaviours because it requires changing their current behaviour and habits. Within lifestyle interventions, such as The Chronic Disease Risk Reversal and Reduction Programme, behaviour modifications are incorporated to help increase the adherence to, and effectiveness of risk related behaviour changes. One of the

goals with behaviour modification is to first identify existing behaviours that contribute to increased health risk. Understanding the patient's barriers to change and adherence also need to be understood to allow for modifications to take place. Part of this process is also the relationship developed between the patient and healthcare provider. In patient-centred programmes, it is important that the healthcare provider displays an understanding of the patient's condition and allow the patient to feel in control and part of their treatment process. The patient needs to show self motivation for change and leadership in managing their treatment [81]. Studies by Armstrong et al (2011) demonstrated the positive effect of behaviour modification, specifically motivational interviewing in treating obese patients who were unsure about making change [82].

Changes to behaviour should be goal orientated and involve small changes. Goals should be applied using the SMART principle (setting goals that are specific, measurable, realistic and time-bound.) This principle enables individuals to be involved with their treatment as well as be realistic about their expectations of treatment and making change [83].

This process of changing behaviour is very complex and is based on the individual's readiness to take action. The Stages of Change model for behaviour change, describes this as a process that occurs over time and in stages. It states there are five stages, each one representing a different time and task. To reach the next stage, the individual needs to spend time completing the tasks. Norcross et al (2011) outline the five stages as follows [84]:

Table 2.2 Transtheoretical Model of the stages of change in behaviour [84]

Stage	**Readiness to change**	**Description**
Pre contemplation	No intention to change	Individual unaware of, or underestimates the problem.
Contemplation	Contemplating change	Individual aware that problem exists but uncommitted to taking action.
Preparation	Planned change	Individual has a definite time set to take action and might be making small changes
Action	Change has been made to behaviour and/or environment	Individual has successfully altered behaviour for a period of less than 6 months.
Maintenance	New behaviour is maintained and relapse has not occurred	Individual consistently engages in new behaviour and works to prevent relapse (> 6 months from initial change)

Another theory that can also be used in lifestyle interventions and by healthcare providers to enable patients to apply change is the Social Cognitive Theory. This theory stipulates that individual characteristics, current behaviour patterns and their environment influence behaviours. According to this theory, for an individual to successfully make change they need to have the motivation and ability to create an environment that will allow behaviour modification [85]. The individual needs to show a high

level of self-efficacy. Social Cognitive theory also includes the individual's ability to change is linked to how capable they are in dealing with environment stressors [86].

There are many concepts shown in both the Stages of Change model and the Social Cognitive theory that allow for both theories to be useful for healthcare provider who treat chronic disease patients. A study by Wadden et al[87] (2005) showed that the inclusion of behaviour modification, in addition to physical activity and dietary interventions resulted in greater success of weight loss as well as the maintenance of weight loss [87].

The use of the these theories as well as motivational interviewing in lifestyle interventions will help create patient-centred programmes aiming to reduce risk factors for chronic disease. Behaviour modification, along with physical activity and dietary intervention should be used in conjunction with one another to allow for the best possible outcome in chronic disease treatment and prevention.

2.10 Conclusion

In conclusion, the burden and impact of chronic disease globally and within South Africa will cripple not only the healthcare system but also the workforce of healthy workers and essentially impact negatively on the economy. Factors contributing to the increase of chronic disease are directly related to poor lifestyle behaviour choices leading to the increase in risk factors associated with chronic disease.

Interventions designed to treat chronic disease are shifting towards patient-centred programmes to allow for the existence of more than one chronic disease treatment in patients with multiple co-morbidities. The literature has shown the positive effect these programmes with regard to reducing risk factor status as well as changing risky behaviours. Multi-component interventions that include physical activity, dietary and stress management have shown the greatest improvements in patients with chronic disease and maintenance thereof.

This thesis aims to examine the difference in rehabilitation outcomes for a group of patients with chronic disease who have been referred and funded by their medical insurer and compare this group to a group of patients who self-referred and funded themselves through a 12 week (36 sessions)

chronic disease lifestyle intervention programme. It is hypothesized that patients will show improvements in the outcome variables and decreases their risk factor levels. However, when comparing the medical insurer referred and funded group of patients to the self funded group of patients, it is hypothesised that the self funded patients will show greater improvement in physiological variables because they might be in a more advanced stage of their readiness to change as they have paid for the programme personally and therefore have a greater “vested interest” in their compliance and extent of participation.

CHAPTER 3

The effects of a comprehensive lifestyle modification programme in cardiac patients: A comparison of rehabilitation outcomes in insurer-funded vs. self-funded patients

3.1 Introduction

More than 50 % of the global deaths are due to chronic non- communicable diseases [9]. The prevalence of these diseases has shown a decline in both industrialized and developed countries but has shown an increase in poorer, low income developing countries [1;2;7].

In South Africa, a third of all deaths are due to chronic disease [1;18]. Cardiovascular disease accounted for 11 %; cancer 7 %; chronic respiratory disease and diabetes were 3 % each respectively and 4 % to other chronic diseases and injuries [1;18]. The chronic disease trends within South Africa are affected by the HIV/AIDS epidemic and socioeconomic factors such as poverty, urbanization and industrialization [19;20]. Furthermore, the impact of these chronic diseases is compounded by the high injury rate due to violence, high crimes and traffic accidents. Thus, this complex burden of disease places an excessive demand on the already stretched health services in South Africa beyond its available resources. However, there has been very little recognition given to the severity of the burden of chronic diseases of lifestyle in South Africa [19;88].

Both globally and within the South African context, cardiovascular disease is the most prevalent of chronic diseases but previous research conducted in this unit (ESSM, University of Cape Town) has shown that more than 60 % of patients taking part in chronic disease rehabilitation programme have significant co-morbidities [14;89].

Furthermore, our research has shown that besides existing medical co-morbidities, musculoskeletal conditions such as osteoarthritis and chronic low back pain are common amongst these patients [67]. Thus, the management of these patients should be patient focused rather than disease focused.

A comprehensive lifestyle intervention programs focuses on promoting regular physical activity, improving dietary factors, managing psychosocial stress, addressing unhealthy social habits (smoking and excess alcohol consumption) and providing comprehensive targeted health education. In contrast, single disease-management programs often place greater emphasis on the management of the complications of one specific chronic disease (e.g. diabetes mellitus), symptoms, and of health-seeking behaviours [8;13].

Interventions designed to modify and control multiple risk factors can have a favourable impact on the progression and even reversal of chronic disease (secondary/tertiary prevention) [41]. Therefore the objective of a comprehensive lifestyle intervention program is to provide patients with information, education and skills to enhance their own involvement and ability to participate in the management of their own health [24].

Lifestyle intervention programmes have generally shown to be effective [51;52;54;64;90-94]. Evidence of improved lifestyle behaviours was seen in two recent studies [91;92] that showed the favourable association between lifestyle factors and the reduced risks of hypertension in healthy women aged 27-44 years old and heart failure in healthy men (mean age 53 years old). Adherence to lifestyle factors, namely, normal body mass index, optimal dietary intake, daily exercise and low alcohol intake were shown to be associated with significantly lower incidence of hypertension [91;92].

Although there is evidence to support the benefits of chronic disease rehabilitation programmes and interventions, the utilization of these programmes is still very low [68]. The referral of patients in need of a lifestyle intervention programme is infrequent due to various factors including financial costs, awareness of healthcare providers specialising in these intervention and the involvement and support of medical insurers [68;74].

A major role of primary health care organisations and medical insurers is to communicate and create networks of referral services to support patients engaging in lifestyle interventions. Brief interventions implemented by general practitioners may not be sufficient to achieve the necessary changes needed in high risk patients with chronic disease [71;72]. Interventions aimed at improvement and rehabilitation of chronic disease should consider all the lifestyle factors and therefore be multi-component in nature, and include promotion of regular physical activity, psychosocial interventions, educational aspects including dietary modification, risk factor management and monitoring to ensure safe participation in

exercise [71]. Educating referring doctors, organizations and medical insurer funders about programme philosophy and cost benefit issues is pivotal in improving chronic disease rehabilitation referral.

Evidence showed that when patients who were eligible for chronic disease rehabilitation in the United States and Canada were asked why they did not attend such programmes, the most frequent response was cited as lack of referral into such programmes. Referrals should include all necessary information and communication between the patient as well as the healthcare provider and the programme they will be enrolling into. Communication and education between the referring doctor and the programmes philosophy and costing information must be included as part of this process [95-97]. This type of system does exist in Australia and Canada where patients in need of a lifestyle intervention after an event requiring hospitalization are automatically referred for such programmes [72].

The Chronic Disease Risk Reduction and Reversal program (CDRRRP) is a patient centred, comprehensive lifestyle intervention programme based at the Sport and Exercise Medicine Clinic that is located at the Sports Science Institute of South Africa. The programme is designed for patients with established chronic disease including cardiovascular disease, diabetes mellitus, chronic respiratory disease, cancer, fibromyalgia, chronic renal disorders, myopathies, and joint degeneration.

This medically supervised programme involves a systematic assessment followed by a lifestyle intervention that includes supervised exercise to increase the functional capacity and psychological well-being of patients. Upon entering the programme each patient is screened and risk stratified by a Sport & Exercise Medicine Physician. Following risk-stratification, patients are further assessed by a biokineticist before commencing their supervised exercise sessions.

Patients enter or are referred to the programme through varying channels. Most patients are self referred having learned of the programme by word-of-mouth or through marketing, or advised to attend by their treating physician. These patients typically pay for the programme themselves and are therefore self-funded. Some of these patients may attempt to claim back the costs of the programme with varying levels of success. Recently, one medical insurer (Fedhealth) has adopted a unique strategy that involves automatic patient identification, notification, referral and payment for patients who are part of their scheme within a 20 km geographic radius of the Programme. It is possible that as the programme is not paid for out of the patients own pocket and they are not self referred to the

programme but referred by a third party (the fund) that the motivation for adherence, effort and therefore adaptation to the programme might not be the same as the self funded and referred group.

Thus, the main aim of this study is to compare physiological, functional and metabolic outcomes between the group of patients referred and funded to the CDRRRP by their medical insurer, (FH) versus a self funded and referred group (SF) of patients with chronic disease, to determine if any differences exist in these groups with respect to their outcomes achieved after completing the 12 week programme. A secondary aim of this thesis was to determine the magnitude of changes in the combined group of patients throughout the duration of the programme.

3.2 Methods

3.2.1 Type of study

This study is a retrospective cohort study to determine if there were differences in outcomes between patients that were funder identified and funded (FH) and a cohort of patients who were self referred and self funded (SF) following a 12-week comprehensive lifestyle intervention programme..

3.2.2. Patient recruitment

As previously described, the chronic disease lifestyle intervention programme of the Sport and Exercise Medicine Clinic, admits patients with a variety of chronic disease states including chronic obstructive pulmonary disease, diabetes, cancer, frailty, depression, chronic arthritis and other conditions. Patients entered the programme through two points of entry. The first group of patients were referred by a single private medical insurer (Fedhealth – FH group) who opted to pro-actively refer patients with certain pre-determined ICD-10 codes within a 20 km radius of the Institute. The second group were either self or cardiologist referred patients who undertook to self fund the programme (SF group).

In this study, to ensure that both groups are similarly matched by diagnosis, only patients who entered the programme with an ICD-10 code for cardiovascular disease (acute myocardial infarction ICD10 code: I21, angioplasty ICD10 code: Z95.5, stent placement ICD10 code: Z95.5, bypass surgery Z95.1, pacemaker ICD10 code: Z95.0) as their primary diagnosis were entered and analyzed. The clinical data was audited from consecutive patients matching these codes who were entered into the

programme between 2006 -2011. The total number of patients who entered the programme and matched the inclusion criteria during the study period was 209. Of the 209 individuals who entered into the programme, 25 did not complete the programme and 5 had incomplete records. These participants were therefore excluded from the analysis (Table 3.1). Reasons for withdrawal included a re-event or illness, financial constraints, difficulty in committing to the dedicated class times, location and accessibility of the programme. Thus, 179 participants with complete data were studied. There were 44 participants in the FH group and 135 participants in the SF had (Table 3.1)

Table 3.1 Recruitment of participants

Cardiovascular Patients	Number of Individuals with complete data	Number of Individuals with incomplete data		Total
		Dropouts	No Records	
All participants	179	25	5	209
SF group	135	21	4	160
FH group	44	4	1	49

SF = Self funded group, FH = Fedhealth group

3.2.3. Clinical assessment

- *History and physical examination*

Upon entry to the programme, all patients underwent a clinical assessment with a sports physician at the Sports and Exercise Medical Clinic located at the Sports Science Institute of South Africa. During this evaluation the doctor performed a thorough medical history and physical examinations as well as necessary special investigations in order to risk stratify the patient. This was conducted in order to determine co-morbidities necessitating other rehabilitation considerations or if contraindications to exercise testing and participation existed and also to determine risk factors or pre-existing musculoskeletal conditions which would necessitate modifications to the patients exercise prescription.

- *Stress electrocardiogram (ECG)*

A requirement for patients at evaluation was to have a recent (within the last 3 months) multistage symptom/sign limited maximal effort electrocardiogram (ECG). The sport physician assessed the patients stress ECG if this had been performed by their cardiologist. If the ECG was not done or

the quality of the effort ECG was not adequate, the patient then completed a stress ECG at the Sports and Exercise Medicine Clinic located at the Sports Science Institute of South Africa. Depending on the risk status of the patient either the Bruce protocol or Modified Bruce protocol was used according to the criteria determined by the American College of Sports Medicine (ACSM)[42]. The treadmill used for this test was a Technogym Medical Range treadmill (Technogym, Pentasystems, and Johannesburg). During this test, systolic and diastolic blood pressure was monitored every three minutes using a Welch Allyn FlexiPort™ sphygmomanometer (Welch Allyn, Skaneateles Falls, NY) and Welch Allyn stethoscope (Welch Allyn, Skaneateles Falls, NY). The sphygmomanometer was placed on the patients left arm and a blood pressure was recorded while they continued with their stress test. A standard 12-lead electrocardiogram (ECG; Mortara Instrument, Inc. Milwaukee, Wisconsin) was used to monitor the patient throughout the protocol. Heart rate was recorded every minute during the stress ECG using the above system. The stress ECG test was terminated according to the ACSM indications for test termination [42]. The purpose of completing a stress ECG before joining the CDRRRP was to ensure the appropriate exercise intensity is prescribed by using a safe and effective heart rate limit.

Patients who had absolute contraindications to exercise testing and exercise training [42] were referred back to their cardiologist for further management of their condition and were asked to return for reassessment once their condition had stabilized. These conditions included; recent changes in resting ECG, unstable angina, acute or chronic heart failure, uncontrolled ventricular and atrial arrhythmia's, third degree AV block without a pacemaker, suspected or known dissecting aneurysm, narrowed aortic stenosis, myocarditis or pericarditis, thrombophlebitis or intra-cardiac thrombi, recent systemic or pulmonary embolus, acute infections, or significant emotional stress. Relative contraindications to programme initiation included inadequately controlled hypertension: resting diastolic blood pressure > 110 mmHg or resting systolic blood pressure > 200 mmHg, moderate valvular disease, electrolyte abnormalities, fixed rate pace-maker , frequent or complex ventricular ectopy, ventricular aneurysm, uncontrolled metabolic disease (i.e. diabetes), chronic infectious disease, neuromuscular, musculoskeletal, or rheumatoid disorders which could be exacerbated by exercise [42].

Patients who did not have any of the above contraindications underwent further assessment that included anthropometrical assessment and tests of functional capacity.

The purpose of this initial evaluation is to ensure safe and individualized exercise prescription and participation in the programme.

3.2.4. Measurement of outcome variables

3.2.4.1 Physiological variables

Physiological variables included the assessment of resting heart rate, blood pressure and anthropometric variables.

- Resting heart rate and brachial blood pressure

A seated resting heart rate and blood pressure was measured after the participant sat and relaxed for a period of five minutes. Heart rate was measured by fitting the patient with a heart rate monitor belt to their chest and wrist watch (Polar Heart rate monitor, model FT2, Finland).The right arm was then lifted so that the brachial artery was level with the heart. A Welch Allyn FlexiPort™ sphygmomanometer cuff (Welch Allyn, Skaneateles Falls, NY) was wrapped around the participant's upper arm, just above the elbow and a Welch Allyn stethoscope (Welch Allyn, Skaneateles Falls, NY) was placed on the hollow of the elbow, over the brachial artery. The cuff pressure was inflated to 160 mm Hg. The cuff pressure was slowly released at a rate equal to 2 to 5 mm Hg per second. Systolic blood pressure was the point where the first of two or more Korotkoff sounds were heard and diastolic blood pressure was the point before the disappearance of the Korotkoff sounds [42].

Anthropometric assessment included height and weight measurements and calculation of body mass index (BMI). Furthermore, skin folds (4 site: triceps; bicep; subscapular and suprailiac), waist and hip circumferences were measured and a waist-to-hip ratio was calculated.

- Body, height and body mass index (BMI)

Body weight was measured using a TCS-A 300 kg Platform Scale (Clover Scales, Maitland, and Cape Town) and height was measured using a Leicester 214 portable stadiometer. *(*Lifemax,

Randparkridge, Johannesburg). Body Mass Index (BMI) was calculated based on these two measurements as described by the ACSM [42].

$$BMI = Weight\ (kg)/Height\ (m)^2$$

- Body fat percentage

Skin folds were measured using a Harpenden Skin fold Dial Gauge Calliper. (Lifemax, Randparkridge, Johannesburg). This is performed to provide an indication of body fat percentage, which was calculated by using the Durnin and Womersley Skin fold Method. Sum of 4 skin fold equation.) [98]. This method involved the measurement of skin folds on the following 4 sites: Biceps, Triceps, Subscapular and Suprailiac.

- Waist-to-hip ratio.

A standard tape measure was used to measure the patient's waist and hip measurement. The patient was asked to stand upright, feet together and arms placed out to the side, whilst breathing normally. The hip measurement is taken from a lateral view at the widest part of the gluteus maximus. The waist measurement is then taken at the base of the rib cage in line with the navel. A ratio was then calculated from the two measurements using the following calculation [42]:

$$\text{Waist-to-Hip ratio:} \quad \frac{\text{Waist measurement (cm)}}{\text{Hip measurement (cm)}}$$

3.2.4.2 Functional variables

The tests of functional capacity used to evaluate patients both at entry and after 12 weeks were the 6 minute walk test and the sit and reach test as an assessment of flexibility.

- The six minute walk test

This test was conducted to assess both functional capacity and heart rate response and recovery [99-101]. Patients were instructed to walk around a 140 m track for a period of 6 minutes and cover as much distance as possible without becoming symptomatic. Prior to starting the test, blood pressure and heart rate was measured and patients were fitted with a heart rate monitor (Polar Heart rate

monitor, model FT2, Finland) to ensure that they exercised within an acceptable heart rate range. Heart rate was also recorded at each lap, as well as at the termination of the test. Time was monitored as each lap that was completed. A 1 minute seated recovery heart rate was also recorded.

- Sit and reach test

This test gave an indication of lower back and hamstring flexibility [102]. A standard measured sit and reach box of 50 cm was used [42]. Patients removed their shoes and started the test with their feet flat against the box and legs straight. The patient started from an upright position, arms straight; keeping middle fingers together and slowly breathed out and leaned forward along the measured box until they could not reach any further, whilst keeping their legs straight [42]. They then returned to the start position. The test was repeated 3 times and the best score of 3 was used. The score was expressed in centimetres (cm).

3.2.4.3 Metabolic variables

Blood test-results upon entry to the program were obtained from the patient's cardiologist and/or general practitioner and the results reviewed. The blood tests analyzed for the purpose of this study, were fasting total cholesterol, LDL, HDL, triglyceride and fasting glucose concentrations. Blood tests were conducted using private pathology laboratories, namely Pathcare (Goodwood, Cape Town) and Metropolis (Milnerton, Cape Town) according to the South African National Accreditation System (SANAS PM SANAS Policy Manual SANAS A01 References, Acronyms and Definitions ISO 15189 Medical Laboratories – Particular requirements for quality and competence ISO/IEC 17025:2005 General requirements for the competence of testing and calibration Laboratories, 2010). Patients were requested to repeat these blood tests (which were important for risk-factor assessment) after 12 weeks on the programme.

3.2.3 Psychological Screening

Upon entry into the programme each participant completed a screening evaluation consisting of several psychological questionnaires, namely the Conner-Davidson Resilience Scale (CD-RISC), Temperament & Character Inventory (TCI) and Tridimensional Personality Questionnaire (TPQ), Kessler Psychological Distress Scale (K10), Life Events Scale, SSSI, STAIT. The purpose for these

questionnaires was to assess the patient's personality type, and provide a marker of anxiety, depression and psychosocial stress. Patients who were assessed as being at risk with respect to these parameters were referred for further psychological counselling. The data from these questionnaires are not reported in this study.

3.2.4 Intervention programme

Patients from both groups attended the CDRRR program for 12 weeks (36 sessions). CDRRP is a medically supervised and closely monitored lifestyle intervention programme that is based at the Sport and Exercise Medicine Clinic that is located at the Sports Science Institute of South Africa. It is presently in its 16th year and over 600 patients completed it. The programme consists of the following components: risk screening, supervised physical exercise sessions and monitoring during exercise, dietary education and intervention, educational modules provision, injury prevention and psychological/psychosocial stress assessment and intervention. The programme biokineticist in consultation with the Sport and Exercise Medicine physician prescribed the intensity, duration, frequency, mode and progression of exercise as well as injury prevention strategies for each patient. Personalized exercise programmes were designed and the patients entered phase 1 namely, the MediFit Elite Care 12 week (36 session) Programme. The programme compromised of 36 one hour exercise sessions, held three times a week at either 7-8am or 2-3pm, Monday, Wednesday and Friday. There were 6 components to the exercise training; cardiovascular fitness, muscular strength muscular endurance, flexibility, core stability and proprioception exercises. These components also formed part of the injury prevention aspect. Patients were taught the correct techniques and exercises for core strengthening and stability, as well as individualized exercises specific to their orthopaedic conditions. The main aim of this program was to increase functional capacity and emotional wellbeing of each patient and encourage the maintenance of healthier lifestyle and behaviour modifications in attempting to reduce chronic disease and related disabilities.

The educational modules comprised of weekly tutorials that were handed out to each patient during their exercise session. During the sessions for the week, the doctor and other staff on duty had the opportunity to discuss these topics and their relevance to improving health status and chronic disease. There were twelve topics, one for each week of the rehabilitation programme. Topics

included introduction to lifestyle and diseases of lifestyle, cardiovascular disease, exercise training and monitoring, "when not to exercise", chronic respiratory disease, diabetes mellitus, cancer, metabolic syndrome, hypertension, dislipidaemia, arthritic conditions, depression, osteoporosis, obesity, and low back pain. Relaxation, breathing and mindfulness based short interventions lasting 10 minutes were given at regular intervals during the programme and patients were encouraged to continue their own practice of these techniques by themselves at home.

The dietary intervention involved referring patients to the dieticians within the Sport Science Institute of South Africa for a comprehensive, individualised dietary consultation.

This study was approved by the Human Ethics Research Committee of the University Of Cape Town Faculty Of Health Sciences (REC REF 332/2007). All patients that engaged in the programme provided written informed consent prior to participation in the lifestyle intervention programme. The patients' personal and medical information was kept within the confines of the CDRRRP database and was not disclosed in any published or written material resulting from this study.

3.2.5 Statistical analysis

The statistical analysis of the study was conducted by the Biostatistics Unit of the Medical Research Council of South Africa (MRC). All data was collected and entered into an excel spreadsheet. The data was analysed using R[1], an open source statistical programming language. (R Development Core Team: A language and Environment for Statistical Computing. *R* foundation for Statistical Computing, http://www.R-project.org)

Firstly to determine whether the programme had an effect on the above mentioned physiological outcomes, a paired t-test, testing for a non-zero difference in the outcome measurements between the first testing occasion (T1) and second testing occasion, 12 weeks later (T2) was carried out.

Secondly, T-tests were performed to determine whether there is a difference in the impact of the programme (T2-T1) between the FH and SF group. T-tests were also used to test for a difference in the baseline measurements between those who completed the programme and those who did not.

Thirdly, to determine whether the data is missing at random with respect to the outcome variables, for each outcome, the baseline outcome (response at time point T1) was regressed against the missingness at time point T2, medical funder status and the interaction between the two.

Fourthly, Chi square tests were performed to test for an association between completion status and medical funder status with and without the individuals with no records. To determine if there was an association between medical funder status and the absence of data for each outcome, chi square tests were also performed.

Lastly, Fisher tests were conducted to test for differences between the two groups with respect to gender, completion status, medications, number of deceased, and the following risk factors: high blood pressure, hypercholesterolemia, diabetes, family history, overweight, sedentary, and smoker status.

3.3. Results

3.3.1 Demographics, disease profile, risk factors and medications use in all participants and in the FH and SF groups

The demographics of all participants, the Fedhealth group (FH) and the Self funders group (SF) is depicted in table 3.2

Table 3.2 Demographics of all participants, the FH group and SF group

	All (n = 179)	FH (n = 44)	SF (n = 135)	P-value
Age (years)	59 (12)	59 (11)	59 (13)	ns
Male (%)	86	82	87	ns
Height (m)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)	ns
Weight (kg)	87.9 (18.4)	85.4 (16.9)	88.7 (18.7)	ns
BMI (kg/m^2)	29.7 (5.8)	29.5 (5.7)	29.6 (5.7)	ns

n= represents the number of participants,
Values are represented by the mean and standard deviation in brackets, except for males, represented as a % of the group.
FH = Fedhealth group, SF = Self funders group.
% = percentage; m = meters; kg = kilogram; kg/m^2 = kilogram per meter squared.
ns = no significant difference between the FH and SF groups

The mean age of all participants was 59 ± 12 years, and more participants in the study were male (86 %). The mean height was 1.7 ± 0.1 m, weight was 87.9 ± 18.4 kg and body mass index was 29.7 ± 5.8 kg/m^2.

Within the FH group, the mean age of all participants was 59 ± 11 years, and more participants were male (82 %). The mean height was 1.7 ± 0.1 m, weight was 85.4 ± 16.9 kg and body mass index was 29.5 ± 5.7 kg/m^2. Within the SF group, the mean age of all participants was 59 ± 13 years, and more participants were male (87 %). The mean height was 1.7 ± 0.1 m, weight was 88.7 ± 18.7 kg and body mass index was 29.6 ± 5.7 kg/m^2. There were no significant differences in age, gender, height, weight or body mass index between the FH and SF groups.

The disease profiles upon entry into the CDRRRP of all participants, the Fedhealth group and Self

funders group is depicted in table 3.3

Table 3.3 The disease profiles of all participants, the FH group and SF group

Diagnosis	ALL (n=179)	FH (n = 44)	SF (n=135)	P-value
1.Cardiovascular disease	175 (97.8)	44 (100.0)	131 (97.0)	ns
a. Ischemic heart disease	143 (79.9)	41 (93.2)	102 (75.6)	0.01
• Myocardial infarction	75 (41.9)	24 (54.5)	51 (37.8)	ns
• Angioplasty with no stent	4 (2.2)	2 (4.5)	2 (1.5)	ns
• Angioplasty and Stent	66 (36.9)	23 (52.3)	43 (31.9)	0.019
• Bypass	55 (30.7)	16 (36.4)	39 (28.9)	ns
b. Arrhythmias	38 (21.2)	8 (18.2)	30 (22.2)	ns
• Arrhythmia medicated	18 (10.1)	2 (4.5)	16 (11.9)	ns
• Arrhythmia and pacemaker	18 (10.1)	4 (9.1)	14 (10.4)	ns
c. Valvular heart disease	18 (10.1)	6 (13.6)	12 (8.9)	ns
d. Heart Failure	16 (8.9)	2 (4.5)	14 (10.4)	ns
• Cardiomyopathy (dilated / idiopathic)	8 (4.5)	-	8 (5.9)	ns
• Ischemic cardiomyopathy	2 (1.1)	-	2 (1.5)	ns
e.Cardiac transplant	1 (0.6)	1 (2.3)	-	ns
f. Peripheral vascular disease	8 (4.5)	2 (4.5)	6 (4.4)	ns
g. Other (including aneurysm)	3 (1.7)	-	3 (2.2)	ns
2.Chronic respiratory disease	15 (8.4)	4 (9.1)	11 (8.1)	ns
a. Bronchiectasis	2 (1.1)	-	2 (1.5)	ns
b. Chronic obstructive pulmonary disease	4 (2.2)	-	4 (3.0)	ns
c. Asthma	8 (4.5)	3 (6.8)	5 (3.7)	ns
d. Sarcodosis	1 (0.6)	1 (2.3)	-	ns
3.Metabollic disease	48 (26.8)	11 (25.0)	37 (27.4)	ns
a. NDDM	39 (21.8)	10 (22.7)	29 (21.5)	ns
b. IDDM	5 (2.8)	-	5 (3.7)	ns
c. Gout	6 (3.4)	1 (2.3)	5 (3.7)	ns
e. Amiodron induced thyrotoicsis	1 (0.6)	1 (2.3)	-	ns
4.Rheumatological disease	14 (7.8)	4 (9.1)	10 (7.4)	ns
a. Rheumatoid arthritis	7 (3.9)	4 (9.1)	3 (2.2)	ns
b. Fibromyalgia	2 (1.1)	-	2 (1.5)	ns
c. Hematocrosis	1 (0.6)	-	1 (0.7)	ns
d. Polyerythromia Ruba Vera	1 (0.6)	-	1 (0.7)	ns
e. Osteoporosis	3 (1.7)	1 (2.3)	2 (1.5)	ns
f. Polymyalgia Rheumatica	1 (0.6)	-	1 (0.7)	ns
5.Immuniological disease	16 (8.9)	2 (4.5)	14 (10.4)	ns
a. Cancer	14 (7.8)	2 (4.5)	12 (8.9)	ns
b. Ulcerative Colitis	1 (0.6)	-	1 (0.7)	ns
c. Myeloproliferative Syndrome	1 (0.6)	-	1 (0.7)	ns
d. Anaemia	1 (0.6)	-	1 (0.7)	ns

6.Cognitive and psychological	9 (5.0)	-	9 (6.7)	ns
a. Depression	4 (2.2)	-	4 (3.0)	ns
b. ADHD	1 (0.6)	-	1 (0.7)	ns
c. Sleep apnoea	3 (1.7)	-	3 (2.2)	ns
d. Anxiety	1 (0.6)	-	1 (0.7)	ns
7.Neurological disease	6 (3.4)	1 (2.3)	5 (3.7)	ns
a. Right side CVA	4 (2.2)	1 (2.3)	3 (2.2)	ns
b. Peripheral neuropathy	1 (0.6)	-	1 (0.7)	ns
c. Epilepsy	1 (0.6)	-	1 (0.7)	ns
8.Orthopaedic conditions	9 (5.0)	3 (6.8)	6 (4.4)	ns
9.Renal	6 (3.4)	1 (2.3)	5 (3.7)	ns
10.Other	6 (3.4)	-	6 (4.4)	ns

FH= Fedhealth group; SF= Self funded group; NDDM = Non insulin dependent diabetes mellitus; IDDM = Insulin dependent diabetes mellitus; ADHD = Attention deficit hyperactivity disorder; CVA = Cerebral-vascular accident
ns = no significant difference between the FH and SF groups

Of all participants who entered the programme 79.9 % had ischemic heart disease. The majority of these ischemic heart disease participants had myocardial infarction (36.9 %) and an angioplasty with stent (36.9 %). Other participants with cardiovascular diseases included those with arrhythmias (21.2 %), bypass (30.7 %), valvular heart disease (10.1 %), heart failure (8.9 %), peripheral vascular disease (4.5 %) and other disease including aneurysms (1.7 %). In addition, 26.8 % had existing metabolic disease, 8.9 % immunological diseases, 8.4 % chronic respiratory diseases, 7.8 % had rheumatological diseases and less than 5 % had orthopaedic, cognitive and psychological and neurological conditions.

Of the FH group 93.2 % had ischemic heart disease. The majority of these patients had myocardial infarction (54.5 %) and an angioplasty with stent (52.3 %). Other cardiovascular diseases included those with bypass (36.4 %), arrhythmias (18.2 %), valvular heart disease (13.6 %), heart failure (4.5 %) and peripheral vascular disease (4.5 %). In addition, 25 % had existing metabolic disease, 9.1 % chronic respiratory diseases and rheumatological diseases each and less than 5 % had immunological, orthopaedic, neurological and cognitive and psychological conditions.

Of the SF group, 75.6 % had ischemic heart disease. The majority of these had myocardial infarction (37.8 %) and an angioplasty with stent (31.9 %). Other cardiovascular diseases included those with bypass (28.9 %), arrhythmias (22.2 %), valvular heart disease (8.9 %), heart failure (10.4 %) , peripheral vascular disease (4.4 %) and other including aneurysms (2.2 %). In addition 27.4 % had

existing metabolic disease, 10.4 % immunological diseases, 8.1 % chronic respiratory diseases, 7.4 % rheumatological diseases, 6.7% cognitive and psychological conditions and less than 5 % had orthopaedic and neurological conditions.

There was a significant difference in the FH group and SF groups with respect to prevalence of ischemic heart disease (p: 0.01) and angioplasty with stent placement (p: 0.019). The FH group had a higher prevalence of participants with ischemic heart disease and angioplasty with stent placements (p: 0.019) when compared to the SF group.

The prevalence of risk factors for cardiovascular disease in all participants and the FH and SF groups is depicted in table 3.4.

Table 3.4 The prevalence (% of participants) of risk factors for cardiovascular disease in all participants and in the FH group and SF group

Risk Factor	All (n = 179)	FH (n = 44)	SF (n = 135)	P-value
Gender (males)	154 (86)	36 (82)	118 (87)	ns
Hypertension	100 (56)	22 (50)	78 (58)	ns
Hypercholesterolemia	129 (72)	34 (77)	95 (70)	ns
Diabetes	46 (26)	9 (21)	37 (27)	ns
Family history	113 (63)	28 (64)	85 (63)	ns
Overweight	103 (57)	26 (59)	77 (57)	ns
Sedentary	122 (68)	34 (77)	88 (65)	ns
Smoker	28 (16)	6 (14)	22 (16)	ns

FH= Fedhealth group; SF= Self funded group
Values are the number of participants with percentage of group in brackets
ns = no significant difference between the FH and SF groups

Of the total 179 participants who entered the programme 56 % were hypertensive, 72 % had elevated serum cholesterol concentrations (hypercholesterolemia), 26 % had diabetes mellitus, 63 % had a family history of cardiovascular disease, 57 % were classified as overweight, 68 % were sedentary and 16 % were smokers (Table 3.4).

In the 44 participants from the FH group who entered the programme 50 % were hypertensive, 77 % had elevated cholesterol (hypercholesterolemia), 21 % had diabetes, 64 % had a family history of cardiovascular disease, 59 % were classified as overweight, 77 % were sedentary and 14 % were

smokers (Table 3.3). Within the 135 participants from the Self funded group who entered the programme 58 % were hypertensive, 70 % had elevated cholesterol (hypercholesterolemia), 27 % had diabetes, 63 % had a family history of cardiovascular disease, 57 % were classified as overweight, 65 % were sedentary and 16 % were smokers (Table 3.3). There were no significant differences in the prevalence of risk factors for cardiovascular disease between the FH group and the SF group.

The medications used by all participants, the FH group and the SF group is depicted in table 3.5.

Table 3.5 Medication use in all participants, the FH group and the SF group

Medications	All (n = 179)	FH (n = 44)	SF (n = 135)	P-value†
Platelet aggregation inhibitors	139 (77.7)	41 (93.2)	98 (72.6)	0.003
Statin agents	133 (74.3)	40 (90.9)	93 (68.9)	0.003
Antiarrhythmic agents	10 (5.6)	2 (4.5)	8 (5.9)	ns
Nitrates	6 (3.4)	6 (13.6)	-	< 0.001
Calcium channel blockers	17 (9.5)	4 (9.1)	13 (9.6)	ns
Vitamin K antagonists	19 (10.6)	3 (6.8)	16 (11.9)	ns
Anti-diabetic agents: Oral	36 (20.1)	7 (15.9)	29 (21.5)	ns
Beta-receptor blockers	64 (35.8)	17 (38.6)	47 (34.8)	ns
Alpha- and beta receptor blockers	20 (11.2)	5 (11.4)	15 (11.1)	ns
Angiotensin receptor antagonists	22 (12.3)	7 (15.9)	15 (11.1)	ns
Oestrogens	1 (0.6)	1 (2.3)	-	ns
Bronchodilators	1 (0.6)	-	1 (0.7)	ns
Folic acid and derivatives	6 (3.4)	4 (9.1)	2 (1.5)	0.033
Anti-protozal agents (anti-microbials)	1 (0.6)	-	1 (0.7)	ns
Diuretics	26 (14.5)	4 (9.1)	22 (16.3)	ns
ACE inhibitors	66 (36.9)	16 (36.4)	50 (37.0)	ns
Anti-depressants	16 (8.9)	4 (9.1)	12 (8.9)	ns
Serotonin and noradrenaline reuptake inhibitors	1 (0.6)	-	1 (0.7)	ns
Endocrine system - Thyroid	3 (1.7)	1 (2.3)	2 (1.5)	ns
Anti-diabetic agents: Insulin	12 (6.7)	2 (4.5)	10 (7.4)	ns
Coxibs - selective inhibitors of COX-2	3 (1.7)	-	3 (2.2)	ns
Hormone replacement therapy	2 (1.1)	-	2 (1.5)	ns
Glucocorticoids	9 (5.0)	3 (6.8)	6 (4.4)	ns
Positive iniotropic agents - cardiac glycosides	3 (1.7)	-	3 (2.2)	ns
Anti-viral agents	1 (0.6)	1 (2.3)	-	ns
Anti-gout agents	11 (6.1)	1 (2.3)	10 (7.4)	ns
Antiepileptic agents	3 (1.7)	-	3 (2.2)	ns
Antimetabolites - Folic acid analogues	3 (1.7)	2 (4.5)	1 (0.7)	ns
Proton pump inhibitors	11 (6.1)	1 (2.3)	10 (7.4)	ns

Hypnotics and sedatives - benzodiazepine derivatives	8 (4.5)	2 (4.5)	6 (4.4)	ns
Anxiolytics - Benzodiazepine derivatives	5 (2.8)	1 (2.3)	4 (3.0)	ns
Topical corticosteroids	3 (1.7)	-	3 (2.2)	ns
Anaesthetic	1 (0.6)	-	1 (0.7)	ns
Potassium supplements	4 (2.2)	-	4 (3.0)	ns
Analgesics	1 (0.6)	-	1 (0.7)	ns
Drugs used in benign prostatic hypertrophy alpha-adrenoreceptor antagonists	2 (1.1)	-	2 (1.5)	ns
Chemotherapy	1 (0.6)	1 (2.3)	-	ns
nasal decongestant	2 (1.1)	1 (2.3)	1 (0.7)	ns
Ascorbic acid (vitamin C)	1 (0.6)	1 (2.3)	-	ns
Tetracyclines	1 (0.6)	1 (2.3)	-	ns
Anticholinergics	1 (0.6)	1 (2.3)	-	ns
Antihistamine	1 (0.6)	-	1 (0.7)	ns
Magnesium supplements	1 (0.6)	-	1 (0.7)	ns
Androgens - testosterone	1 (0.6)	-	1 (0.7)	ns
Propionic acid derivatives	1 (0.6)	-	1 (0.7)	ns
Vitamin B Group	-	1 (0.7)	1 (0.6)	ns

FH= Fedhealth group; SF= Self funded group
Values are the number of participants with percentage of group in brackets
ns = no significant difference between the FH and SF groups

Within the total group of participants, platelet aggregation inhibitors (77.7 %) and statins (74.3 %) were the mostly prescribed medications. 36.9 % of all the participants were using ACE inhibitors and 35.8 % were using Beta-blockers. 20.1 % of all participants were also using oral anti-diabetic medications and 6.7 % used insulin

In the FH group, 93.2 % of participants were prescribed platelet aggregation inhibitors and 90.9 % were using statins. 38.6 % were using beta-blockers and 36.4 % used ACE inhibitors.15.9 % of participants were also using anti-diabetic medications (oral) and 4.5 % used insulin. Within the SF group 72.6 % were prescribed platelet aggregation inhibitors and 68.9 % were using statins. 37 % used ACE inhibitors and 34.8 % were using beta-blockers. 21.5 % of participants were also using anti-diabetic medications (oral) and 7.4 % used insulin.

There was a significant difference between the FH and SF group in some of the medications used. The FH group had a higher use of platelet aggregation inhibitors (93.2%) (p= 0.003) and statins

(90.9%) (p= 0.003) when compared to the SF group. However, the SF group had a higher use of organic nitrates (13.6%) than the FH group (3.4%) (p<0.001).

3.3.2 The physiological, functional and metabolic variables for all participants, the Fedhealth group (FH) and the Self funders group (SF) at entry into the programme (T1)

The physiological variables for all participants, in both the FH group and the SF group is depicted in table 3.6.

Table 3.6 Physiological variables for all participants, in the FH group and the SF group at entry into the programme (T1)

	All (n = 179)		FH (n = 44)		SF (n = 135)		
Physiological variable	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**P-Value**
Resting HR (b/min)	73 (13)	178	72 (12)	44	73 (13)	131	ns
Resting BP: Systolic (mmHg)	126 (16)	178	127 (13)	44	126 (16)	131	ns
Resting BP: Diastolic (mmHg)	78 (10)	178	77 (10)	44	78 (10)	131	ns
Weight (kg)	87.9 (18.4)	178	85.4 (16.9)	44	88.7 (18.7)	131	ns
Height (m)	1.7 (0.1)	177	1.7 (0.1)	44	1.7 (0.1)	131	ns
BMI (kg/m^2)	29.7 (5.8)	178	29.5 (5.7)	44	29.8(5.9)	132	ns
Percentage Body Fat (%)	29.9 (6.1)	171	30.4 (7)	43	29.7 (5.8)	123	ns
Sum Of Skin folds (mm)	73.6 (28.2)	172	74.4 (30.5)	43	73.4 (27.6)	126	ns
Waist (cm)	100 (15)	177	99 (14)	44	101 (15)	129	ns
Hip (cm)	105 (12)	177	105 (11)	44	105 (12)	129	ns
Waist to Hip Ratio	1 (0.1)	178	0.9 (0.1)	44	1 (0.1)	133	ns

FH = Fedhealth; SF = Self funders group
N = number of participants; SD = standard deviation
HR = heart rate; B/min = beats per minute; BP = blood pressure; mmHg =millimetres of mercury; kg = kilograms; m = meters; kg/m^2 = kilogram per meter squared; % = percentage; Mm = millimetre; Cm = centimetre
ns = no significant difference between the FH and SF groups

Upon entry into the programme (T1), there were no significant differences in resting heart rate, resting systolic and diastolic blood pressure, weight, height, body mass index, body fat percentage, sum of skin folds, waist and hip circumference and waist to hip ratio between the FH group and SF groups. However, weight and waist circumference tended to be higher in the SF group compared to the FH group.

The functional variables for all participants, the FH group and the SF group is depicted in table 3.7.

Table 3.7 The cardiovascular and functional capacity variables for all participants, the FH group and the SF group at entry into the programme (T1)

	All (n = 179)		FH (n = 44)		SF (n = 135)		P-Value
Variables	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**N**	ns
Resting HR (b/min)	73 (13)	178	72 (12)	44	73 (13)	134	ns
Resting BP: Systolic (mmHg)	126 (16)	178	127 (13)	44	126 (16)	134	ns
Resting BP: Diastolic (mmHg)	78 (10)	178	77 (10)	44	78 (10)	134	ns
Flexibility (cm)	12 (12)	151	11 (9)	38	12 (12)	113	ns
6 minute walk distance (m)	561 (154)	171	537 (125)	42	569 (162)	129	ns
Max HR (b/min)	118 (21)	166	115 (19)	40	117 (23)	120	ns
Rec HR 1min (b/min)	92 (16)	139	91 (14)	38	91 (17)	93	ns

FH = Fedhealth; SF = Self funders group
N = number of participants; SD = standard deviation
HR = heart rate; B/min = beats per minute; BP = blood pressure; mmHg =millimetres of mercury; Cm = centimetre; m = meters; max = maximum heart rate during six minute walk test; Rec = recovery
ns = no significant difference between the FH and SF groups

There were no significant differences in the resting cardiovascular and functional capacity variables (resting heart rate, systolic and diastolic blood pressure, flexibility, six minute walk test distance, maximum heart rate achieved during the six minute walk test and recovery heart rate after the six minute walk test) between the FH group or SF group upon entry (T1) into the programme. However, the SF group's six minute walk distance tended to be higher (569 m) than the FH group (537 m).

The metabolic variables for all participants, the FH group and the SF group is depicted in table 3.8.

Table 3.8 The metabolic variables for all participants, the FH group and the SF group at entry into the programme (T1)

	All (n = 179)		FH (n = 44)		SF (n = 135)		P-Value
Metabolic variable	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**N**	ns
[Total cholesterol] (mmol/L)	4.6 (1.2)	122	4.5 (1.1)	35	4.6 (1.2)	87	ns
[HDL] (mmol/L)	1.2 (0.7)	117	1.4 (0.9)	33	1.1 (0.5)	84	ns
[LDL] (mmol/L)	2.9 (1)	117	2.8 (0.9)	34	2.9 (1.0)	83	ns
[Triglyceride] (mmol/L)	1.4 (0.6)	114	1.5 (0.8)	32	1.4 (1.0)	82	ns
Fasting [glucose] (mmol/L)	6.0 (1.4)	86	6.3 (1.9)	31	6.0 (1.5)	55	ns

FH = Fedhealth; SF = Self funders group
N = number of participants; SD = standard deviation
Mmol/L = millimole per litre; HDL =high density lipoprotein; LDL; low density lipoprotein
ns = no significant difference between the FH and SF groups

There were no significant differences in the majority of metabolic variables (total cholesterol, HDL, LDL, triglycerides and fasting glucose) between the FH group and SF group upon entry (T1) into the programme.

3.3.3 The effects of the 12 week intervention (CDRRRP) on the physiological, functional and metabolic variables in the FH group and SF group (T1 = entry, T2 = after 12 weeks of intervention)

The physiological variables upon entry (T1) and at completion of the 12 weeks (36 sessions) (T2) in the FH group and SF group in depicted in table 3.9.

Table 3.9 The physiological variables upon entry (T1) and at completion of the 12 weeks (36 sessions) (T2) in the FH group and SF group

Variable	Group *	T1**	T2**	P-value
Weight (kg)	FH (44)	85.4 (16.9)	84.8 (15.9)	ns
	SF (131)	88.7 (18.7)	88.9 (18.8)	ns
BMI (kg/m2)	FH (44)	29.5 (5.7)	29.2 (5.2)	ns
	SF (132)	29.8 (5.7)	29.7 (5.6)	ns
Percentage Body Fat (%)	FH (42)	30.4 (7)	29 (6.8)	0.0008
	SF (123)	29.7 (5.8)	28.1 (5.7)	<0.0001
Sum Of Skin folds (mm)	FH (42)	74.4 (30.5)	66.9 (26.1)	<0.0001
	SF (126)	73.5 (27.3)	65.4 (24.6)	<0.0001
Waist (cm)	FH (43)	99 (14)	96 (12)	0.0017
	SF (129)	101 (15)	98 (14.3)	<0.0001
Hip (cm)	FH (43)	104.5 (11)	103 (10)	0.0059
	SF (129)	105 (12)	104 (12)	0.0001
Waist to Hip Ratio	FH (43)	0.9 (0.1)	0.9 (0.1)	ns
	SF (133)	1 (0.1)	0.9 (0.1)	0.0001

*= number of participants analyzed for each variable
** = value represented as the mean with standard deviation in brackets
FH = Fedhealth; SF = Self funders group; ns = no significance
kg = kilograms; m = meters; kg/m^2 = kilogram per meter squared; % = percentage; Mm = millimetre; Cm = centimetre

The main aim of this study was to identify if a difference existed between the two groups of cardiovascular patients who completed the CDRRRP. As the results indicated no significant difference between the groups, further analysis was conducted to identify the differences seen from T1 to T2 for each group respectively. Tables 3.9 to 3.11 provide the data for this comparison.

In the FH group, the mean weight decreased by 0.6 kg and mean body fat percentage decreased by 1.4 % over the 12 weeks. Body fat percentage was significantly different at these two occasions (p= 0.0008). At T2 there was also a significant difference in the mean sum of skin folds, whereby the mean sum of skin folds decreased by 7.5 mm. The mean body mass index at 12 weeks was 29.2

kg/m^2, which was not significantly different from the T1. The mean waist-to-hip ratio remained the same at 0.9 cm. All physiological variables, weight and body mass index were significantly different at 12 weeks.

Over 12 weeks, the mean weight of the SF at T2 was not significantly different from T1, but the mean body fat percentage reduced by 1.6 %, this was significantly different ($p<0.0001$). There was a significant difference in the mean sum of skin folds, which decreased from 73.5 mm to 65.4 mm at 12 weeks (p-value: < 0.0001). The mean body mass index at 12 weeks was 29.7 kg/m^2, which did not differ significantly from 29.8 kg/m^2. The mean waist-to-hip ratio differed significantly from 1.0 to 0.9 ($p < 0.0001$). All the physiological variables, except weight and body mass index at 12 weeks were significantly different and the mean differences were decreased from baseline (paired t-test, all $p < 0.001$).

There was no statistically significant difference between the FH and SF groups in the outcomes measured at baseline and at 12 weeks.

The functional variables upon entry (T1) and at completion of the 12 weeks (36 sessions) (T2) in the FH group and SF group in depicted in table 3.10.

Table 3.10 The functional variables upon entry (T1) and at completion of the 12 weeks (36 sessions) (T2) in the FH group and SF group

Functional Variable	Group *	T1**	T2**	P-value
Resting HR (b/min)	FH (42)	72 (12)	69 (9)	ns
	SF (131)	73 (13)	70 (12)	0.0004
Resting BP: Systolic (mmHg)	FH (42)	127 (13)	122 (13)	0.0083
	SF (131)	126 (16)	120 (13)	<0.0001
Resting BP: Diastolic (mmHg)	FH (42)	77 (10)	72 (10)	0.0007
	SF (131)	78 (10)	73 (9)	<0.0001
Flexibility (cm)	FH (36)	11 (9)	16 (8)	<0.0001
	SF (109)	12 (12)	16 (11)	<0.0001
6 minute walk Distance (m)	FH (41)	537 (125)	617 (134)	<0.0001
	SF (123)	569 (162)	668 (208)	<0.0001
Max HR (b/min)	FH (38)	115 (19)	125 (19)	0.0049
	SF (115)	119 (23)	125 (24)	0.0001
Rec HR 1min (b/min)	FH (35)	91 (14)	91 (15)	ns
	SF (87)	91 (17)	96 (19)	ns

*= number of participants analyzed for each variable
** = value represented as the mean with standard deviation in brackets
FH = Fedhealth; SF = Self funders group
N = number of participants; SD = standard deviation
HR = heart rate; B/min = beats per minute; BP = blood pressure; mmHg =millimetres of mercury; Cm = centimetre; m = meters; Rec = recovery

The FH groups mean distance walked at 12 weeks was 617 m, this was significantly different from the baseline mean of 537 m (p<0.0001). The mean difference reflected an improvement of 80 m or 12 %. There was a significant difference in the mean systolic blood pressure, at 12 weeks, the mean was 122 mmHg, which was a reduction from 127 mmHg (p: 0.0083). The mean diastolic blood pressure at 12 weeks was 72 mmHg, reflecting a reduction from 77 mmHg, this was also significantly different from the T1 (p: 0.0007). The mean resting heart rate at 12 weeks was 69 b/min, which decreased from 72 b/min. This however was not significantly different.

The SF groups mean distance walked at 12 weeks was 668 m and was also significantly different from the baseline mean of 569 m ($p<0.0001$). The SF mean difference also reflected an improvement of 99 m or 14 % at 12 weeks. The mean diastolic blood pressure at 12 weeks was 73 mmHg, this also differed significantly from the T1 ($p < 0.0001$). The mean resting heart rate at 12 weeks was 70 b/min, which was significantly different from the T1 (p: 0.0004).

The mean flexibility of the FH and SF group at 12 weeks was 16 cm, both were significantly different ($p < 0.0001$) from their starting values (T1). Overall, there was no significant difference between the responses of these two groups for these measures of functional capacity from baseline to 12 weeks.

All the functional variables, except resting heart rate and recovery heart rate for the FH group at 12 weeks were significantly different and the mean differences were decreased from baseline.

There was no statistically significant difference between the FH and SF groups in the outcomes measured at baseline and at 12 weeks.

The metabolic variables upon entry (T1) and at completion of the 12 weeks (36 sessions) (T2) in the FH group and SF group in depicted in table 3.11.

Table 3.11 The metabolic variables upon entry (T1) and at completion of the 12 weeks (36 sessions) (T2) in the FH group and SF group

Metabolic Variable	Group *	T1**	T2**	P-value
Total [cholesterol] (mmol/L)	FH (23)	4.5 (1.1)	4.3 (1.0)	ns
	SF (48)	4.6 (1.2)	4.2 (1.0)	0.0035
[HDL] (mmol/L)	FH (23)	1.4 (0.9)	1.1 (0.3)	ns
	SF(48)	1.1 (0.5)	1.1 (0.4)	ns
[LDL] (mmol/L)	FH(23)	2.8 (0.9)	2.6 (0.7)	ns
	SF (47)	2.9 (1.0)	2.6 (0.8)	0.0005
[Triglyceride] (mmol/L)	FH (21)	1.5 (0.8)	1.2 (0.5)	0.047
	SF (47)	1.4 (0.6)	1.4 (0.9)	ns
Fasting [glucose] (mmol/L)	FH (19)	6.3 (1.9)	6.1 (1.4)	ns
	SF (20)	6.0 (1.5)	5.9 (0.9)	ns

*= number of participants analyzed for each variable
** = value represented as the mean with standard deviation in brackets
FH = Fedhealth; SF = Self funders group
N = number of participants; SD = standard deviation
mmol/L = millimole per litre; HDL =high density lipoprotein; LDL = low density lipoprotein

In the FH group, there was no significant difference in total cholesterol which decreased from 4.5 mmol/L to 4.3 mmol/L, LDL also reflected no significant difference, with the mean decreasing from 2.8 mmol/L to 2.6 mmol/L, there was no significant difference in HDL , which also decreased from 1.4 mmol/L to 1.1 mmol/L. However, triglycerides did significantly differ and the mean value decreased from 1.5 mmol/L to 1.2 mmol/L (p= 0.047). Fasting glucose showed no significant difference but the mean value decreased from 6.3 mmol/L to 6.1 mmol/L. Total cholesterol in the SF group significantly differed from T1 to T2, the mean value decreased from 4.6 mmol/L to 4.2 mmol/L (p= 0.0035), LDL significantly differed and the mean value decreased from 2.9 mmol/L to 2.6 mmol/L (p= 0.0005), HDL remained the same at 1.1 mmol/L, triglycerides also remained the same 1.4 mmol/L and fasting glucose showed no significant difference. There was no significant difference between the SF and FH groups in the metabolic variables measured at baseline and at 12 weeks.

3.3.4 The effects of the 12 week intervention (CDRRRP) on the physiological, functional and metabolic variables in all participants

The analysis of the 12-week intervention programme on the physiological, functional and metabolic variables in the FH and SF groups showed that there were no significant differences between the two groups (section 3.3.3) Therefore, the effect of the 12 week intervention programme on the combined participants (n=179) was analyzed. This analysis is important as it will depict the overall benefits of the intervention on the physiological, functional and metabolic variables in patients with cardiovascular disease.

The physiological variables upon entry (T1) and at completion of the 12 weeks (36 sessions) (T2) for all participants is depicted in table 3.12.

Table 3.12 The physiological variables upon entry (T1) and at completion of the 12 weeks (36 sessions) (T2) for all participants

Physiological variable	N	T1*	T2*	P-Value
Weight (kg)	175	87.9 (18.4)	87.9 (18.1)	ns
Height (m)	175	1.7 (0.1)	1.7 (0.1)	ns
BMI (kg/m^2)	176	29.7 (5.8)	29.6 (5.5)	ns
Percentage body fat (%)	165	29.9 (6.1)	28.4 (6)	< 0.0001
Sum of skin folds (mm)	168	73.6 (28.2)	65.8 (24.9)	<0.0001
Waist (cm)	172	100 (15)	98 (14)	<0.0001
Hip (cm)	172	105 (12)	104 (11)	<0.0001
Waist to hip ratio	176	1 (0.1)	0.9 (0.1)	<0.0001

*= mean value with standard deviation
ns = no significance
T1 = Assessment at baseline; T2 = assessment at completion of 12 weeks (36 sessions) intervention; kg = kilograms; m = meters; kg/m^2 = kilogram per meter squared; % = percentage; Mm = millimetre; Cm = centimetre
P value = significant differences between T 1 and T2

In all participants, mean weight did not change over 12 weeks but percentage body fat significantly differed from baseline by 1.4 % ($p < 0.0001$). The mean sum of skin folds difference decreased from 73.6 mm at baseline to 65.8 mm at 12 weeks ($p < 0.0001$). The mean body mass index at 12 weeks was 29.6 kg/m^2, which did not change significantly from baseline (29.7 kg/m^2). However, mean waist-to-hip ratio was significantly different, the mean improved from 1.0 cm to 0.9 cm ($p<0.0001$).

Therefore, there was a significant improvement body fat percentage by 1.4 %, sum of skin folds by 10 %, waist circumference, hip circumference and waist-hip ratio in the group of all participants.

The functional variables upon entry (T1) and at completion of the 12 weeks (36 sessions) (T2) for all participants is depicted in table 3.13.

Table 3.13 The functional variables upon entry (T1) and at completion of the 12 weeks (36 sessions) (T2) for all participants

Functional variable	N	T1*	T2*	P-Value
Resting HR (b/min)	173	73 (13)	70 (11)	0.0001
Resting BP: Systolic (mmHg)	173	126 (16)	120 (13)	<0.0001
Resting BP: Diastolic (mmHg)	173	78 (10)	72 (9)	<0.0001
Flexibility (cm)	145	12 (12)	16 (11)	<0.0001
6 minute walk Distance (m)	164	561 (154)	655 (193)	<0.0001
Max HR (b/min)	153	118 (21)	125 (23)	<0.0001
Rec HR 1min (b/min)	122	97 (16)	95 (18)	ns

*= mean value with standard deviation
T1 = assessment at baseline; T2 = assessment at completion of 12 weeks (36 sessions) intervention; N = number of participants; SD = standard deviation; ns = no significance
HR = heart rate; B/min = beats per minute; BP = blood pressure; mmHg =millimetres of mercury; Cm = centimetre; m = meters; max = maximum heart rate achieved during six minute walk test; Rec = recovery heart rate after six minute walk test
P value = significant differences between T 1 and T2

The mean systolic blood pressure showed a decrease at 12 weeks from what 126 mmHg o 120 mmHg, this was significantly different ($p < 0.0001$), and the mean diastolic blood pressure also decreased at 12 weeks from 78 mmHg to 72 mmHg, and was also significantly different ($p . < 0.0001$). The mean resting heart rate at 12 weeks was 70 b/min, which also showed a significant difference from 73 b/min at baseline (p: 0.0001). The mean 6 minute walk test distance was significantly different ($p < 0.0001$) at 12 weeks. The mean 6 minute walk test improved to from 561 m at baseline 655 m (an improvement of 14 %). The mean flexibility at 12 weeks was significantly different at 16 cm, improving from 12 cm at baseline (25 % improvement; $p < 0.0001$). Overall, there was a significant improvement in the functional variables at 12 weeks (36 sessions) for all participants.

The metabolic variables upon entry (T1) and at completion of the 12 weeks (36 sessions) (T2) for all participants is depicted in table 3.14.

Table 3.14 The metabolic variables upon entry (T1) and at completion of the 12 weeks (36 sessions) (T2) for all participants

Metabolic variable	N	T1*	T2*	P-Value
Total [cholesterol] (mmol/L)	71	4.6 (1.2)	4.2 (1.0)	0.0015
[HDL] (mmol/L)	71	1.2 (0.7)	1.1 (0.4)	ns
[LDL] (mmol/L)	70	2.9 (1.0)	2.6 (0.8)	0.0001
[Triglyceride] (mmol/L)	68	1.4 (0.6)	1.3 (0.8)	ns
Fasting [glucose] (mmol/L)	39	6 (1.4)	6 (1.5)	ns

*= mean value with standard deviation
T1 = assessment at baseline; T2 = assessment at completion of 12 weeks (36 sessions) intervention; N = number of participants; SD = standard deviation; ns = no significance
mmol/L = millimole per litre; HDL =high density lipoprotein; LDL = low density lipoprotein
P value = significant differences between T 1 and T2

There was a significant difference in total fasting cholesterol concentration, the mean difference decreased by 0.4 mmol/L (p= 0.0015). LDL concentration was also significantly different, the mean decreased by 0.3 mmol/L (p: 0.0001). However, there were no significant changes in HDL, triglycerides and fasting glucose concentrations after 12 weeks. Overall, there was a significant improvement in some metabolic variables at 12 weeks (36 sessions).

3.3.4 Patients that withdrew from the programme

The risk factor profile for all participants that withdrew from the programme and did not have a re-assessment is depicted in table 3.15.

Table 3.15 Risk factor profile for participants that withdrew from the programme.

Total group of participants that withdrew	
T1 (n=25)	
Risk factor	**Count**
Gender (Males)	19 (76)
Hypertension	15 (60)
Hypercholesterolemia	17 (68)
Diabetes	8 (32)
Family history	17 (68)
Overweight	17 (68)
Sedentary	19 (76)

N = number of participants
Value represented as the number of participants with the percentage in brackets

Within the total group 11.9 % (25/209) of patients did not complete the programme.76 % were male. 16 % (4/25) were from the FH group and 84 % (21/25) from the SF group. 60 % had high blood pressure, 68 % had high cholesterol, 32 % had diabetes, 68 % had a family history of cardiovascular disease, 76 % were sedentary and 28 % were smokers.

The physiological, functional and metabolic variables upon entry (T1) for all participants that withdrew from the programme are depicted in table 3.16.

Table 3.16 The physiological, functional and metabolic variables for all participants who withdrew from the programme (T1)

Total group that withdrew		
Variable	**Mean (SD)**	**N**
Age (years)	58 (11)	25
Total cholesterol (mmol/L)	5.3 (1.1)	9
HDL (mmol/L)	0.9 (0.1)	9
LDL (mmol/L)	3.1 (0.9)	9
Triglycerides (mmol/L)	2.8 (2.3)	9
Fasting Glucose (mmol/L)	7.0 (3.3)	8
Resting HR (b/min)	77 (11)	24
Resting BP: Systolic (mmHg)	120 (14)	24
Resting BP: Diastolic (mmHg)	75 (11)	24
Weight (kg)	89.6 (16.6)	25
Height (m)	1.7 (0.1)	25
BMI (kg/m^2)	29.7 (4.9)	25
Percentage Body Fat (%)	31.1 (6.3)	24
Sum of skin folds (mm)	79.3 (30.3)	25
Waist (cm)	99 (13)	25
Hip (cm)	106 (11)	25
Waist to hip ratio (cm)	0.9 (0.1)	25
Flexibility (cm)	11 (8)	19
Distance (m)	500 (158)	21
Max HR (b/min)	114 (24)	21
Rec HR 1min (b/min)	90 (15)	19

SD= Standard deviation; N = number of participants; HDL = high density lipoprotein; LDL = low density lipoprotein; Mmol = millimole; HR = heart rate; b/min = beats per minute; BP = blood pressure; mmHg = millimetres of mercury; kg = kilogram; m = meters; kg/m^2= kilogram per meter squared; % = percentage; mm = millimetres; cm = centimetres; Rec = recovery

3.4. Discussion

The main aim of this study was to determine if there was a difference in physiological, functional and metabolic variables, following a 12 week lifestyle intervention program, between a group of patients with chronic disease who were referred and funded by their medical insurer (FH group) compared to a group of patients with chronic disease who were self referred and funded (SF group). The main finding from this study was that the 12-week comprehensive lifestyle intervention significantly improved the majority of the physiological, functional and metabolic variables in both groups. In general, there were no significant differences in the outcomes measured between a medical insurers

funded group and the self funded group. Furthermore, dropout rates between the two groups were also similar, (Fedhealth group = 8 % and Self-funders = 13 %) indicating that there was very little difference in adherence and readiness to make changes to lifestyle behaviours between the two groups. This dropout rate was less than that reported in a study by Worcester et al [103] investigating cardiovascular rehabilitation non-attendance. In that study, there was a 24 % drop out rate amongst the participants[103].

To our knowledge, there has been no other published study where two groups of patients entering a chronic disease programme from different referral and funding sources (such as the ones used in this study) were compared. Therefore, we cannot compare our results to other study results. These data do however suggest that the compliance of the patients with chronic disease in our lifestyle intervention program was similar irrespective whether they have been referred and fully funded or have taken the initiative to self-fund the intervention programme. This is an important finding because it could be suggested that there are differences in motivation, adherence, completion of the programme and outcomes achieved, in self-funded compared with externally funded patients. A possible explanation for this finding is that all the patients did experience a significant event affecting their health status, and this was sufficient to prompt them to enrol and complete the programme. This life-changing event could be the reinforcing factor that motivates patients sufficiently to sustain lifestyle changes and attempt to improve their health so that the risk of future events is reduced.

Therefore, as previously mentioned, the effects of the 12-week lifestyle intervention was analysed for the entire group, because no differences were observed between the two groups. These results are important because they determine if the 12-week intervention program was effective in improving physiological, functional and metabolic variables in patients with chronic cardiovascular disease and co-morbidities.

Thus, the second major finding of this study was that we observed clinically significant improvements in most of the outcome variables (physiological, functional, and metabolic) within the total group of participants who completed the 12-week lifestyle intervention program. These results are similar to those documented for other lifestyle intervention programmes aimed at reducing chronic disease risk

factors. Collectively these data suggest that a multi-component lifestyle approach is an effective intervention for reducing the risk factors for chronic disease [51;52;56;61;64;70;93;94;104;105]. Our study is however unique in that 1) the beneficial effects were observed in a short period (12 weeks) compared with other similar studies such as the Lifestyle 180 programme (30 week intervention)[55], 2) it is medically supervised, and 3) it is multidisciplinary in nature.

More specifically we showed that the improvements in all the physiological variables in our study were similar to those reported in the Lifestyle 180 programme [56], with the exception of body weight and body mass index (BMI). The Lifestyle 180 programme reported greater improvements in body weight and BMI at 30 weeks compared to our intervention at 12 weeks. The most likely explanation for this difference in response is the longer period of the Lifestyle 180 program [56].

Not only were there changes in body weight and percentage body fat, but also abdominal obesity decreased, reflected by the mean difference decrease in waist circumference. This is of clinical importance, due to the association between abdominal obesity and type II diabetes mellitus, which is also a risk factor for cardiovascular disease. However, there was no difference observed in the waist to hip ratio. A possible explanation for this finding could be the observed decrease in weight, waist and hip circumference. Greater improvements in these variables were seen in the SLIM study [106] whereby the authors reported a mean difference of 3.5 cm in waist circumference, however, this was recorded at one year post intervention. Our study showed a mean difference decrease of 2 cm at 12 weeks.

Perhaps the single most important risk factor for cardiovascular disease is hypertension [2;89;92;107;108]. Indeed, a large number of studies have examined the effects of exercise training on various indices of cardiovascular function. The single most replicable effect of aerobic training on cardiac function is a decreased resting heart rate [109].

The physical conditioning achieved by regular exercise decreases heart rate and blood pressure at rest [42]and reduces workload on the heart, helping to alleviate cardiovascular disease related symptoms including angina [42]. A study by Maiorana et al [110] showed a similar mean decrease in resting heart rate of 3 b/min and mean systolic and diastolic blood pressure of also 3 mmHg. These findings were shown after 8 weeks of an exercise intervention. The TOMHS[50] study showed a mean

difference decrease in systolic blood pressure of 10 mmHg and mean difference decrease in diastolic blood pressure of 8 mmHg. These variables were measured at one year post intervention. The Lifestyle 180 programme [55] also showed similar results in their resting heart rate (mean difference decrease of 7 b/min). Whilst it is important to note that the patients in our study were not clinically hypertensive or were well controlled on medication yet there was still an effect on the measured cardiovascular parameters. Indeed, the results of the studies mentioned above, are consistent with our study which showed a mean difference reduction of 3 b/min in resting heart rate and a mean difference decrease of 6 mmHg in both systolic and diastolic blood pressure at 12 weeks post intervention. The main difference between these studies is the period of the intervention, which will affect the outcome of these variables being measured. Future studies conducted on this present cohort will address the longer period of intervention.

Therefore, our intervention was effective in improving the resting heart rate and resting blood pressure (systolic and diastolic) in patients with chronic disease. The results from our study and supporting studies provide evidence that a holistic lifestyle intervention program that combines exercise, diet and management of other risk factors result in reduced risk factors for chronic disease [111].

The third important finding from the present study was that, we showed that the intervention resulted in significant improvements in the functional variables measured. Of significance was the improvement seen in the 6-minute walk test. This test is commonly used in clinical settings and chronic diseases rehabilitation programmes such as the CDRRRP to measure the impact of multiple co-morbidities (including cardiovascular disease, respiratory disease, diabetes, arthritis and psychological diseases) on exercise capacity and endurance [16].The 6-minute walk test has been shown to be a reliable measurement of functional capacity in patients with chronic disease. [99]. It has been shown that an improvement of more than 70 m walked or 12 % is clinically important to patients [16;112]. Even the slightest difference in six minute walk test distance can be associated with a noticeable difference in patients personal assessment of their walking ability, thus indicating improvement in their functional capability [113].

This is relevant because the average improvement in the 6-minute walk test in our study was 94 m (Table 3.13) which equates to a 14 % improvement. Similar improvements in 6-minute walk test

results were also documented previously in patients with heart failure after 12 weeks of exercise prescription[105].

The sit-and-reach test used in our study estimates the flexibility of the hamstrings and lower back, which could be potential precursors for lower back injuries and pain [42]. Our intervention showed a mean difference increase of 4cm, showing a 25 % improvement. This change is clinically important to patients with chronic disease in possibly helping to prevent further incidences of lower back injury and pain. In comparing our results to the other similar studies, none used the sit and reach test (or any other flexibility test) as a functional measure, therefore no comparison can be made. Therefore in summary, our intervention was effective in improving the functional capacity of patients with chronic disease with respect to these measured variables.

The fourth finding from this study was that we documented a small but significant improvement in total cholesterol and LDL concentrations in the overall group as well as in the two sub-groups. In general however, upon entry onto the CDRRRP, the lipid profiles were well managed and mostly controlled in our patient population through the use of medications (table 3.5). Indeed, over 70 % of all patients in our cohort were using cholesterol-lowering medications. Yet, in our study we documented additional small yet statistically significant improvements in most measured metabolic variables, and this suggests that this additive impact might be an effect of the programme. The reductions observed in triglycerides, total cholesterol, and LDL cholesterol are consistent with other similar chronic disease programs[50, 51, 55, 63, 93, 94, 105].

The Lifestyle 180 programme[55] reported a mean difference decrease of 0.7 mmol/L in total fasting cholesterol, 0.1 mmol/L in HDL, 0.5 mmol/L in LDL and 0.4 mmol/L in triglyceride concentrations at 30 weeks. In the present study we documented similar changes but over a shorter intervention period of 12 weeks. Total fasting cholesterol showed a mean difference decrease of 0.4 mmol/L, 0.1 mmol/L in HDL, 0.3 mmol/L in LDL and 0.1 mmol/L in triglyceride concentration. Our study did not however show a change in fasting glucose concentrations. Indeed, the mean fasting glucose concentrations in the patients in this study indicate that control could be improved. A possible explanation for this finding could be the relatively small change seen in weight reduction which is known to be associated with improved insulin function as well as the short duration of the intervention compared to other

studies over a longer period of time [106].

Study limitations

This study has several limitations, which include the following:

- In our study we did not have a control group with no intervention. Our study design was started as a pilot study for the Fedhealth group and data were analysed retrospectively. Furthermore, as lifestyle intervention is firstly line therapy for patients with chronic disease, there are ethical considerations in withholding this form of advice or intervention form patients with chronic disease.
- As this was a retrospective study over a 5-year period, a limitation is missing data. Some patients had incomplete records, which contributed towards missing variables of some measurements. In addition, there were 25 patients who did not complete the programme; therefore no re-assessment data was available on these patients.Some of the missing data relates to repeat blood testing. This may be due to the additional financial costs of repeat blood testing in the patients from the self -funded group. It is well documented that one of the barriers to exercise and lifestyle changes, is financial because there are cost implications in maintaining changes that include medication adherence, continued follow-up consultations with medical staff, and repeat clinical examinations and procedures [67].
- The location of the programme was restricted to one centre, therefore geographical limitations prevented all patients from the main funder (Fedhealth) to be included in the study – this could have resulted in some selection bias and is presently being addressed by presenting this programme across a wider National representation.
- Although this was a relatively large cohort, more detailed analysis of multiple factors and sub-groups (e.g. different profiles of co-morbidities) was not possible due to small sample sizes of sub-groups.
- In this study we did not measure all aspects of fitness, such as muscle strength testing. This will be addressed in future planned studies of patients on this programme.

- A longer observation period would have provided a better opportunity for further favourable changes to occur. A six-month study observation period is presently being analysed in a further study on this programme.

In summary, the findings from our pilot study provide a clear indication that the CDRRR program is successful in reducing risk factors for chronic disease, improving outcome measurements amongst participants regardless of the referral and funding strategy used into the programme, reducing physical inactivity as a risk factor for chronic disease and improving functional capacity of the patients to a level that will permit better performance of daily tasks, activities and overall quality of life.

Chapter 4

Summary and conclusion

Summary

The global burden of chronic disease has highlighted the need for more holistic, comprehensive interventions for the management and prevention of the progression of chronic disease. Due to the high prevalence of patients with more than one chronic disease and co-morbidities, these interventions have shifted from disease specific treatments to patient centred approaches. The key components of chronic disease rehabilitation should include individualised exercise prescription and training, education, dietary and nutrition interventions, psychosocial support and strategies to modify other risk factors. One of the biggest challenges individuals with chronic disease face is the implementation of these new healthy behaviours. The focus of this dissertation was to determine the effectiveness of a multi disciplinary chronic disease programme on outcomes in patients with chronic disease. In particular, the difference in outcomes between the two groups of patients who were referred and funded with different models.

Whilst previous studies have shown the benefits of a multidisciplinary lifestyle intervention programme on chronic disease patients' health and risk factor status, [2;61;66] there has not, to the best of our knowledge, been any research comparing two groups from different referral and funding strategies into a medically supervised chronic disease rehabilitation programme.

The data from this study revealed the effectiveness of the CDRRR programme on most outcomes for patients who completed the programme. Indeed patients enrolled on this programme showed improvements in percentage of body fat; sum of skin folds, waist and hip circumference, waist to hip ratio; resting heart rate, systolic and diastolic blood pressure, flexibility, six minute walk test distance, maximum heart rate achieved and recovery heart rate, total fasting cholesterol and low density lipoprotein. The results of the study also showed that no difference exists in outcomes achieved between the two groups with different referral and funding strategies for the programme.

Conclusion

Chronic diseases continue to drive the healthcare costs even though they are largely preventable. Whilst specific treatments and medications continue to target the established pathology of the disease-related condition, it is important that lifestyle factors are addressed in a safe and patient-centred manner Multi-component lifestyle interventions such as The Chronic Disease Risk Reduction and Reversal Programme described in this study are aimed at inducing physiological adaptations and improvement of risk factor awareness, hopefully leading to behaviour modifications that support long-term healthier lifestyle choices.

The findings of the present study indicate that no difference in measured outcome exists between patients who are proactively referred and funded compared to those who are self referred and funded through a lifestyle intervention programme. This implies that there is no difference between compliance, adherence and adaptation of these patients to modifying their lifestyle behaviours. It is therefore evident that patients with chronic disease can improve their disease related risk factors by engaging and completing a multi-component lifestyle intervention consisting of physical activity, educational modules, dietary and stress management. All physiological, metabolic and functional measures in this study were improved at 12 weeks of intervention.

In conclusion, the multi disciplinary chronic disease programme described is effective in improving the health status of patients with established chronic disease. The referral strategy of patients into this programme also proved no difference to achieved, outcomes and patients who engage and complete the programme demonstrate the first step in taking control and managing their health. These findings could be used to encourage medical insurers to support and provide the financial support necessary to improve the overall long term cost of chronic disease.

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