RISK FACTORS AND THE EFFECT OF PHYSICAL ACTIVITY MODIFICATION FOR ISCHEMIC HEART DISEASE IN INDIVIDUALS LIVING WITH HIV

Ronel Roos

A thesis submitted to the Faculty of Health Sciences, University of the Witwatersrand, in fulfillment of the requirements for the degree of Doctor of Philosophy

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DECLARATION

I, Ronel Roos, declare that this thesis is my own work. It is being submitted for the degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

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…31…….day of ……October……., 2014

DEDICATION

This thesis is dedicated to my parents,
Mr Paul P. Roos and Mrs Henriëtte Roos,
for their encouragement and support throughout this project

PUBLICATIONS AND PRESENTATIONS IN SUPPORT OF THIS THESIS

PUBLICATIONS

Roos R, Myezwa H, Van Aswegen H 2013 Physical activity levels and activity preferences of a cohort of South African Individuals living with HIV. *South African Journal of Physiotherapy* Wits Special Edition: 15 – 20.

Roos R, Myezwa H, Van Aswegen H, Musenge E Physical activity and risk factor screening for ischaemic heart disease in South African individuals living with HIV. *(Submitted for publication to Journal of Clinical Research in HIV AIDS and Prevention: currently under review).*

Roos R, Myezwa H, Van Aswegen H 2014 "Not easy at all but I am trying": Barriers and facilitators to physical activity in a South African cohort of PLWHA participating in a home-based pedometer walking programme. *AIDS Care* 30: 1 - 5.

Roos R, Myezwa H, Van Aswegen H, Musenge E 2014 Effects of an education and home-based pedometer walking programme on ischemic heart disease risk factors in people infected with HIV: a randomised trial. *Journal of Acquired Immune Deficiency Syndromes* 67 (3): 268 – 276.

Roos R, Myezwa H, Van Aswegen H 'If you have a problem with your heart, you have a problem with your life': Self-perception and behaviour in relation to the risk of ischaemic heart disease in people living with HIV. *(Submitted for publication to African Journal of Primary Health Care and Family Medicine: currently under review).*

RESEARCH PRESENTATIONS

Roos R, Myezwa H, Van Aswegen H, Musenge E 2014 Effects of an education and home-based pedometer walking programme on IHD risk factors in PLWHA: a randomised control trial (Platform presentation). *Faculty of Health Sciences Research Day, University of the Witwatersrand, September 2014.*

Roos R, Myezwa H, Van Aswegen H 2014 Self-perception and behaviour in relation to the risk of IHD in a cohort of South African individuals living with HIV (Platform presentation). *WCPT Africa Congress, Lusaka Zambia May 2014.*

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Roos R, Myezwa H, Van Aswegen H, Musenge E 2012 Risk factors and the effect of physical activity modification for IHD in individuals living with HIV (Platform presentation). *PhD Progress Feedback to Right to Care and Themba Lethu Clinic.*

Roos R, Myezwa H, Van Aswegen H 2012 Physical activity assessment in individuals infected with HIV as risk factor screening for ischemic heart disease: a pilot study (Platform presentation). *South African Society of Physiotherapy Congress in Bloemfontein March 2012.*

ABSTRACT

Background:

Individuals infected with the human immunodeficiency virus (HIV) are living longer due to effective disease management with highly active antiretroviral therapy (HAART). International literature suggest that mortality in people living with HIV and AIDS (PLWHA) is shifting to non-AIDS defining diseases such as cardiovascular disease. It is suggested that PLWHA are at an increased risk for developing ischemic heart disease (IHD) due to HIV mediated processes, traditional risk factors of IHD and factors related to HAART exposure. In the South African context risk factors for IHD are reported to be on the increase in the general population but published information regarding the risk factors for IHD in PLWHA is limited. Human immunodeficiency virus infection is a significant Sub-Saharan Africa challenge with 5.26 million people living in South Africa (SA) reported to be infected with HIV. Only Swaziland, Lesotho and Botswana report higher prevalence rates of HIV infection. Due to the high prevalence rate of HIV in SA, the reported increase in risk factors for IHD in the general population and the suggested increased risk for IHD in PLWHA, screening these risk factors in PLWHA in the South African context may be necessary. Innovative prevention strategies for IHD are also required to manage the risk for IHD in PLWHA in SA due to the high prevalence rate. A home-based education and pedometer walking programme could be such a strategy. The aims of the research project were therefore firstly to screen selected risk factors for IHD in PLWHA attending a primary care clinic and secondly to evaluate said individuals' self-perception regarding their risk of IHD. Lastly the project set out to determine the effects of an individualised education and home-based pedometer walking programme on the risk of IHD as a potential prevention management strategy for IHD in PLWHA.

Methodology:

The research project consisted of four studies divided into phase 1 (study 1, 2, 3) and phase 2 (study 4). The study aims, methods and data analysis approaches were:

Study 1: Aimed to screen a sample of PLWHA (on HAART) for physical activity and selected risk factors of IHD using the Yamax SW200 pedometer and other appropriate methods respectively. This study was an observational study and data analysis consisted of descriptive analysis and reviewing associations with univariate logistic regression analysis. A p–value less than 0.05 was considered statistically significant.

Study 2: Aimed to evaluate participants' self-perception and behaviour in relation to the risk of IHD using a semi-structured interview and card sort technique. This study was a qualitative study and data analysis consisted of descriptive and conventional content analysis.

Study 3: Aimed to develop the education physical activity diary that was used in phase 2. The methodological processes included a literature review, a review of the education material to be included in the physical activity diary by an academic peer–review panel, review by a clinician working with PLWHA and a sample of PLWHA. Following these activities the diary was constructed and translated into isiZulu.

Study 4: Aimed to assess the effects of an education and home-based pedometer walking programme on the risk factors of IHD in a sample of PLWHA (on HAART) with an increased risk for IHD as determined in study 1. The study was a randomised controlled trial consisting of an intervention and control group. Assessments were done at baseline, six and 12 months. Control participants continued with standard clinic care and were phoned once a month for five months during the baseline and six month interval. The intervention participants received a Yamax SW200 pedometer, an education physical activity diary, individualised walking programme and had once a month face-to-face education sessions in the baseline to six month interval. Intervention participants were instructed to continue with their physical activity modification programme during the six to 12 months period. No contact was made with control or intervention participants during this time. Intention-to-treat analysis was the primary approach for study 4. Data analysis consisted of descriptive analysis (mean [±SD] and frequencies [percentages]) and randomisation to group allocation was assessed using a two sample/ independent t-test or Wilcoxon rank–sum (Mann–Whitney) for non-normally distributed continuous data. Categorical data were evaluated with the Pearson Chi Square test. A p–value less than 0.05 was considered statistically significant. To evaluate the effect of time on outcomes assessed, repeated measures ANOVA for within-group changes were performed. To evaluate the effect of the programme on outcomes assessed, repeated measures ANCOVA with baseline values as co-variates were performed to highlight the between-group effect. To assess the associations between dependent variables and the time and intervention/control interaction the pedometer data were log-transformed due to skewness. The generalised estimation equation (GEE) and mixed effects model (MEM) approaches were used to fit the univariate and multivariable models. The correlation structure selected was the exchangeable option with the identity link function suitable for Gaussian data. The relationship between high sensitivity C-reactive protein (hs-CRP) at baseline and evaluated risk factors for IHD was assessed with the Pearson correlation coefficient and univariate logistic regression in MEM respectively on log-transformed hs-CRP.

Results:

Study 1: Two hundred and five PLWHA (on HAART) were screened for selected risk factors for IHD. The demographic characteristics of participants consisted of the following: mean age (38.2 [±9.5] years), gender (men [n=47; 22.9%] and women [n=158; 77.1%]), most participants had a secondary educational level (n=95; 46.3%), were employed (n=115; 56.1%) and were supporting

dependents (n=158; 85.4%). The majority of participants perceived their general health as good (n=120; 58.5%), but felt their body shape had changed in the last six months (n=123; 60%). This was mostly due to a reported increase in weight (n=132; 64.4%). The mean time on HAART was 8.7 (±2.3) months, with the majority of participants being diagnosed as HIV positive between 2009 to 2011 (n=134; 66%). The majority of participants were on Lamivudine, Efavirenz and Tenofovir (n=139; 67.8%) therapy with a mean CD_4 count of 285.1 (±157) cells/mm^3 and viral load of 12 513.2 (±59 710.6) copies/ml. The physical activity levels of participants were reduced with the mean pedometer step count per day found to be 7 673.2 (±4 017.7) with men being more active (10 076.3 [±4 885.6] steps per day) than women (6 993.3 [±3 462.6] steps per day). The majority of study participants (n=150; 77%) took less than 10 000 steps per day. Taking less than 10 000 steps per day was related to waist circumference (WC) (odds ratio=1.04; 95% CI: 1.00–1.08; p=0.03) when adjusted for age and gender. Eight participants (3.9%) participated in formal sporting activities that were supervised and 123 participants (60%) tried to incorporate exercise into their daily lives. The preferred activity method for exercise was walking (n=56; 45.5%) and running (n=33; 26.8%). Perceived stress was moderately high with a mean Cohen's Perceived Stress score at 19.2 (±7.8) with women reporting higher levels of stress (20 [±7.1]) than men (16.9 [±9.1]). A family history of IHD was low in participants (n=29; 14.2%) as well as a known diagnosis of diabetes mellitus (n=1; 0.005%), hypertension (n=19; 9%) and current smoking status (n=33; 16.1%). The majority of participants reported not being able to consume fish weekly (n=114; 55.6%) and reported weekly consumption of fruit and vegetables (n=110; 53.7%). Few participants were able to consume three to five vegetables and fruit combined per day (n=68; 33.2%). The mean resting heart rate (RHR) of the sample was slightly elevated (82.7 [±11.4] bpm) with having a RHR ≥ 80 bpm related to diastolic blood pressure (DBP) (odds ratio=1.07; 95% CI: 1.03–1.11; p<0.00) and physical activity (odds ratio=0.99; 95% CI: 0.99–0.99; p=0.02) as adjusted for age and gender. The sample as a whole was overweight with a mean body mass index (BMI) of 25.6 (±1.4) kg/m^2. Having a BMI ≥ 25 kg/m^2 was related to systolic blood pressure (SBP) (odds ratio=1.07; 95% CI: 1.04–1.10; p<0.00), WC (odds ratio=1.34; 95% CI: 1.22–1.46; p<0.00), hip circumference (odds ratio=1.53; 95% CI: 1.38–1.75; p<0.00) and CD_4 count (odds ratio=1.00; 95% CI: 1.00–1.01; p=0.01) as adjusted for age and gender.

Study 2: Thirty PLWHA (on HAART) were purposefully sampled according to the following criteria: individuals had to be on HAART for six to 12 months, between the ages of 20 and 65 years and ambulatory without an assistive device with no pre-existing history of cardiovascular disease, mental illness, current acute infection, current pregnancy or breast-feeding women. The demographic details of participants were as follows: median age 36.5 (31.8–45.0) years; women (n=25; 83.3%) and men (n=5; 16.7%); the majority of participants (n=16; 53.3%) had a secondary school education, were employed (n=17; 56.7%) and were supporting dependents (n=26; 86.7%). Knowledge and understanding related to IHD, insight into own risk for IHD and health character in

the HIV context were identified as three prominent themes. An important finding that the study highlighted was that participants did not perceive themselves to be at risk for IHD due to being HIV^+ or using HAART in any way. The majority of participants (n=15; 50%) did not perceive themselves to be at risk for IHD due to reporting having adequate coping behaviour and living a healthy lifestyle. Twelve (40%) participants did however perceive a risk for IHD due to physical symptoms experienced and their behaviour consisting of a poor diet, elevated stress levels and lack of exercise. Three (10%) participants were unsure concerning their risk for IHD in the future.

Study 3: A selection of pages from the education physical activity diary can be found in Appendix 31.

Study 4: Eighty four PLWHA (on HAART) participated in study 4.
The education and home-based walking programme implemented in study 4 was successful in improving physical activity levels in both the control and intervention groups, as participants' pedometer-determined step-count increased from baseline. The within-group change at six months were statistically significant (p=0.03) for both groups but not so for the 12 month period (control group [p=0.33] and intervention group [p=0.21]). It was however of clinical value in the intervention group, due to the group exceeding the step count aim of the programme, that being 3 000 steps above baseline at each assessment point. Translating the step count into time, would amount to approximately 30 minutes of added walking per day. The group therefore reached the Public Health recommendations for physical activity. Social support in the form of encouragement, motivation and participation from friends and family was noted as important enablers that assisted intervention participants to adhere to their programme.

No significant differences were observed in the sociodemographic profile, HIV related clinical markers and antiretroviral therapy and IHD risk factors evaluated at baseline. The study highlighted that inflammation (hs-CRP) was a significant risk factor for IHD in the study cohort due to mean baseline values of 8.6 (±8.4) mg/l in the intervention and 5.4 (±6.5) mg/l in the control group. Inflammation (hs-CRP) was related to perceived stress (Pearson correlation [r=0.23; p=0.03] and MEM univariate logistic regression [*log B*=0.04; 95% CI: 0.0004– 0.08; p=0.03]), weight (Pearson correlation [r=2.8; p=0.01] and MEM univariate logistic regression [*log B*=0.02; 95% CI: 0.01–0.04; p=0.01]), BMI (Pearson correlation [r=0.35; p<0.00] and MEM univariate logistic regression [*log B*=0.07; 95% CI: 0.03–0.12; p<0.00]), WC (Pearson correlation [r=0.28; p=0.01] and MEM univariate logistic regression [*log B*=0.03; 95% CI: 0.06–0.36; p=0.01]) and hip circumference (Pearson correlation [r=0.28; p=0.01] and MEM univariate logistic regression [*log B*=0.02; 95% CI: 0.01–0.04; p=0.01]). The risk for IHD according to Framingham Risk Score (FRS) calculation was low as baseline FRS points were 3.3 (±6.5) points in the control group and 2.5 (±6.5) points in the intervention group.

The education and home-based walking programme was effective in increasing physical function capacity (six-minute walk test mean difference: 15.70 [±9.33] meters), reducing waist: hip ratio (mean difference of -0.003 [±0.01] cm), reducing glucose level (mean difference of -0.12 [±0.09] mmol/l) and increasing HDL (mean difference of 0.07 [±0.05] mmol/l) as evaluated during between-group analysis.

The within-group analysis indicated that a significant reduction in SBP occurred in both groups at the six months time period (control group: $p=0.03$ and intervention group: $p<0.00$). A slight increase in BMI occurred in both groups at the six and 12 month period that were statistically significant ($p<0.00$). A significant reduction in total cholesterol ($p=0.04$) and LDL ($p<0.00$) at the 12 month period were also noted in the control group.

The log-transformed univariate logistic regression model highlighted many associations between the interaction (time and treatment: control or intervention group effect) and secondary outcomes assessed. The inverse associations between perceived stress levels ($p<0.00$) and BMI ($p=0.02$) with the six month time interval of the control and intervention groups compared to baseline control findings were confirmed during multivariable analysis in the log-transformed GEE model. Additionally an inverse association between perceived stress levels ($p<0.00$), BMI ($p<0.00$), LDL ($p=0.01$) and triglycerides (TG) ($p=0.01$) at the six month time interval of the intervention group compared to baseline control findings were confirmed in the multivariable analysis in the log-transformed MEM model.

Conclusion:

This project showed that physical inactivity, elevated perceived stress levels, inadequate diet of fruit, vegetable and fish intake, elevated RHR, increased BMI and raised hs-CRP were risk factors for IHD in the study cohort. These risk factors screened indicated an elevated risk for IHD in the future even though the FRS demonstrated a low risk for IHD. An IHD predictive model that incorporate hs-CRP when evaluating risk for IHD and which has been validated for use in PLWHA is therefore necessary to adequately evaluate the risk for IHD in this population. This is especially of relevance in the South African context considering the prevalence of HIV infection in women and the association of female gender with hs-CRP as indicated in the literature.

The project highlighted that an elevated stress level was a significant risk factor for IHD in the study cohort and was also given as one reason why participants perceived themselves to be at risk for IHD. The positive association between perceived stress and hs-CRP was also of value. The stress lowering effect of the education and home-based pedometer walking programme was therefore of significant importance as it could manage this risk factor. Additionally if stress declines

it could potentially also influence hs-CRP in the long term. The study therefore contributes to the body of knowledge related to the effects of exercise on psychological parameters in PLWHA.

Additionally the project confirmed that an optimistic bias in individuals living with HIV is present regarding their future possibility for developing IHD. Their perception for the risk for IHD did not always align with the risk factors present as screened. This might be due to the fair application of knowledge related to IHD when evaluating their risk for IHD. It also confirmed that education strategies are needed to explain the risk factors for IHD and how HIV infection and HAART influence these risk factors of IHD.

Lastly the project found that an education and individualised home-based pedometer walking programme was able to influence physical activity levels positively and was successful in reducing the risk of some factors for IHD in PLWHA at primary care level. Such a programme can be implemented as an innovative method to manage risk factors for IHD in PLWHA by physiotherapists especially in regions where physiotherapy numbers are low and HIV prevalence high.

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*A very special thank you to the **Participants** that consented to this research project, thank you for allowing me into your lives. I hope that you learned as much from our interactions as I did. May God bless you, protect you and allow you to lead a long productive life!*

Keep on walking…

DISCLAIMER

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ACSM	-	American College of Sports Medicine
AIDS	-	Acquired immune deficiency syndrome
ALT	-	Alanine transaminase
AMI	-	Acute myocardial infarction
AST	-	Aspartate transaminase
ATS	-	American Thoracic Society
BMI	-	Body mass index
Bpm	-	Beats per minute
COPD	-	Chronic obstructive pulmonary disease
CRP	-	C-reactive protein
DBP	-	Diastolic blood pressure
DALYs	-	Disability-adjusted life years
FRS	-	Framingham Risk Score
GEE	-	Generalised estimation equation
GGT	-	Gamma glutamyl transpeptidase
HAART	-	Highly active antiretroviral therapy
HDL	-	High density lipoprotein
HIV	-	Human immunodeficiency virus
HR_{max}	-	Maximal heart rate
HRR	-	Heart rate reserve
HTN	-	Hypertension
Hs-CRP	-	High sensitivity C-reactive protein
IHD	-	Ischemic heart disease
IL	-	Interleukin
IPAQ	-	International Physical Activity Questionnaire
ITT	-	Intention-to-treat analysis
LDL	-	Low density lipoprotein
MEM	-	Mixed effects model
MmHg	-	Millimetres per mercury
NCEP ATP-III	-	National Cholesterol Education Program Expert Panel Adult Treatment Panel-III
NNRTI	-	Non-nucleoside reverse transcriptase inhibitor
NRTI	-	Nucleoside reverse transcriptase inhibitor
OR	-	Odds ratio
PLWHA	-	People living with HIV and AIDS

PI	-	Protease inhibitor
RHR	-	Resting heart rate
RR	-	Relative risk
SA	-	South Africa
SMS	-	Short message service
6MWT	-	Six minute walk test
6MWORK	-	Six minute walk test work
SOB	-	Shortness of breath
Stats SA	-	Statistics South Africa
SBP	-	Systolic blood pressure
SMC	-	Smooth muscle cells
TB	-	Tuberculosis
TG	-	Triglycerides
TNF-α	-	Tumour necrosis factor alpha
UNAIDS	-	United Nations Programme on HIV/AIDS
UK	-	United Kingdom
USA	-	United States of America
VO_2R	-	Oxygen uptake reserve
WC	-	Waist circumference
WHR	-	Waist: hip ratio
WHO	-	World Health Organisation

“Above all else, guard your heart, for it is the wellspring of life.”

(Proverbs 4: 23)

CHAPTER 1

1. BACKGROUND AND NEED

1.1 INTRODUCTION

Individuals infected with the human immunodeficiency virus (HIV) are living longer due to effective management with highly active antiretroviral therapy (HAART) (United Nations Programme on HIV/AIDS [UNAIDS], 2013; Bhaskaran et al., 2008; Palella et al., 1998). Sub-Saharan Africa remains the region most affected by the disease, accounting for 24.7 million people living with HIV (UNAIDS, 2013). The estimated number of people receiving HAART in this region increased by 59% (an additional 2.3 million people) between 2010 and 2012 alone (UNAIDS, 2012). South Africa increased roll-out of HAART by 75% over this period, providing 1.7 million people with access to antiretroviral therapy (UNAIDS, 2012). It is claimed that antiretroviral therapy has saved nine million life-years in sub-Saraharan Africa, allowing individuals to improve their health and contribute to their society (UNAIDS, 2012). With this increased longevity, chronic lifestyle diseases, such as ischemic heart disease (IHD), are becoming a greater cause for concern. This is due in part to known controllable risk factors for IHD, e.g. smoking, and also to the metabolic effects of HAART, e.g., metabolic syndrome (Grinspoon et al., 2008; Jerico et al., 2006; Grinspoon and Andrews; 2005; Saves et al., 2003) and viral effects, e.g., increased inflammatory markers (Triant et al., 2009).

Ischemic heart disease is a health concern worldwide, and the leading cause of death in most First World countries (Lozano et al., 2012; Mackay and Menash, 2004). Globally, IHD and stroke combined killed 12.9 million people in 2010, and the ratio of deaths due to IHD increased to one in four people in 2010, compared to one in five in 1990 (Lozano et al., 2012). Globally, the burden of this disease, as reflected by disability-adjusted life years (years of life lived with disability), is second only to HIV in men and third, following unipolar depressive disorders and HIV, in women aged 15 years and above (Mackay and Menash, 2004). The greatest burden associated with this disease occurs in developing countries, due to epidemiological transition: increased longevity of individuals, urbanization and lifestyle changes (Mensah, 2008; Gaziano, 2005). In sub-Saharan Africa, epidemiological transition is resulting in an increase in risk factors for IHD, such as hypertension, diabetes, overweight/obesity, physical inactivity and dyslipidaemia (Onen, 2013; Danaei et al., 2011; Finucane et al., 2011). It is estimated that age-standardised mortality rates for IHD will rise by 27% in African men and 25% in women by 2015 in this region (Onen, 2013). It is also postulated that by 2030 IHD will be the leading cause of death in low and middle income countries (Abegunde et al., 2007).

In the South African context the anticipated burden of cardiovascular disorders is of particular concern due to the increased prevalence of lifestyle risk factors, and also to the high prevalence of individuals infected with HIV (Mayosi et al., 2009). International studies have suggested that individuals infected with HIV are at greater risk of developing IHD than those with a negative status (Triant, Meigs and Grinspoon, 2009; Triant et al., 2007; De Socio et al., 2007; Currier et al., 2003; Saves et al., 2003). The incidence of IHD among young men (before age 34) and women (up to age 44) living with HIV is significantly higher than non-infected individuals (Currrier et al., 2003). The prevalence and degree of subclinical coronary arteriosclerosis is also greater in young asymptomatic HIV-infected individuals than negative individuals (Abbara et al., 2010). Additionally, Triant, Meigs and Grinspoon (2009) indicated that the chance of an acute myocardial infarction is four times more likely in an individual who is HIV positive with an elevated C-reactive protein level compared to a non-infected individual. Lastly, atherosclerotic cholesterol plaque in HIV-infected individuals has also been reported to be more vulnerable than non-infected individuals, which could lead to plaque rupture and an increased risk of myocardial infarction (Zanni et al., 2013). As the roll-out of HAART increases in South Africa (SA) the disability related to HIV and IHD could escalate and place a significant burden on the economy, health services and society. It is therefore important to screen for risk factors for IHD and implement interventions where needed to prevent, and possibly reduce, the future burden of this disease.

Promoting a healthy lifestyle and prevention of IHD by screening, and thus identifying and treating controllable risk factors at primary care level, are recommended as cornerstone management strategies in the general population (Mensah, 2008). The American Heart Association State of Science conference proposed two broad screening strategies for IHD in individuals living with HIV due to their increased risk (Hsue et al., 2008). The first is to identify IHD-predisposing risk factors, e.g., physical inactivity, and the second is to detect IHD at the earliest possible stage. A literature search produced limited information on research on physical activity in individuals infected with HIV at conceptualization of the project. Similarly, no published information on the South African population was available. In all, only three international studies on physical activity evaluation were available. Fillipas et al. (2008) assessed physical activity with the International Physical Activity Questionnaire (IPAQ); Bopp et al. (2004) did likewise with an Actigraph accelerometer, and Ramirez-Marrero et al. (2008) used the IPAQ, Yamax Pedometer and Actigraph accelerometer. These studies were performed in Australia, the United States of America (USA) and Puerto Rico respectively. Ramirez-Marrero et al. (2008) reported that the IPAQ overestimated physical activity when compared with objective tools, namely a pedometer and accelerometer. It is therefore suggested that an objective tool should be used to assess

physical activity when conducting research. A pedometer is less expensive than an accelerometer, and hence it would be sensible to use it in evaluating physical activity in individuals infected with HIV at primary care level in the SA context.

Promoting wellness and a healthy lifestyle is also encouraged in individuals living with HIV (American Heart Association, 2013; Mascolini, 2010). Physical activity levels of individuals can be modified by making healthy activity choices, e.g., climbing stairs instead of taking a lift, and by participating in a specific structured exercise programme (Haskell et al., 2007). A substantial body of knowledge is available concerning the effects of exercise in individuals infected with HIV. Randomized controlled trials are evaluated regularly and two reviews are particularly worth discussing: O'Brien et al. (2010); and Nixon et al. (2005). It has been established that performing aerobic exercise or a combination of aerobic and resistance exercise for 20 minutes, three times per week for at least five weeks appears to be safe, and may improve physical fitness, body composition and well-being in individuals infected with HIV (O'Brien et al., 2010). In these two reviews most of the studies were conducted at a centre, laboratory or gymnasium. It is uncertain if such an intervention would be possible for modifying physical activity levels of individuals in a real-world situation, or, specifically, in the SA context. Publicly-funded health services in SA provide services to the majority of the population and face enormous challenges, including inadequate staffing, inadequate financing of health care and poor access to health facilities (Bradshaw et al., 2007). Structured supervised exercise programmes at a health centre are therefore not always possible due to limited facilities, lack of equipment and limited availability of health care staff. Adherence to such an intervention may also be inadequate due to the participants' lack of access to facilities close to their homes and financial constraints e.g. costs related to travelling to a facility. Study participants in the two systematic reviews were also mostly men. Considering SA HIV infection rates, higher in women than men (Statistics South Africa, 2013 [Stats SA]; Rehle et al., 2010), these reviews do not give a true reflection of difficulties that might be common in the SA and African context. The effect of exercise on the inflammatory risk factor for IHD, namely high sensitivity C-reactive protein (hs-CRP), has also not yet been investigated in the HIV population.

Adherence to the exercise programmes in the above two reviews was also often poor (O'Brien et al., 2010; Nixon et al., 2005). In the first instance, it has been suggested that adherence to exercise in the wider population is better with a home-based rehabilitation programme (Ashworth et al., 2005). One such study is available in the HIV population. Dolan et al. (2006) conducted a supervised home-based aerobic and progressive resistant training programme in women infected with HIV in the USA. Home visits were made to participants with mobile equipment. The researchers found a significant improvement in

oxygen uptake and muscle endurance, but no significant improvements in IHD risk factors, such as body mass index (BMI), blood pressure and lipid profile at the end of the 16-week intervention period. In this study no mention was made of progression, such as instructing participants to try to increase physical activity on days when they were not supervised. The focus was thus on supervised activity, rather than on improving self-monitored physical activity as a means of reducing IHD risk over the longer term.

Secondly, self-management has also been reported to play an important part in adhering to IHD preventive therapies (Ockene et al., 2011). Walking is often given as an example of how to accumulate physical activity throughout the day and achieve the general public health physical activity guidelines (Tudor-Locke, 2012; Haskell et al., 2007). It could also be a way to enhance self-management of risk factors for IHD, as walking is often the preferred physical activity (Burton, Khan and Brown, 2013; Forbes et al., 2010). Walking is well-suited to enhancing physical activity in any individual, as it does not require any specific skill or access to a sport facility. It also bypasses barriers such as “lack of time” or not being a “sporty type”, as often mentioned (Murtagh et al., 2010). A self-monitoring tool to increase walking activity is a pedometer (step counter) (Tudor-Locke, 2009). Activity programmes including the use of pedometers have been shown to reduce some of the risk factors associated with IHD, e.g., physical inactivity, blood pressure and BMI (Richardson et al., 2008; Bravata et al., 2007). No published information focusing on home-based education and walking programmes (incorporating a pedometer) and their effect on IHD risk factors in the HIV population could be found at the commencement of this study.

Perceptions of one’s own risk for IHD can greatly influence decision-making with regard to making healthcare choices. Limited information is available concerning perceptions, knowledge and attitudes related to IHD in individuals, especially prior to a diagnosis of IHD. Two recent studies were found for review in the general population. Ansa, Oyo-Ita and Essien (2007) conducted a study in senior and junior staff at a Nigerian university. They found that knowledge of risk factors was poor and mostly influenced by educational level. Smoking was identified by 70.6% as a risk factor, excessive alcohol abuse by 52.8% and obesity by 41.6%. Sedentary lifestyle (16.6%) and oral contraceptive (6.4%) were least identified as risk factors for IHD. The study also revealed that lifestyle modification strategies were not yet greatly accepted. The second study by Hart (2005) evaluated women’s perceptions of IHD risk. The researcher found that their participants’ perception of IHD risk was often underestimated, their health-promoting behaviours were not influenced by their risk perceptions and that society often imposed barriers to their participation in health-promotion behaviour. In general, then, there is a dearth of published data concerning IHD in individuals living with HIV. Considering the increased risk of IHD in individuals

infected with HIV and the findings of the studies detailed above (Ansa, Oyo-Ita and Essien, 2007; Hart, 2005) it seems important to establish correct perceptions of the risk of developing IHD in the general population, and particularly individuals living with HIV.

The present study aims to add to the body of knowledge in the field of HIV rehabilitation by filling several gaps. It could provide information regarding: the physical activity levels (specifically, walking) of individuals living with HIV in SA; challenges surrounding physical activity evaluation in SA; the effects of a home-based education and walking programme (with pedometer as self-monitoring tool) on the risk factors for IHD; adherence to the programme implemented; and information regarding the affected individuals' self-perception concerning their risk for IHD. Lastly, the study should result in evidence-based education material in the form of a physical activity diary that could be used at primary care clinics to assist with promoting a physically active lifestyle. Finally, this study may also add to the existing knowledge of controllable risk factors for IHD in the SA context.

1.2 PROBLEM STATEMENT

Little is known about the risk factors for IHD or perceptions of the risk of developing IHD in the South African HIV population (on HAART). The effect of an individualised home-based education and walking programme on the controllable risk factors in individuals infected with HIV (on HAART) in the South African context is also unclear.

1.3 RESEARCH QUESTIONS

The appropriate research questions are:

1. What are the risk factors for IHD in individuals that are HIV+ (on HAART), and resident in Johannesburg, SA?

2. What is the affected individual's perception of the risk of developing IHD, and what is his/her behaviour regarding this risk?

3. Does an individualised home-based education and walking programme reduce the associated risk factors for IHD in HIV+ individuals resident in Johannesburg, SA?

1.4 AIMS AND OBJECTIVES OF THE STUDY

Aim 1: To determine the associated risk factors for IHD in individuals who are HIV+ (on HAART) in Johannesburg, SA.

Objectives of aim 1:

1) To determine, in individuals infected by HIV and on HAART:

- current physical activity levels
- perceived levels of stress
- the presence of selected known associated risk factors for IHD (smoking history, diet, resting heart rate [RHR], blood pressure, waist circumference [WC], waist:hip ratio [WHR], BMI)

Aim 2: To determine the nature of the individual's self-perception and behaviour in relation to the risk of IHD.

Aim 3: To determine the effects of a six-month individualised education and home-based walking programme on the associated risk factors of IHD in individuals infected by HIV, on HAART.

Objectives of aim 3:

1) To determine, in individuals infected by HIV:

   - physical activity level
   - perceived level of stress
   - RHR and blood pressure
   - waist and hip circumference, WHR and BMI
   - hs-CRP
   - lipid profiles (total cholesterol, high density lipoprotein [HDL], low density lipoprotein [LDL] and triglycerides [TG] level)
   - glucose levels

2) To create an education physical activity diary.

3) To implement an individualised education and home-based walking programme for affected individuals at risk of IHD, and monitor adherence to the programme.

4) To determine whether an education and home-based walking programme has an effect on physical activity level, perceived stress level, RHR, blood pressure, WC, WHR, BMI, hs-CRP, lipid profile and glucose levels of affected individuals.

5) To determine if a correlation exists between Hs-CRP and evaluated related IHD risk markers.

6) To calculate the 10-year relative risk for IHD events in individuals living with HIV using the Framingham Risk equation, and to determine what effect, if any, the education and home-based walking programme had on the relative risk.

1.5 SETTING OF THE STUDY

The project was conducted at Themba Lethu clinic at Helen Joseph hospital, Gauteng. Themba Lethu is an Nguni phrase that means “our hope”. This clinic was selected as a research site as it is the largest national antiretroviral roll-out site in SA, and has been active since 2004 (Right to Care, 2010). The clinic forms part of Right to Care and the Medicine department of Helen Joseph hospital, which forms part of the academic complex of the University of the Witwatersrand. Right to Care is a non-profit organisation that provides prevention, care and treatment for individuals living with HIV and associated diseases (Right to Care, 2010). The client base at the clinic is more than 24 000 patients since the start of the clinic, of whom 14 000 patients have been initiated on HAART (Right to Care, 2010). The clinic serves patients across Gauteng, and many patients travel from outside Gauteng province, due to the clinic’s high quality of care (Right to Care, 2010). Individuals infected with HIV and on HAART were invited to participate in the project. In the first part of the project IHD risk factors were screened in affected individuals. Participants then continued with the fourth study. To determine which Yamax pedometer should be used in the project, the first pilot study was conducted, using full-time Wits University staff members.

1.6 SIGNIFICANCE OF THE STUDY

This study aims to contribute to understanding IHD among people infected with HIV, and also to the body of knowledge regarding associated risk factors for IHD in South African individuals with HIV. Furthermore, understanding the individual’s self-perception for the risk of developing IHD may provide information regarding subjective internal risk factors for IHD. In addition, the study will test the effect of an individualised home-based education and walking programme, and its effect on cardiovascular risk factors at primary care level. In conclusion, this study may result in evidence-based education material, and provide an example of a low-cost exercise programme. Such a programme could be implemented as part of the primary care management of individuals living with HIV in Johannesburg in an attempt to decrease the future morbidity and mortality caused when HIV and IHD occur together.

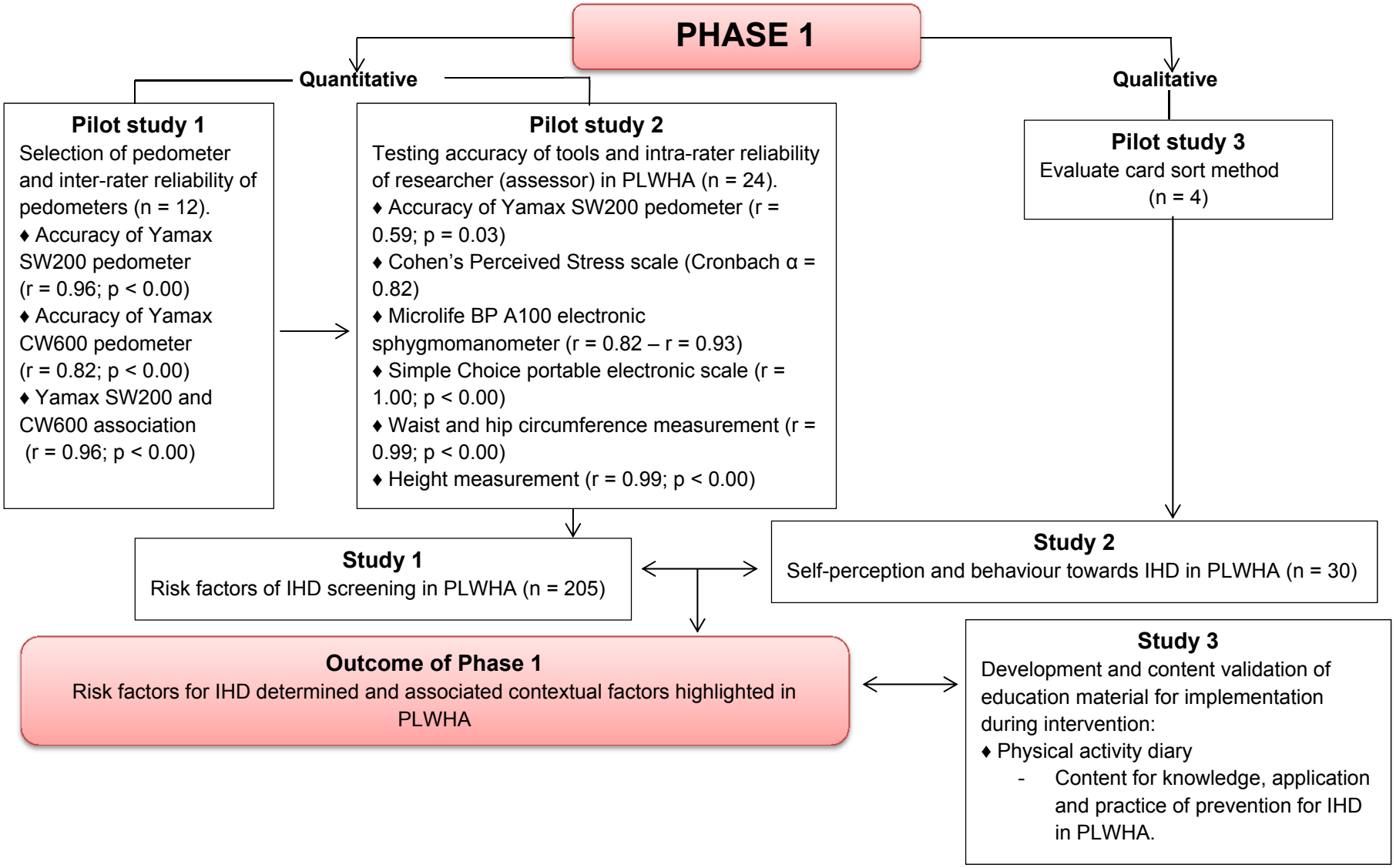
1.7 ETHICAL CONSIDERATIONS DURING THE STUDY

The PhD research project was submitted to the University of the Witwatersrand’s Human Research Ethics Committee, and ethical clearance was granted (clearance certificate

10238; 23 March 2010 [Appendix 1]). The project was approved by the Faculty of Health Sciences of the University of the Witwatersrand (Appendix 2, 3 June 2010). Permission to conduct the project at Helen Joseph hospital and Themba Lethu clinic was received from the hospital management following consultation with the medical manager of the clinic (Appendix 3). The physiotherapy department at Helen Joseph hospital was informed about the project, and verbal permission was received to use the physiotherapy room in Themba Lethu clinic for data collection. Project particulars were explained to participants by two research assistants during recruitment, and participants provided informed consent. The information document (Appendix 4) and consent forms (1) (Appendix 5) and (2) (Appendix 6) are attached. Participants' names and contact details were collected on a coding form (Appendix 7) and kept separate from data-capturing evaluation forms to ensure anonymity. During data collection and analysis study participants' codes were used for identification purposes. Consultations with participants were held in a private physiotherapy room in the clinic to ensure privacy. Participants were paid R50 to cover their transport expenses for each session scheduled with the researcher. Study 4 was registered with the Department of Health (DOH) of South Africa as clinical trial (DOH trial number: DOH-27-0512-3982; Appendix 8; 4 May 2012). During study 4 blood sampling from study participants was necessary to achieve the aims stated above. The glucose and serum sampling tubes and laboratory requisition forms used during the laboratory analysis contained the study participants' code, and not his/her name or surname, to ensure confidentiality.

1.8 OUTLINE OF THE STUDY

The study was designed as depicted in the flow diagram below to address the research questions.


PHASE 1
Quantitative
Qualitative
Pilot study 1
Selection of pedometer and inter-rater reliability of pedometers (n = 12).
♦ Accuracy of Yamax SW200 pedometer (r = 0.96; p < 0.00)
♦ Accuracy of Yamax CW600 pedometer (r = 0.82; p < 0.00)
♦ Yamax SW200 and CW600 association (r = 0.96; p < 0.00)
Pilot study 2
Testing accuracy of tools and intra-rater reliability of researcher (assessor) in PLWHA (n = 24).
♦ Accuracy of Yamax SW200 pedometer (r = 0.59; p = 0.03)
♦ Cohen's Perceived Stress scale (Cronbach α = 0.82)
♦ Microlife BP A100 electronic sphygmomanometer (r = 0.82 – r = 0.93)
♦ Simple Choice portable electronic scale (r = 1.00; p < 0.00)
♦ Waist and hip circumference measurement (r = 0.99; p < 0.00)
♦ Height measurement (r = 0.99; p < 0.00)
Pilot study 3
Evaluate card sort method (n = 4)
Study 1
Risk factors of IHD screening in PLWHA (n = 205)
Study 2
Self-perception and behaviour towards IHD in PLWHA (n = 30)
Outcome of Phase 1
Risk factors for IHD determined and associated contextual factors highlighted in PLWHA
Study 3
Development and content validation of education material for implementation during intervention:
♦ Physical activity diary
- Content for knowledge, application and practice of prevention for IHD in PLWHA.

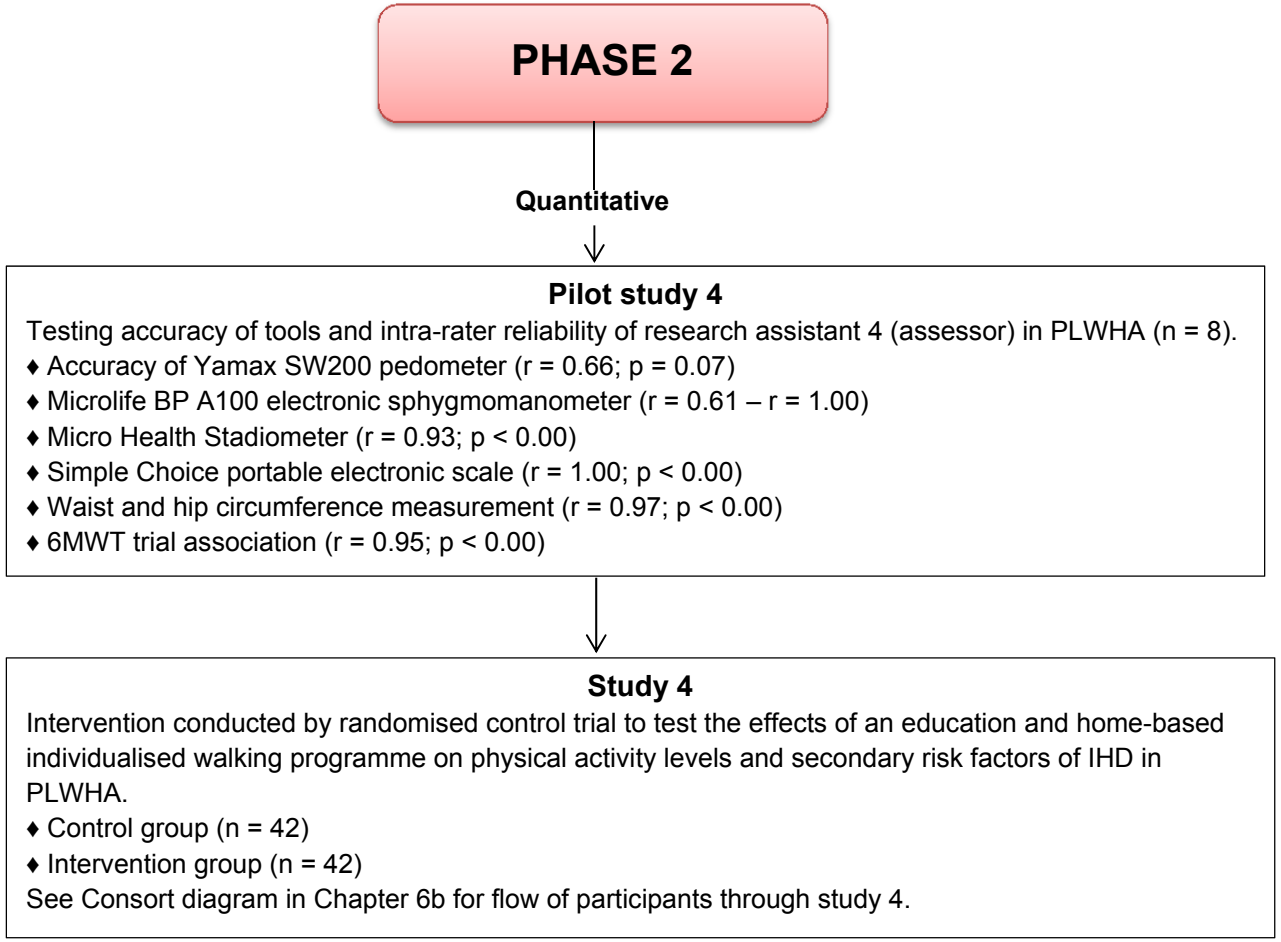


Figure 1.1: Flow Diagram of Phases 1 and 2 of the Research Project

1.9 GENERAL OUTLINE OF THE THESIS

The general outline of the thesis is summarised below:

Chapter 2 : Literature Review
Chapter 3 : Instrumentation for testing and measuring outcomes
Chapter 4 : Study 1 – Screening non-invasive risk factors for IHD
Chapter 5 : Study 2 – Self-perception and behaviour towards IHD
Chapter 6a : Study 3 - Development of the education physical activity diary
Chapter 6b : Study 4 – Physical activity modification as prevention strategy for IHD
Chapter 7 : Conclusion, limitations and recommendations

Chapter 2 consists of a review of the literature supporting the rationale for the research questions.

CHAPTER 2

2. LITERATURE REVIEW

2.1 INTRODUCTION

The literature review is divided into three sections. Section 1 consists of a presentation of the literature related to the burden of diseases in SA as a means of contextualising the burden related to HIV and IHD. Section 2 provides information related to the definition of IHD, and its pathophysiology, risk factors, risk calculation and self-perception. This is done to provide the background for phase 1 of the research, in which the risk factors for IHD were screened and individuals' self-perception of the risk of IHD was assessed in people living with HIV and acquired immune deficiency syndrome (AIDS) (PLWHA). Lastly, section 3 is a discussion related to physical activity modification as a therapeutic management strategy for IHD risk factors. Section 3 provides the literature related to phase 2 of the research project, in which the effects of an education and home-based pedometer walking programme in PLWHA was assessed.

Methodology of Literature Review

The literature review was carried out according to the following research pathways as a means of generating the literature in this chapter. Various research portals were accessed to search for articles related to the topic of interest e.g. PubMed, Science Direct, Mary Liebert, Springer, Wiley Interscience, Pedro database, Scopus, Cochrane reviews and Google Scholar. Specific websites were accessed for gathering explanatory information e.g. Google, Centre for Disease Control, World Health Organisation (WHO), American Heart Association, Medical Research Council, UNAIDS and South African National AIDS Council. In addition, the following research methods were conducted to gather information relevant to the project: individual review of journals and textbooks; individual review of specific researcher publications, congress presentations and abstracts.

2.2 SECTION 1 - BURDEN OF DISEASES IN SOUTH AFRICA

South Africa is facing a health transition characterised by an escalation of non-communicable diseases, while the need for managing infectious diseases persists. A quadruple burden of disease split exists between HIV, chronic lifestyle diseases, perinatal and maternal disease and violence-related injuries in SA (Mayosi et al., 2009). The ten leading underlying natural causes of death in SA in 2010 for both sexes and all ages as per death notifications were, in descending order, as follows: tuberculosis (TB), influenza and pneumonia, intestinal infectious diseases, other forms of heart disease, cerebrovascular

disease, diabetes mellitus, HIV, hypertension (HTN), chronic lower respiratory tract diseases and, lastly, other viral diseases (Stats SA, 2013). It is important to note that 65% of individuals infected with TB in SA are said to have HIV co-infection (Mayosi et al., 2012). Secondly, communicable diseases such as influenza and pneumonia are opportunistic infections that often present in individuals living with HIV (Van Dyk, 2008). Thus mortality due to HIV and HIV-related opportunistic illnesses presented in the Stats SA data might camouflage the true burden of HIV in SA.

The order and rank of certain causes of mortality change when age groups are introduced into the analysis as demonstrated by Stats SA (2013). HIV is ranked higher in the 15 to 49 age group, and risk factors for IHD, e.g. diabetes mellitus and HTN are ranked higher in the 50 to 64 age group. IHD is also included as the eighth leading cause of death in individuals 50 to 64 years of age. A number of strategies have been implemented recently in SA specifically to address the influence of HIV on the causes of death in an attempt to attain the sixth United Nation's Health Millennium Development Goal.

The sixth United Nation's Health Millennium Development Goal aims to reduce the impact of HIV/AIDS, malaria and other diseases in populations by 2015 (WHO, 2013). The 2012 to 2016 National Strategic Plan for HIV, sexually-transmitted infections and tuberculosis of SA, aims to halve the number of new HIV infections, and to ensure that at least 80% of individuals eligible for treatment are receiving it (South African National AIDS Council, 2011). Highly active antiretroviral therapy initiation guidelines in SA are now aligned with international guidelines allowing for HAART initiation when the CD_4 count is less than 350 cells per µL in adults (Department of Health, 2013; Mayosi et al., 2012). The country is also said to have the largest HAART programme in the world (Mayosi et al., 2012; Rehle et al., 2010), with 1.7 million people receiving it (UNAIDS, 2012). The estimated number of adults and children receiving HAART increases yearly, and this scenario has resulted in mortality rates of HIV or AIDS reducing progressively from 52.3% in 2006 to 43.6% in 2011 (Mayosi et al., 2012). The increased accessibility of HAART in conjunction with good adherence to treatment could result in individuals living longer lives, though with conceivable disability related to HIV and its related opportunistic infections, as well as side effects of HAART. The HAART roll-out modification could also alter future causes of mortality in SA, shifting the focus from communicable diseases to a more pronounced non-communicable diseases pattern such as IHD and/or stroke, in both the HIV and general population.

2.2.1 **Prevalence and Incidence Rates of HIV**

Prevalence of HIV infection is a significant sub-Saharan Africa problem, as 23.5 million people are living with HIV in this region (UNAIDS, 2012). Only Swaziland, Botswana and

Lesotho report higher rates of HIV infection than SA (WHO, 2010). Moreover, SA is reported to have the highest number of HIV infections (UNAIDS, 2012). Table 2.1 shows the prevalence estimates according to age groups and the total number of PLWHA from 2002 to 2013 in SA.

Table 2.1: HIV Prevalence Estimates and Number of PLWHA in SA (2002 – 2013)

Year	Prevalence (%)				Incidence Adults 15–49 (years)	HIV population (Millions)
	Women 15–49 (years)	Adults 15–49 (years)	Youth 15–24 (years)	Total Population		
2002	15.9	15.1	13.6	8.7	1.26	4.00
2003	16.0	15.1	12.8	8.9	1.25	4.10
2004	16.1	15.1	12.0	8.9	1.28	4.18
2005	16.2	15.1	11.4	9.0	1.32	4.25
2006	16.4	15.2	10.9	9.1	1.29	4.34
2007	16.5	15.3	10.5	9.2	1.21	4.46
2008	16.7	15.4	10.1	9.3	1.12	4.59
2009	16.9	15.5	9.7	9.5	1.03	4.74
2010	17.1	15.6	9.3	9.6	0.98	4.88
2011	17.2	15.7	9.0	9.8	0.95	5.01
2012	17.3	15.8	8.7	9.9	0.87	5.13
2013	17.4	15.9	8.5	10.0	0.85	5.26

(Source: Stats SA, 2013)

Adult HIV incidence in SA is higher amongst women than men, and a ratio of 1.5 female to male exists in those aged 15-49 (Stats SA, 2013). Approximately 17% of South African women in their reproductive years are HIV positive (Stats SA, 2013). A positive finding from Stats SA (2013) is that new incidences of HIV infection in the 15–49 age group is slowly on the decline when reviewing information of incidence rates from 2002–2013. In addition, the South African National HIV Prevalence, Incidence and Behaviour Survey conducted in 2012 indicated an encouraging finding among young females aged 15-24 years. The survey indicated that HIV incidence declined from 5.3% in 2002-2005 to 2.1% in 2008-2012 in this age group indicating a significant reduction of 60% HIV incidence (Shisana et al., 2014).

2.2.2 Disability-Adjusted Life Years of HIV

The mere prevalence and mortality rates of HIV do not adequately describe the burden of disease related to this condition on the Health Care system of SA, as it does not reflect the added social implications on the community. Disability-adjusted life years (DALYs) of a condition need to be considered for an estimate of total disease burden, as this measure calculates the years lived with disability (Bradshaw et al., 2003). HIV accounts for the largest portion of DALYs in SA, namely, 40.7% as a percentage of total DALYs in 2004 (WHO, 2009). Neuropsychiatric conditions rated second at 6.3% and cardiovascular disease third at 5.8% of DALYs in 2004 (WHO, 2009). In light of the high DALYs attributed to HIV, the need for rehabilitative professionals is great, to assist in screening, preventing, treating and managing disability in individuals living with HIV.

2.2.3 Changing Causes of Death in Individuals Living with HIV on HAART

HIV is no longer a terminal disease, but is considered chronic in the HAART era where therapy is accessible. Since the roll-out of HAART individuals infected with HIV are living longer (Johnson et al., 2013; UNAIDS, 2013; Bhaskaran et al., 2008; Palella et al., 1998). Various researchers have recommended that a CD_4 count threshold of 350 cells/µl should be considered as a guide for when to initiate HAART, as mortality rates are reduced if therapy is initiated prior to dropping to that level (When to Start Consortium, 2009; Hammer, Eron and Reiss, 2008). Studies conducted in SA report that pre-treatment and early HAART-treated deaths are associated with advanced immunodeficiency at enrolment (Peltzer et al., 2011; Lawn et al., 2006). Causes of mortality in individuals living with HIV in the sub-Saharan region appear to be related to conditions such as TB, acute sepsis, cryptococcal meningitis, malignancy and wasting syndrome (Lawn et al., 2008). Additionally, in SA, TB remains the leading cause of death in PLWHA with 87 000 TB deaths occurring in 2011 alone (UNAIDS, 2013). At present the median time from HIV infection to death is reported to be 10.5 years for men and 11.5 years for women in SA (Stat SSA, 2013). Johnson et al. (2013) did however estimate that the life-expectancy of men when initiated on HAART at age 20 was 27.6 years (95% CI: 25.2-30.2) compared to 10.1 years (95% CI: 9.3-10.8) at age 60. The estimated life-expectancy of women were significantly higher than men following HAART initiation: 20 year old women (36.8 years [95% CI: 34.0-39.7] and at 20 [14.4 years [13.3-15.3]). With current South African HAART guidelines, mortality rates could decline and causes of death begin to match findings found from international studies.

Researchers in the USA and Brazil have noted that AIDS-related illnesses are decreasing, while non-AIDS-defining illnesses are increasing to varying degrees (Grinsztejn et al., 2013; French et al., 2009; Palella et al., 2006). Palella et al. (2006) reported the highest increase,

13.1%, in 1996 to 42.5% in 2004 in individuals participating in the HIV Outpatient study in the USA. Both Palella et al. (2006) and French et al. (2009) noted that non-AIDS-defining illnesses in their respective studies included cardiovascular disease, non-AIDS malignancy and liver disease. However, the latter authors also noted that trauma was a frequent cause of death, and that depressive symptoms were an independent predictor of mortality in their Women's Interagency HIV study in the USA. It is therefore important for health care professionals to be aware of the increasing incidence of non-AIDS-defining illnesses, such as cardiovascular disease, in individuals living with HIV on HAART. Health care professionals should vigorously screen, monitor, treat and manage such conditions (Hsue et al., 2008).

2.2.4 Prevalence, Incidence and Mortality Rates of Ischemic Heart Disease

Current incidence rates for IHD are not available for either the general or the HIV population in SA. It is therefore not possible to determine how morbidity related to IHD in SA compares to the rest of the world. The definition of IHD includes a number of conditions, e.g. myocardial infarction or angina pectoris, and so the statistics are often misleading, and fail to reveal the composite extent of incidence due to these different conditions. Composite evaluation of IHD can therefore only be made by reviewing mortality rates of IHD. Kim and Johnson (2011) reviewed the relative burden of stroke and IHD between various countries. Ishemic heart disease mortality rates per 100 000 individuals (as percentage of total mortality rate) from selected countries in the WHO Global Burden of Disease Programme mortality rate estimates in 2004 were as follows: SA 114 per 100 000 (5.7% of total mortality rate); USA 98 per 100 000 (18.2% of total mortality rate) and the United Kingdom (UK) 90 per 100 000 (17.9% of total mortality rate). Mortality from IHD was higher in the USA and UK than SA due to infectious diseases being the leading cause of death in SA at that time – as it continues at present (Statistics South Africa, 2013; Bradshaw et al., 2010). The DALYs attributed to IHD in SA is also much less than those attributed to HIV. Kim and Johanson (2011) reported that the DALYs attributed to IHD in SA, as expressed per 100 000 (and as a percentage of total DALYs loss rate) was 990 (2.1).

When reviewing the statistics related to IHD it is important to bear in mind that risk factors of IHD such as diabetes mellitus and HTN already rank within the ten leading causes of death in SA (Stat SA, 2013). The prevalence of risk factors for IHD among South Africans is also reported to be increasing as revealed by findings on selected risk factors of IHD from specific studies (Ibrahim and Damasceno, 2012; Finucane et al., 2011; Shaw, Sicree and Zimmet; 2010). The prevalence of HTN in SA increased from 54% to 78% from 1998-2003, with urban prevalence said to be higher (25%) than rural (10.5%) (Ibrahim and Damasceno, 2012). The prevalence of diabetes mellitus in SA is anticipated to increase from 4.5% of the

national population in 2010 to 4.9% by 2030 (Shaw, Sicree and Zimmet, 2010). Obesity in Southern African individuals also increased from 1998-2008. Mean BMI in Southern African men is reported to be lower than women, with mean BMI values in women in 1998 being 25.8–26.6 kg/m^2 (Finucane et al., 2011). Mean BMI values in women were noted to have increased to more than 28 kg/m^2 in Southern Africa by 2008 (Finucane et al., 2011). If management of these respective risk factors improve to such an extent as not to result in death, the longitudinal effect of the presence of these risk factors could influence the burden of cardiovascular disease in SA in the future.

Section 2 of the literature review consists of pertinent literature pertaining to IHD, and is presented in section 2.3 below.

2.3 SECTION 2 - ISCHEMIC HEART DISEASE

This section will be discussed as follows: definition of IHD, its pathophysiology, risk factors, risk calculation and self-perception of risk.

2.3.1 Definition of IHD

The definition of IHD includes a number of medical conditions. The International Classification of Diseases divides IHD into the following conditions: acute myocardial infarction (AMI), other acute and sub-acute forms of IHD, other forms of chronic IHD, angina pectoris and old MI (International Classification of Diseases, 2013). IHD develops over time due to narrowing of the coronary arteries that perfuse the myocardium (Collins and Dias, 2009). The narrowing is most often caused by arteriosclerosis.

2.3.2 Pathophysiology of IHD

Arteriosclerosis occurs due to a process involving local blood flow, wall shear stress and an inflammatory cascade. Wall shear stress is the force applied to the blood vessel walls, and is the product of the wall shear rate (speed of blood flow) and viscosity of the blood (Caro, 2009). Arteriosclerosis is said to occur in a patchy distribution pattern in areas where the wall shear stress due to blood flow is low, allowing for fatty streaking of the endothelium (Caro, 2009). The fatty streak is thought to be the result of the transformation of monocytes to macrophages with the subsequent uptake of cholesterol lipoproteins at the endothelium (Pearson et al., 2003). Inflammation plays a key role in this process.

Certain risk factors of IHD promote systemic inflammation that gives rise to a number of noxious stimuli. Under normal physiological conditions the endothelium produces vasodilator nitric oxide that protects the arterial wall against atherothrombosis (Van Leuven et al., 2008). Systemic inflammation results in a decreased expression of endothelial nitric

oxide synthase in conjunction with an increased expression of inducible nitric oxide synthase, resulting in an imbalance, causing endothelium dysfunction (Van Leuven et al., 2008). The noxious stimuli that are the result of systemic inflammation further promote secretion of leukocyte soluble adhesion molecules which result in the attachment of monocytes to endothelium cells (Pearson et al., 2003). Proinflammatory cytokines, namely interleukin one alpha (IL-1α), interleukin one beta (IL-1ß), tumour necrotic factor alpha (TNF-α) and interleukin 18 (IL-18), enhance chemotactic factors release (Mehra et al., 2005). These chemotactic factors encourage monocyte migration into the sub-intimal space of blood vessels that subsequently lead to cholesterol lipoprotein uptake over time and the development of plaque.

Plaque growth and the formation of a fibrous cap are the result of the localisation of smooth muscle cells (SMC), monocyte-macrophage and monocyte-generated foam cells (Mehra et al., 2005). Pro-inflammatory cytokines, namely, IL-1 and TNF-α, enhance the production of SMC and monocytes to facilitate this process (Mehra et al., 2005). Plaque macrophages also secrete inflammatory cytokines such as TNF-α and matrix metalloproteinase, which can degrade the fibrous plaque cap (Zanni and Grinspoon, 2012). Over time death of the cellular components by apoptosis results in a lipid-rich plaque with minimal SMC that can lead to plaque rupture (Mehra et al., 2005). A coagulation cascade is stimulated when a plaque ruptures, and that again activates inflammatory mediated processes to manage the rupture site. It is, however, important to note that systematic inflammation in itself can also result in a coagulation cascade long before the rupture of a plaque (Van Leuven et al., 2008). This consequence of systematic inflammation further assists with the development of atherothrombosis by activating platelets and promoting platelet adherence to the endothelium (Van Leuven et al., 2008). Thus, virtually every step in the formation of atherosclerosis involves processes related to inflammation and can therefore be monitored by evaluating risk factors that promote systemic inflammation as well as specific biochemical inflammatory markers. Section 2.3.2.1 explains how HIV infection influences the pathophysiology of arteriosclerosis, thereby increasing risk of IHD in PLWHA.

2.3.2.1 **HIV infection-mediated effect on the pathophysiology of arteriosclerosis**

Literature suggests HIV infection in itself contributes significantly to arteriosclerosis development, independent of known risk factors of IHD and HAART exposure. Figure 2.1 is a representation of how HIV infection is suggested to advance arteriosclerosis as explained by Zanni and Grinspoon (2012).

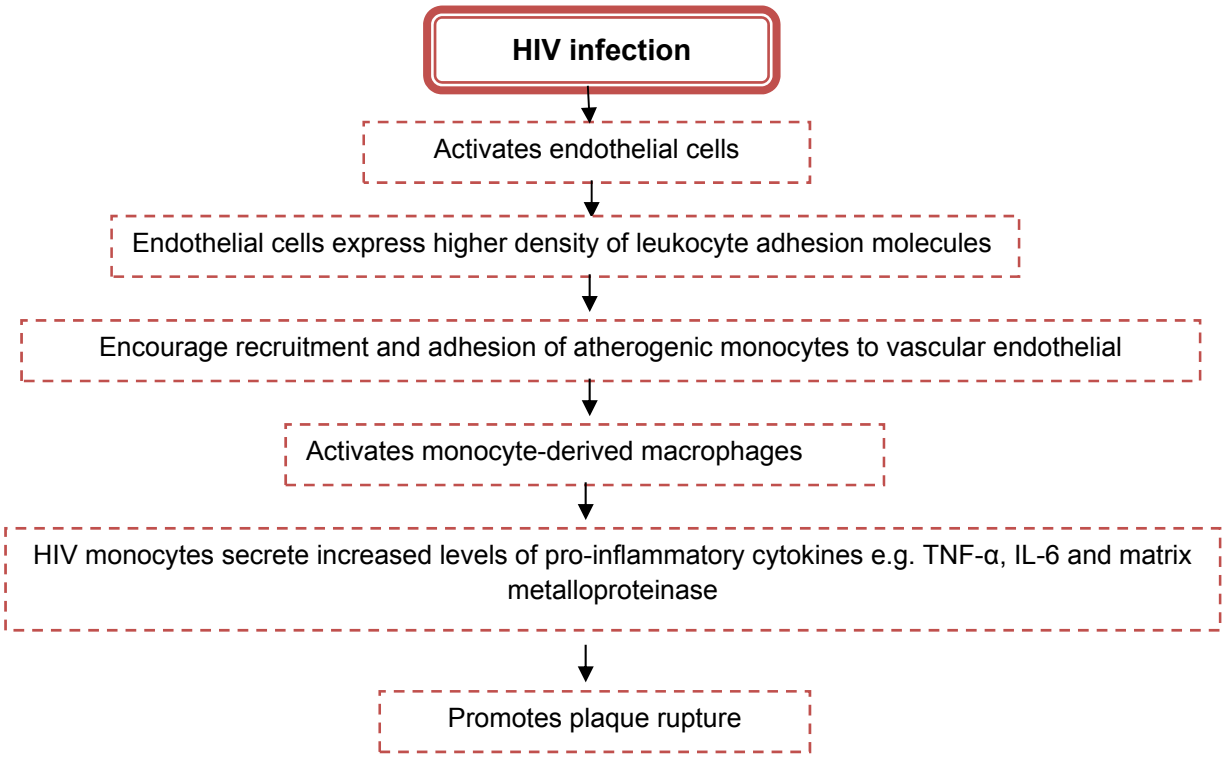


Figure 2.1: HIV Infection-Mediated Effect on Pathophysiology of Arteriosclerosis

2.3.3 Risk Factors for IHD

The development of IHD occurs over time due to the presence of risk factors for IHD leading to arteriosclerosis. Traditional risk factors for IHD also contribute to increased risk of IHD in PLWHA (Triant et al., 2007). They found AMI rates per 1 000 person-years in HIV patients to be 11.13 (95% CI: 9.58–12.68) compared with 6.98 per 1 000 person-years (95% CI: 6.89–7.06) for non-infected individuals. The authors reported that, in addition to HIV infection, risk factors for AMI included male gender (relative risk (RR)=1.72; 95% CI: 1.68–1.77; p<0.0001), age (RR=17.24 for ages 75–84 versus 18-34; 95% CI: 15.87–18.52; p<0.0001), African-American race (RR=1.44; 95% CI: 1.38–1.50; p<0.0001), diabetes (RR=1.98; 95% CI: 1.93-2.04; p<0.0001), HTN (RR=1.62; 95% CI: 1.57–1.66; p<0.0001) and dyslipidaemia (RR=3.03; 95% CI: 2.93–3.13; p<0.0001), as assessed in a combined model. Of notable interest, however, is that the difference in AMI rates was more pronounced in women infected with HIV than non-infected individuals. In gender-stratified models adjusting for age, race, HTN, diabetes and dyslipidaemia the RR of AMI was 2.98 (95% CI: 2.33–3.75; p<0.0001) in women and 1.40 (95% CI: 1.16–1.67; p=0.0003) for men (Triant et al., 2007). This finding is important when considering that the prevalence of HIV infection is higher in women than men in SA, leading to the potential for increased number of individuals being at risk for IHD (Stats SA, 2013).

Traditional risk factors for IHD can be divided into non-controllable and controllable (National Cholesterol Education Program Expert Panel Adult Treatment Panel-III [NCEP ATP-III], 2002). A focus on traditional risk factors for IHD is presented first, followed by how it differs in PLWHA, where applicable.

2.3.3.1 **Non-controllable risk factors for IHD**

Non-controllable risk factors for IHD include age, gender and family history of premature IHD (NCEP ATP-III, 2002). Risk for IHD increases in individuals with advancing age due to the progressive accumulation of arteriosclerosis in the blood vessels (NCEP ATP-III, 2002). Risk of IHD is increased in men older than 45 years and in women older than 55 years in the general population (NCEP ATP-III, 2002). Similarly, in PLWHA the incidence of IHD is reported to increase from 0.77 cases per 100 person-years in the 18–24-year age group to 5.5 in the 75 years and older age group in HIV-infected men (Currier et al., 2003). In HIV-infected women the incidence of IHD increases from 0.40 cases per 100 person-years in the 18–24-year age group to 5.43 in the 56–74-year age group (Currier et al., 2003). Of notable interest however is that the RR for IHD was higher in younger HIV-infected men and women than the general population (Currier et al., 2003). The authors reported the RR for IHD in HIV infected men aged 18–24 years was 6.76 (95% CI: 3.36–13.58), and between 25–34 years was 2.16 (95% CI: 1.81–2.58). The RR in women aged 18–24 years was 2.47 (95% CI: 1.23–4.95), 25–34 years was 1.53 (95% CI: 1.10–2.13) and 35–44 years 1.67 (95% CI: 1.41–1.97). Screening and monitoring controllable risk factors of IHD are therefore important from an earlier age in PLWHA than the general population.

2.3.3.2 **Controllable risk factors for IHD**

Lifestyle-controllable risk factors related to behaviour are physical inactivity, smoking, unhealthy diet and excessive stress (NCEP ATP-III, 2002). These behaviours have physiological, anthropometric, metabolic and inflammatory consequences resulting in the following risk factors: elevated RHR; HTN; obesity; abdominal obesity; diabetes mellitus; altered cholesterol profiles and increased hs-CRP (Hsia et al., 2009; Steyn et al., 2005; Yusuf et al., 2004; Pearson et al., 2003; Greenland et al., 1999). The controllable risk factors of IHD specific to individuals' behaviour is discussed in section 2.3.3.2.1 to section 2.3.3.2.4.

2.3.3.2.1 **Behavioural risk factor: Physical inactivity**

Physical activity protects against IHD by influencing known modifiable risk factors for IHD, and also having protective cardiovascular effects despite the presence of risk factors. It is known that an inverse relationship exists between physical activity levels and risk for mortality (Reddigan et al., 2011; Mora et al., 2007; Lee and

Skerrett, 2001; Lakka et al., 1994). Lee and Skerrett (2001) maintain that minimal adherence to the public health recommendations for physical activity (an energy expenditure of approximately 1 000 kcal/wk) is associated with a 20–30% reduction of risk of all-cause mortality in men and women. Lakka et al. (1994), while evaluating the relationship between leisure-time physical activity and first AMI in men, found the relative hazard for AMI to be 0.31 (95% CI: 0.12–0.85; p=0.02) in those who undertook more than two hours of physical activity per week. In individuals who engaged in 0.7 to 2.2 hours per week the relative hazard was 1.11 (95% CI: 0.58–2.12; p=0.75) (Lakka et al., 1994). Mora et al. (2007) quantified the contribution of traditional - e.g. BMI - and novel risk factors, e.g. hs-CRP, to the activity-related reduction in cardiovascular events in the large Women's Health Study. The authors noted that the RR for cardiovascular events decreased by 27% to 32% to 41% as physical activity level energy expenditure increased from 200 to 599 kcl/wk, 600 to 1499 kcl/wk and more than 1500 kcal/wk respectively. The authors noted that 59% reduction in cardiovascular events associated with physical activity was explained by risk factor modification, and a reduction in hs-CRP contributed most to reduced risk of a cardiovascular event. Furthermore, Reddigan et al. (2011) proposed that engaging in light to moderate or vigorous physical activity is associated with a 30% reduction in cardiovascular disease mortality, which is independent of adjustment for metabolic risk factors such as dyslipidaemia, diabetes mellitus and obesity. This decrease in risk that is independent of alteration in known risk factors for IHD is suggested to be due to the positive effect of physical activity on endothelial blood vessel function (Reddigan et al., 2011; Joyner and Green, 2009). Engaging in regular physical activity is therefore important in attempting to reduce one's risk factors for IHD, but, in the absence of risk factor reduction, cardiovascular mortality could also be reduced by additional benefits of physical activity on blood vessel function.

A relationship between amount, type and intensity of physical activity has also been shown to be relevant to risk for IHD. Tanasescu et al. (2002) conducted the Health Professional's Follow-up study from 1986-1998 in men from the USA to assess the influence of amount, type and intensity of leisure-time physical activity on the risk of IHD. The sample consisted of 44 452 participants, who attended follow-ups every two years during the study period. Tanasescu et al. (2002) indicated that the RR for IHD reduced significantly ($p<0.001$) as volume of physical activity (hours per week [hrs/wk]) increased: 6.33–14.49 hrs/wk (RR=0.93; 95% CI: 0.80–1.06), 14.50–25.08 hrs/wk (RR=0.90; 95% CI: 0.78–1.05), 25.09–41.98 hrs/wk (RR=0.87; 95% CI: 0.71–1.01) and more than 41.99 hrs/wk (RR=0.74; 95% CI: 0.63–0.87) - adjusted

for alcohol consumption, smoking, family history of AMI, nutrient intake, diabetes, high cholesterol, HTN and BMI. Furthermore, the RR reduced significantly (p=0.01) as exercise intensity increased from moderate to vigorous: RR=0.93; 95% CI: 0.83–1.04 and RR=0.82; 95% CI: 0.71–0.97 respectively, adjusting for the variables mentioned above (Tanasescu et al., 2002). In multivariate analysis running (p<0.001), walking (p=0.04) and weight training (p=0.03) were significantly associated with a reduction in RR for IHD. Walking pace was also shown to significantly reduce (p<0.001) RR for IHD, with a faster pace lowering risk more: two to three mph (RR=0.72; 95% CI: 0.54–0.94), three to four mph (RR=0.61; 95% CI: 0.45–0.81) and more than four mph (RR=0.51; 95% CI: 0.31–0.84). Walking pace was independently associated with reduced risk, irrespective of the number of hours walked. In addition, the authors found that 30 minutes or more of walking at a brisk pace was associated with an 18% RR reduction (RR=0.82; 95% CI: 0.67–1.00) in IHD.

Lee, Sesso and Paffenbarger (2000) set out to determine whether a difference could be noted between duration of physical activity bouts and RR of IHD in the Harvard Alumni Health Study. The study was conducted between 1988-1993, with 7307 men participants. The authors reported the RR for IHD to reduce significantly (p=0.04) as bouts of physical activity differed when adjusting for age: less than 15 minutes (RR=0.85; 95% CI: 0.55–1.31), 16–30 minutes (RR=0.76; 95% CI: 0.57–1.03), 31–45 minutes (RR=0.85; 95% CI: 0.58–1.24), more than 60 minutes (RR=0.78; 95% CI: 0.62–0.98). Interestingly, the largest reduction was noted when 16–30 minutes of activity was performed. During multivariate analysis when findings were adjusted for age and total energy expenditure or age, total energy expenditure, cigarette smoking, HTN, diabetes, early parental death, alcohol, red meat, vegetable consumption and participation in vigorous exercise, no significant differences (p=0.68, p=0.25) were noted in RR for IHD and time bouts of physical activity respectively (Lee, Sesso, Paffenbarger, 2000). The dose response literature related to physical activity and RR for IHD has contributed to providing the evidence for the Public Health physical activity recommendations and guidelines. Information related to the Public Health physical activity recommendations and guidelines for adults are discussed in section 2.4.2 in section 3 of this literature review.

Physical inactivity is a health concern worldwide, due to the increased burden related to this risk factor for many non-communicable diseases, including IHD. The prevalence of physical inactivity in the sub-Saraharan African region is reported to be 19.6% in men and 22.9% in women (Onen, 2013), with urbanisation reported to

be one reason for this statistic (Belue et al., 2009). The prevalence of physically inactive individuals in SA is much higher than the general sub-Saraharan African region data. The World Health Survey reported the crude prevalence rates for physical inactivity in SA to be 43% for men and 47% for women in 2002–2003 (Guthold et al., 2008). When the burden of physical inactivity is reviewed in relation to IHD, 30% of IHD cases in SA are attributed to physical inactivity (Joubert et al., 2007), compared to international statistics of 6% (Lee et al., 2012). Physical activity modification by encouraging individuals to increase their activity level is therefore of significant importance in the South African context specifically.

Literature regarding PLWHA's physical activity levels is available internationally. Fillipas et al. (2008) evaluated the physical activity levels of PLWHA (n=191) attending a public hospital infectious disease clinic in Melbourne Australia compared to an HIV- negative group of patients (n=70) attending the same clinic due to complaints related to general infectious diseases. Physical activity levels were assessed with the short version of the IPAQ. The authors reported that 73.8% of PLWHA and 65.8% of non-infected study participants achieved the recommended physical activity guidelines of ≥ 150 min/wk (Fillipas et al., 2008). There was no significant difference ($p>0.05$) between the proportion of study participants who met the physical activity recommended guidelines according to age, gender or HIV status. A possible explanation for the higher percentage of PLWHA that achieved the recommendations could be due to the fact that they were healthier at the time of assessment. Three-quarters of them were on HAART, the mean CD_4 count was 368 cells/mm^3 and viral load 50 $\log_{10}$ copies. Secondly, they might have exaggerated their activity level as a means of indicating that they comply with their HIV management, as exercise forms part of HIV management. On the other hand, those not infected with HIV were of impaired health, as the reason for them attending the clinic was due to them having general infectious diseases.

In contrast, Ramirez-Marrero et al. (2008) evaluated the physical activity levels of 58 Hispanic adults (35 men and 23 women) living with HIV in San Juan, Puerto Rico. Physical activity levels were assessed with the short version of the IPAQ, Yamax SW200 pedometer and Actigraph GT7164 accelerometer. The authors classified individuals as active if they took ≥ 10 000 steps per day as measured with the pedometer or if they achieved ≥ 150 min/wk of moderate to vigorous physical activity as measured with the IPAQ and accelerometer. The proportion of participants that were considered active in the study was 81% as measured with the IPAQ, 54% with the accelerometer and 17% with the pedometer respectively. The

walking behaviour of the study cohort as measured in mean steps per day was 7 418 (±2 714) as assessed with the pedometer and 6 862 (±2 246) with the accelerometer. Both Ramirez-Marrero et al. (2008) and Fillipas et al. (2010) subsequently reported that the IPAQ overreads physical activity levels, and an objective physical assessment tool such as a pedometer or accelerometer is preferred for precise levels. Even though Ramirez-Marrero et al. (2008) found a difference in steps recorded between the pedometer and accelerometer, agreement was still significant (61%, Kappa=0.25, p=0.01) and the sensitivity of the pedometer high (96%).

Information regarding physical activity levels of PLWHA longitudinally is also available internationally as assessed over a one year period. Fillipas et al. (2012) monitored physical activity levels and cardiovascular fitness in PLWHA in Melbourne Australia over a period of a year. They found that 19-37% of participants reported suboptimal physical activity levels at each study visit at six and twelve months. Higher cardiovascular fitness was associated with better body composition (p=0.05) and greater energy expenditure with improved body image (r=0.325, p=0.027). Being in a permanent relationship was also associated with higher activity levels (p=0.032) providing evidence that less support might increase the risk for physical inactivity.

Information pertaining to the physical activity levels of PLWHA in SA is limited. When reviewing literature regarding disability amongst PLWHA in SA, two studies were found that provided information regarding the physical mobility of PLWHA. Myezwa et al. (2009) and Van As et al. (2009) used the International Classification of Function Disability and Health to evaluate PLWHA in a hospital and out-patient setting respectively. The authors found that the physical mobility of their study participants was affected. Explanatory factors reported to influence physical mobility significantly in their respective study cohorts included sensory function and pain, neuromusculoskeletal and movement-related function, muscle power, energy and drive function (Myezwa et al., 2009; Van As et al., 2009). The authors' findings could suggest that physical activity levels might be less than health recommendation levels and thus predispose PLWHA in SA to risk of IHD.

In a further article pertaining to how HAART exposure influenced physical activity levels in PLWHA in SA, Kinsey, McVeigh and Chantler (2008) evaluated habitual physical activity levels by questionnaire, and assessed the relationship to CD_4 count in PLWHA. The questionnaire was developed combining components of the

Modifiable Activity Questionnaire, the Minnesota Leisure-Time Physical Activity Questionnaire and the Baecke Questionnaire of Habitual Physical Activity. The authors found a positive and significant correlation between length of HAART exposure and CD_4 count ($r=0.45$; $p<0.0001$) and CD_4 count and physical activity levels ($r=0.20$; $p<0.0067$). Exposure to HAART was therefore associated with higher immune parameters and improved habitual physical activity levels. These findings are of particular importance in the South African context when one aligns it with the country's HAART initiation practice. In SA until recently HAART was initiated when individuals were already severely immunocompromised (Peltzer et al., 2011; Lawn et al., 2006). According to the WHO PLWHA with severe immune deficiencies can be placed in Performance Scale 4 when reviewing their activity level (Van Dyk, 2008). Individuals in this Performance Scale are reported to have been bedridden for more than 50% of the day during the preceding month (Van Dyk, 2008). Habitual physical activity levels would therefore be significantly reduced in these individuals, and inadequate to promote health. It can therefore be concluded that during the early stage of HAART initiation such individuals could benefit from therapy to improve their activity level sufficiently to such promote health. During this literature review, no published information pertaining to the walking behaviour of PLWHA in SA and how it relates to IHD risk could be found. This project will provide this additional physical activity level information.

2.3.3.2.2 **Behavioural risk factor: Smoking**

Cigarette smoking is an important modifiable risk factor for IHD in the general population, as well as in PLWHA, especially men. Smoking is believed to influence the pathophysiology of IHD by impairing the vasodilatory function of blood vessels, promoting systemic inflammation and modifying cholesterol profiles, thereby initiating and aggravating arteriosclerosis (Ambrose and Barua, 2004). Smoking contributes to the inflammatory cascade by increasing circulating pro-inflammatory markers such as IL-6, TNF-α and CRP (Ambrose and Barua, 2004). Furthermore, smokers are reported to have significantly higher total cholesterol (3%), LDL (1.7%), TG (9.1%), very low LDL (10.4%) and a lower concentration of HDL (5.7%) than non-smokers (Graig, Palomaki and Haddow, 1989). This altered lipid profile increases smokers' risk of IHD.

The extent of the relationship between smoking and IHD was determined in the INTERHEART study, a large international case-controlled study including 52 countries. It was specifically designed to assess the risk factors for IHD worldwide. The study reported the odds ratio (OR) to be 2.87 (2.58–3.19) between smoking

and the risk of having an AMI when adjusting for all other risk factors for IHD (Yusuf et al., 2004). Similarly, in the African context, Steyn et al. (2005) found the OR to be 2.17 (1.70–2.77) in the INTERHEART Africa study. In addition, the study also reported that on cessation of smoking the OR declined to 1.87 (1.55-2.24) within three years of stopping, but that a residual risk remained for up to 20 years (OR 1.22 [1.09-1.37]) (Teo et al., 2006). Smoking cessation is said to have the biggest effect on reducing the risk of IHD when compared to other risk factor modifications, as it diminishes this risk by 50% (Lundgren et al., 2008). Smoking cessation should therefore be a core management strategy for primary and secondary management of IHD.

International data from studies conducted in PLWHA report that smoking prevalence among PLWHA is higher than non-infected individuals. Saves et al. (2003) found that 55% of a sample of 223 HIV-infected men and 58% of a sample of 51 HIV-infected women were smokers. By comparison, only 32.7% of a sample of 527 non-infected men and 28.1% of a sample of 511 non-infected women were smokers (Saves et al., 2003). The authors reported that the estimated attributable risk of IHD due to smoking was 65% in HIV-infected men and 29% in HIV-infected women (Saves et al., 2003). In SA a relative comparison regarding smoking status between HIV-infected and non-infected individuals can be made when reviewing the following two articles. In the general SA population smoking prevalence is reported to be 10 to 11% in women, 35% in men, with lower prevalence associated with higher income and education, and higher prevalence with living in an urban area (Peer et al., 2009). A further article was available for review regarding smoking status in PLWHA admitted to a hospital for management of cardiac symptoms. Sliwa et al. (2012) reported that the smoking prevalence was 45% in a sample of 196 PLWHA when the influence of HIV infection was evaluated in the Heart of Soweto Study cohort. Individuals included in this study consisted of individuals admitted to Chris Hani Baragwanath hospital for secondary management due to the presence of cardiac symptoms. The authors also reported that men (77%) included in the study were more likely to be smokers than women (23%). It therefore appears that smoking in South African PLWHA could also be a more significant problem. Published information pertaining to smoking prevalence of PLWHA at primary care level in SA could not be sourced. Considering that more women are reported to access HAART in Sub-Saharan Africa (Braitstein et al., 2008), as well as in the South African context (Cornell et al., 2012), it would be prudent to assess the smoking status of PLWHA at a primary care level. It would generate the information

necessary to evaluate the need for smoking cessation programmes as a means of managing IHD at primary care level.

2.3.3.2.3 **Behavioural risk factor: Diet**

Diet can reduce or increase the risk of IHD. The INTERHEART study assessed the relationship between following an oriental diet (high intake of tofu, soy with sauces), western diet (high intake of fried foods, salty snacks, eggs and meats) and prudent diet (high intake of fruit and vegetables) with the risk of AMI (Iqbal et al., 2008). The authors found that the prudent diet was associated with a reduced risk for AMI, the western diet was weakly associated with an increased risk for AMI and the oriental diet had no relationship with AMI (Iqbal et al., 2008). The investigators further analysed the influence of selected food items on the risk for AMI. A significant inverse association between the intake of the following items and AMI existed respectively for: raw vegetables, green leafy vegetables, cooked vegetables and fruits. Conversely, a positive association between AMI and the intake of fried foods and salty snacks ($p<0.001$) and a weak association with meat intake and AMI ($p<0.08$) existed (Iqbal et al., 2008). In addition, Artalejo et al. (1996) indicated how a Mediterranean diet, that contains fish and wine, influenced the mortality ratio of IHD. The authors reported that a diet containing fish reduced the risk of dying from IHD ($r=-0.32$; $p=0.037$) and that a moderate consumption of wine had an inverse relationship with IHD mortality ($r=-0.31$; $p=0.038$). They, however, highlighted that heavy consumption of wine revealed a positive association with IHD mortality ($r=0.35$; $p=0.037$). From all this, the WHO suggests an intake of at least five vegetables and fruit combined (400 grams) per day in an attempt to prevent non-communicable diseases such as IHD (WHO, 2013). A high intake of fruit and vegetables and fish as preferred protein source is also suggested in both the general and the HIV population as a means of prevention and secondary management of IHD (Alpert, 2011; Lundgren et al., 2008).

International data suggest that the dietary quality of PLWHA on HAART requires improvement. Duran et al. (2008) conducted a cross-sectional study in 56 HIV-infected adults between the ages of 20–59 years of age in Sao Paulo, Brazil. Dietary intake was assessed as the average of two 24-hours dietary recall of participants spaced a week apart. Foods were grouped according to their composition and classification following the dietary guidelines of Brazil. The majority of participants in the study were men (82%), and the authors found that most individuals had an inadequate diet (64.3%) that required improvement, but only 8.7% had a poor diet. The diet quality was better in those individuals that were not

overweight (p=0.033) as they also had higher dairy and grains scores (p=0.039 and 0.005 respectively). Participants in the study had a low intake of fruit and vegetables irrespective of their weight status, as well as a high intake of meats, eggs, total fat and cholesterol (Duran et al., 2008).

A study conducted in SA among PLWHA, not on HAART, and non-infected individuals had slightly different findings. Voster et al. (2004) investigated the nutritional status of "apparently healthy" asymptomatic HIV-infected Africans compared to non-infected Africans older than 15 years in the Thusa study, conducted in the North West Province of SA. Thusa is an acronym for Transition and Health during Urbanisation of South Africans. The main aim of the larger Thusa study was to monitor the impact of urbanisation on health to provide information on specific interventions needed to improve health. The authors reported that all groups seemed to follow a prudent diet containing vegetables with total fat providing 26% of total energy intake, in line with the guideline of less than 30%. An interesting finding was that a moderate to high intake of maize meal porridge and/or samp resulted in higher liver enzymes than individuals who consumed a diet of meat and vegetables (Vorster et al. 2004). The relationship between the dietary content and liver function parameters is worth bearing in mind, considering that PLWHA often present with, or develop, liver dysfunction (Crum-Cianflone et al., 2009). In such cases advice regarding reducing the consumption of maize meal porridge and/or samp as their main source of dietary intake could influence their liver function favourably.

By contrast, more recent literature on the general South African population has shown that vegetable and fruit intake is less than the WHO recommended daily amount. Faber, Laubscher and Laurie (2013), when assessing the consumption of fruit and vegetables in individuals living in a peri-urban area in KwaZulu Natal, found that intake in two- to five year old children was 99 grams daily, and 124 grams per day for their adult caregivers. Similarly, Peltzer and Phaswana-Mafuya (2012), in a national cross-sectional study found that the overall prevalence rate for insufficient fruit and vegetable intake in adults older than 50 years of age was 68.5%, with a mean intake of four servings reported per day. In multivariate analysis, coming from a Black African or coloured population group, lower educational level and being a smoker were associated with inadequate fruit and vegetable intake (Peltzer and Phaswana-Mafuya, 2012). Putting the burden of disease attributable to low fruit and vegetable intake in SA into perspective is possible due to findings from Schneider et al. (2007). They reported that, for both men and women, the largest portion of total

years of healthy life lost due to low fruit and vegetable intake was for IHD (60.6% and 52.2% gender respectively). Considering the contrasting findings related to fruit and vegetable intake reported above, the need for assessing the intake of fruit and vegetable in PLWHA on HAART at primary care level as a means of screening for risk for IHD is indicated.

2.3.3.2.4 **Behavioural risk factor: Perceived stress levels**

Psychosocial stress is a modifiable risk factor for IHD, as it is independently associated with IHD, but facilitates changes in health behaviour, thereby influencing the pathophysiology of IHD. The INTERHEART study highlighted the association of psychosocial stress with the risk of AMI after adjustment for age, sex and geographical region with an OR of 3.49 (95% CI: 2.41–5.04) in women and 2.58 (95% CI: 2.11–3.14) in men (Yusuf et al., 2004). Psychosocial stress was assessed by evaluating responses to four questions regarding stressful factors, namely, stress at work and home, financial stress and major life events in the past year (Rosengren et al., 2004). People presenting for their first AMI had higher prevalence of all four stress factors ($p<0.0001$) than their matched control subjects (Rosengren et al., 2004).

The close relationship between IHD and stress can firstly be explained by the internal body response to stress. Psychosocial stress adversely affects autonomic and hormonal homeostasis, resulting in metabolic abnormalities, systemic inflammation and insulin resistance (Das and O'Keefe, 2008). Secondly, due to different ways of processing psychosocial stress, it has the ability to influence individuals' health behaviour. Rod et al. (2009) indicate that individuals with higher levels of stress were less likely to quit smoking (OR=0.58; 95% CI: 0.41–0.83) and more likely to become physically inactive (OR=1.90; 95% CI: 1.41–2.55) than those with low levels of stress. The authors also found that stressed women were more likely to become overweight (OR=1.55; 95% CI: 1.12–2.15) and stressed men were twice as likely to develop diabetes mellitus (OR=2.36; 95% CI: 1.22–4.59). Consequently, stress management strategies could decrease the risk of IHD by influencing how individuals perceive and interpret stressful stimuli and also by preventing or minimising poor health style habits.

Literature of perceived psychosocial stress levels for SA is available. Hamad et al. (2008) assessed the perceived stress levels of low-income individuals in Cape Town, Port Elizabeth and Durban who applied for loans at a local microcredit lending organisation. Stress in individuals was evaluated with the 10-item version of

the Cohen's Perceived Stress Scale (PSS) and the authors found that men had a mean PSS score of 17.5 and women 19.6 (standard deviations were not included). The HIV status of those in the study was not collected, though the authors reported that an HIV-positive status might significantly influence participants' stress levels. This suggestion is supported by findings from Garcia et al. (2013). They evaluated Ghanaian women's perceived stress levels with the 4-item PSS 12 months after childbirth. The authors found that being HIV-positive had an independent relationship (OR=2.31; 95% CI: 1.29–4.12) with the PSS score compared to non-infected mothers. Literature pertaining to perceived stress levels in PLWHA in SA could not be sourced. Comparing the South African findings of Hamad et al. (2008) with an international study is, however, beneficial in highlighting the differences in levels of perceived stress between countries.

The South African mean PSS scores were higher than PSS scores collected in a survey conducted on the general USA public in 2009. Cohen and Janicki-Deverts (2012) reported that the mean PSS score in the survey for men was 15.52 (±7.44) and women 16.14 (±7.56) when the 10-item version of the PSS was used. It therefore seems that the South African public experiences higher levels of stress than that of the USA. Review of the findings of perceived stress in the INTERHEART study and the studies reported above shows a trend towards women experiencing higher levels of stress than men. This particular risk factor for IHD could be more significant for PLWHA in SA as the prevalence rate of HIV infection is higher in women than men (Stats SA, 2013). In view of the absence of literature regarding perceived stress levels of PLWHA in SA, collecting this data would determine whether high stress levels among PLWHA is a problem. This, in turn, would provide support for implementing strategies to manage stress as a means of improving individuals' health. The physiological parameters of stress, namely, elevated RHR and blood pressure that are considered controllable risk factors for IHD, will be discussed in section 2.3.3.2.5 and the effects of HIV infection on these parameters will be highlighted.

2.3.3.2.5 Physiological risk factors: RHR and blood pressure

An elevated RHR has been shown to be a risk factor for IHD as it is an independent predictor of IHD events in men and women. A RHR more than 79 beats per minute (bpm) is suggested as a risk factor for IHD (Hsia et al., 2009; Palatini, 2007). They evaluated the relationship between RHR and IHD events in postmenopausal women included in the Women's Health Initiative study over a 7.8 (±1.6) year follow-up period. The authors found the hazard ratio to be 1.29 (95% CI: 1.11–1.42) for the

highest RHR (>76 bpm) versus the lowest RHR (≤62 bpm; p=0.001). The relationship between RHR and IHD events did not differ between ethnic groups or between women with or without diabetes. It was, however, stronger in women aged 50-64 years at baseline than those aged 65-79 years. Similarly, Greenland et al. (1999) evaluated the relationship between RHR and risk of IHD, cardiovascular disease, cancer and all-cause mortality in age-specific cohorts in black and white men and women over a 22 year period. The authors' findings specific to IHD were as follows: for men aged 18-39 years, RR=1.27 (95% CI: 1.08–1.48); for men aged 40-59 years, RR=1.13 (95% CI: 1.05–1.21); for men aged 60-74 years, RR=1.00 (95% CI: 0.89–1.12); for women aged 40-59 years, RR=1.21 (95% CI: 1.07–1.36); and for women aged 60-74 years, RR=1.16 (95% CI: 0.99–1.37). Heart rate was not associated with mortality in women in the age group of 18-39 years. The relationship between an elevated RHR and the risk for IHD can be explained by the relationship of this parameter with other known modifiable risk factors for IHD, as well as the physiological changes that occur as a result (Palatini, 2007; Greenland et al., 1999).

An elevated RHR could be the result of known modifiable risk factors for IHD. Greenland et al. (1999) indicated that RHR correlated significantly and positively with SBP and DBP and smoking status in all age groups (p<0.01). In contrast, correlations with cholesterol levels and BMI were small or inconsistent between age groups (Greenland et al., 1999). The suggested physiological mechanisms for the relationship between elevated RHR and the risk of IHD can be explained thus: the relationship is considered to be due to heightened sympathetic nervous system activity resulting in the rapid RHR (Palatini, 2007). The rapid RHR increases the pulsatile nature of the arterial blood flow and causes greater mechanical stress and shear forces on the endothelium, resulting in increased arteriosclerosis (Palatini, 2007). In addition, the elevated RHR causes an increase in cardiac work load, and that, over time, greatly stresses the heart (Palatini, 2007). Evaluating RHR is often the first vital sign assessed in a health care environment, and is therefore a convenient parameter for assessing risk for IHD.

An international study suggests that elevated RHR occurs in PLWHA on HAART when compared to age-matched healthy control group volunteers. Lebech et al. (2007) conducted a study with PLWHA (n=16) and non-infected individuals (n=12) that were non-smokers, did not have diabetes and had not previously received any medication for HTN or dyslipidaemia. The PLWHA included in the study had to have been on HAART for three years. The authors found that the RHR of PLWHA was

significantly higher than control participants (69 bpm [62–74] compared with 57 bpm [52–60]; p<0.001). In addition, the authors found that heart rate variability and parasympathetic activity in PLWHA was also lower than their age-matched controls. They concluded that the elevated RHR might be due to parasympathetic nervous system dysfunction. Considering the findings of Lebech et al. (2007), evaluating RHR in PLWHA in SA at primary care level would be beneficial in determining whether this physiological risk factor for IHD is present.

Hypertension is an important modifiable risk factor for IHD internationally, and also in the African context, due in part to the increased prevalence of this risk factor. Hypertension is defined as a blood pressure reading of more than 140/90 millimetres mercury (mmHg) (Seedat et al., 2006). The INTERHEART study indicated that the association, as reflected by OR between HTN and AMI adjusted for age, sex and geographical area, was 2.95 (95% CI: 2.57–3.39) in women and 2.32 (2.12–2.53) in men (Yusuf et al., 2004). The INTERHEART Africa study highlighted that this risk factor was more closely related to AMI in Black Africans (OR=6.99; 95% CI: 4.23–11.55) than Coloured Africans (OR=2.31; 95% CI: 1.61–3.32) or European or Other Africans (OR=3.90; 95% CI: 1.92–7.94) (Steyn et al., 2005). Additional literature suggests that prevalence of HTN in women is twice that of men for Black Africans, Coloured and Indian or Asian individuals in SA as assessed during a nationwide survey (Hasumi and Jacobsen, 2012). No significant difference in prevalence rates for HTN was observed by gender for White South Africans (Hasumi and Jacobsen, 2012). Literature regarding the effect of HIV infection on blood pressure differs when reviewing data concerning HAART exposure.

Bärnighausen et al. (2008) conducted a study in 25-49-year-old men and women living in Umkhanyakude in rural KwaZulu-Natal in SA as a means of evaluating the influence of HIV infection on BMI and HTN in individuals not on HAART compared to non-infected controls. The study took place in 2003–2004, before HAART was widely available in SA, and this area was reported to have high prevalence rates of HIV (Bärnighausen et al., 2008). The authors found that SBP was on average 3 mmHg lower and BMI 1.9 kg/mm^2 lower in PLWHA than their controls. Further analysis highlighted that HIV infection reduced SBP independently of its lowering effect on BMI (Bärnighausen et al., 2008). Possible reasons for this finding included HIV-related hypoadrenalism or side effects of traditional medicines against HIV (Bärnighausen et al., 2008).

International data provide information regarding the prevalence of HTN in PLWHA. Medina-Torne et al. (2012) reported that the prevalence of HTN was not significantly different (p=0.47) between HIV-positive individuals on HAART (32%) compared to those not receiving HAART (29%) (Medina-Torne et al., 2012). Factors associated with HTN included increasing age, longer duration of HIV infection, higher BMI and diabetes, and a trend also existed for African American ethinicity. Considering the reported increase of HTN in the general SA population, it would be beneficial to investigate whether HTN is a significant health concern in PLWHA on HAART at primary care level that requires therapeutic strategies to improve. Section 2.3.3.2.6 consists of a discussion related to the anthropometric risk factors for IHD and how this differs in PLWHA.

2.3.3.2.6 Anthropometric risk factors: BMI, WC and WHR

Obesity, measured by BMI, and abdominal obesity measured by WC and WHR are considered risk factors for IHD. The INTERHEART study indicated that an elevated BMI had a modest association with AMI (OR=1.44; 95% CI: 1.32–1.57) that decreased when adjusting for WHR (OR=1.12; 95% CI: 1.03–1.22), and was absent when adjusting for all other risk factors for IHD (OR=0.98; 95% CI: 0.88–1.09) (Yusuf et al., 2005). On the other hand, WC and WHR were significantly associated with AMI when adjusting for all other risk factors for IHD (OR for top quartile versus lower quartile were 1.33 and 1.75 respectively [p<0.0001]) (Yusuf et al., 2005). When evaluating obesity it is therefore suggested that BMI, WC and WHR measures be included in risk factor screening for IHD to provide a more reliable evaluation.

The European AIDS Clinical Society guidelines on the prevention and management of metabolic diseases in HIV suggest that screening of body composition, e.g., BMI, WC and WHR, should be done on every patient at diagnosis, before initiation of HAART and annually thereafter (Lundgren et al., 2008). Specific BMI, WC and WHR ranges are available to facilitate effective screening. The following ranges are suggested as normal abdominal obesity measurements for men and women respectively: men, WC<102 cm and WHR<0.95; women, WC<88 cm and WHR<0.86 (American College of Sports Medicine [ACSM], 2010; NCEP ATP-III, 2002). The International Classification of adult underweight, overweight and obesity as per BMI measurements are presented in Table 2.2 (WHO, 2004).

Table 2.2: The International Classification of Adult Underweight, Overweight and Obesity According to BMI

Classification	BMI (kg/m^2)
Underweight ▪ Severe thinness ▪ Moderate thinness ▪ Mild thinness	< 18.50 < 16.00 16.00 – 16.99 17.00 – 18.49
Normal range	18.50 – 24.99
Overweight	≥ 25.00
Pre-obese	25.00 – 29.99
Obese ▪ Obese class 1 ▪ Obese class 2 ▪ Obese class 3	≥ 30.00 30.00 – 34.99 35.00 – 39.99 ≥ 40.00

Obesity in PLWHA is an increasing health concern as individuals are living longer. Crum-Cianflone et al. (2010) found that 62% of individuals included in the US Military HIV Natural History Study (1985–2004) gained weight during HIV infection (Crum-Cianflone et al., 2010). Weight-gain in itself should not be considered problematic, considering that an HIV-positive status is reported to reduce individuals' BMI by 1.9 kg/m^2 prior to initiation of HAART (Bärnighausen et al., 2008). The concern is about weight-gain in individuals already overweight or obese at diagnosis or initiated on HAART. Of notable interest, as reported by Crum-Cianflone et al. (2010), is that 37% of individuals were already overweight and 9% obese at diagnosis of HIV infection. Factors that influenced a higher BMI value at diagnosis were African-American ethnicity, age, being HIV-positive and earlier HIV stage (Crum-Cianflone et al., 2010). Weight gain in the study was related to lower BMI at diagnosis, a higher CD_4 count, lower viral load values, a lack of AIDS diagnosis and longer HIV duration (all parameters $p<0.05$). Similarly, Hurley et al. (2011), when evaluating weight gain in a group of South African individuals initiated on a Stavudine-containing HAART regimen, found a mean BMI change of 2.4 kg/m^2 (95% CI: 1.7–3.1; $p<0.001$) in men and 2.2 kg/m^2 (95% CI: 1.5–2.9; $p<0.001$) in women during the first year of HAART. At commencement of HAART 12% of the study cohort were obese and 21% were overweight. That changed to 22% obese and 36% overweight at 12 months (Hurley et al., 2011). Increase in BMI was positively associated with age ($p=0.001$) in both genders, and inversely associated with TB diagnosis in female participants ($p=0.018$) (Hurley et al., 2011). The presence of obesity with the subsequent increase in weight following initiation of HAART could therefore increase individuals' risk of IHD. Abdominal obesity is also a body composition change that can occur in PLWHA.

Body composition changes are known to occur in PLWHA, and consist of subcutaneous lipoatrophy in the face, limbs and buttocks, with increased accumulation of central body fat representing visceral adipose tissue (Grinspoon and Carr, 2005). Saves et al. (2003), in evaluating risk factors for IHD in PLWHA compared to non-infected individuals, found that body composition changes as measured with WHR were higher in PLWHA. They noted the mean WHR of HIV-positive men to be 0.94 (±0.06) compared to HIV-negative men 0.92 (±0.06), and HIV-positive women 0.85 (±0.07) compared to HIV-negative women 0.80 (±0.07) (Saves et al., 2003). The higher WHR in PLWHA could be due to the influence of HAART. Lipodystrophy (body composition changes in fat distribution) is associated with HAART (Friis-Møller et al., 2003). In multivariate analysis the authors indicated that the association between HAART and lipodystrophy was as follows: nucleoside reverse transcriptase inhibitor (NRTI) OR=8.93 (95% CI: 6.45–12.3; p=0.0001); non-NRTI (NNRTI) OR=12.99 (95% CI: 9.46–17.8; p=0.0001); protease inhibitor (PI) OR=12.40 (95% CI: 9.10–16.9; p=0.0001); NNRTI and PI combined OR=15.62 (95% CI: 1.23–21.7; p=0.0001). Thus HAART could increase the likelihood of PLWHA developing lipodystrophy to varying degrees, but an advanced regimen containing PI seems to contribute more to its development.

Body composition changes were investigated by George et al. (2009) in a cohort of PLWHA in SA initiated on a HAART regimen containing Stavudine over a two-year period. This HAART regimen was the first line HAART regimen in use in SA. The authors reported that participants that developed lipodystrophy tended to have a greater BMI prior to initiation of HAART ($p<0.05$). In addition, all participants had a significant increase in WC from baseline to the end of the study, with changes occurring more in participants that developed lipodystrophy ($p<0.005$) than those who did not ($p<0.001$) (George et al., 2009). Additionally Hurley et al. (2011) also noted a significant ($p<0.001$) increase in WC from baseline of 7.2 cm in men and 7.8 cm in women during the first year when initiated on a Stavudine containing regimen. Waist circumference was positively associated with age in women ($p=0.003$) and men ($p=0.006$) in the study conducted by Hurley et al. (2011). Increasing WC in individuals is an indication of visceral adipose tissue accumulation (Katzmarzyk, Heymsfield and Bouchard, 2013). The presence of visceral adipose tissue has been linked to an increased risk of IHD in the general population (Smith et al., 2012). These authors indicated that markers for insulin resistance (e.g. fasting glucose and insulin levels), lipid profile (e.g. total cholesterol, LDL) and inflammation (e.g. CRP levels) increased with visceral adipose tissue accumulation in men and women with and without diabetes mellitus. They also found that visceral adipose

tissue was positively associated with type two diabetes for men (OR=1.25; 95% CI: 1.09–1.44) and more so in women (OR=1.78; 95% CI: 1.50–2.12). They further reported that cardiovascular disease increased with visceral adipose tissue categories irrespective of whether individuals had diabetes mellitus. Thus the body composition changes associated with an increased WC and WHR as found by the various authors could increase the risk for IHD in PLWHA and require management. Section 2.3.3.2.7 consists of a discussion of the metabolic risk factors for IHD and how management of HIV infection increases them in PLWHA.

2.3.3.2.7 **Metabolic risk factors: Diabetes Mellitus and altered lipid profile**

Diabetes mellitus and an altered lipid profile are known risk factors for IHD. The INTERHEART study demonstrated that the association between diabetes mellitus and AMI when adjusting for age, sex and geographical region was OR=4.26 (95% CI: 3.51–5.18) for women and OR=2.67 (95% CI: 2.36–3.02) for men (Yusuf et al., 2004). Jeppesen et al. (1997) indicated that the age-adjusted incidence of an IHD event during an eight-year follow-up period differed according to lipid profile component changes in men. The prevalence of an IHD event was 11.4% in individuals with high TG and low HDL, 8.2% in high LDL and 17.5% in individuals with combined high TG, low HDL and high LDL levels.

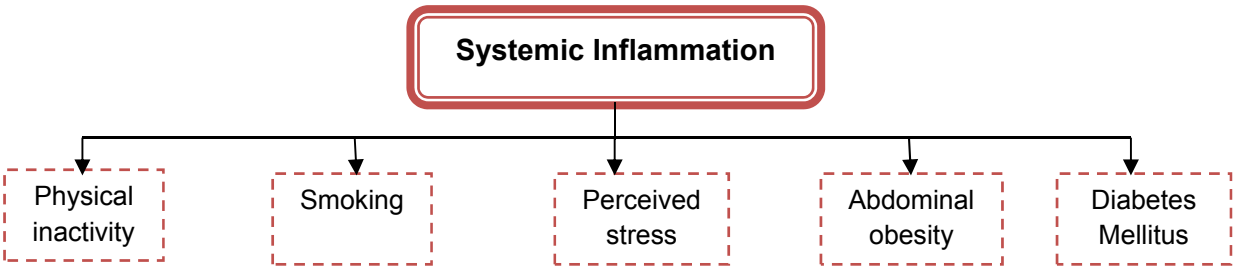
Diabetes and altered lipid profiles are a concern in PLWHA due to the relationship between HAART and diabetes and altered lipid profiles. De Wit et al. (2008) have shown the incidence of diabetes per person-years of follow-up to be 5.72 per 1 000 person-years of follow-up (95% CI: 5.31–6.13) in PLWHA. The incidence also increased significantly with cumulative exposure of HAART (p=0.0001) (De Wit et al., 2008). The following antiretroviral drugs were associated with diabetes: Stavudine (RR=1.13; 95% CI: 1.08–1.15; p=0.0001), Zidovudine (RR=1.05; 95% CI: 1.01–1.10; p = 0.01) and Didanosine (RR=1.06; 95% CI: 1.01–1.11; p=0.02) Additional factors associated with new-onset diabetes were a reduction in HDL (RR=0.75; 95% CI: 0.58–0.96; p=0.02), an increase in TG (RR=1.64; 95% CI: 1.50–1.80; p=0.0001) and fat gain (RR=1.36; 95% CI: 1.09–1.68; p=0.006) (De Wit et al., 2008).

Changes in lipid profiles occur in PLWHA, but there are differences when individuals are on HAART compared to HAART-naïve. Borato et al. (2012) found that a significant reduction in HDL occurs in PLWHA treated with HAART compared to those who were not. In contrast, individuals receiving therapy also had significant increases in total cholesterol, LDL and TG (Borato et al., 2012). Literature from

Friis-Møller et al. (2003) sheds light on how the various antiretroviral drug classes influence the lipid profile in PLWHA. They demonstrated an altered cholesterol level ≥ 6.2 mmol/l associated with NNRTI (OR=1.79; 95% CI: 1.45-2.22; p=0.0001), PI (OR=2.35; 95% CI: 1.92–2.87; p=0.0001) and NNRTI and PI combined (OR=5.48; 95% CI: 4.34–6.91; p=0.0001). In addition, an HDL lower than 0.9 mmol/l was associated with NRTI (OR=1.35; 95% CI: 1.06–1.71; p=0.02) and PI (OR=1.46; 95% CI: 1.20–1.77; p=0.001). Lastly, a TG greater than 2.3 mmol/l was associated with all drug classes: NRTI (OR=1.48; 95% CI: 1.22–1.79; p=0.0001), NNRTI (OR=2.06; 95% CI: 1.73–2.45; p=0.0001), PI (OR=2.90; 95% CI: 2.47–3.40; p=0.0001) and NNRTI and PI combined (OR=4.66; 95% CI: 3.82–5.67; p=0.0001). Thus the development of diabetes and an altered lipid profile could be risk factors for IHD in PLWHA, and require monitoring and management in the HAART era. Section 2.3.3.2.8 consists of an explanation of the inflammatory risk factor marker hs-CRP, and why this marker can be used to monitor risk for IHD.

2.3.3.2.8 Inflammatory risk factor marker: Hs-CRP

Systemic inflammation plays an important part in the pathophysiology of IHD, and is stimulated by certain risk factors for IHD. A summary of these risk factors is presented in Figure 2.2 below.



(Smith et al., 2012; Das and O'Keefe, 2008; Mora et al., 2007; Ambrose and Barua, 2004; Spranger et al., 2003).

Figure 2.2: Risk Factors for IHD that Stimulate Systemic Inflammation

High-sensitivity CRP is a marker of inflammation with predictive abilities for cardiovascular events in the general population (Pearson et al., 2003), and also in PLWHA (De Luca et al., 2013; Triant, Meigs and Grinspoon, 2009). The suggested categories of hs-CRP as risk for cardiovascular events are as follows: low risk (less than 1.0 mg/l), average risk (1.0-3.0 mg/l) and high risk (Hs-CRP>3.0 mg/l) (Pearson et al., 2003). For PLWHA De Luca et al. (2013) indicated that a high hs-CRP value was independently associated with a cardiovascular event (OR=1.69;

95% CI: 1.09–2.64; p=0.02). Furthermore, Triant, Meigs and Grinspoon (2009) showed that both an elevated Hs-CRP value (OR=2.13; 95% CI: 1.92–2.37; p<0.0001) and HIV status (OR=1.93; 95% CI: 1.21–2.93; p=0.004) were independently associated with AMI when adjusting for age, sex, race, HTN, diabetes and dyslipidaemia. Masia et al. (2007) investigated the relationship of known IHD risk factors with CRP in PLWHA. They found that CRP levels correlated positively with total cholesterol (p=0.01), LDL (p=0.001), TG (p=0.04) and the Framingham Risk Score (FRS) (p=0.006) and negatively with HDL (p=0.004) during univariate analysis. In multivariate analysis factors independently associated with CRP were LDL (p<0.001), HDL (p=0.001), cigarette smoking (p=0.019) and HAART (p=0.021). Managing risk factors for IHD at primary care level that could influence Hs-CRP and potentially decrease the risk for IHD should therefore be a priority. Section 2.3.4 provides information regarding IHD risk calculation as a means of evaluating individuals' 10-year relative risk of developing IHD.

2.3.4 **IHD Risk Calculation**

Once individuals have been screened for risk factors of IHD the information can be used to calculate an individual's absolute risk of developing IHD by using a prediction equation. IHD prediction equations specific to PLWHA are not available for use, and the FRS is suggested as an effective alternative at present (Schambelan et al., 2008). When comparing FRS of PLWHA with non-infected individuals findings suggest PLWHA have higher scores. De Socio et al. (2007) evaluated the estimated IHD risk in PLWHA compared to a general population. The authors found the FRS to be higher (7 [±5]) in PLWHA than non-infected individuals (6.3 [±5]). In contrast, Hadigan et al. (2003) indicated that the FRS for HIV-infected subjects (with fat redistribution) compared with age, sex and BMI matched non-infected participants was significantly different (p=0.002) at 7.4 (±0.6) compared to 5.3 (±0.3). An interesting additional finding was that FRS differed according to pattern of fat redistribution in PLWHA: lipoatrophy (9.2 [±1.8]), lipohypertrophy (4.3 [±0.7]) and mixed lipodystrophy (7.6 [±0.8]). This is therefore an additional component specific to PLWHA that can further influence their 10-year risk of IHD. Section 2.3.5 consists of information pertaining to individuals' self-perception of IHD risk as a means of providing information regarding subjectively perceived mediated risk for IHD.

2.3.5 **Self-Perception of IHD Risk**

Perceptions of own risk of developing IHD is a factor that could influence individuals' health behaviour, and may impede preventive efforts of lowering individuals' IHD risk. Perceptions of IHD are reported to be often underestimated by individuals (Ansa, Oyo-Ita and Essien, 2007; Hart, 2005; Avis, Smith and McKinlay, 1989). Factors said to influence these

perceptions are perceptions of generally poor health; presence of other risk factors for IHD and a greater knowledge regarding risk factors (Meischke et al., 2000). Only one study of perception of risk for IHD in PLWHA is available. Cioe, Crawford and Stein (2013) evaluated PLWHA's perception regarding risk for cardiovascular disease using the Perception of Risk of Heart Disease Scale. They also collected data concerning individuals' knowledge of cardiovascular disease using the Heart Disease Fact Questionnaire, and estimated individuals' own estimate of risk with the FRS. The authors found the risk factor knowledge score to be fairly high (19 [±3.5]), mean total score on the Perception of Risk of Heart Disease Scale 53.1 (±5.9) and FRS 7.9 (±6.0). The authors found a statistically significant (p=0.01), though weak, association between estimated (FRS) and perceived risk for IHD (r=0.24). In addition, they found no significant relationship between demographic variables and perceived risk (p=0.98) or risk factor knowledge (p=0.21). The authors suggested that intervention programmes are needed in PLWHA to improve risk-perception of individuals by focusing on the role that risk factors, such as physical inactivity, play in increasing cardiovascular disease risk.

Section 3 of the literature review is presented in section 2.4, and consists of information regarding physical activity modification as a means of influencing the risk for IHD.

2.4 SECTION 3 – PHYSICAL ACTIVITY MODIFICATION AS PREVENTION STRATEGY FOR IHD

The literature regarding physical activity modification in this section is discussed under headings: definition of physical activity, Public Health physical activity recommendations, moderate-intensity exercise effects in PLWHA, methods of promoting physical activity at primary care level and, lastly, home-based pedometer walking programmes.

2.4.1 Definition of Physical Activity

The definition of physical activity needs to be clear, in order to distinguish this term from fitness terminology, such as exercise and physical fitness. Physical activity is defined as any body movement produced by the contraction of skeletal muscles that results in increased caloric requirements above resting energy expenditure (ACSM, 2010). Exercise, on the other hand, is a type of physical activity that is planned, structured and includes repetitive body movements to improve or maintain one or more components of physical fitness (ACSM, 2010). Physical fitness is related to ability to perform physical activity due to certain physical attributes (ACSM, 2010). Physical activity is related to what an individual does throughout the day, where exercise focuses only on a certain part of the daily routine.

Physical activity modification can thus be defined as an attempt to include more body movement in the daily routine in an effort to achieve the Public Health recommendations.

2.4.2 Public Health Physical Activity Recommendations

Public Health physical activity recommendations are available as a guide to promote health and prevent chronic conditions such as IHD in the general population. At conception of the research project the ACSM and American Heart Association's physical activity recommendations (Haskell et al., 2007) were used to guide phase 2 of the research project. Since then additional guidelines with slight differences have been published, e.g. the *British Association of Sport and Exercise Sciences' ABC of Physical activity for Health* (O'Donovan et al., 2010) and the 2011 *Canadian Physical Activity Guidelines* (Trembly et al., 2011). Table 2.3 gives a summary of the recommendations for adults 18–65 years of age from the ACSM and American Heart Association, as used in the walking programme formulation in the research project.

Table 2.3: Public Health Physical Activity Recommendations for Adult

Authority	Physical activity recommendations	Reference
ACSM/AHA	*Adults aged 18–65 years of age* Moderate-intensity aerobic physical activity for a minimum of 30 minutes on five days each week or vigorous-intensity aerobic activity for a minimum of 20 minutes on three days each week. Combination of moderate- and vigorous-intensity activity can be combined to meet recommendations. Moderate-intensity aerobic activity (equivalent to brisk walking) with noticeable acceleration in heart rate can be accumulated toward the 30 minutes minimum by performing bouts each lasting 10 or more minutes. Vigorous-intensity aerobic activity (e.g. jogging) with rapid breathing and a substantial increase in heart rate. In addition, at least twice a week performing activities using the major muscles of the body that will result in muscle strengthening and endurance. Persons who wish to further improve their personal fitness, reduce risk for chronic diseases and disabilities, or prevent unhealthy weight gain will likely benefit by exceeding the minimum recommended amount of physical activity.	Haskell et al. (2007)

It is important to remember that the moderate- and vigorous-intensity physical activity proposed in the recommendations are in addition to the physical activity accumulated in the course of normal daily living. Walking more than 10 000 steps per day has also been suggested as recommendation to achieve health benefits by being active (ACSM, 2010). The physical activity recommendations for PLWHA are very similar, except that moderate-intensity physical activity is preferred over vigorous-intensity to prevent possible immune suppression with more intense exercise (ACSM, 2010). This recommendation is proposed

by the European AIDS Clinical Society (Lundgren et al., 2008) and supported by a systematic review on the effects of aerobic exercise in PLWHA (O'Brien et al., 2010). That review included 14 randomised controlled trials, and found that performing aerobic exercise or a combination of resistive and aerobic exercise for at least 20 minutes, at least three times per week for at least five weeks, was safe for PLWHA who are medically stable. Table 2.4 consists of the physical activity recommendations for PLWHA as proposed by the European AIDS Clinical Society.

Table 2.4: Physical Activity Recommendations for PLWHA

Authority	Physical activity recommendations	Reference
EACS	Promote an active lifestyle to prevent obesity, hypertension, and diabetes. Encourage moderate-intensity rather than vigorous exercise. Encourage self-directed moderate-intensity physical activity e.g. use stairs, walk to work or cycle, swim and/or hike. Achieve cardiovascular fitness, e.g. 30 minutes of brisk walking five days per week. Maintain muscular strength and flexibility.	Lundgren et al. (2008)

♦ EACS (European AIDS Clinical Society)

Studies have evaluated the effects of moderate-intensity exercise in PLWHA, and a summary is set out in section 2.4.3.

2.4.3 Moderate-Intensity Exercise Effects in Adult PLWHA

Moderate-intensity exercise is beneficial in PLWHA as it is reported to influence a number of factors. As expressed in metabolic equivalents it is equal to 3.0-6.0 metabolic equivalents (Haskell et al. 2007), and can be evaluated as a percentage of heart rate reserve (HRR), oxygen uptake reserve (VO_2R) or maximal heart rate (HR_{max}) (ACSM, 2010). Moderate-intensity physical activity quantified in these parameters is 40%-59% HRR or VO_2R or 64%-76% HR_{max}. A summary of moderate-intensity exercise effects on selected IHD risk factors in PLWHA is supplied in Table 2.5.

Table 2.5: Moderate-Intensity Exercise Effects in Adult PLWHA

Reference	Population	Study length	Intervention	Outcome
Dudgeon et al. (2012)	HIV-infected men (n=26) Mean age (yrs): IG (43.1 [±1.3]) CG (46.6 [±1.5])	Six weeks	IG: Supervised three to five minutes warm-up, 30 minutes at 60-75% HR_{max} on stationary cycle or treadmill, three to five minutes of cool-down. Upper and lower body resistance exercise at correct intensity level. Two times/week. CG: Did not receive intervention. No other specific instructions noted.	Significant increase in lean tissue mass in IG (p<0.001). No significant change in physical activity in IG (p=0.38) or CG (p=0.42) and no between-group difference (p=0.29). No significant changes in IG or CG in the following measures: selected pro-inflammatory cytokines, growth hormone: IG (p=0.3), CG (p=0.5), cortisol: IG (p=0.3), CG (p=0.1). No significant changes in anthropometric and strength measures.
Ogalha et al. (2011)	HIV-infected men (n=34) and women (n=29) Mean age (yrs): IG (42.06 [±7.45]) CG (44.25 [±11.45])	Six months	IG: Monthly dietary counselling (50 minutes). Supervised aerobic, resisted and stretching gym programme, one hour, three/week at training target HR_{max} of 75%. CG: Monthly dietary counselling (50 minutes). Thirty minute orientation of benefits of regular physical activity. Encouraged to perform running, biking or walking for one hour, three times/ week.	Significant decrease in body fat % (p=0.04), RHR (p=0.001), hip circumference (p=0.001), glucose level (p=0.04) in the IG. Significant increase in muscle mass (p=0.001) and CD_4 count (p=0.001) in the IG. Significant decrease in BMI (p=0.02) and hip circumference (p=0.001) in the CG. Significant increase in CD_4 count (p=0.04) in the CG. Significant changes occurred in QOL in both groups.
Mutimura et al. (2008)	HIV infected men (n=40) and women (n=60) Mean age (yrs): IG (37.8 [±5.5]) CG (37.5 [±6.9])	Six months	IG: Supervised aerobic, resisted and stretching gym programme, three/ times, one and a half hour/sessions, alternating days. Intensity of exercise increased from 45% HR_{max} in the first three weeks to 60% HR_{max} in the next six weeks to 75% HR_{max} by the end of study. CG: Did not receive exercise. No other specific instructions noted.	Significant reduction in body fat redistribution (p<0.0001), BMI (p<0.05), WC (p<0.0001), WHR (p<0.0001), body fat % (p<0.0001) changes in IG compared to CG. Significant increase in VO_2max (p<0.0001) and QOL (p<0.05) changes in IG compared to CG.

Table 2.5 continued

Reference	Population	Study length	Intervention	Outcome
Fillipas et al. (2006)	HIV-infected men (n=40) Mean age (yrs): IG (43.3 [±7.7]) CG (43.7 [±10])	Six months	IG: Supervised aerobic, resistance exercise group class, twice weekly. Each session (60 minute) began with five minutes warm-up, aerobic and strengthening routine and ended with five minutes cool-down. Exercise intensity started at 60% HR_{max} and progressed to 75%. CG: Community walking 20 minutes, twice/weekly with monthly group sessions. Walking intensity 60% HR_{max} and progressed to 75%.	Significant improvement in IG's self-efficacy ($p<0.001$), RHR ($p<0.001$), overall health QOL factor ($p<0.05$) and cognitive function ($p<0.05$) compared to CG.
Dolan et al. (2006)	HIV-infected women (n=40). Mean age (yrs): IG (43 [±2]) CG (40 [±2])	14 weeks	IG: Home-based supervised aerobic and strength training programme, three times/week on alternating days. Each session started with five minutes warm-up, followed by exercise programme and cool-down period. Aerobic exercise intensity was set at 60% HR_{max} first two weeks, followed by 75% thereafter. CG: Did not receive exercise. No other specific instructions noted.	Significant improvement in VO_2 max ($p<0.001$), submaximal bike exercise time (p.0.001), six minute walk test distance ($p=0.009$), upper and lower body muscle strength measures, total muscle area ($p=0.02$) and muscle attenuation ($p=0.03$) in the IG compared to the CG. Significant reduction in WC ($p=0.03$) in the IG compared to the CG.

♦ IG (intervention group), CG (control group), QOL (Quality of life), yrs (years)

Additional benefits of moderate-intensity exercise in PLWHA include improvement in functional aerobic capacity, as demonstrated by increased treadmill time (Hand et al., 2008), life satisfaction (Gomes et al., 2010) and decreased levels of depression (Neidig et al., 2003). No published literature is available concerning the effects of a home-based pedometer walking and education programme on the risk factors for IHD in PLWHA; nor is there any on the effects of an exercise programme on the IHD inflammatory marker Hs-

CRP. The present research project will provide evidence for such a programme that can be implemented to promote physical activity in PLWHA at primary care level.

2.4.4 Methods of Promoting Physical Activity at Primary Care Level

Brisk walking is included in physical activity recommendations for incorporating moderate-intensity activity into one's daily routine. Ogilvie et al. (2007) investigated effective methods of promoting walking in adults in a systematic review consisting of 19 randomised and 29 non-randomised controlled trials. They found that interventions tailored to participants' needs, focusing on the most sedentary, and including individuals motivated to change were effective (Ogilvie et al., 2007). In addition, interventions targeted at individual level by including advice and motivational components e.g., pedometers or telephone calls, and secondly through group programmes, can encourage individuals to walk more, increasing activity by 30 to 60 minutes per week (Ogilvie et al., 2007). A systematic review evaluating the characteristics of physical activity promotion programmes indicated that programmes done at home, unsupervised, informal and which could be done at any time, were most effective (Hillsdon et al., 1995). Programmes involving frequent professional contact (usually by telephone) and which promoted moderate-intensity exercise, such as walking, were also successful (Hillsdon et al., 1995). In addition, Foster, Hillsdon and Thorogood (2009) reiterated Hillsdon's findings in a Cochrane review, stating that physical activity promotional strategies have a moderate effect on increasing self-reported physical activity in the short- to medium term. The authors found that a mixture of professional guidance with self-directed activity plus continuing professional support led to a more consistent result (Foster, Hillsdon and Thorogood, 2009). Thus programmes consisting of motivational components (professional contact or group support) and monitoring (professional contact or pedometers), are flexible and home-based could be possible means to promote physical activity effectively.

2.4.5 Home-Based Pedometer Walking Programmes

Pedometers are small calculators that can be worn to monitor walking quantity, as the device counts the number of steps (Tudor-Locke and Lutes, 2009). More than 10 000 steps/day is considered "active", 7 500 to 9 999 steps/day is "somewhat active", 5 000 to 7 499 steps/day is "light active", and less than 5 000 steps/day is sedentary (Tudor-Locke and Bassett, 2004). Intervention studies have evaluated the effect of pedometer walking programmes on physical activity levels.

A systematic review conducted by Bravata et al. (2007) investigated the effects of pedometer-based walking programmes on physical activity levels and health outcomes. The authors found that programmes were beneficial in promoting physical activity ($p<0.00$)

and participants on average increased their steps/day by 26.9% above baseline. A reduction in BMI was possible (p=0.03), and was related to age (p=0.00) and having a step-count goal (p=0.04). Participants could also significantly reduce their SBP (p<0.00), and this was related to a higher baseline blood pressure value (p=0.00) and increase change in steps/day (p=0.08). In addition, Richardson et al. (2008) investigated the effect of a pedometer-based walking programme on weight loss in a meta-analysis of which nine studies met the specific inclusion criteria. The median duration of studies ranged from four weeks to one year, with a median of 16 weeks. The pooled estimation of weight change possible with such programmes was a loss of 1.27 kg (95% CI: -1.85 to -0.70 kg), with longer intervention having greater effect (Richardson et al., 2008). Providing a pedometer as a self-monitoring tool while walking is therefore a possible means of promoting increased activity and gaining health benefits that could influence IHD risk.

To assist in meeting the Public Health physical activity recommendation of 30 minutes of moderate-intensity brisk walking while using a pedometer, walking has been translated to steps. Marshall et al. (2009) and Tudor-Locke et al. (2005) indicated that walking at a speed of 100 steps/minute was found to be approximately equal to moderate-intensity walking. To meet the physical activity recommendations individuals are therefore encouraged to walk a minimum of 3 000 steps in 30 minutes, or alternatively, three bouts of 1 000 steps in 10 minutes (Marshall et al., 2009; Tudor-Locke et al., 2005).

The effects of pedometer walking programmes on selected IHD risk factors in the general population have been evaluated by a number of authors. Table 2.6 is a summary of such programmes. Studies presented were not included in the systematic review of Bravata et al. (2007) or the meta-analysis of Richardson et al. (2008).

Information presented in the table provides evidence regarding the following:

- The influence of pedometer exercise prescription on the outcome (risk factors for IHD) of a pedometer walking programme.

- The difference in result between several short bouts of walking (10 minutes three times per day) compared to a single long one (30 minutes).

- The difference in result between accumulating 10 000 steps per day compared to 30 minutes of additional walking per day.

- The contrasting results between participating in a programme which progresses incrementally to achieve a 3 000 step increase in step-count compared to a programme starting with the 3 000 step goal.

- The added benefit of prescribing a walking programme according to heart rate levels or asking individuals to document their daily step-count or dyspnoea level in a physical activity diary.

- The effect of a pedometer walking programme on inflammatory markers, as conducted by Gray et al. (2009).

- Dropout rates of home-based pedometer walking programmes and information regarding adherence to pedometer exercise prescriptions.

Table 2.6: Pedometer-Based Walking Programmes Focusing on Achieving Physical Activity Recommendations as Prevention Strategy for IHD Risk Factors

Study	Methods	Participants	Interventions	Outcomes	Adherence
Serwe et al. (2011) Total population: 60 participants	Randomised controlled trial with two walking groups (walking bouts differed) and control group	60 inactive premenopausal healthcare women self-reported not to engage in ≥ 30 minutes of physical activity on more than two days/week for the past three months. Mean age: Walking group #one (38.2 [±7.3]) Walking group #two (37.1 [±7.2]) Control group (36.3 [±8.1])	Eight weeks home-based pedometer walking programme. (Both walking groups consisted of n=20) Intervention group (IG): The intervention participants received a pedometer, walking log and were instructed not to change their diet. IGs were instructed to walk for 30 minutes daily at 60%-70% HRR five days/week. Walking group #one performed three x 10 minutes of walking five days/week. Walking group #two completed the prescribed walking in one continuous 30-minute bout five days/week. Walking logs were returned weekly, and participants received biweekly telephone calls for monitoring purposes. Control group (CG): Asked to maintain normal physical activity and diet during intervention period	Significant increase in pedometer steps per day in both walking groups ($p<0.001$) from baseline, but no significant differences between the two groups. Significant reduction in hip circumference ($p<0.05$), SBP ($p<0.05$) and DBP ($p<0.01$) in walking group #one from baseline. Significant increase in six-minute walk test distance ($p<0.05$) in walking group #one from baseline. Significant decrease in hip circumference ($p<0.001$) and DBP ($p<0.05$) in walking group #two from baseline. Significant increase in six-minute walk test distance ($p<0.01$) in walking group two from baseline. No significant changes noted in control group.	Fifty-three of the original 60 participants completed the study. Dropout rate at eight weeks was thus 12%. Lost to follow-up: CG (n=1) Walking group #one (n=3) Walking group #two (n=3) Reasons for lost to follow-up not supplied. Adherence to walking programme was calculated as a percentage of total prescribed sessions completed. Adherence in walking group #one was 69% and 80% in walking group #two. Adherence was not significantly different between groups (p=0.239).

Study	Methods	Participants	Interventions	Outcomes	Adherence
Zoelliner et al. (2010) Total population: 83 participants	Longitudinal feasibility study	83 vulnerable African-Americans of whom 94% were female. Mean age: 44 [±13] years	Six months community pedometer walking programme led by community coaches. All participants received a pedometer diary and pedometer, and were instructed on the proper use of the device and instructed to record daily steps in diary. Participants attended weekly goal-setting appointments with coaches, and educated on the 10 000 steps/day walking recommendation. *Immediate aim:* Set own realistic walking aim per week. No specific instructions regarding time spent walking, steps/week achieved or intensity level.	63% of participants increased daily steps, 25% had no change and 12% regressed in activity level. Significant association between reduction in TG (p=0.04) and % of body fat (p=0.01) with physical activity levels.	Sixty six of the original 83 participants completed the study. Thus the dropout rate was 20%. Reason for loss to follow-up not supplied.
Musto et al. (2010) Total population: 84 participants	Longitudinal quasi-experimental study. Participants grouped as active or control following intervention.	84 university women taking less than 5000 steps/day. Mean age: Active group (46.3 ±10.4) years Control group (45.7 ±9.5) years	12-week university worksite programme. All participants received a pedometer, guide to programme details, daily step log and an education booklet. The education booklet provided information regarding health benefits of physical activity, tips for increasing steps through lifestyle activity and basic nutrition information. *Ultimate aim:* Incremental 10% increase in step-count per week from baseline. Once a participant reached the 10 000 step-count	Significant increase in pedometer step-count (p≤0.001) in active and control group with significant self-reported activity (SUAQ) (p≤0.001) in activity group. Significant reduction in weight (p≤0.001), BMI (p≤0.001) and RHR (≤0.001) in active group.	Seventy seven of the original 84 participants completed the study. Dropout rate was thus 8% at 12 weeks. Lost to follow-up: (n=7) Reasons for lost to follow-up: personal reasons. Twenty control participants did not log their weekly steps in their daily step log.

Study	Methods	Participants	Interventions	Outcomes	Adherence
			goal, weekly progression reduced to three percent.		
Gray et al. (2009) Total population: 66 participants	Randomised control trial with walking and control group	66 participants (gender distribution not specified) self-classified as not meeting PA recommendations. Mean age: Walking group (48.1 [±9.2]) years Control group (51.3 [±8.3]) years	12-week community walking intervention in Glasgow. *Intervention group (IG) (n=32):* One physical activity consultation combined with pedometer-based walking programme. *Ultimate aim:* Gradually increase mean step count by 3 000 steps/day on at least five days of the week over first six weeks. Remaining six weeks instructed to maintain walking aim. *Control group (CG) (n=34):* Asked to maintain normal walking levels.	Significant increase in IG's pedometer step-count ($p<0.001$) by 3 300 (±2 215) steps/day. No significant change in CG activity level. No significant changes in weight, BMI, % body fat, waist:hip ratio, blood pressure, fasting glucose and insulin, homeostatic model assessment of insulin resistance, hs-CRP and selected pro-inflammatory cytokines of IG or CG.	Forty eight of the original 66 participants completed the study. Dropout rate was thus 27%. Lost to follow-up: IG (n=8) CG (n=10) Reasons for lost to follow-up: injury, personal reasons, failed to turn up, not contactable, other commitments, randomised to control group, dissatisfaction with pedometer and inability to fast.
Baker et al. (2008) Total population: 79 participants	Randomised control trial with walking and control group	63 women and 16 men from lower socioeconomic group self-classified as not meeting PA recommendations. Mean age: 47.3 (±9.3) years	12-week community walking intervention in West of Scotland. *Intervention group (IG) (n=39):* One physical activity consultation with 12-week unsupervised home-based incremental pedometer walking programme. *Ultimate aim*: 3000 steps from baseline on five days per week. *Control group (CG) (n=40):* Asked to maintain normal walking levels.	Significant increases in IG's pedometer step count ($p<0.001$), leisure-time walking (IPAQ) ($p=0.02$) and positive effect (PANAS) ($p=0.027$). Mean between-group different change in step-count was 3022 per day ($p < 0.001$). Significant decrease in time in weekday ($p=0.03$), weekend ($p=0.001$) and total sitting ($p=0.001$) as measured with IPAQ. No overlapping changes in CG. No significant changes in PANAS negative, EQ-5D	Sixty-four of the original 79 participants completed the study. Dropout rate was thus 19%. Lost to follow-up: IG (n=7) CG (n=8) Reasons for lost to follow-up: injury, personal reasons, not contactable, other commitments, dissatisfaction with pedometer.

Study	Methods	Participants	Interventions	Outcomes	Adherence
				Quality of life, BMI, waist and hip circumference, WHR, % body fat, blood pressure, heart rate, total cholesterol, HDL, cholesterol: HDL ratio.	
Tully et al. (2007) Total population: 106 participants	Randomised control trial with two walking groups (differing in frequency per week) and a control group	64 women and 42 men sedentary adults (not more than one moderate-intensity exercise per week in the last six months). Mean age: Walking group #one (47.80 [±5.97]) years Walking group #two (46.37 [±4.76]) years Control group (49.05 [±6.31]) years	12 week unsupervised home-based pedometer walking programme. *Intervention groups (IG) (Walking group #one: n=44), (Walking group #two: n=42):* Participants received a pedometer and diary. They were asked to document steps, duration of the walk, level of dyspnoea and any comments or difficulties experienced during each walk. Every two weeks dairies were returned and new diaries were posted to participants. The researcher phoned the participants every two weeks to resolve difficulties. *Immediate aim:* Walk briskly for 30 minutes for 12 weeks. Participants could choose to do a long bout of 30 minutes or 10 minutes three times/day. Walking group #one: frequency three times/week. Walking group #two: frequency five times/week. *Control group (CG) (n=18):* Maintain lifestyle for 12 weeks. Given a diary and asked to	Walking group #one: Significant decrease in weight (p=0.02), BMI (p=0.03), waist (p<0.001) and hip (p=0.004) circumference, SBP (p=0.002), log transformed TG (p=0.002), total cholesterol: HDL (p<0.001), distance walked with the 10 meter shuttle walk test (p<0.001). Walking group #two: Significant decrease in waist (p<0.001) and hip (p=0.02) circumference, SBP (p<0.001) and DBP (p=0.01) and distance walked with the 10 meter shuttle walk test (p<0.001). Small percentages of both walking programmes were completed in multiple bouts (three day: 2.7% and five day: 6.5%) CG: No significant changes observed in CG. Significant differences in distance walked with the 10	Ninety three of the original 106 participants completed the study. Dropout rate was thus 12%. Walking group #one: Completed (n=39) Withdrew (n=5) Ill health (n=2) Lack of time (n=3) Walking group two: Completed (n=36) Withdrew (n=6) Ill-health (n=3) Lack of time (n=2) Walking-induced injury (n=1) CG: Completed (n=18) Withdrew (n=2) Ill health (n=2) Walking adherence was defined as number of days completed as a percentage of number of days prescribed. Adherence was 89.3% in walking group one and 82.6% in walking group two. No significant difference observed between groups (p=0.42).

Study	Methods	Participants	Interventions	Outcomes	Adherence
			document any exercise that they did above their normal activity. After 12 weeks they were given a pedometer and invited to begin their own walking programme. IG and CG were asked not to change their diet during the 12 weeks.	meter shuttle walk test (p=0.04) and TC: HDL (p=0.04). Significant between group differences observed in walking groups for time spent walking (p=0.04): Significant differences between walking groups for time spent walking (p=0.04): walking group #one (29.5 ±10.5) and walking group #two (26.9 ±10.8).	
Tully et al. (2005) Total population: 31 participants	Randomised control trial with walking and control group	18 women and 13 men sedentary adults (taking less than 20 minutes of moderate intensity on 2 days or less per week in the last six months). Mean age: Walking group (55.52 [±3.99]) years Control group (57.75 [±4.64]) years	12 week unsupervised home-based pedometer walking programme. *Intervention group (IG) (n=12):* Participants received a pedometer and diary. Follow-up telephone calls every two weeks to encourage compliance and assess any difficulties. *Immediate walking aim:* Walk briskly for 30 minutes, five days/week for 12 weeks. Participants could choose to do a long bout of 30 minutes or 10 minutes three times/day *Control group (CG) (n=10):* Maintain habitual lifestyle and not to change their activity.	Significant increase in distance walked with the 10 meter shuttle walk test (p=0.015) in IG compared to CG. Significant decrease in SBP (p=0.02), DBP (p=0.0001) and 10-year risk estimate for stroke based on SBP (p=0.00) in IG. Significant decrease in 10-year risk estimate for IHD based on SBP in IG (p=0.032) and in CG (p=0.00). No differences between groups for above. Only four individuals performed walking programme in multiple bouts per day. The majority (n = 17) preferred a 30-minute stint. Mean time spent walking per day was	Twenty-six of the original 31 participants completed the study. Dropout rate was thus 16%. Lost to follow-up: IG (n=4) CG (n=1) Reasons for lost to follow-up: ill health and lack of time. Walking adherence was defined by expressing the number of minutes walked as a percentage of the number of minutes prescribed. Adherence was 90.3%.

Study	Methods	Participants	Interventions	Outcomes	Adherence
				27.72 (±9.79) minutes. No significant changes in weight, BMI, WC, WHR and lipid profile.	
Tudor-Locke et al. (2002) Total population: 9 participants	Observational pilot study	Six women and three men, recently diagnosed with type two diabetes, accumulating less than one hour of physical activity per week. Mean age: 53 (±6) years	All participants received education regarding diabetes self-management: nutrition, blood glucose monitoring, medication and exercise. Initial eight-week First Step Programme included one month of weekly meetings and unsupervised home-based pedometer walking. The following month participants continued with walking without contact from programme staff.	Significant changes were observed in WC (p=0.005), resting SBP (p=0.02), and walking time (22.6 minutes per day) No significant changes in weight, WHR, hip circumference, RHR and DBP.	Adherence issues not reported and all participants completed assessments at baseline, four and eight weeks.

♦ SUAQ (Stanford Usual Activity Questionnaire), PANAS (Positive and Negative Affect Schedule), IPAQ (International Physical Activity Questionnaire), EQ-5D (Euro Quality of Life), RHR (resting heart rate), SBP (systolic blood pressure), DBP (diastolic blood pressure), WC (waist circumference) and WHR (waist:hip ratio).

The walking programme in study four was structured using the findings of Table 2.6 as guide. The programme's weekly step count increased incrementally and frequency per week started at three times per week and then progressed over time to ultimately reach five times per week as a means to maintain participants' adherence to the programme. Participants had the freedom of performing their walking in short bouts or one long bout while monitoring breathlessness and heart rate. The specifics regarding the intervention programme is available for review in Appendix 47.

2.5 CONCLUSION

Human immunodeficiency virus infection is a significant health burden in SA, with prevalence higher in women and affecting both genders between 15-49 years of age more frequently. With local HAART initiation guidelines now being aligned with those recommended internationally, the future causes of mortality in PLWHA in SA could shift to non-AIDS-related conditions, such as IHD. Risk factors for IHD are already reported to be increasing in the South African public. International data suggests that PLWHA are at a higher risk of IHD due to HIV infection-mediated factors, traditional risk factors for IHD and HAART exposure. The need for rehabilitation services to prevent, manage and control risk factors for IHD - that could also lead to disability - is therefore extremely important in the general population, as well as in the emerging chronic disease era of HIV. Healthcare workers such as physiotherapists will have to consider innovative ways to offer rehabilitative services, as the burden related to HIV is greater in SA than other parts of the world. A home-based walking programme, including a self-monitoring tool such as a pedometer could be one such intervention, promoting walking amongst PLWHA and thereby decreasing the risk of IHD, and promoting general health.

Chapter 3 consists of the literature related to the instrumentations and outcome measures used in the research project.

CHAPTER 3

3. INSTRUMENTATION FOR TESTING AND MEASURING OUTCOMES

3.1 INTRODUCTION

This chapter discusses the instruments and outcome measures used in the data collection process. Justification of their choice will also be discussed. The instruments and outcome measures are linked to the study objectives of each aim of the research. The project was divided into two phases: Phase 1 consisted of an observational study (1) and a qualitative study (2), the two running concurrently. Both provided support for the material for the education physical activity diary. This diary was developed in study 3 before phase two, as it was used in the intervention. Phase 2 consisted of an intervention that was evaluated with a randomised controlled trial (study 4). Table 3.1 is a representation of the instruments or outcome measures used to evaluate a specific variable related to an aim or objective of a particular study in the research project.

Table 3.1: Overview of Instruments and/or Outcome Measures and the Relationship with the Specific Objectives and Aims

Aim/objective	Variable	Instrument/Outcome measure
Phase 1: Study 1		
To determine physical activity levels, in individuals living with HIV (on HAART).	Physical activity levels	Demographic questionnaire (1) Yamax SW200 pedometer
To determine perceived stress levels, in individuals living with HIV (on HAART).	Perceived levels of stress	Cohen's Perceived Stress Scale-10 (PSS-10)
To determine selected known associated risk factors for IHD, in individuals living with HIV (on HAART).	Smoking history Diet RHR and Blood pressure Waist and hip circumference WHR BMI (kg/m^2) ▪ Weight ▪ Height	Demographic questionnaire (1) Demographic questionnaire (1) Microlife BP A100 automated sphygmomanometer Butterfly non-stretch tape measure Calculation: Waist (m)/Hip (m) Simple Choice portable electronic scale Poster paper, Fagram non-stretch tape measure, non-flexible ruler, clinic wall
Phase 1: Study 2		
To determine the nature of the individual's self-perception and behaviour in relation to the risk for IHD.	Self-perception and behaviour	Semi-structured interview questionnaire Card sort with placement sheet Olympus VN-5500PC Digital voice recorder Nikon camera

Table 3.1 continued

Aim/objective	Variable	Instrument/Outcome measure
Phase 1: Study 3		
To create an education physical activity diary.	Record of events	Methodological and procedural processes explained in chapter 6a. Education physical activity diary
Phase 2: Study 4		
To determine physical activity levels in individuals at a higher risk of IHD as determined by study 1.	Physical activity levels	Demographic questionnaire (2) Yamax SW200 pedometer Six minute walk test (6MWT)
To determine perceived levels of stress in individuals at a higher risk of IHD as determined by study 1.	Perceived levels of stress	Cohen's Perceived Stress Scale-10 (PSS-10)
To determine selected known associated risk factors for IHD in individuals living with HIV (on HAART).	RHR and Blood pressure Waist and hip circumference WHR BMI (kg/m^2) ▪ Weight Height	Microlife BP A100 automated sphygmomanometer Butterfly non-stretch tape measure Calculation: Waist (m)/ Hip (m) Simple Choice portable electronic scale Micro Health Stadiometer
To determine Hs-CRP, lipid profiles and glucose levels in individuals at a higher risk of IHD, as determined by study 1.	Hs-CRP Lipid profiles ▪ Total cholesterol ▪ HDL ▪ TG Glucose levels LDL	Roche/Hitachi cobas c 501 analyser using the following tests respectively: Cardiac C-Reactive Protein (Lasex) High Sensitive test Cholesterol Gen.2 test HDL-Cholesterol plus 3rd generation test Triglycerides test Glucose HK, Gen.3 test LDL was calculated using the Friedewald equation
To calculate the ten-year relative risk of IHD events in individuals living with HIV/AIDS using the Framingham Risk equation.	Ten-year relative risk of IHD events	Framingham Risk Score

♦ RHR (resting heart rate), WHR (waist: hip ratio), BMI (body mass index), Hs-CRP (high sensitivity C-reactive protein), HDL (high density lipoprotein), LDL (low density lipoprotein) and TG (triglycerides).

3.2 INSTRUMENTATION, OUTCOME MEASURES AND TOOLS

A full description, based on literature of each of the instruments/outcome measures, their properties, and validity and reliability, is discussed below.

3.2.1 **For the Objectives of Aim 1:** To determine, in individuals living with HIV (on HAART):

- physical activity levels
- perceived levels of stress
- non-invasive known associated risk factors for IHD

A pedometer was chosen to assess the level of physical activity as the interest of this study was to evaluate the amount of walking done by individuals, measured in steps. Walking is often given as a functional activity to address the risk of IHD and gain health benefits to manage IHD (Murtagh et al., 2010; Balady et al., 2007; Haskell et al., 2007; Giannuzzi et al., 2003). An objective way of measuring walking was selected to minimise the influence of education level and home language of study participants on reliability of data collected, had reported data been used. Two questions related to physical activity were added to the demographic questionnaire (1) to determine whether study participants did any form of formal (supervised) exercise and/or exercised on their own when entering the research project. The questionnaire provided information regarding participants' baseline motivation to be physically active and their preferred method of exercise.

i) **Yamax SW200 pedometer**

The Yamax SW200 pedometer detects each step taken, and is useful to evaluate ambulation activities. It is an objective, low-cost tool when compared to an accelerometer (Berlin, Storti and Brach, 2006). The cost of a Yamax SW200 pedometer range between 20-25 US dollars compared to an accelerometer at 50-400 US dollars per device (Tudor-Locke et al., 2002). It provides information regarding the quantity of ambulation, activity and is not specific to intensity level. The pedometer contains a horizontal spring-suspended lever arm that deflects with the up-and-down motion of the leg in hip movement when walking. An electrical circuit opens and closes with each detected leg motion, and an accumulated step count is displayed digitally on a small screen (Tudor-Locke and Lutes, 2009). The Yamax pedometer requires a force of ≥ 0.35 gram to register and record a movement (Tudor-Locke and Lutes, 2009). This force sensitivity threshold censors out "non-step activity", such as vibrations in a car journey (Tudor-Locke and Lutes, 2009).

<u>Validity and reliability of the Yamax SW200 pedometer</u>

The Yamax SW200 pedometer is considered valid for assessing physical activity involving ambulation in free-living physical activity (Schneider, Crouter and Bassett, 2004; Tudor-Locke et al., 2002). It is often used as the criterion when evaluating other pedometers (Tudor-Locke and Lutes, 2009; Schneider, Crouter and Bassett, 2004). The convergent validity of this pedometer with a dual-mode accelerometer was noted to be strong at r=0.74–0.86 (Tudor-Locke et al., 2002) but only fair at r=0.32–0.44

when comparing four different physical activity questionnaires with the pedometer in healthy volunteers (De Cocker, De Bourdeaudhuij and Cardon, 2008). It has been reported that overestimation of physical activity can occur when using a questionnaire compared to an objective measure such as the pedometer or an accelerometer (Tutor-Locke et al., 2002). The Yamax SW200 pedometer has been used in the HIV research sphere to evaluate individuals' physical activity levels. Ramirez-Marrero et al. (2008) demonstrated a strong relationship between that brand of pedometer and the moderate physical activity category of the IPAQ (r=0.76, p=0.04) and fair correlation between it and an Actigraph accelerometer (r=0.46, p=0.0004) in Hispanic individuals infected with HIV. The agreement between the Actigraph and pedometer was significant (61%, kappa=0.25, p=0.01) and the sensitivity of the device was high (96%).

Swartz et al. (2003) reported that the BMI category did not significantly influence pedometer step counts at any walking speed when the pedometer was used to measure step-count in a group of healthy volunteers. Individuals were included in this study if they were normal weight, overweight or obese. The findings of BMI influence on pedometer step-count at different walking speeds were as follows: 54 m x min^{-1}, p=0.991; 67 m x min^{-1}, p=0556; 80 m x min^{-1}, p=0.591; 94 m x min^{-1}, p=0.426 and 107 m x min^{-1}, p=0.869. The researchers concluded that this particular pedometer had similar accuracy in groups differing in WC and BMI. This particular study's findings were of noteworthy interest, as PLWHA are reported to develop varying degrees of lipodystrophy on HAART that could influence WC and/ or BMI. Thus, using the pedometer in PLWHA that might have lipodystrophy would still produce reliable walking activity findings.

No data is available concerning the reliability of using the Yamax SW200 pedometer in the South African context. It has been used in a rural South African population (Cook et al., 2010; Cook, Alberts and Lambert, 2008) and in South African individuals with diabetes (Van Rooijen, Viviers and Becker, 2010) to evaluate individuals' physical activity levels. Concerns about reliability were not reported in these studies.

Number of pedometer assessment days

Variability of step-count exists between days of the week, with the lowest step-counts registered on a Sunday (Clemes and Griffiths, 2008; Tudor-Locke et al., 2005). A common protocol used when evaluating pedometer physical activity is to ask individuals to wear a pedometer for seven days, and calculate the average number of steps per day (total steps divided by the number of days) (Berlin, Storti and Brach, 2006). Tudor-Locke et al. (2005) reported that a minimum of three days of observation are necessary to achieve an intra-class correlation coefficient of 0.80. Clemes and

Griffiths (2008) later recommended using a seven-day assessment period for a reliable estimate of habitual activity, including Sundays, considering that variability is noted between days of the week, gender, BMI and age. The authors also noted that when using seven days of assessment there was a significant relationship between the mean step-count and the criterion (adjusted R^2=0.91, p<0.001). It was therefore decided to use a seven-day pedometer assessment period in this research project.

Reactivity to pedometer physical activity assessment

Reactivity is defined as a change in behaviour that could occur due to an individual wearing a measuring instrument – in this case the pedometer - for physical activity assessment (Clemes, Matchett and Wane, 2008). Conflicting literature is available dealing with this concern when using a pedometer to assess physical activity. Eastep et al. (2004) reported no reactivity in their study participants when they wore a sealed pedometer for a three-week period following a non-sealed three week period of assessment. On the other hand, two similar studies, by Clemes, Matchett and Wane (2008) and Clemes and Parker (2009) reported that reactivity occurs when individuals wear an unsealed pedometer and are also asked to log their daily step-count. Both these studies reported that the probability of reactivity is higher in studies where less than seven days of pedometer assessment is involved. Owing to these contrasting findings, reactivity was evaluated in pilot study 2 of this project before study 1 to determine if a sealed or open pedometer should be used.

ii) **Cohen's Perceived Stress Scale-10 (PSS-10)**

Cohen's Perceived Stress Scales were created by Dr Sheldon Cohen of the Psychology Department of Carnegie Mellon University. Three scales are available for use; PSS-14, PSS-10 and PSS-4. Permission to use the PSS-10 scale was received from Dr Cohen (Appendix 9). It was decided to use the PSS-10 scale, as it had been used previously in SA (Hamad et al., 2008) and also in an international HIV population group (Paddison et al., 2009; Koopman et al., 2000). This scale was also recently included in a proposed protocol for evaluating perceived stress in conjunction with physical activity levels in an American HIV population (Jaggers et al., 2013).

The PSS-10 measures the degree to which a person perceives their life as having been stressful in the past month. The instrument was designed to evaluate stress in communities with at least a junior high school educational level. It consists of 10 questions, rated on a 5-point Likert scale that ranges from "0 = never" to "4 = very often". The scale consists of four positive (4, 5, 7, and 8) and six negative questions (1, 2, 3, 6, 9, and 10). Scoring for the positive questions is obtained by reversing responses e.g. 0=4, 1=3 and 2=2 and calculating a value. Scoring for the negative

questions is calculated adding the values in the following manner e.g. 0=0, 1=1, 2=2, 3=3 and 4=4. Scores range from 0 to 40 with a higher score indicating a higher degree of perceived stress (Cohen and Williamson, 1988). Normative data for the PSS-10 is available for a large probability sample of USA adults (Cohen et al., 2012). As no normative data are available for South Africans, a strategy of setting the 75th percentile as a cut-off to signify a "high" stress level was used in this project. This procedure was previously suggested by Hamad et al. (2008) when reviewing South African PSS-10 information.

Validity and Reliability of the PSS-10

The scales are considered valid instruments for assessing perceived stress (Cohen et al., 1988; Cohen, Kamarck and Mermelstein, 1983). The internal reliability of the PSS-10 was noted to have a Cronbach's alpha coefficient of 0.78 compared to the PSS-14 at 0.75 and the PSS-4 at 0.60 in a large adult USA population (Cohen and Williamson, 1988). This finding suggests that the PSS-10 is a slightly more reliable instrument, due to the higher internal consistency than the other PSS scales. This scale has previously been used in international studies conducted in PLWHA (Paddison et al., 2009; Koopman et al., 2000). Koopman noted a strong internal reliability of α=0.88 when using the PSS-10 to evaluate perceived stress and the relationship with coping strategies, attachment styles and social support in PLWHA in California. The PSS-10 was used by Hamad et al. (2008) and Fernald et al. (2008) to evaluate the perceived levels of stress in low-income South Africans living in Cape Town, Port Elizabeth and Durban. The internal reliability of the PSS-10 was reported as Cronbach's alpha of α=0.72. Owing to the suggested validity of the PSS-10 and the high internal reliability of this scale when assessing perceived levels of stress in PLWHA - and also in a South African group - it was decided to use the PSS-10 as outcome measure in this study.

iii) **Demographic questionnaire (1)**

Demographic variables such as age and gender are known risk factors for IHD, and always collected in large-cohort IHD studies (Steyn et al., 2005; Yusuf et al., 2004; NCEP ATP-III, 2002). In the South African context the distribution of non-communicable diseases shows inequality according to socio-economic status, with the heaviest burden identified in poor communities in urban settings (Mayosi et al., 2009; Schneider et al., 2009). It is also reported that a poorer health status is often found in SA in less-educated persons (Mfenyana et al., 2006). These factors necessitated including questions regarding participants' age, gender, educational level and employment status on the demographic questionnaire. The questionnaire thus consisted of questions in four categories: personal background; exercise, as

reported above; HIV history and IHD risk factors. Two questions were added to provide information regarding when the HIV-positive status was diagnosed and when antiretroviral therapy was initiated. This feedback was collated, by reviewing the participants' clinic files. Information pertaining to medical and surgical history was received from the participants, and again, by review of the participants' clinic files.

The WHO Step Surveillance Manual (2008), the INTERHEART study (Yusuf et al., 2004) and the INTERHEART Africa study (2005) were reviewed to assist with the selection of questions pertaining to risk factors, including smoking and diet. The literature reported that a diet low in vegetable and fruit intake is considered a risk factor for IHD, and so questions pertaining to vegetable and fruit intake were added. A diet high in alcohol and low in fish intake is also reported to increase one's risk for IHD (Artalejo et al., 1996), so relevant questions were added. Lipodystrophy is reported to develop over time in PLWHA on antiretroviral therapy (Hurley et al., 2011; George et al., 2009; Pujari et al., 2005), and is also said to increase risk of IHD (NCEP ATP-III, 2002). Questions pertaining to perception regarding weight gain, weight loss or changes in body shape were added to the questionnaire to facilitate subjective screening for lipodystrophy. The personal background pertaining to risk of IHD included questions related to family history of IHD, as this is again said to increase risk of IHD (NCEP ATP-III, 2002). Symptom-specific screening questions for shortness of breath, fatigue and chest pain were included as they are known IHD symptoms (Collins and Dias, 2009), and also often experienced by PLWHA (Myezwa et al., 2009; Van As et al., 2009). Information on risk facilitated identification and clarification of when such symptoms were first experienced, and assisted with deciding whether a participant should be referred to a clinic medical practitioner.

Information regarding smoking, diet, weight and body shape changes also enhances the trustworthiness of the second study. That study assessed the nature of the individual's self-perception and behaviour in relation to the risk of IHD, and thus triangulation was achieved, by using both the quantitative and qualitative data to confirm the presence of risk factors.

iv) **Automated sphygmomanometer**

A new, portable, Microlife BP A100 automated blood pressure sphygmomanometer was used in this project to assess RHR and blood pressure. Details of this device were: model number BP A100; width 151 cm x length 115 cm x height 88 cm; gross weight 610 g with batteries, and blood pressure range 30-280 mmHg. This device is of Swiss design, and the manufacturers report that it has been tested according to the protocol of the British Hypertension Society, and provides the highest possible

grading for systolic and diastolic measurement accuracy. It consists of a small display monitor with a cuff attachment. It calibrates automatically after a pause of one minute after each blood pressure measurement.

Validity and reliability related to using an automated sphygmomanometer

Using an automated blood pressure device is said to be a valid means of assessing blood pressure, and less "white coat effect" occurs when using this instrument than the conventional mercury sphygmomanometer (Myers et al., 2011). Pavan et al. (2012) evaluated the correlation and agreement between blood pressure measurements when using an automated digital device compared to the conventional auscultatory sphygmomanometer. The authors noted that the mean difference was only 1.9 mmHg in SBP and 0.5 mmHg in DBP when the two different devices were compared. The Pearson correlation coefficients between these two devices when evaluating SBP and DBP were r=0.97 and r=0.91 (p=0.001) respectively indicating high association. The Bland-Altman method to test agreement between the two devices also indicated less than 1% of measures fell outside the two standard deviation ranges when assessing SBP and DBP reflecting good agreement (Pavan et al., 2012). Thus the authors concluded that an automated device is a valid tool for evaluating blood pressure in an adult population. The Microlife blood pressure technology complies with international guidelines for blood pressure devices, and is recommended for clinical use in an adult population (Saladini et al., 2011; Stergiou et al., 2008; Cuckson et al., 2002).

v) **Non-stretch tape measure**

A non-stretch, commercially available Butterfly brand tape-measure was used for waist and hip circumference measurements. The range of the measuring tape was 0 to 150 cm. An additional Fragram tape-measure was available for use in individuals where the Butterfly length was insufficient. The Fragram tape measure was sufficient for up to three meters.

Validity and reliability of tape-measure

A non-stretch tape measure is advocated in the ACSM Guidelines for exercise testing and prescription (2010) as a means of assessing waist and hip circumference measurements, and this technique was used clinically in a number of projects (Canoy et al., 2007; Mosca et al., 2006; Dalton et al., 2003). The non-stretch characteristic reduces variability and improves reliability when performing the technique, simply because it is unable to stretch.

vi) **Portable electronic scale**

A Simple Choice portable electronic scale was used for assessing weight. Details for this bathroom scale were: weight capacity 150 kg; mass graduation 100 g; 25 mm LCD display and lithium battery-operated. The device calibrated before each weight measurement when the researcher tapped the right corner of the scale. This device was selected as it was easy to transport. The physiotherapy room in Themba Lethu clinic was used for research sessions. This space was also used by Helen Joseph hospital physiotherapists intermittently to treat outpatients. Research equipment could not be stored in the room for lack of space. An easily transportable device for use was thus needed, and the scale was selected.

Validity and reliability of portable scales

Portable scales are commercially available to the public for self-monitoring of weight. They are often used in studies when evaluating self-reported- against measured weight (Lawler et al., 2002; Schmidt et al., 1993). It is thus a clinically valid means of determining weight, and using the same instrument and standardised assessment procedure in the research project improved its reliability.

vii) **Height measurement instruments phase 1: non-stretch tape measure, poster paper, non-flexible ruler and clinic wall**

The height of study participants in study 1 was measured using white poster paper taped to the wall of the physiotherapy room, the Fragram tape measure, a non-flexible ruler and a pen. A stadiometer to measure height was not available in study 1 because clinic stadiometers were in use by nursing staff for clinic activities, the physiotherapy department of Helen Joseph hospital did not have a stadiometer, all Wits physiotherapy department stadiometers were in use by other researchers, and this researcher had not yet acquired enough additional funding to purchase her own. In study 4 a Micro Health stadiometer became available, and was put to use.

Validity and reliability of using a non-stretch tape measure, poster paper and non-flexible ruler for height measurement

Valid means of making standing height measurements are a stadiometer, or if that is not available, a tape measure, with the subject standing against a wall (Hall, 2006). Using this equipment, with a standardised assessment procedure, ensured that reliable height data was collected.

3.2.2 **For the Objective of Aim 2:** To determine the nature of the individual's self-perception and behaviour in relation to the risk of IHD.

Data was generated in study 2 using a qualitative design. The following instruments were used: a semi-structured interview questionnaire; flash cards (used in card-sort in the interview); a digital voice recorder for taping the interviews and a conventional Nikon camera for photographing the cards selected by participants in the card-sort technique.

i) **Semi-structured interview questionnaire**

The questionnaire was divided into two sections: questions pertaining to living a healthy lifestyle and others that focused on IHD. These sections contained key primary questions and follow-up questions to prompt respondents. Space was made available for the researcher for field notes.

Content validity of the semi-structured interview questionnaire

The questionnaire was constructed according to the aim of the study. The questionnaire was reviewed by the Faculty of Health Sciences Postgraduate Protocol Assessors group and the University of the Witwatersrand Ethics committee. Both groups consisted of experienced researchers, whose suggestions were incorporated. The content validity of the questionnaire was further evaluated by sending it to four qualitative researchers for review in relation to the study objectives. One researcher declined participation in the process due to other obligations. The remaining three researchers' suggestions were implemented.

ii) **Flash card for card-sort technique**

The card-sort technique is associated with the constructivist approach, specifically Kelly's Personal Construct Theory: "they assume that people make sense of the world by categorising it, and that people can describe their own categorisation of the world with reasonable validity and reliability" (Rugg and McGeorge, 1997; p.81). Another explanation is: "Personal Construct Theory is based on the belief that different people categorize the world differently, but with enough commonality to let us understand each other but enough differences to make us individuals" (Fincher and Tenenberg, 2005; p.89). Thus the card-sort's advantages are that it can elicit our individual understanding about topics and their relationships with each other. It is systematic and easy to use for both respondents and researchers (Fincher and Tenenberg, 2005; Rugg and McGeorge, 1997).

Several varieties of sorting techniques are available: closed-card sort technique (e.g. Q sorts), hierarchical sorts; open card-sort (e.g. "all-in-one sorts") and repeated

single-criterion sorts (Kerr, Hilari and Litosseliti, 2010; Rugg and McGeorge, 1997). In open card-sort techniques cards are usually given for participants to categorise. This might be done once, as in the case of “all-in-one sorts”, or a number of times, as with repeated single-criterion sorts (Rugg and McGeorge, 1997). Performing a sort involves several cognitive processes: creating a category for each card, recall of categories already created, rejecting or accepting categories, generating new categories and moving cards from one category to another (Kerr, Hilari and Litosseliti, 2010). This card-sort technique might be difficult for individuals from a lower educational level or for those with a medical condition that might affect cognitive function. In a multi-cultural population a wide variety of response categories might be generated, due to different socio-cultural beliefs that could make data analysis very difficult when an open card-sort is used. In closed card-sort participants are given the cards to sort according to pre-determined categories e.g. from most important to least important or into specific clusters (Kerr, Hilari and Litosseliti, 2010). Thus, fewer cognitive processes are involved, making it easier to perform, and data analysis might also be less problematic for the researcher.

Card-sort is a qualitative data-collection technique that has been used in the Social Sciences (Ernest, 2011; Saunders and Thornhill, 2011; Whaley and Longoria, 2009) and Health Sciences (Killam et al, 2012; Kerr, Hilari and Litosseliti, 2010; Lugina et al, 2004). Three examples of a closed card-sort method used in the Health Sciences are worth reviewing. Lugina et al. (2004) used semi-structured interviews and card-sort to evaluate postpartum concerns of women in Dar-es-Salaam, Tanzania. Participants had to have a minimum of seven years of primary school education to participate in this study. They were required to sort cards into three predetermined clusters: worry, interest and confidence. The authors noted that the card-sort technique was more sensitive in obtaining information about areas of concerns than the results of the semi-structured interviews. Killam et al. (2012), on the other hand, used a card-sort method to evaluate nursing students’ viewpoints on the most unsafe aspects of the clinical setting. In data-collection study participants were asked to rank 43 cards with statements from “most disagree” to “most agree” on a template. Due to the large number of cards, students often requested additional time to sort them. This suggests using fewer cards in the card-sort when constructing a research project. Kerr, Hilari and Litosseliti (2010) conducted focus groups with individuals living with stroke to determine what information they would want to have included on a website for stroke survivors. The authors requested the participants to sort cards according to five clusters to explore preferences for structuring information on the website: equipment, keeping well, home and money, out-and-about and friends, and family. The authors created cards consisting of pictures and words in order to exploit reading and visual

recognition, that they proposed would increase semantic knowledge of the particular idea. The cards were of the same size, and were numbered so as not to bias participants in any way. Information from these three studies supported the use of the card-sort technique in study 2. In addition, the studies provided information regarding things to consider when constructing and using flash cards.

Content validity of study flash cards used in the card-sort technique

A review of the literature was carried out regarding aspects of living a healthy lifestyle and IHD, as in the objectives of study 2, that needed to be included on the flash cards. Focus areas were identified: infection control, sexual practices, sleep, diet, physical activity, smoking, stress and adherence to prescribed medication. This information was used in creating the sentences/phrases on the flash cards. The cards thus created could support or refute the above categories, thus ensuring participants had to evaluate each one according to their own knowledge, attitudes and beliefs, before making a selection. A copy of the set of cards thus created was sent to the qualitative researchers, together with the semi-structured interview, for content validity review. Following a suggestion received in feedback, sentences on the cards were translated into isiZulu, and pictures explaining the statements were added to provide a visual depiction of the sentence on each card. This method is supported by Kerr, Hilari and Litosseliti (2010) to enhance semantic knowledge of each particular idea. Each card thus consisted of a picture with accompanying English and isiZulu sentences. The sentences or phrases on the cards were short, and in layman's English and isiZulu, to ensure participants would find it easy to understand. The cards were identical in size and writing font to ensure uniformity. Twenty four cards were created, 23 with pictures and sentences or phrases, and one blank. This was for each participant to elaborate on other aspects of living a healthy lifestyle in his/her opinion. The inclusion of this blank card was suggested by an expert clinician with experience in using card-blank card-sort methodology.

iii) **Olympus VN-5500PC digital voice recorder**

A battery-operated Olympus VN-5500PC digital voice recorder was used in qualitative interviews for verbatim transcription at a later stage. That particular voice recorder had computer connection capability for downloading files onto the researcher's computer for safekeeping. Recording interviews by means of an audiotape recorder is a recognised method of collecting qualitative data (Dicicco-Bloom and Crabtree, 2006).

iv) **Conventional Nikon camera**

Triangulation is commonly used in qualitative research to enhance quality and credibility of data collected (Patton, 1999). One such method is triangulation of sources: "examining the consistency of different data sources within the same method" (Patton, 1999; p. 1193). A conventional Nikon camera was used to photograph the card-sort layout of each participant for record-keeping and analysis. The photographs facilitated triangulation of sources, with the field notes regarding cards selected being reviewed together with the photographs.

3.2.3 **For the objectives of aim 3:**

1) To determine, in individuals at a higher risk of IHD as determined by study 1:
   - physical activity level
   - perceived level of stress
   - RHR and blood pressure
   - waist and hip circumference, WHR and BMI
   - Hs-CRP
   - lipid profiles (total cholesterol, HDL, LDL, and TG level)
   - glucose levels

2) To create an education physical activity diary.

3) To implement an individualised education and home-based walking exercise programme, and monitor adherence to the programme.

4) To determine if an education and home-based walking programme has an effect on the physical activity level, perceived stress level, RHR, blood pressure, WC, WHR, BMI, Hs-CRP, lipid profile and glucose levels of affected individuals.

5) To determine whether a correlation exists between hs-CRP and evaluated related IHD risk markers.

6) To calculate the ten-year relative risk of IHD events in individuals living with HIV/AIDS using the Framingham Risk equation, and determine whether the education and home-based walking programme had an effect on the relative risk.

Phase 1 was concerned with pre-participation screening of IHD risk factors for study 4, which consisted of an intervention focusing on physical activity modification. The physical activity levels of participants were evaluated with the Yamax SW200 pedometer and the six-minute walk test (6MWT) in study 4. Exercise testing for all risk stratification categories

is suggested as good practice before the implementation of an intervention, as this establishes safe and effective exercise prescription (ACSM, 2010; Noonan and Dean, 2000). A sub-maximal exercise test, the 6MWT, was selected. The 6MWT is a self-paced functional outcome measure, and aligns with the specific intervention where self-monitored moderate intensity walking is encouraged. The sub-maximal exercise test was added to evaluate the presence and severity of cardiovascular symptoms e.g. shortness of breath, fatigue, dizziness and/or chest pain when performing a focused walk. The cardiopulmonary response and distance walked provided information on exercise tolerance in individuals. It was necessary, as the intervention of study 4 focused on increasing step-count by means of an incremental walking programme that might have had an effect on exercise tolerance of participants. Pre- and post-6MWT heart rate and oxygen saturation values were evaluated with a digital finger probe, the 9550 Onyx II Nonin pulse oximeter. Pre- and post-6MWT perceived breathlessness and fatigue was measured with the Borg scale as suggested by the American Thoracic Society statement (ATS) (2002).

In the course of study 1 it became apparent that certain social factors could influence physical activity levels, e.g. the type of housing would influence the number of steps taken at home. This information was not formally collected in study 1, but was gleaned in informal discussion with participants. The researcher needed to be aware of these social factors when implementing the home-based education and walking programme, and demographic questionnaire (2) was created to standardise questions posed to participants in study 4.

i) **Six-minute walk test (6MWT)**

The 6MWT is a self-paced sub-maximal exercise test that provides information regarding physical function capacity and change in that capacity in individuals without health problems, and also those with moderately severe impairments due to a variety of conditions (Chang, 2006; Noonan and Dean, 2000). The test involves study participants walking as far as possible in six minutes, between two points 30 meters apart, with standardised prompts issued intermittently (ATS statement, 2002). The outcomes measured with this test are distance walked, cardiopulmonary variables and perceived breathlessness and fatigue (Rasekaba et al, 2009; ATS statement, 2002). The 6MWT is also reported to be a moderate-to-vigorous intensity exercise test when reviewed against VO_2 max in healthy working-aged adults (Burr et al., 2011).

The distance findings obtained from the 6MWT can be compared with predicted normal values of an individual, and it is suggested that percentage change could be a valuable clinical parameter to review (Seale, 2006). A number of predictive equations

for 6MWT distance in individuals are available for use in clinical research (Dourado, 2010). Predictive equations in healthy individuals are, however, often limited in their application to the suggested age ranges of such equations. For example, the equation by Gibbons et al (2001) can be used in individuals 22 to 79 years of age, while, on the other hand, that of Enright and Sherrill (1998) can be used in individuals 40 to 80 years of age. When reviewing 6MWT distance findings against the predicted value it is suggested that a value less than 82% should be considered as abnormal (Troosters, Gosselink and Decramer, 1999). There is at present no specific predictive 6MWT equation available for use in individuals living with HIV. The Gibbons et al. (2001) 6MWT predictive equation for healthy individuals over 20 years of age was used to calculate study 4 participants' predicted 6MWT distance, as it aligned with the age inclusion criteria of the research project.

The 6MWT work (6MWORK) is a product of body weight times distance walked, as body weight directly affects the work, or energy, required to perform the walk (Carter et al., 2003; Chuang, Lin and Wasserman, 2001). Authors suggest including this calculation when reviewing findings from the 6MWT to enhance understanding of functional capacity (Carter et al., 2003; Chuang, Lin and Wasserman, 2001). Considering that overweight and obesity are an increasing cause for concern in individuals living with HIV (Crum-Cianflone et al., 2010), it is possible that participants in study 4 could have been overweight or obese. For that reason the 6MWORK calculation was incorporated in the study.

Validity and reliability of the 6MWT

The study focused on physical activity modification in relation to IHD risk management in an HIV population, and information pertaining to the 6MWT validity and reliability in a cardiac and HIV setting was therefore sought. The validity, reliability and responsiveness of the 6MWT in outpatient cardiac rehabilitation programmes were reviewed by Bellet, Adams and Morris (2012) in a systematic review. The analysis noted that the 6MWT was responsive to clinical change in individuals following cardiac rehabilitation. An estimated mean difference of 60.43 meters (95% CI: 54.57-66.30; $p<0.001$) was noted following cardiac rehabilitation interventions (12 trials, with a total of 2 487 subjects). Percentage change was 10% to 28%. The repeatability of the 6MWT in cardiac rehabilitation (two trials with a combined number of 103 subjects) indicated a 2% to 8% test-retest change, with a correlation of 0.97. No information pertaining to inter- or intra-rater reliability was available. Reliability between the 6MWT and other symptom- limited exercise tests ranged from $r=0.58$ to $r=0.69$.

Shoemaker et al. (2013) evaluated the minimum detectable difference and minimum clinically important difference when conducting the 6MWT in 22 individuals living with chronic heart failure. They reported a minimum detectable difference of 32.4 meters at the 95% CI, and minimum clinically important difference as 30.1 meters (95% CI: 20.8-39.4). In this study the researchers reported the test-retest reliability of the 6MWT to be excellent with r=0.99 (95% CI: 0.97-0.99). In contrast, Gremeaux et al. (2011) estimated the minimum clinically important difference in patients with coronary artery disease in a cardiac rehabilitation programme of eight weeks, and reported a minimum clinically important difference of 25 meters for the 6MWT.

Suitability for using the 6MWT in PLWHA

The 6MWT has been used in a few studies evaluating individuals living with HIV, and provide support for its inclusion for evaluating functional exercise capacity in PLWHA, as was done in study 4. Neumann et al. (2007) included the 6MWT in the HIV-HEART study protocol to evaluate functional exercise capacity in outpatient HIV-infected individuals with suspected heart failure diagnosis. Dolan et al. (2006) used it as an outcome measure to evaluate the effects of a home-based exercise programme in a group of HIV-infected women in Boston. The baseline 6MWT distance in the intervention group was 489 meters and in the control group 474 meters. The authors noted a change of 34 meters in the intervention group after the four-month period. Mbada et al. (2013) compared quality of life, 6MWT and 6MWORK between 37 HIV^+ and 37 HIV^- individuals in Nigeria. The authors reported that the 6MWT and 6MWORK findings in the HIV^- group were significantly higher ($p=0.001$) than the HIV^+ group. The actual 6MWT mean values were not reported in the article. Oursler et al. (2009) investigated the utility of the 6MWT in an older HIV^+ population (age=57.5 [±6.5]) consisting of 97 individuals in Baltimore, USA. A moderate correlation of $r=0.60$ ($p<0.001$) was found between 6MWT distance and the VO_2 peak collected in a treadmill exercise test. The mean 6MWT distance reported in this sample was 514 (± 91) meters. Information pertaining to intra-rater and inter-rater reliability of assessors when performing the 6MWT in these studies was not reported in the relevant articles.

ii) **Digital finger probe 9550 Onyx II Nonin pulse oximeter**

Peripheral pulse oximetry is a monitoring modality to facilitate review of non-invasive oxyhaemoglobin saturation levels of patients in many clinical health care settings (Milner and Mathews, 2012). The pulse oximeter works in the following way: “a probe with an electro-optical sensor is placed on a finger and emits two wavelengths of light to differentiate oxygenated from deoxygenated hemoglobin” (West, 2009; p. 449). The ATS guidelines on the 6MWT support the inclusion of pulse oximetry as a means of evaluating pulse rate and oxygen saturation levels (2002). The digital finger probe

9550 Onyx 11 Nonin pulse oximeter was included in a few studies related to patients living with chronic obstructive pulmonary disease (COPD). Schermer et al. (2009) used this device when evaluating patients with stable and acute exacerbation of COPD by general practitioners (Schermer et al., 2009). Majewski, Rozek and Alawale (2010) included this device to evaluate pulse oximetry in a pulmonary rehabilitation programme. No problems were reported by the authors.

Validity and reliability of pulse oximetry

The accuracy of pulse oximeters used in adults was evaluated against arterial oxygen saturation levels in a meta-analysis done by Jensen, Onyskiw and Prasad (1998). The authors found that pulse oximeters are accurate within 2% (±1) to 5% (±2) of in vitro oximetry when arterial oxygenation was 70% to 100%. The authors also noted that finger probes were more accurate than ear probes. They also noted, however, that accuracy could be lost when the patient experienced severe or rapid desaturation, hypotension or hypothermia. Given the inclusion and exclusion criteria of study 4, none of the participants would have fallen into these categories.

iii) **Demographic questionnaire (2)**

Demographic factors are known to be associated with physical inactivity (Linetzky et al., 2013; Bauman et al., 2012; Allen and Morey, 2010). These include age, female gender, non-white ethnicity, low socioeconomic status and lower educational level. In low- and middle income countries social support, such as support of family, is also reported to be positively associated with physical activity levels (Bauman et al., 2012). In sub-Saharan Africa urbanization often leads to significant growth in cities, leading to informal settlements that may lead to deterioration in health (Belue et al., 2009). This consequence was confirmed in research done by Belue et al. (2008) in Khayelitsha, SA. Khayelitsha is a partial informal settlement in the Western Cape. The researchers noted that the lack of potable water in the home and the inability to depend on a partner had the strongest association with perceived stress. Mobility and transport stress often occurs in informal settlements (Belue et al., 2009; Belue et al., 2008). It is therefore to be expected that environmental factors such as transport are associated with physical activity levels in individuals living in low- and middle income countries (Bauman et al., 2012). Owing to these factors the following questions were added to the demographic questionnaire (2): question pertaining to current employment status, as this could have changed since study 1; monthly income and/or grants received by participants; marital status for information regarding support; housing environment for an estimation of size of housing and transport.

iv) **Laboratory analysis of collected blood samples**

A primary prevention strategy for non-communicable diseases such as IHD is identifying risk factors for the disease in individuals (Hsue et al., 2008; Mensah, 2008; WHO STEPS Surveillance, 2008). The WHO STEPS surveillance programme suggests that identification of risk factors in individuals should occur according to three progressive steps: step one: gathering information regarding demographics and behaviour; step two: physical measurements, and step three: collecting blood samples for biochemical review (WHO STEPS Surveillance, 2008). Not all individuals who are screened undergo blood sampling, but only those individuals that were identified in steps one and two.

Biochemical screening of glucose level and cholesterol profile (total cholesterol, HDL, LDL, TG) is recommended for IHD risk factor screening, as these tests identify individuals with diabetes mellitus and hyperlipidemia (Klug et al., 2012; NCEP ATP-III, 2002). C-reactive protein is considered an independent predictor of increased coronary risk, as demonstrated in a systematic review and meta-analysis (Buckley et al., 2009). High-sensitivity CRP is a novel IHD risk biomarker (Pearson et al., 2003) that could be included to evaluate IHD risk, as it provides information regarding inflammation in otherwise healthy individuals (Center for Devices and Radiological Health, 2005). In this study, participants underwent non-invasive IHD risk factor screening in phase 1 and were included in phase 2 if they presented with an IHD risk factor. In phase 2 blood sampling for glucose, cholesterol profile (total cholesterol, HDL, LDL, TG) and Hs-CRP were added to conclude IHD risk factor screening and also to evaluate the effects of the intervention on these parameters.

<u>Validity and reliability of laboratory analysis of collected blood samples</u>

Laboratory analysis of blood samples was carried out at Contract Laboratory Services at the main chemistry laboratory in Johannesburg, SA - practice number 5204240, and registration number 1997/015443/07 (Appendix 11). Contract Laboratory Services is an accredited laboratory with the South African National Accreditation board - facility accreditation number: M0074 (Appendix 11).

Laboratory analysis was done with the Roche/Hitachi Cobas C system using a 501 analyzer, according to the set protocols for this system. The Roche system was indicated as one of the two most reliable systems according to analytical performance in a study evaluating five different blood glucose monitoring systems in four hospitals in Paris (Daly et al., 2011). It has also been used as the criterion against which other systems are evaluated e.g. measuring viral load assays (Katsoulidou et al., 2011).

Low density lipoprotein levels of participants were calculated using the Friedewald equation. This is said to be valid when calculating LDL specifically for the use of cholesterol risk classification (Warnick et al., 1990).

Quality assurance strategies at Contract Laboratory Services

Contract Laboratory Services has internal and external quality control strategies to ensure that valid and reliable results are obtained. An example of internal quality control strategy is the availability of manufacturer-suggested result values for assays assessed. The laboratory uses a standard deviation of ± two in analysis, and if results fall beyond this range the machine automatically calibrates for normalisation. A second example is the systematic tracking of specimen samples throughout the analysis process from delivery to the laboratory to the final electronic report being produced. This is possible because the Roche Cobas C system is interfaced with the Disa laboratory computer system in use at the laboratory.

External quality assurance strategies for Contract Laboratory Services include:

- Frequently audited by large research studies to ensure laboratory practices are followed.
- Assessed by the South African National Quality Assurance Council in terms of assessment frequency required by the organisation.
- Belongs to Patient Safety Monitoring in International Laboratories that monitors the laboratory analysis results against other international laboratories that also use the Hitachi/ Roche Cobas C system.

v) **Education physical activity diary**

Physical activity diaries, or physical activity logs, have been used extensively for assessing physical activity in various populations. In such literature individuals are often asked to document time spent in a specific activity or to document motion sensor readings. Examples of studies that have used diaries are: Moore et al. (2009) used a pedometer and activity diary when measuring physical activity in individuals living with COPD. The authors reported the daily diary to be more effective in this population due to slower walking speeds caused by physical complications, such as shortness of breath. Saves and Ades (2008) determined walking levels of individuals by pedometer when entering a cardiac rehabilitation programme, comparing non- rehabilitation days with rehabilitation days. Individuals were required to document their daily step-counts in an activity log every day for seven days. The participants' step-counts on cardiac rehabilitation days were significantly higher ($p<0.0001$). Similarly, Butler et al. (2009) followed the same physical assessment method in individuals when evaluating baseline pedometer

activity levels before instituting a post-cardiac rehabilitation maintenance programme. Saunders et al. (2013), on the other hand, evaluated physical activity in the six-year longitudinal Quebec family study by asking study participants to document time spent performing a specific activity in an activity diary over a three-day period. Activities were organised according to specific categories. The relationship between sedentary behaviour and cardio-metabolic parameters were evaluated.

Physical activity diaries are also used as self-monitoring tools to enable individuals to log activity levels when participating in physical activity-promoting programmes. In the Cochrane review by Foster, Hillsdon and Thorogood (2009) interventions promoting physical activity were reviewed. The studies included in this review often provided participants with an education diary (verbal or written) for self-monitoring. Likewise, Richardson et al. (2008) demonstrated that diaries or logs used for recording step-count, together with education of participants, were the norm in studies in the meta-analysis of pedometer-based walking programmes where weight loss was the primary aim.

Literature is available supporting what patients diagnosed with IHD would wish to have included in an education diary tailored for them. Redfern et al. (2006) assessed the expressed requirements of patients with IHD of what should be included in education leaflets. Patients reported that they would appreciate space to document their own particular values, e.g. blood pressure measurement, and information regarding the recommended levels of risk factors, and how those risk factors affected the heart. Regarding physical inactivity, the patients requested information regarding duration and frequency, and suggested a chart for motivation. The findings of these studies clearly support the use of the education physical activity diary in study 4 as an education and self-monitoring tool; and findings from Redfern et al. (2006) were considered in its design.

vi) **Framingham Risk Score (FRS)**

The Framingham Heart study was the first to evaluate the causal relationship between IHD risk factors and IHD, and consisted of 5209 men and women living in Framingham, Massachusetts, in 1948. The researchers enhanced risk assessment by formulating the Framingham IHD risk prediction equation. This equation determines absolute global risk for IHD by using prominent risk factors together with the cause of cardiovascular disease; thus it is a multifactorial equation (D'Angostino, 2012; Bitton and Gaziano, 2010). Since the Framingham Heart study in 1948 the research entity has continued with research in the cardiovascular field with an

Offspring Cohort, initiated in 1971 (2489 males and 2646 females), and the Third-Generation Cohort initiated in 2001 (more than 4 000 participants) (D'Angostino, 2012). The Framingham IHD risk prediction equation incorporates the following facets to calculate an individual's 10-year RR for cardiovascular disease: gender, age, total cholesterol level, smoking status, high HDL level and SBP value (Blom, 2011; NCEP ATP-III, 2002).

Validity of the FRS

The FRS is often used as the criterion against which other scores are tested, e.g. the Reynolds Risk Score (Cook et al., 2012). It has been validated in various ethnic groups with gender-specific categories, performing well in white and black participants in different settings (D'Argostino et al., 2001). The FRS was also validated in the developing world, specifically China (Liu et al., 2004). For these reasons the South African Dyslipidaemia Guidelines supports the use of the FRS when estimating cardiovascular risk in South African individuals (Klug et al., 2012). There are no validated IHD risk prediction equations available for use in an HIV population. The State of the Science Conference that focused on initiatives to decrease cardiovascular disease in individuals living with HIV suggested that the FRS could be used in the interim (Grinspoon et al., 2008). The FRS tables were used in this study to assist with calculating participants' IHD risk.

Chapter 4 consists of an explanation of the methodology, procedures, results and discussion related to study 1 of phase 1 of this project. The focus of study 1 was to screen the physical activity levels and other known non-invasive risk factors for IHD in PLWHA attending the Themba Lethu clinic in Johannesburg, SA. This provided information regarding the extent of the behavioural and clinically-assessed IHD risk factor status in PLWHA at an outpatient clinic level.

CHAPTER 4

4. STUDY 1: SCREENING OF NON-INVASIVE RISK FACTORS FOR IHD

4.1 INTRODUCTION

A lifestyle disease such as IHD is becoming a concern in PLWHA due to HIV having progressed to a chronic disease state, as well as side-effects of HAART. International data suggest that the predominant causes of mortality in PLWHA are shifting towards non-communicable diseases e.g. IHD (Grinsztejn et al., 2013; French et al., 2009; Palella et al., 2006). Screening and monitoring risk factors for IHD in PLWHA are thus considered an important management strategy (Grinspoon et al., 2008). Published information regarding the physical activity levels and non-invasive risk factor status of IHD in PLWHA at primary care level in SA is lackng. This study set out to provide information regarding these risk factors for IHD in PLWHA at a primary care level in SA. This information is important in providing support for preventive management strategies. This chapter consists of an explanation of the methodology, procedures, results, and discussion related to study 1 of phase 1 of the research project.

4.2 STUDY 1

4.2.1 Aim and Objectives

Aim:

To determine the associated risk factors for IHD in HIV+ individuals (on HAART) in Johannesburg, SA.

Objectives:

To determine, in individuals infected by HIV and on HAART:

- current physical activity levels
- perceived levels of stress
- the presence of selected known associated risk factors for IHD (smoking history, diet, RHR, blood pressure, WC, WHR and BMI)

4.3 METHODOLOGY

4.3.1 Study Design

An observational quantitative study was conducted from October 2010 to June 2012.

4.3.2 Sample Size

No prevalence rates for IHD were available in the South African context at the start of this research project, either for the general or the HIV^+ population. Hypertension is said to be a significant risk factor for IHD in the black African group of the INTERHEART Africa study (Steyn et al., 2005). The client base at Themba Lethu clinic was mostly of black African origin. Prevalence rates of HTN in the general South African population were used to calculate the sample size of study 1. Data available from Steyn (2008) indicated a prevalence rate of 55% in a study sample of 9 731. The sample size of study 1 was estimated at 195 subjects, with alpha set at 5% and the power set at 80%. The sample was increased by 5% for allowance of attrition rate during the data-collection period. The final sample size for study 1 was therefore 205 participants. A statistician assisted with sample size calculation for this study.

4.3.3 Study Subjects

The study participants were individuals infected with HIV, on HAART, living in Johannesburg and attending the Themba Lethu HIV clinic at the Helen Joseph hospital. A consecutive sampling method was used, according to the following inclusion and exclusion criteria:

4.3.3.1 Inclusion criteria

The following individuals were included:

- Those infected with HIV.
- On HAART.
- Attending Themba Lethu clinic at Helen Joseph hospital in Johannesburg, SA.
- Aged between 20 and 65 years.
- Those on HAART for ≥ six to 12 months.
- Those with HIV on HAART who were ambulatory without an assistive device.

4.3.3.2 Exclusion criteria

The following individuals were excluded from participation in the study:

- Pre-existing history of angina, myocardial infarction, stroke and peripheral vascular disease.
- Acute infection or active/current opportunistic AIDS-defining illness.
- Pre-existing history of dementia, confusion, psychosis or current signs of emotional distress.
- Known diagnosed peripheral neuropathy or a physical complaint of “sore” or “burning feet” influencing walking ability.
- Pregnant or breast-feeding women.

4.3.4 Measuring Instruments

The following instruments were used: demographic questionnaire (1) referred to in this chapter below as “the questionnaire (1)” (Appendix 12), PSS-10 (Appendix 10), phase 1 evaluation form (Appendix 13), Yamax SW200 pedometer, with pedometer activity walking log sheet (Appendix 14), pedometer accuracy sheet (Appendix 15), Microlife BP A100 automated sphygmomanometer, Butterfly non-stretch tape measure, Simple Choice portable weight scale, poster paper, clipboards and pens. The literature review and justification for the use of these measuring instruments are provided above (chapter 3, section 3.2.1).

4.3.5 Translation Considerations

4.3.5.1 Gauteng language review

South Africa has 11 official languages: Afrikaans, English, isiNdebele, isiXhosa, isiZulu, Sesotho sa Leboa, Sesotho, Setswana, siSwati, Tshivenda and Xitsonga. English is the country’s *lingua franca,* due to it being the language of business, politics and media (Stats SA, 2011). Languages most frequently spoken in Gauteng province where this study was conducted were isiZulu (19.8%), English (13%), Afrikaans (12.4%) and Sesotho (11.6%) (Stats SA, 2011). Unpublished data from two PhD theses at the University of the Witwatersrand (Ballington et al., 2012; Wood et al., 2010) reported that participants in research studies in Gauteng province, very rarely select information in their home language, their preference most often being English. English and isiZulu were therefore chosen as the languages considered for translation.

4.3.5.2 Documents considered for translation

Content validity of the questionnaire was established by giving it, together with the study objectives, to two physiotherapists for review: one with clinical and academic experience in the HIV population, and the other with experience in cardiopulmonary physiotherapy. Their suggestions were implemented, and minor adjustments made accordingly. The questionnaire was also reviewed by the Faculty of Health Sciences Postgraduate Protocol Assessors group and the University of the Witwatersrand Ethics committee. The Ethics committee suggested minor alterations, such as removing “relationship status” from the questionnaire, which were implemented.

The following documents pertaining to study 1 were translated into isiZulu: information document (Appendix 16), consent form (1) (Appendix 17), the questionnaire (1) (Appendix 18) and the pedometer activity walking log (Appendix 19). These documents were forwarded for translation from English to isiZulu by one translator, and then back-translated from isiZulu to English by a second translator. This was done to ensure objectivity in the translation process, and to ensure consistency of English and isiZulu formats. The

translations were performed by Bangula Translation Services. The researcher reviewed the original English versions against the back-translated versions of the documents to identify any discrepancies that might have occurred. The documents were very similar, and no significant alternations were noted that could affect understanding.

4.3.6 Orientation of Research Assistants

Study 1 included two research assistants that worked as physiotherapists at Helen Joseph hospital. The home language of one was English, though she could also speak Afrikaans. That of the second was isiZulu and he was also fluent in English. Their function was to obtain informed consent from eligible study participants. They were briefed about the aims of the study and their role in it, and were given a document with the most important facts to remember. They were also given copies of the information document and consent forms (English and isiZulu versions). A third research assistant was a "runner/place-keeper" in the clinic queue while testing was under way. The need for the "runner" had become apparent in pilot study 2, and the same person became part of study 1. She was fluent in English and isiZulu, and knew the logistics of the clinic, having attended as a patient there. She had received HAART for many years, so could not participate as a subject in the project. She assisted with translation in consultation sessions where participants had difficulty understanding English. The researcher's first language was Afrikaans but she was fluent in English.

4.3.7 Pilot Studies of Study 1

Two pilot studies were conducted before the main study to assist with selection of the Yamax pedometer and review the intra-rater reliability of tools and the researcher when assessing participants. Details of these pilot studies will be presented in section 4.3.7.1 and 4.3.7.2.

4.3.7.1 Pilot study 1

The physiotherapy department of the University of the Witwatersrand had access to two types of Yamax pedometers: the Yamax SW200 and the Yamax CW600. In pilot study 1 the differences between these two devices when conducting physical activity assessment were determined.

4.3.7.1.1 Aim and objectives: Pilot study 1

Aim:

To determine the instrument intra- and inter-rater reliability of the Yamax SW200 and Yamax CW600 pedometer in physical activity assessment.

Objectives:

To determine, in full-time University of the Witwatersrand staff:

- physical activity, as measured with the Yamax SW200 and CW600 pedometers,
- the relationship between the Yamax SW200 and Yamax CW600 pedometers in physical activity assessment,
- the extent of agreement between these pedometers,
- whether there were any difficulties related to physical activity assessment over a period of seven days with these pedometers.

4.3.7.1.2 Study design: Pilot study 1

An observational quantitative study was undertaken in June and July 2010.

4.3.7.1.3 Sample size: Pilot study 1

A sample size of ten participants was selected to compare step-count between the two pedometers. Schneider et al. (2004) used 20 participants to evaluate 13 models of pedometers in free-living activity. It was thus concluded that 10 participants to compare one variable between two pedometers should be adequate to provide statistically significant findings.

4.3.7.1.4 Study participants: Pilot study 1

Twelve physiotherapy and two occupational therapy department staff members from the School of Therapeutic Sciences of the University of the Witwatersrand were invited to participate in the study. They were invited because they available in the time set aside for this pilot study. The only requirements for participation were that they be independently mobile without a mobility aid, willing to wear both pedometers for seven days and document pedometer step-count findings daily on a physical activity log sheet. Two declined participation, resulting in a sample size of 12 participants. The participants were sampled consecutively.

4.3.7.1.5 Measuring instruments: Pilot study 1

Of the two pedometers, the SW model offered a step-count function only, whereas the CW model included a clock, physical activity time function, a seven-day memory and a two-week accumulated memory function. The last two functions were considered beneficial in the research environment where participants could easily forget to record their daily information on the activity log. The participants were asked to document their pedometer findings on a physical activity log sheet (Appendix 14). The procedure involved, and the results, with a brief discussion and conclusion, are presented in Appendix 20.

4.3.7.1.6 Key recommendations: Pilot study 1

The pilot study supplied valuable information in preparation for study 1. It found that the accuracy of the SW200 model was greater ($r=0.96$; $p<0.00$) than the CW600 ($r=0.82$; $p<0.00$). The study also highlighted that the CW600 tended to underestimate pedometer steps when compared to the SW200. These findings supported the use of the SW200 pedometer in the project.

The pilot study also highlighted potential difficulties, requiring correcting strategies:

- Participants might be predominantly female and only wear dresses. In that case a belt would need to be available for mounting the device. Alternative pedometer placements, such as wearing it on tights underneath a dress, might be suggested in a seven-day assessment.

- Participants with children would need to ensure that they did not carry a child on their hip where the pedometer was positioned, as it might influence readings.

4.3.7.2 Pilot study 2

Pilot study 2 followed pilot study 1, and was conducted at Themba Lethu clinic with the research population of interest: individuals living with HIV and on HAART. The inclusion and exclusion criteria, as well as the measuring instruments, were the same as in study 1 (4.3.3 and 4.3.4. above).

4.3.7.2.1 Aims and objectives: Pilot study 2

Aim 1:

To determine the reliability of the Yamax SW200 pedometer in physical activity assessment.

Objectives of aim 1:

To determine, in affected individuals:

- physical activity with the pedometer.
- accuracy of the pedometer.
- reactivity between first and last day of physical activity assessment.

Aim 2:

To determine researcher intra-rater reliability in vital signs- and anthropometric measurement assessments in individuals that are HIV^+ (on HAART).

Objectives of aim 2:

To determine:

- vital signs: RHR and blood pressure.
- anthropometric measurements: WC, hip circumference, height and weight.

Aim 3:

To evaluate the utility of the demographic questionnaire (1) and PSS-10.

Objectives of aim 3:

To determine:

- the internal consistency of the PSS-10
- any problems experienced in completing the demographic questionnaire (1)

4.3.7.2.2 **Study design: Pilot study 2**

An observational quantitative study was undertaken from October to December 2010.

4.3.7.2.3 **Sample size: Pilot study 2**

The sample size for the pilot study (n = 21) was calculated at 10% of that of the larger main study one (n = 205), as suggested in the literature (Hertzog, 2008). Twenty-four individuals were assessed and included. The procedure, with results and brief discussion and conclusion are given in Appendix 21.

4.3.7.2.4 **Key recommendations: Pilot study 2**

The pilot study yielded valuable information on clinical research in PLWHA at clinic level. The most pertinent difficulties encountered included:

- Participants stood in the clinic queue for a long time when attending appointments, and were thus not willing to leave their place in the queue to attend research sessions. To overcome this, a “runner” was recruited (research assistant three) to keep participants’ place in the queue.

- The cue used in the pedometer accuracy test: “walk at a normal comfortable pace” resulted in slower walking speeds than what was found with pilot study 1 participants. The cue was changed to: “walk at a normal fast pace as if you are trying to catch a taxi”.

- Acquiring the participants' file for review was often difficult, due to it being in use in the clinic at the time. The researcher therefore relied on subjective feedback from participants when reviewing the inclusion and exclusion criteria. Information on participants' blood results in clinic files was often absent or very old (>1 year). The manager of the clinic allowed the researcher to review blood results from the National Health Laboratory database system, to which the clinic had access. Further explanations of the obstacles are offered in Appendix 21.

Pilot study 2 found that the intra-rater reliability of the researcher when evaluating participants' body measurements (height, waist and hip circumference) was excellent ($r=0.99$; $p<0.00$ to $r=1.00$; $p<0.00$). The intra-rater reliability of the sphygmomanometer ($r=0.82$; $p<0.00$ to $r=0.93$; $p<0.00$) and the weight scale ($r=1.00$; $p<0.00$) was also excellent, indicating that the equipment was reliable. No significant reactivity ($p=0.40$) occurred when participants wore the pedometer and recorded their findings on the log sheet. The Cronbach's alpha of the PSS-10 was 0.82, indicating internal consistency when assessing perceived stress levels with the PSS-10. It was therefore concluded that the measuring equipment and instruments were reliable, and could be used for the procedures in main study 1.

4.4 PROCEDURE

Knowledge gained from the pilot studies was incorporated in the procedure of study 1. Patients attending Themba Lethu clinic at Helen Joseph hospital were approached while they were queuing. Eligible participants were identified at this stage by the researcher. Each eligible participant was introduced to a research assistant (Helen Joseph hospital physiotherapist) who then explained the study and obtained informed consent. Once the consent had been obtained a third research assistant ("runner") kept the participant's place in the queue while the researcher conducted the first interview (on the same day as recruitment).

Participants provided information regarding their time on HAART, and this information was checked with the file, as well as the type of HAART medication prescribed. Information regarding CD_4 count, viral load and liver function tests was collected from clinic files and/or the National Health Laboratory database. At the first interview the demographic questionnaire (1) and PSS-10 were completed, with the researcher at hand for any questions that might have arisen.

A. **Procedure for testing pedometers**

The pedometer and physical activity log sheet were then explained to the participant. Factors relating to use of the pedometer covered in this training session included: how to open and close it, how to reset it, and when and where to wear the waist-mounted instrument. Participants were requested to continue with their daily life as normal for the seven consecutive days of wearing the pedometer, and asked to wear it from the time they got up in the morning until they went to bed at night. They were instructed not to wear the pedometer when bathing, showering, swimming or sleeping. Before fitting the pedometer each morning, they had to reset the counter to zero. They were asked to document the step-count recorded on the log sheet in the evening when they removed the device.

An accuracy test was done with each participant as the pedometer was issued at the first session. Accuracy was determined by demarcating a 10-meter distance in a quiet corridor outside the physiotherapy room. Participants were instructed to wear the pedometer on the right side of the body, at waist level. Pedometer placement in each participant was standardised by instructing the participants always to wear the pedometer anterior to the right hip, in approximately mid-thigh position. The researcher checked the pedometer placement for correctness. This position was suggested by the manufacturers (Yamax, 2011). The participants were instructed to walk at a normal fast pace “as if they were trying to catch a taxi” over the 10-meter distance, starting with the right leg. The researcher counted the actual steps taken by the participant, remaining positioned at a distance behind the participant so as not to influence the walking speed. This procedure was followed twice. The counted steps were evaluated against the pedometer reading, and the findings documented on a pedometer accuracy sheet. A follow-up appointment was then scheduled for 10 to 14 days later. One day before the second appointment, the researcher sent each participant a reminder cellphone short message service (SMS) regarding their physiotherapy appointment the next day.

B. **Procedure for body measurements**

In the return appointment the pedometer and activity log were returned. The participants were asked whether they experienced any problems related to the pedometer or their health since the last session.

Positioning of participants

This discussion took place while participants were resting comfortably in an office chair. They were asked if they had drunk any coffee, Coca-Cola or smoked a cigarette in the previous half-hour, as these could have influenced their vital signs. None of them had. Vital signs and anthropometric measures were then assessed by the researcher.

Test Procedures

a) *Heart rate and blood pressure*

The participants were asked to expose their arms and remove any tight-fitting clothes that could affect circulation in the upper extremities during blood pressure evaluation. Each participant sat quietly for approximately five minutes on a comfortable office chair with his/her back supported by a pillow. The cuff of the sphygmomanometer was positioned, firstly on the left upper arm approximately two to three centimeters above the elbow joint, as recommended by the manufacturers, with the limb resting pointing forwards at heart level on the table. Two readings were taken on the left arm. The procedure was repeated on the right arm. The device was used and cared for in accordance with the manufacturer's instructions. Once the start button had been activated the cuff inflated, and an automatic measurement was made. The values were displayed for one minute on the display monitor before disappearing. After each reading a minute elapsed before the sphygmomanometer automatically re-calibrated to zero, and a follow-up reading could be done. Pulse rate and blood pressure values were collected with the Microlife BP A100 automated sphygmomanometer. The measuring unit for pulse rate was bpm, and for blood pressure mmHg.

b) *Respiratory rate*

In the cardiovascular assessment the researcher observed participants' chest rise and fall to determine the respiratory rate. This was to provide information regarding relaxation level, and was not part of risk factor screening for IHD. The measuring unit for respiratory rate was breaths per minute.

c) *Weight, height, waist and hip measurements*

The participants were then instructed to remove their shoes, hats and any bulky clothing, as well as any articles in their pockets e.g. wallet or cellphones. Their weight was measured twice with the portable scale. The scale was calibrated before each assessment in accordance with the manufacturer's guidelines, and a minute elapsed between readings. Participants were then instructed to stand upright against a wall in the physiotherapy room facing the researcher with their head in a neutral resting position. A ruler was positioned against the top of the head normal to the wall. A mark was made on the poster paper. The participant stepped aside and the researcher measured the distance from the mark to the floor to determine height. This procedure was followed twice. Weight and height were measured to the nearest 0.1 kg and 0.1 cm respectively.

Waist and hip circumferences were measured with a Butterfly non-stretch tape measure according to the ACSM Guidelines for anthropometric measurements (2010). Waist circumference was measured at the narrowest circumference halfway between the lowest ribs and iliac crests with the arms of participants lowered next to their sides and feet placed together. The participants were encouraged to exhale gently, and measurements were then taken to ensure the abdomen was relaxed. A horizontal measure was taken at the narrowest portion of the trunk (above the umbilicus but below the xiphoid process). Hip circumference was measured at the broadest circumference of the buttocks with participants' feet placed together while standing upright. Two measurements of waist and hip circumference were taken. The measuring unit for weight was kg and height, waist and hip circumference were measured in cm.

d) WHR and BMI

Body mass index was calculated with the following equation: kilograms divided by height in meters squared (WHO, 2004). The WHR of study participants was calculated by dividing the WC by the hip circumference, both in meters (ACSM, 2010). At completion of the session participants received feedback concerning their findings and were informed regarding normal values of each parameter. If parameters suggested an increased risk of IHD the participants were invited to participate in study 4 that followed study 1. If an individual had difficulty understanding information research assistant three acted as translator. She was instructed to translate word-for-word, or as close as possible, depending on the availability of the word in the vernacular.

All the assessed variables were recorded on the phase 1 evaluation form of the study for data capture at a later stage. Blood pressure and pulse rate were measured twice on each arm, resulting in four blood pressure and four pulse rate measurements. The South African Hypertension Society Guidelines suggest that when measuring blood pressure it should be assessed on both arms, and an average of two readings should be taken (Seedat et al., 2006). The means of these variables were calculated in statistical analysis. Anthropometric measurements resulted in two measurements of each variable. The means of these variables were calculated in statistical analysis.

4.5 STATISTICAL ANALYSIS

Data collected in study 1 were captured in Microsoft Excel 2007 spread sheets. The data sheets were reviewed to highlight any anomalies or absences of data, and corrected accordingly. Data analysis was done with STATA 12 by an external statistician, and IBM

SPSS 20 by the researcher. Data were evaluated for normal distribution. Continuous data were summarised as means and standard deviations. Categorical data were summarised as frequencies and percentages. Demographic data of the study sample was assessed as a whole, but smoking status, physical activity levels, perceived levels of stress and anthropometric measurements were also reviewed by gender groups, as literature supports gender differences in these variables (ACSM, 2010; Peer et al., 2009; Guthold et al., 2008; Hamad et al., 2008). This was also observed in pilot study 2. Bivariate analysis was carried out to determine which variables - physical inactivity (step-count ≤ 9 999 steps/day), overweight/obesity (BMI ≥ 25 kg/m^2) or RHR (≥ 80 bpm) - had an association as abnormal values. These were noted in these sample mean variables. Univariate logistic regression analysis was then done to explain the odd ratios between physical inactivity, RHR and BMI with their independent variables. The odd ratios were adjusted for age and gender in further logistic regressions. Findings were significant, with $p < 0.05$. Data are represented up to one decimal value. The results are presented in section 4.6.

4.6 RESULTS

The results of study 1 are reported in six sections: Socio-demographic profile, HIV-related profile, physical activity levels, perceived stress levels, other non-invasive IHD risk factors screened, and lastly logistic regression analysis findings. Figure 4.1 is a flow diagram of the representation of the number of participants, from interest to participation to second session assessment in study 1.

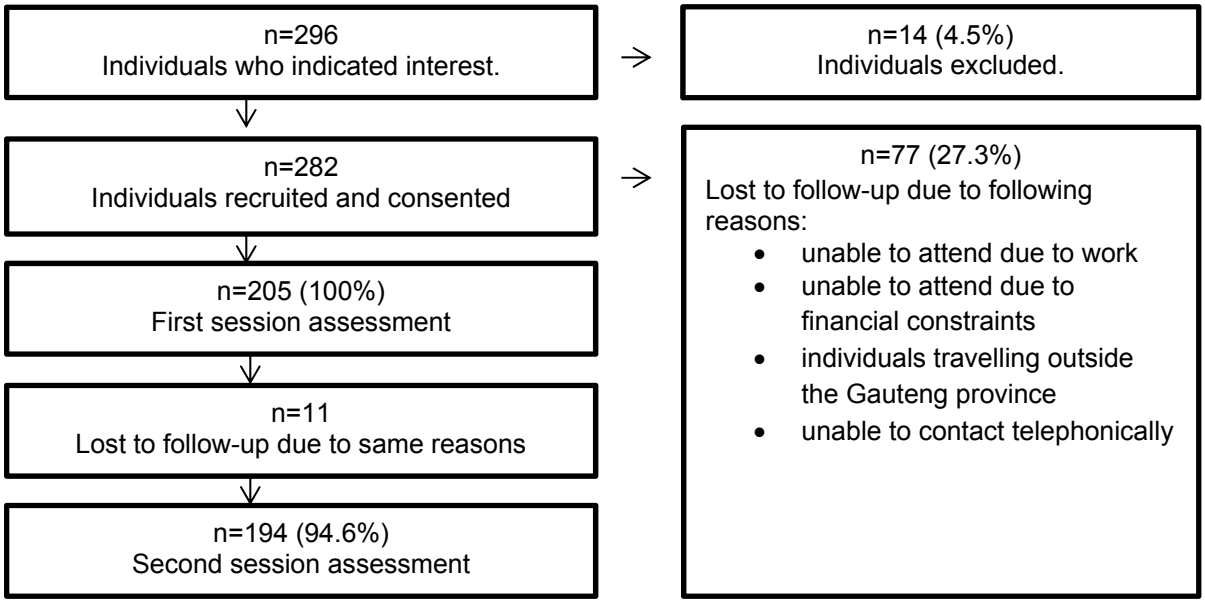


Figure 4.1: Flow Diagram to Illustrate Participants' Retention from Interest to Assessment in Study 1

Fourteen individuals were excluded from participation in the study because: two would be travelling outside Gauteng Province, and were unsure of their return; eight had been on HAART for more than 12 months, two were pregnant, one had a history of myocardial infarction and one had TB myopathy.

4.6.1 Socio-Demographic Profile of Study 1 Participants

Table 4.1 provides information on socio-demographic profile, as obtained through the questionnaire.

Table 4.1: Socio-Demographic Information of Study 1 Participants (N = 205)

Variable	N	n (%) or Mean (±SD)
Age (years)	205	38.2 (±9.5)
Gender ▪ Male ▪ Female	205	 47 (22.9) **158 (77.1)**
Educational level ▪ None ▪ Primary ▪ Secondary ▪ Post-secondary	205	 6 (2.9) 50 (24.4) **95 (46.3)** 54 (26.3)
Employment status ▪ Unemployed ▪ Employed ▪ Self-employed	205	 83 (40.5) **115 (56.1)** 7 (3.4)
Participants who had dependants	205	**158 (85.4)**

The majority of participants were female (n=158; 77.1%), had a secondary education (n=95; 46.3%), were employed (n=115; 56.1%) and supporting dependants (n=158; 85.4%).

The occupation (where employed), was as follows: domestic worker (n=46; 22%), administrative (n=25; 12%), handyman-type (n=18; 8%), cashier or sales person (n=18; 8%), cook or waiter (n=12; 6%), security officer (n=6; 3%), street vendor (n=6; 3%), teaching assistant or nanny (n=6; 3%), taxi- or truck driver (n=3; 1.5%), cleaner (n=3; 1.5%), auxiliary nurse (n=3; 1.5%), counsellor (n=3; 1.5%), carer (n=2; 1%), hairdresser (n=2; 1%), student (n=2; 1%) and jockey (n=1; 0.5%).

Table 4.2 provides information regarding previous medical information.

Table 4.2: Past Medical Information of Study 1 Participants (N = 205)

Variable	n (%)
Respiratory history	
▪ Pulmonary TB	**55 (27)**
▪ Upper respiratory tract infection	17 (8)
▪ Pneumonia	15 (7)
▪ Asthma	9 (4)
▪ Sarcoidosis	1 (0.5)
▪ Pneumocystosis	1 (0.5)
Neurological history	
▪ Shingles	9 (4)
▪ Meningitis	5 (2)
▪ Bell's palsy	2 (1)
▪ Unspecified polyneuropathy	2 (1)
▪ Epilepsy	1 (0.5)
▪ HIV encephalopathy	1 (0.5)
Musculoskeletal history	
▪ General or specific joint discomfort	14 (7)
▪ Gout	1 (0.5)
▪ Headache	1 (0.5)
▪ Myalgia	1 (0.5)
Dermatological history	
▪ Acne and rashes	12 (6)
Gastric history	9 (4)
Genitalia history	
▪ Genital warts	13 (6)
Extra-pulmonary TB	
▪ Meningitis	4 (2)
▪ Abdominal cavity	2 (1)
Renal dysfunction	3 (1.5)
Wasting syndrome	1 (0.5)
Malnutrition	1 (0.5)
Thyroid dysfunction	1 (0.5)
Lipodystrophy	1 (0.5)
Hyperlipidaemia	1 (0.5)
Depression	1 (0.5)

♦ TB (tuberculosis)

The condition most often identified in previous medical history was pulmonary TB (n=55; 27%). Unspecified polyneuropathy was noted in 2 (1%) files, but was not reported verbally as factors influencing their health and walking ability.

Table 4.3 provides information regarding surgical history.

Table 4.3: Surgical History of Study 1 Participants (N = 205)

Variable	n (%)
Abdominal wall surgery	
▪ Caesarian section	**27 (13)**
▪ Laparotomy	9 (4)
▪ Hysterectomy	8 (4)
▪ Mini-laparotomy for ectopic pregnancy	4 (2)
▪ Appendicectomy	3 (1.5)
Musculoskeletal surgery	10 (5)
Biopsy	
▪ Breast biopsy	4 (2)
▪ Uterus biopsy	2 (1)
Head and neck surgery	
▪ Dental surgery	2 (1)
▪ Tonsillectomy	2 (1)
▪ Eye procedure	1 (0.5)
Procedures performed on the genitalia	
▪ Genital wart removal	4 (2)
▪ Circumcision	1 (0.5)
Dermatological procedures	
▪ Repair of skin lacerations	3 (1.5)
▪ Removal of wart on hand	1 (0.5)
Chest wall procedures	
▪ Intercostal drain insertion	1 (0.5)
Removal of varicose veins	1 (0.5)

The majority of surgical interventions performed in participants were confined to the abdominal cavity, and were mostly obstetric and gynaecological.

Medication, excluding HAART, included: anti-hypertensive (n=9; 4%), collected from the local clinic in their community; bronchodilator therapy through metered-dose inhalers (n=2; 1%); statin therapy and aspirin (n=1; 0.5%); Glucophage (n=1; 0.5%); anti-depressants (n=1; 0.5%), and one participant (0.5%) was taking thyroxin sodium for thyroid dysfunction. No participant reported using recreational drugs; nor was any such history established in their file review. Section 4.6.2 contains information regarding participants' HIV-related profile.

4.6.2 HIV-Related Profile

Table 4.4 provides information regarding the HIV-related profile of participants' defining parameters, screened by the questionnaire.

Table 4.4: Information of HIV Characteristics of Study 1 Participants (N = 205)

Variable	N	n (%) or Mean (±SD)
Time on HAART (months)	205	8.7 (±2.3)
Confirmed to have HIV ▪ Before 2005 ▪ 2005 - 2008 ▪ 2009 - 2011	205	 25 (12) 44 (22) **136 (66)**
HAART categories ▪ Lamivudine, Efavirenz, Tenofovir ▪ Lamivudine, Efavirenz, Stavudine ▪ Other	205	 **139 (67.8)** 38 (18.5) 28 (13.6)
Perceived health perception ▪ Poor ▪ Average ▪ Good ▪ Excellent	205	 5 (2.4) 40 (19.5) **120 (58.5)** 40 (19.5)
Body shape changes in last six months	205	**123 (60)**
Weight gain in last six months	205	**132 (64.4)**
Weight loss in last six months	205	49 (23.9)

The majority of participants (n=136; 66%) were confirmed as having HIV between 2009 and 2011, and received the previous first line HAART regimen. The “other” HAART category contained alternative combinations of drugs e.g. Nevirapine and/or Zidovudine, and were collapsed into an “other” category for ease of data analysis.

The majority (n=120; 58.5%) perceived their health as good, and reflected on how their health had improved since initiation of HAART. The majority also reported weight gain (n=132; 64.4%) and body shape changes (n=123; 60%). The body shape changes were explained as: general weight gain or general weight loss or gaining weight centrally (around the abdomen, or at the breasts, or at both abdomen and breasts, or around the hips and buttocks, or at the breasts and buttocks).

Table 4.5 provides information regarding the immune parameters and liver function test results.

Table 4.5: Results of immune parameters and liver function tests of study 1 participants (N = 205)

Variable	N	n (%) or Mean (± SD)	Normal range
CD_4 count (cells/mm^3)	205	**285.1** (±157.9)	600-1500 (Van Dyk, 2008)
Viral load (copies/ml) ▪ < 400	170 *	133 (64.9)	
Full liver function (U/L) ▪ ALT ▪ AST ▪ GGT	110 *	35.1 (±42.7) **42.2** (±34.7) **101.6** (±127.5)	7 – 56 0 – 35 9 – 85 (Gowda et al., 2009)
Isolated ALT (U/l)	188 *	31.6 (±24.3)	7 – 56 (Gowda et al., 2009)
Isolated AST (U/l)	25 *	**47** (±54.0)	0 – 35 (Gowda et al., 2009)

♦ Cells/mm3 (cells per cubic millimeters of blood), copies/ml (copies of HIV RNA in milliliters of blood), U/l (units per liter), ALT (Alanine transaminase), AST (Aspartate transaminase) and GGT (Gamma glutamyl transpeptidase).

* No results of viral load and liver function tests available in all of the study participants.

The sample cohort' CD_4 count was below the suggested normal range. Viral load was available in only 170 individuals from review of their clinic files and the National Health Laboratory database, and the majority of participants had a value less than 400 copies/ml.

Abnormal mean values were noted in aspartate transaminase (AST) and gamma glutamyl transpeptidase (GGT) liver function findings of the sample. It is important to note that full liver function tests were most often older than six months. No results of liver function assessments were available for all study 1 participants.

Section 4.6.3 answers objective 1 of study 1:

- To determine, in affected individuals (on HAART), their physical activity level with the Yamax SW200 pedometer.

4.6.3 Physical Activity Levels of Study 1 Participants

Physical activity data for 195 participants were available for analysis. Three were excluded in analysis due to not completing seven days of pedometer assessment. Furthermore, one of those three left her pedometer and log sheet with a staff member for collection, and did not attend her second assessment session. Seven participants did not attend their second visit or return their pedometer and log sheet. Three participants could not attend their second session, and sent a friend or family member to return their pedometer and physical activity log sheet.

The mean pedometer step-count finding was 7 673.2 (±4 017.7), with women (n=152) walking less [6 993.3 (±3 462.6)] than men (n=43) [10 076.3 (±4 885.6)]. The sample as a

whole was therefore “somewhat active”, as the mean steps per day were between 7 500 – 9 999. Table 4.6 is a representation of the pedometer physical activity categories of participants.

Table 4.6: Pedometer Physical Activity Categories of Study 1 Participants (N = 195)

Pedometer physical activity categories†	**N**	**n (%)**
Sedentary: less than 5 000 steps per day	195	**52 (26.7)**
Light active: 5 000 to 7 499 steps per day	195	**57 (29.2)**
Somewhat active: 7 500 to 9 999 steps per day	195	**41 (21.0)**
Active: 10 000 to 12 499 steps per day	195	23 (11.8)
Very active: more than 12 500 steps per day	195	22 (11.3)

† Pedometer physical activity categories as per Tudor-Locke and Bassett (2004)

The majority fell into categories less than “active”, walking less than 10 000 steps per day - indicating room for improvement. This finding is similar to those of pilot study 2. Physical activity preferences concerning mode of activity as determined by the questionnaire are depicted in Table 4.7.

Table 4.7: Physical activity preferences of study 1 participants (N = 205).

Physical activity mode	**N**	**n (%)**
Formal sporting activities	205	**8 (3.9)**
▪ Aerobic exercise		2 (25.0)
▪ Soccer		2 (25.0)
▪ Basketball		1 (12.5)
▪ Netball		1 (12.5)
▪ Running group		1 (12.5)
▪ Horse racing (jockey)		1 (12.5)
Self-initiated exercise	205	**123 (60)**
Individual exercise		
▪ Walking		56 (45.5)
▪ Running		33 (26.8)
▪ Strengthening exercises		19 (15.4)
▪ Own aerobics		6 (4.8)
▪ Stretching		3 (2.4)
▪ Dancing		3 (2.4)
▪ Jumping		2 (2.0)
▪ Cycling		2 (2.0)
▪ Yoga		1 (1.0)
▪ Vibration machine		1 (1.0)
Social exercise		
▪ Netball		3 (2.4)
▪ Soccer		2 (2.0)
▪ Squash		1 (1.0)
Physical activity through home-related activities		
▪ Housework		1 (1.0)
▪ Gardening		2 (2.0)
Physical activity through work-related activities		
▪ Active at work		1 (1.0)

Eight (3.9%) participants reported participating in a supervised formal sporting activity. One hundred and twenty three (60%) participants incorporated exercise in their lives. Walking

(n=56; 45.5%) and running (n=33; 26.8) were most often reported as the preferred activity that individuals performed individually. Soccer (n=2; 2%) and netball (n=3; 2.4%) were most often reported as the activities that individuals engaged in a group situation.

Section 4.6.4 answers objective 2 of study 1:

- To determine, in affected individuals (on HAART), their perceived levels of stress.

4.6.4 Perceived Levels of Stress of Study 1 Participants

Table 4.8 is a representation of the perceived levels of stress of the participants.

Table 4.8: Perceived Levels of Stress of Study 1 Participants (N = 205)

Variable	N	Mean (±SD)
Perceived stress level	205	**19.2 (±7.8)**
▪ Men	47	16.9 (±9.1)
▪ Women	158	**20 (±7.1)**

Women (20 [±7.1]) reported higher perceived stress levels than men (16.9 [±9.1]). The 75th percentile value for the perceived stress rating of the sample was 25. Thus the perceived stress level of the sample as a whole, and women particularly, was moderately high.

Section 4.6.5 answers objective 3 of study 3:

- To determine, in individuals infected by HIV and on HAART: the presence of non-invasive known associated risk factors for IHD (smoking history, diet, RHR, blood pressure, WC, WHR and BMI)

4.6.5 Non-Invasive IHD Risk Factors Screening of Study 1 Participants

The questionnaire provided information regarding general symptoms experienced by participants, and the findings are presented in section 4.6.5.1 for review.

4.6.5.1 Screening of general symptoms

Symptoms of shortness of breath (SOB), fatigue and chest pain were screened in the questionnaire. One hundred and sixteen (56.6%) reported feeling fatigued. Their explanations included: very busy at work, feeling tired when waking up in the morning, or when walking a lot or when the weather was hot.

Fifty nine (28.8%) participants complained of often feeling SOB. Explanations included: physical activity, e.g. walking, running, walking uphill or working a lot; emotional factors, e.g. being angry, feeling stressed or panicking; hot weather; talking a lot; respiratory illness or being in enclosed spaces. Three individuals (2%), however, reported SOB when sleeping flat, and they required additional pillows, perhaps indicating that they suffered from orthopnoea. They were advised to consult their medical doctor.

Fifty two (25.4%) reported previous chest pain. They linked it to respiratory illness and severe coughing; musculoskeletal complaints that diminished when oral analgesia or creams were applied to the area; heartburn. One participant, however, complained of left-sided chest pain, had difficulty sleeping flat, regular heart palpitations and a family history of heart disease. Her resting heart rate was above 115 bpm on examination, and she was referred to a medical doctor at the clinic for further investigation.

4.6.5.2 **Results of non-invasive risk factor screening for IHD**

Table 4.9 consists of a representation of family, diabetes and HTN history, smoking status, diet, RHR and blood pressure.

Table 4.9: Family, Diabetes and HTN History, Smoking Status, Diet, RHR and Blood Pressure of Study 1 Participants (N = 205)

Variable	N	n (%) or Mean (±SD)	Normal range
Family history of IHD	205	**29 (14.2)**	
History of diagnosed diabetes mellitus	205	**1 (0.5)**	
History of diagnosed HTN	205	**19 (9)**	
Smoking status ▪ Current smokers ▪ Men ▪ Women ▪ Former smokers	205	 **33 (16.1)** 19 (40.4) 14 (8.9) 53 (25.9)	
Diet *Alcohol consumption* ▪ None ▪ Monthly ▪ Weekly ▪ Daily *Fish consumption* ▪ No weekly ▪ Once weekly ▪ Twice or three times weekly ▪ Do not eat fish *Vegetable and fruit consumption* ▪ Weekly ▪ Daily ▪ Daily consumption of three to five fruit and vegetables combined	205	 **177 (86.3)** 18 (8.8) 9 (4.4) 1 (0.5) **114 (55.6)** 36 (17.6) 22 (10.7) 33 (16.1) **110 (53.7)** 95 (46.3) 68 (33.2)	 PLWHA should not drink alcohol (Maartens et al., 2012) Emphasise consumption of fish as primary source of protein (Alpert, 2011; Lundgren et al., 2008) Consumption of a minimum of five fruit and vegetables combined daily (WHO, 2013)
Resting heart rate (bpm)	194 *	**82.7 (±11.4)**	Less than 80 (Palatini, 2007)
Blood pressure (mmHg) • SBP • DBP	194 *	 118.6 (±13.0) 77.8 (±9.9)	 Less than 120 Less than 80 (Collins and Dias, 2009)

***** n = 194 participants attended their second assessment session where these parameters were assessed.

The number of current smokers was low (n=33; 16.1%), with more men (n=19; 40.4%) than women (n=14; 8.9%). Reasons for stopping smoking were: being diagnosed as HIV^+; own choice; family requested they stop, and health reasons.

The prevalence of medically-diagnosed diabetes mellitus (n=1; 0.5%) and HTN (n=19; 9%) was low. Only 9 of the 19 participants were on antihypertensive medication. One additional participant reported having had HTN in her pregnancy. Family history of heart disease was low (n=29; 14.2%), with 27 (13.2%) reporting that the history of heart disease involved their parents and/or grandparents.

The majority (n=177; 86.3%) did not consume alcoholic beverages. One (0.5%) reported consuming one to two units of alcoholic beverages per day. The majority (n=114; 55.6%) were not able to eat fish weekly. All reported a diet that contained vegetables and fruit, but 110 (53.7%) consumed it weekly, and only 95 (46.3%) were able to obtain it daily. The majority (n=137; 66.8%) were unable to obtain three to five vegetables and fruit combined daily.

Resting heart rate was above the recommended normal range, and mean blood pressure values were normal. Individual patients were referred to the medical team of the clinic due to blood pressure and heart rate values being significantly above normal. A number of these also reported palpitations.

Table 4.10 provides information regarding the anthropometric body measurements of participants.

Table 4.10: Anthropometric Body Measurements of Study 1 Participants (N = 194)

Variable	n	Mean (±SD)	Normal ranges
Waist circumference (cm) ▪ Men ▪ Women	194 44 150	84.9 (±11.1) 82.7 (±9.6) 68.7 (±14.3)	 Less than 102 Less than 88 (ACSM, 2010)
Hip circumference (cm)	194	103.5 (± 11.6)	None available
Waist:hip ratio ▪ Men ▪ Women	194 44 150	0.8 (±0.1) 0.9 (±0.1) 0.8 (±0.1)	 Less than 0.95 Less than 0.86 (ACSM, 2010)
Body mass index (kg/m^2) ▪ Men ▪ Women	194 44 150	**25.6 (±1.4)** 22.3 (±3.1) **26.6 (±5.5)**	 18.5 to 24.9 (WHO, 2004)

♦ cm (centimeters), kg/m^2 (kilograms per square meter)

The anthropometric values were within acceptable normal ranges, except that the BMI finding for the sample was overweight (25–29.99 kg/m^2), due to the women in the overweight category (WHO, 2004).

4.6.6 Independent Predictors at Univariate Logistic Regression of Physical Inactivity, Increased Resting Heart Rate and BMI

Findings are presented in the tables below, firstly without adjustment for age and gender and then with adjustment. The variables are those identified in bivariate analysis and found to be significantly related to the specific variable of interest, namely physical inactivity, RHR and BMI. Findings are presented up to two decimal values.

Table 4.11: Independent Predictors of Physical Inactivity

Variable	n	Odds ratio	95% CI	p-value
Unadjusted univariate analysis				
▪ Gender (female)	205	3.33	1.67 – 6.64	**<0.00**
▪ Resting heart rate	194	1.03	1.00 – 1.06	**0.04**
▪ Waist circumference	194	1.04	1.01 – 1.08	**0.02**
Adjusted univariate analysis				
▪ Resting heart rate	194	1.02	0.99 – 1.06	0.11
▪ Waist circumference	194	1.04	1.00 – 1.08	**0.03**

Female gender, RHR and WC were found to be significantly associated with being physically inactive (less than 10 000 steps per day) before adjustment for age and gender. After adjustment WC was still significantly associated with physical inactivity. If WC increased by 1 cm he/she had a 4% probability of taking fewer than 10 000 steps per day.

Table 4.12: Independent Predictors of Increased RHR

Variable	n	Odds ratio	95% CI	p-value
Unadjusted univariate analysis				
▪ Diastolic blood pressure	194	1.04	1.00 – 1.07	**0.03**
▪ Physical activity level	195	0.99	0.99 – 0.99	**0.01**
▪ Active category	195	0.34	0.12 – 0.94	**0.04**
Adjusted univariate analysis				
▪ Diastolic blood pressure	194	1.07	1.03 – 1.11	**<0.00**
▪ Physical activity level	195	0.99	0.99 – 0.99	**0.02**
▪ Active category	195	0.38	0.13 – 1.11	0.08

Diastolic blood pressure was found to be significantly associated with a RHR ≥ 80 bpm before adjustment. Physical activity level and the “active” physical activity category (10 000-12 499 steps per day) were also found to be significantly associated with a RHR ≥ 80 bpm. This association was, however, inversely related to an elevated RHR. After adjustment the relationship persisted. Thus, if DBP increased by 1 mmHg the individual had a 7% chance of having a RHR ≥ 80 bpm. In contrast, with one extra step per day RHR was 99% less likely to be elevated ≥ 80 bpm.

Table 4.13: Independent Predictors of Increased BMI

Variable	n	Odds ratio	95% CI	p-value
Unadjusted univariate analysis				
▪ Gender (female)	205	7.16	3.14 – 16.33	**<0.00**
▪ SBP	194	1.04	1.01 – 1.06	**<0.00**
▪ Waist circumference	194	1.26	1.18 – 1.35	**<0.00**
▪ Hip circumference	194	1.56	1.36 – 1.78	**<0.00**
▪ Physical activity level	195	0.99	0.99 – 0.99	**<0.00**
▪ Very active category	195	0.29	0.09 – 0.92	**0.04**
▪ CD_4	205	1.00	1.00 – 1.01	**<0.00**
▪ Current smoking status	205	0.46	0.20 – 0.97	**0.04**
▪ Former smoking status	205	0.42	0.22 – 0.80	**0.01**
▪ Daily intake of fruit and vegetables	205	1.84	1.06 – 3.21	**0.03**
Adjusted univariate analysis				
▪ SBP	194	1.07	1.04 – 1.10	**<0.00**
▪ Waist circumference	194	1.34	1.22 – 1.46	**<0.00**
▪ Hip circumference	194	1.53	1.38 – 1.75	**<0.00**
▪ Physical activity level	195	0.99	0.99 – 0.99	0.05
▪ Very active category	195	0.60	0.17 – 2.11	0.42
▪ CD_4	205	1.00	1.00 – 1.01	**0.01**
▪ Current smoking status	205	0.90	0.36 – 2.25	0.83
▪ Former smoking status	205	0.80	0.38 – 1.70	0.56
▪ Daily intake of fruit and vegetables	205	1.80	0.99 – 3.27	0.05

Female gender, SBP, WC, hip circumference, CD_4 count and daily fruit and vegetable intake were found to be significantly associated with a BMI ≥ 25 kg/m^2 before adjustment. A "very active" physical activity category (taking more than 12 500 steps per day), and current and former smoking status were found to be significantly associated with, but inversely related to, a BMI ≥ 25 kg/m^2 before adjustment. After adjustment SBP, WC, hip circumference and CD_4 count were still significantly associated with a BMI ≥ 25 kg/m^2. If SBP increased by 1 mmHg a 7% likelihood existed of a BMI ≥ 25 kg/m^2. In addition, if a participant's WC or hip circumference increased by 1 cm a 34% and 53% chance of a BMI ≥ 25 kg/m^2 existed respectively.

A discussion of the results of study 1 is provided in section 4.7.

4.7 DISCUSSION

The aim of study 1 was to screen physical activity levels and other selected risk factors for IHD in individuals living with HIV and on HAART for six to 12 months. This particular period of HAART exposure was selected for the following reasons: firstly, the researcher wished to initiate contact with participants who had been monitored for adherence to HAART treatment for a reasonable period. This period was considered essential for them to have effectively implemented HAART into their lives and adjusted to the effects of therapy.

Secondly, at conceptualisation of the project, literature indicated that 87% of deaths occur in the pre- and early HAART period amongst PLWHA in the South African context (Lawn et al., 2006). Mortality in this early period was independently related to advanced immunodeficiency at initiation of HAART. Early HAART in this study was defined as the first

four months of treatment. The authors reported few late deaths, and that these were related to the patient's response to HAART at four months. Hence the decision to select participants after six months on HAART to ensure improved immune function at entry to the project and reduce the likelihood of loss to follow-up due to death.

Thirdly, two research groups evaluated anthropometric body changes that occurred in PLWHA when initiated on HAART containing Stavudine in the South African context (Hurley et al., 2011; George et al., 2009). Hurley et al. (2011) reviewed participants at three intervals: baseline, six and 12 months following HAART initiation. George et al. (2009) reviewed study participants over the first two years of therapy. The current study thus provides additional information regarding IHD risk factors status in the early part of HAART exposure. This additional information highlights what education and intervention programmes are required at primary care level to improve health, and thus reduce IHD risk.

4.7.1 Review of Socio-Demographics and HIV-Related Profiles

The participants in the study were mostly female. Bias towards the female gender is expected, as prevalence of HIV infection in women in SA is higher than men (Stat SA, 2013; Rehle et al., 2010). More women are also reported to access HAART in sub-Saharan Africa (Braitstein et al., 2008). Similar findings were reported in the South African context: gender differences in survival on HAART were evaluated in a multicentre study consisting of 58 124 adults (Cornell et al., 2012). Cornell et al. (2012) reported a finding of 65% women and 35% men. Hurley et al. (2011) had a similar gender distribution of 37.4% men and 62.6% women. In the current study the distribution was more for women (77.9%) than men (22.1%), but similar with regards to gender distribution compared to Cornell et al. (2012) and Hurley et al. (2011). The information collected in this study provides a picture of the general type of population attending an outpatient HIV clinic in Johannesburg, SA in the early part of HAART exposure. It also highlights selected risk factors for IHD in this particular population that require management.

The majority of participants were in their thirties (mean age: 38.2 [±9.5] years), employed (n=115; 56.1%), had a secondary education (n=95; 46.3%) and supported dependants (n=158; 85.4%). Similarly, Hurley et al. (2011) found the same demographics in their study participants (n=230) attending a semi-private urban outpatient clinic in Durban, Kwa-Zulu Natal when evaluating anthropometric body measurements over the first year of HAART exposure. It is of interest to note that the demographics of individuals accessing HIV clinics in these two studies are similar, irrespective of province or health care spectrum (public sector vs semi-private). It also highlights the fact that the population initiated on HAART is individuals with family responsibilities, and form part of the workforce as demonstrated by the current study and the study conducted by Hurley et al (2011). This finding could

possibly explain the problem of dropout experienced later in the research project in terms of work or family obligations. International clinical exercise trials in the HIV field often report family responsibility and sessions clashing with work schedules as reasons for non-adherence to exercise programmes (O'Brien et al., 2010). Ability to attend consultation sessions was already hindered by some participants' work obligations. On the other hand, this finding implies that if participants' adherence to HAART and episodic disability is managed, they have the potential to contribute to their community and the larger society for a satisfactory length of time.

A positive finding was that the majority of participants (n=120; 58.5%) perceived their health status as good, even though their immune parameters were not yet optimal. The CD_4 value in this study was slightly less than that reported by Cornell et al. (2012) in individuals after 12 months' exposure to HAART. The median CD_4 value in that study was 294 (204–403) cells/mm^3 (women) and 239 (164–337) cells/mm^3 (men). The lower CD_4 count in this study might be because the mean time on HAART was only 8.7 (±2.3) months and not yet 12. Despite the CD_4 count, most participants reflected that the pre-treatment period was the one when they had been ill. A review of the medical histories reinforced the fact that participants had been ill previously, and now noted their health as better. Conditions noted were illnesses associated with WHO Clinical Staging of HIV II, III and IV (Van Dyk, 2008; WHO, 2005). Thus, reviewing the participants' past illnesses in conjunction with immune parameters, it could be suggested that participants were initiated on HAART when advanced immunodeficiency was present. This finding is supported by literature stating that individuals in sub-Saharan Africa are often initiated on HAART when already presenting at an advanced stage of HIV (Peltzer et al., 2011; Braitstein et al., 2008; Lawn et al., 2008; Lawn et al., 2006).

Physical activity has the ability to influence the immune system positively or negatively depending on the intensity of exercise. In the general population moderate-intensity exercise is reported to aid in immune stimulation and reduce disease risk. Intense, vigorous exercise, on the other hand, could suppress the immune system, and increase disease risk (Rosa Neto et al., 2011). Moderate-intensity exercise in the general population has also been shown to improve immune function and lower the risk and severity of respiratory viral infections (Martin, Pence and Woods, 2009). In PLWHA an inverse relationship is reported to exist between viral load and physical activity levels, but this relationship does not extend to CD_4 counts (Bopp et al., 2004). Promoting an increase in physical activity levels of participants could therefore lower viral loads and counteract disease progression. Bopp et al. (2004) noted that intensity of physical activity did not specifically correlate with CD_4 or viral load values in their study population. This might be due to the authors reviewing participants' normal daily activity, and not when they were

performing higher-intensity activity, such as formal exercise. In contrast, randomised control trials included in a systematic review done by O'Brien et al. (2010) found that structured exercise that consist of aerobic and resistance training tend to increase CD_4 counts in exercise participants. The degree of increase differed among studies included in this review and findings were not always statistical significant when compared to non-exercise participants. Additionally, viral load response in exercise participants differed between studies: increased or decreased. The finding of Bopp et al. (2004) is beneficial, as it suggests that including low- to moderate-intensity physical activity in participants' daily routine would not have a detrimental outcome on immune parameters.

Consequently, the immune parameter findings in this study highlighted the need to design the physical activity programme in such a way as to improve, and not further impair, immune function. This could possibly be achieved if intensity and frequency were to begin at a low level and be gradually increased to a moderate level, in order to monitor how participants react functionally to this activity change. Achieving a moderate intensity level of physical activity, such as brisk walking, would be the ultimate goal, as suggested by the European AIDS Clinical Society Guidelines as a means to manage cardiovascular disease in PLWHA (Lundgen et al., 2008).

Most participants (n=123; 60%) perceived a change in their body shape in the previous six months. This shape change was attributed more to weight gain than to weight loss. Body mass index is reported to change with HAART exposure over time in the South African context (Hurley et al., 2011; George et al., 2009). The mean change in BMI in the first year of HAART exposure is reported to be 2.4 kg/m^2 in men and 2.2 kg/m^2 in women (Hurley et al., 2011). In the study conducted by Hurley et al. (2011) male participants' BMI changed more in the observation period, but were always within the normal BMI category. On the other hand, women at baseline were already overweight and progressed further into this category in the year of observation. In this study female participants, when assessed, were overweight compared to male participants, who had a normal BMI. Thus it seems that weight gain to the extent of being overweight or obese is more likely to affect women than men in the South African HIV context.

An important factor to consider when evaluating weight is individuals' perception of their weight status. Hurley et al. (2011) formally investigated PLWHA's perception of weight in a South African cohort. The authors noted that individuals often perceived their weight to be less than the actual objective measured value. A perception of ideal weight could influence individuals' acceptance of education strategies regarding ideal body weight, as they might not agree with a health care provider's evaluation of a particular risk factor for IHD. The authors also noted that weight loss in communities in SA is seen as a sign of HIV/AIDS,

and encourages stigmatisation. This belief is corroborated by comparable international data (Reynolds et al., 2006). This belief could result in reduced compliance with counsel to reduce weight, as it could lead to compromising the confidentiality of status. In this study the majority of participants reported an increase in weight, and women often reported wishing to lose weight in answer to this question. Thus, with motivation for weight-loss present, implementing a weight-loss programme in this study might be better-accepted.

A portion of the sample reported centralisation of weight around their trunk area in their explanations of body shape change. This phenomenon is a component of lipodystrophy (Grinspoon and Carr, 2005), a condition reported to develop in 69% of PLWHA when on HAART for more than 72 weeks. It is then that weight gain around the abdominal area is most often reported (Mutimura et al., 2007). George et al. (2009) noted that those who developed lipodystrophy in the first two years of HAART were more likely to have had a higher BMI at baseline than others. In this particular study the BMI at baseline of individuals who developed lipodystrophy was 23.6 (±3.5) kg/m^2, compared to 22.0 (±2.2) kg/m^2 in those who did not. It should be noted that the study cohorts of George et al. (2009) and Hurley et al. (2011) were on a regimen containing Stavudine. Weight gain in the study conducted by Hurley et al. (2011), however, was related, not to HAART, but positively related to age, and negatively to TB status. The majority of participants (81%) included by Mutimura et al. (2007) were also on a regimen containing Stavudine. In the current study only a small proportion of the study cohort was on Stavudine (n=38; 18.5%). It is also important to remember that a relationship is reported between Stavudine and the risk of diabetes mellitus (RR=1.13; 95% CI: 1.08–1.15; p=0.0001) over time (De Wit et al., 2008). Screening these participants regularly to determine their glucose level as a monitoring method for diabetes mellitus is therefore indicated as a means of reducing their risk of developing IHD.

International data on anthropometric changes in individuals living with HIV produced findings contrasting with South African data. Brown et al. (2006) reported no significant change in BMI in HIV-infected men who, in 1999-2003, were in three antiretroviral treatment groups: no treatment, monotherapy or combination therapy and, lastly, HAART. Similarly, Justman et al. (2008) reported no significant change in BMI in HIV-infected women in 1999-2004. They also reported that HAART was not an independent predictor of BMI or WHR. This contrasting finding might be due to black South African women being reported as more likely to be overweight or obese, irrespective of HIV status (Kruger et al., 2012). Kruger et al. (2012) suggested that this gender difference in BMI might be due to molecular variances, and thus not specific to socio-demographic and/or health-related behaviours in the South African context. Considering that more women in SA access HAART at clinics and are also more likely to be overweight, monitoring of weight and

weight management strategies should therefore be one of the core focus areas at HIV clinics in SA. A discussion regarding participants' pedometer physical activity and how it relates to risk of IHD is presented below.

4.7.2 Screening of Physical Activity Levels

The aim of physical activity screening in the study was, firstly, to determine the physical activity level of a cohort of South African individuals living with HIV and on HAART, and, secondly, to evaluate their physical activity preferences in order to provide information on modes of activity. Findings of the study contribute to the body of knowledge regarding ambulation physical activity, and provide information of a South African group of individuals living with HIV and on HAART. The physical activity levels are very similar to international data on pedometer step-count findings in individuals living with HIV (Santos-Lozano and Garatachea, 2011; Ramirez–Marrero et al., 2008). The mean pedometer step-count finding in this study was 7 673.2 (±4 017.7) with women walking less than men. Ramirez-Marrero et al. (2008) investigated the physical activity levels in 58 Hispanic adults living with HIV in San Juan, Puerto Rico. They reported a mean of 7 418 (±2 714) steps per day, with men accumulating slightly fewer steps than the men in the present study (7 594 [±2 817]). Women in their study were slightly more active at 7 151 (±2 589) steps per day. Fillipas et al. (2010) reported the mean step-count finding in their Australian cohort to be 7 594 steps per day. This trial formed part of a systematic review (Santos-Lozano and Garatachea, 2011). The slightly higher step-count finding in this study could be explained in part by the age variances in the three samples, since an inverse relationship between age and pedometer physical activity step-count is known to exist (Tudor-Locke et al., 2008). The mean age of the three cohorts was: South African 38.2 (±9.5) years, Puerto Rican 45.9 (±9.3) years and Australian 53.2 (±10.2) years. In addition, not all individuals in the study conducted by Ramirez-Marrero et al. (2008) were on antiretroviral therapy, and it is known that physical activity and functional status improves when individuals are on HAART (Kinsey, 2007).

Gender discrepancy concerning physical activity levels in this study compared to international data could be explained if one reviews physical activity data from the general South African population. The World Health Survey reported crude prevalence rates for physical inactivity in SA to be 43% for men and 47% for women in 2002–2003 (Guthold et al., 2008). Thus it seems to be the norm for women in SA to be less active than men, irrespective of HIV status, and that they therefore require more motivation and formal programmes to address this risk factor for IHD.

In the South African context objective assessment of physical activity levels with pedometers was previously done by Cook et al. (2010, 2008) in healthy black South

Africans living in a rural community, and by Van Rooijen et al. (2010) in diabetic patients attending an outpatient hospital clinic in an urban setting. The pedometer step-count in the present study was less than that reported by Cook et al. (2010). The average step-count in their sample was 12 471 steps/day. Cook (2012) also reported that the average daily step range in a rural community was between 1 048–35 534 steps per day with an age range of 14–96 years. The differences between this study and that rural study could be explained in the following manner: it is well known that epidemiological transition, of which urbanisation is a part, results in behavioural change, due to industrialisation and economic development (Mensah, 2008; Vorster et al., 2007; Gaziano, 2005). The change is often noted in diet and physical activity levels. The different settings could have influenced the physical activity levels due to factors such as differences in transportation, geographical location and living environment. The HIV status of the rural population in Cook's study was not mentioned. The differences in immune function between the two study populations could offer a possible explanation for the different step-count findings.

The pedometer step-count findings in this study showed that 75% (n=150) of the sample walked fewer than 10 000 steps per day, and that the majority of these individuals were sedentary or lightly active. This objective finding conflicted with verbal feedback on their performance of exercise on their own. Sixty percent of the sample (n=123) reported that they exercised on their own. The reported activity preference was first, walking, and second running. Both involve ambulation activity, and are ideal for assessing and monitoring with a pedometer. If participants had performed either of these activities regularly in the seven days of assessment, it would have been reflected in their pedometer findings. It could therefore be argued that they *reported* some healthy activity, but that actual implementation was lacking.

One possible reason for this poor implementation could be explained in relation to their expressed occupations. These occupations included jobs involving manual labour, rather than prolonged sedentary behaviour, such as sitting. With these occupations their perceived need for additional regular focused exercise might have been diminished, resulting in lower recorded step-counts. The lower step-count in the majority of participants could also be due to physical symptoms. Fatigue and SOB are reported as symptoms limiting physical function in PLWHA in SA in both in- and out-patient contexts (Myezwa et al., 2009; Van As et al., 2009). In this study a common explanation for fatigue and SOB was related to physical activity – in most cases, increased activity.

The proportion of low recorded step-count in this study is of clinical significance, and also a cause for concern. Fewer pedometer steps per day are associated with increased BMI, WC and DBP in a general population (Chan et al., 2003). Hence it is understandable that this

population was overweight, considering their low mean recorded step-count. An increased WC in the general population is also significantly correlated with FRS ($r=0.24$, $p<0.001$), indicating a higher risk of developing IHD (Mosca et al., 2006). In this study the univariate logistic regressions analysis, after adjusting for gender and age, revealed that WC was significantly associated with walking less than 10 000 steps per day. This finding is supported by Cook et al. (2010) when using a pedometer in a general rural black South African cohort. They reported the association between physical activity and BMI to be $r=-0.08$ ($p<0.03$), and between WC and physical activity to be $r=-0.12$ ($p<0.03$). The relationship between increased WC and lower activity levels has also been established when using other activity surveillance methods, e.g. the physical activity diary (Saunders et al., 2013). Study 1 therefore highlighted the need for an intervention to assist individuals in implementing increased activity levels as a possible means of reducing their WC, and influencing their IHD risk.

This study is of clinical significance, as it has demonstrated that most study participants reported attempting to increase their activity level by performing some type of exercise on their own. It suggests that they knew that it was important to try to exercise, and also a motivation to becoming active, even though the level of actual physical activity measured was modest. Published information on physical activity preferences in a HIV population could not be found, and information for a general population is also scarce. The information on the physical activity method of choice in a cohort of individuals living with HIV provided in this study, is thus a significant contribution. Burton, Khan and Brown (2012) evaluated physical activity preferences in adults at risk of being inactive in a general Australian population. The format (how), location (where) and social setting (with whom) of the physical activity preferences were assessed. The researchers noted that more than 75% of respondents preferred activities at no or limited financial cost, 80% preferred activities that could be done close to home, and 75% preferred activities that could be done alone. Similarly, in this study the majority of participants performed exercise that was not supervised, and could also be done on their own: most often walking or running. Walking has often been reported as the preferred mode of activity in individuals with type two diabetes (Forbes et al., 2010) and sedentary individuals (Booth et al., 1997). This might be due to the fact that the ability to walk does not require learning a new skill, has no cost implications, is not dependent on belonging to an exercise group, and can be done close to home. Even though participants reported walking and running as their preferred activities, the majority of the sample still accumulated fewer than 10 000 steps per day. Thus the need for education on frequency and, possibly, intensity of walking has been highlighted in this study.

4.7.3 Non-Invasive Risk Factor Screening for IHD

Non-modifiable non-invasive risk factors for IHD include age, gender and family history. The risk of IHD is reported to be higher in men, occurs more often in the age range above 45 years, and in individuals with a direct family history of IHD, when using general population information as guide (NCEP ATP-III, 2002). Only a small proportion of participants in this study had a direct family history of IHD, reflecting a generally low family history risk. The age guide for reviewing IHD risk in the general population should not, however, be followed strictly when reviewing PLWHA. Currier et al. (2003) reported that the incidence of IHD in young men (up to age 34) and young women (up to age 44) with HIV was significantly higher than non-infected individuals. In the South African context Sliwa et al. (2012) noted that PLWHA admitted to Chris Hani Baragwanath hospital in Johannesburg due to cardiac symptoms were often younger (39 [±13] years compared to 53 [±17] years) than non-infected individuals. The similarity in mean ages between this study and information from Sliwa et al. (2012) cannot be ignored. PLWHA, when screened by nursing staff or physiotherapists for risk factors for IHD at primary care level, with suspect symptoms and signs, should be referred for medical review to ensure early detection and appropriate management of such cardiac symptoms. This was the procedure followed with this project when individuals complained of, or presented with, suspect symptoms or signs for IHD.

Non-invasive modifiable risk factor screening for IHD provided valuable information regarding what risk factors for IHD are of greater concern at primary care level in SA. The non-invasive modifiable risk factors for IHD will be discussed, firstly, according to behavioural aspects, history of diabetes and/or HTN, and then findings related to body measurements.

4.7.3.1 Screening of behavioural risk factors

Smoking was present in the study population, but was not as prevalent as noted by international authors in HIV populations. Smoking prevalence in PLWHA internationally is estimated to range between 50-70% (Reynolds, 2009) and contributes significantly to the risk of IHD. Saves et al. (2003) reported a high prevalence of smoking in their cohort of French PLWHA, noting the frequency as 65% in men and 29% in women towards the five-year RR for IHD. Smoking status was also strongly associated with mortality from cardiovascular disease in PLWHA, as determined by the Data Collection on Adverse Events of Anti-HIV Drugs Study Group (2010). A possible reason for the lower level of smoking in this study is that the study population consisted mostly of women and individuals of black ethnic origin. Research indicates that South African women are less likely to smoke than their male counterparts (Peer et al., 2009), and that black men and women smoke significantly less than other population groups in SA (Sitas et al., 2013; Peer

et al., 2009). The gender difference in smoking history in an HIV population in SA is supported by findings from Sliwa et al. (2012) and recently by Waweru et al. (2013). They reported that men were more likely to be smokers than women. Waweru et al. (2013) noted 23.2% of men and 7.4% of women of a sample of 207 individuals attending an HIV-clinic at Charlotte Maxeke Johannesburg Academic Hospital were current smokers. Smoking cessation in PLWHA is important, due to the known association between smoking and several pathologies, namely, cardiovascular disease (Data Collection on Adverse Events of Anti-HIV Drug Study Group, 2010), obstructive pulmonary disease (Morris et al., 2011), community-acquired pneumonia and pneumocystis carinii pneumonia (Miquez-Burbano et al., 2005). However, in the South African context, where HIV prevalence remains disproportionally high in females in comparison to males, it might be suggested that more focus is needed, at primary care level, on education and interventions to address physical inactivity and BMI, as opposed to smoking cessation.

A diet low in vegetable and fruit intake is known to increase risk of IHD. A diet consisting of at least five fruits and vegetables combined per day (400 grams) is suggested by the WHO as a means of preventing the risk of non-communicable diseases (WHO, 2013). A Mediterranean diet consisting of regular fish intake is said to have IHD-preventative properties (Artalejo et al., 1996). The majority of participants in this study were unable to partake in daily fruits and vegetables, and also less likely to partake in three to five fruit and vegetables daily. They were also less likely to eat fish every week. They were therefore at an increased risk of developing IHD. In SA prevalence of insufficient fruit and vegetable intake in older adults is estimated at 68.5%, with men noted to be more compliant (64.8%) than women (71.4%) (Peltzer and Phaswana-Mafuya, 2012). The authors reported that being of Black or Coloured ethnic group, having lower educational level and daily smoking habits were associated with inadequate fruit and vegetable intake (Peltzer and Phaswana-Mafuya, 2012). In a general adult rural and semi-urban black South African population 7% of villagers and none of the semi-urban participants were able to partake in five fruit and vegetables per day (Peltzer and Promtussananon, 2004). The cost of purchasing fruit and vegetables is an obstacle that inhibits adequate fruit and vegetable intake for a large number of South Africans (Faber, Laubscher and Laurie, 2013; Peltzer and Promtussananon, 2004). In this study the majority of participants were employed, but in poorly-remunerated manual occupations. A large portion of the sample was also unemployed. Participants frequently expressed financial constraints as a reason for inadequate dietary intake, when completing the demographic questionnaire. A solution for this risk factor would therefore require education regarding diet in relation to risk for IHD, but more importantly, attention needs to be given to the wider addressing of social problems in SA. That includes unemployment. Lastly, community-wide responses that

include land availability that might enable a community to grow their own fruit and vegetables could be another avenue.

Perceived stress has many health implications. The current study's objective was to assess perceived stress levels as a means of screening this risk factor for IHD. It was, however, done in an HIV^+ population, where elevated stress levels have even wider health implications. Perceived stress is a risk factor for IHD, and reported to be associated with other IHD risk factors. Rod et al. (2009) found that individuals with high levels of stress were less likely to stop smoking (OR=0.58; 95% CI: 0.41–0.83) and were more likely to become physically inactive (OR=1.90; 95% CI: 1.41–2.55). Women were more likely to become overweight (OR=1.55; 95% CI: 1.12–2.15) and men were twice as likely to develop diabetes (OR=2.36; 95% CI: 1.22–4.59). The perceived stress levels of study 1 participants were moderately high, with women showing higher levels than men. The interactive relationship reported to exist between stress, physical inactivity and overweight could therefore partially explain why women in this study were overweight and also less active.

This gender difference in stress levels is supported in findings from a general South African cohort of individuals applying for small loans (Hamad et al., 2008). The current study's PSS scores were, however, higher than what was found by Hamad et al. (2008): mean sample score 18.6 (±6.7); women 19.6 and men 17.5. This higher level of stress is to be expected, as the study cohort was HIV^+, and therefore possibly dealing with additional factors related to stigmatisation, having to use chronic medication such as HAART and insecurity about their future. HIV status is also reported to be an independent predictor of PSS scores, as assessed in a peri-urban population of infected women living with HIV (Mkandawire-Valhmu et al., 2013). Hamad et al. (2008) found that PSS scores were related to female gender, being multiracial, increased household members, decreased subjective social status and lastly, a recent birth or catastrophe. The authors did report, however, that information regarding HIV status was not collected in their study, and that this finding could have influenced their results significantly.

Considering wider health implications relevant to the study population, a relationship is reported to exist between PSS scores and CD_4 count in individuals living with HIV, as evaluated by Remor et al. (2007). The authors noted that perceived stress levels significantly predicted CD_4 count (ß=0.74, p=0.000) and that an increase of one in PSS score increased the likelihood of a reduction of 4.82 in CD_4 cell count, as assessed in their Spanish cohort over a six month period. Fatigue is often reported by individuals living with HIV, and in this study this symptom was frequently expressed by participants. A relationship between depression and anxiety on the one hand, and perceived stress and fatigue on the other, is reported to explain 25% to 75% of fatigue ratings in a psychiatric

HIV cohort (Paddison et al., 2009). Considering the relationship between perceived stress, CD_4 count and fatigue, the high levels of stress in this study might have influenced CD_4 values and subjective feelings of fatigue. The current sample is at an increased risk of developing IHD due to these high levels of stress, and this symptom could have wider negative health implications concerning their immune function over time. Screening participants' history of diabetes mellitus and HTN formed part of non-invasive risk factors for IHD assessment, and results regarding these findings are discussed below.

4.7.3.2 **Screening of history for diabetes and HTN**

The study population did not present with a high prevalence of known diabetes mellitus or HTN, as assessed by the demographic questionnaire. Only one individual had diabetes, and 19 had HTN. Causative factors for HTN in an international HIV population are reported to be related to age, length of duration of HIV infection, increased BMI, history of diabetes mellitus, and shows a trend with African-American ethnicity (Medina–Torne et al., 2012). The small number of individuals that presented with a history of HTN in this study could be explained by the sample's young age and relatively short duration of HIV positivity with time since diagnosis as reference point. Of concern in the screening process was that when a history of HTN was reported or documented it became clear that not all participants were receiving pharmacological treatment.

Hypertension management in the general South African context at primary care level has been reported to be less than optimal (Ntusi, 2011). Steyn et al. (1999) reported that only 42.1% of individuals had a blood pressure reading below 140/90 mmHg in a sample of 220 individuals at a centre in Cape Town, SA. Similar findings were reported by Rayner et al. (2007), where only 39.8% of HTN patients at two Cape Town health centres achieved optimal blood pressure readings of below 140/90 mmHg. Patient adherence to HTN medication was reported as a problem that hindered optimal management, as reflected by study subjects' feedback (Rayner et al., 2007). They reported that 61.7% of patients self-reported no missed doses of medication and 37.4% of patients noted more than one medication dose missed per week. When medical doctors were interviewed to assess the nature of hindrances to effective management, they reported poor patient adherence to prescribed medication, language difficulties, heavy patient load, medical staff shortages and patient loss to follow-up as significant difficulties (Parker et al., 2011). Disturbingly, medical doctors showed a lack of knowledge of the South African guidelines for HTN management and indications for treatment (Parker et al., 2011). Advice given to study participants concerning modification of lifestyle was lacking in all reports (Parker et al., 2011; Rayner et al., 2007; Steyn et al., 1999).

Participants in this study who took HTN medication received it from their local primary care clinic. The additional individuals not on HTN medication might either not have adhered to their treatment or not even started on treatment as per medical doctor prescription. A change in care model might be suggested as a means to improve HTN management in PLWHA in SA in favour of holistic management of patients instead of condition-specific silos e.g. HIV and HTN managed separately by HIV and HTN clinics. Holistic management would also reduce the time required for individuals to manage their different conditions. They would spend less time travelling to the different clinics, less cost in transport, less time off work and, almost certainly, less stress would be involved. All these factors could ultimately improve patient adherence to HTN treatment and improve prevention management of stroke and IHD in PLWHA in SA.

4.7.3.3 **Body measurements review**

An increased BMI was identified as a significant risk factor for IHD in this study cohort, as the majority of participants were overweight (mean BMI: 25.6 [±1.4] kg/m^2). Variables associated with overweight in the sample when adjusting for age and gender included: behavioural aspects e.g. physical activity level and daily fruit and vegetable intake; anthropometric measurements, e.g. waist and hip circumference; SBP and CD_4 count. It is important to note that female gender increased the likelihood of being overweight by 7.16 (95% CI: 3.14–16.33; p=0.00), as demonstrated by the odds ratios before adjusted analysis.

These gender differences in BMI in sub-Saharan Africa are well documented (Kruger et al., 2012; Finucane et al., 2011; Belue et al., 2009; Cappuccio et al., 2008). It is salutary to be aware of the high global statistics: Southern African women have the highest prevalence rate for obesity, and only a slightly lower rate for being overweight (Finucane et al., 2011). Kruger et al. (2012) suggested the gender difference in BMI status in black South African adults to be multifactorial, of which three biological factors may play a significant role: the female sex hormone estrogen and its influence in weight regulation; the effect of higher anxiety levels in women, and the influence on the short allele of the serotonin transporter gene. The authors noted that the black South African population belongs to macrohaplo-group L, which has the highest level of genetic variations, that could further influence BMI status. Behavioural aspects should not, however, be excluded when evaluating gender differences in BMI, as reduced physical activity levels (Guthold et al., 2008), reduced smoking status (Peer et al., 2009) and increased stress levels (Hamad et al., 2008) in South African women could possibly further add to the higher BMI values.

In this study smoking status reduced the probability of being overweight or obese before adjusting for age and gender. Justman et al. (2008) also noted that, in their international

cohort, PLWHA who smoked were more likely to have lower BMI values. An increase in SBP increased participants' chances of being overweight. International data suggests a positive relationship between BMI and blood pressure, but the extent of the relationship weakens as BMI increases in the general population (Cappuccio et al., 2008). In the general South African population anthropometric measures such as BMI, WC, hip circumference and WHR were reported to relate positively to SBP and DBP in women (Mkhonto, Labadarios and Mabaso, 2012). Findings in men were only significant for WHR, thus again underscoring the important relationship between anthropometric measures and blood pressure. Individuals who walked more than 10 000 steps per day in this study were also less likely to be overweight or obese. An inverse relationship between BMI and pedometer physical activity levels is known to exist, and a step-count of 12 000 per day is reported to be associated with a healthy body-weight category of BMI < 25 kg/m^2 in the general population (Tudor-Locke et al., 2008).

Interestingly, a diet with daily fruit and vegetable intake in this study increased individuals' chances of being overweight. The focus of this study was not to evaluate general diet, however, but the more important factor of fruit and vegetable intake (or lack thereof) as a risk factor for IHD. In view of reports that purchasing of fruit and vegetables is often hindered in SA by financial limitations (Faber, Laubscher and Laurie, 2013; Peltzer and Promtussananon, 2004), those in this study who were able to consume this produce daily might have enjoyed less financial constraint, leading to a greater food security. Thus these individuals might have consumed a diet high in fat, sugar and starch, that might have predisposed them to being overweight. International data suggests that PLWHA that are overweight often consume a diet high in fat and low in fibre, that could indicate poor diet quality (Duran et al., 2008; Hendricks et al., 2006). It is therefore suggested that further investigation is warranted to evaluate the general diet and its components of PLWHA and its relationship to BMI.

An increase in CD_4 count was associated with being overweight in this sample of individuals on HAART. Justman et al. (2008) found that a lower CD_4 count was independently related to smaller BMI, but did not specifically find that the reverse applied. Crum-Cianflore et al. (2010), on the other hand, did note that a higher CD_4 value was associated with increased BMI values in the US Military HIV Natural History Study. The authors also noted a higher weight-gain in participants with a lower BMI value at diagnosis (Crum-Cianflore et al., 2010). In addition, Palermo et al (2011) noted that higher BMI values at baseline predicted higher CD_4 count findings at 96 and 144 weeks after initiation of antiretroviral therapy. Thus the finding in this study related to increased likelihood of being overweight as immune parameters improve is congruent with that of Crum-Cianflore et al. (2010) and Palermo et al (2011).

The mean gender WC and WHR of the sample were within normal values, but individual participants had abnormal values and yet also complained of weight gain centrally around the trunk area. Waist and hip circumference was associated with overweight. Waist circumference measurement is of clinical value, as it provides information on visceral adipose tissue accumulation (Katzmarzyk, Heymsfield and Bouchard, 2013), which is known to be associated with insulin resistance, altered cholesterol profiles and raised inflammatory markers in the general population (Smith et al., 2012). An increased WC measurement is therefore also known to increase one's risk for IHD (Smith et al., 2012; Yusuf et al., 2004). The association of increased BMI with these anthropometric measurements may suggest that waist- and hip circumference measurements and WHR calculation should be included in general HIV management to monitor individuals at risk of IHD due to the development of abdominal obesity.

The study cohort's mean RHR value was slightly increased when evaluating risk for IHD (Palatini, 2007). An elevated RHR is reported to be an independent predictor of myocardial infarction in women (Hsia et al., 2009; Greenland et al., 1990) and in men (Greenland et al., 1999) in a general population. In the present study, even though the mean RHR value was in the normal range, individual participants who complained of palpitations had abnormal RHR values. Sliwa et al. (2012) noted that individuals infected with HIV had higher RHR values (99 [±22] bpm) than non-infected individuals (84 [±19] bpm) when admitted to Chris Hani Baragwanath hospital with cardiac symptoms. The authors noted that HIV-related cardiomyopathy was the most frequently diagnosed condition, pericarditis and pericardial effusion second, and IHD less often diagnosed. An elevated heart rate (above 80 bpm) in this study was associated positively with DBP and physical activity level, which had an inverse relationship with RHR after adjustment for age and gender. Similarly, Hsia et al. (2009) reported an inverse relationship between physical activity level and RHR in an international cohort of women. Resting heart rate and blood pressure are routinely monitored in PLWHA at primary care clinics. With HIV-related cardiomyopathy reported to be a common condition noted in PLWHA in SA, symptoms such as palpitations and raised RHR values should be seriously considered for management. Further medical review seems indicated to evaluate the specific cardiac condition present in such individuals. The conclusions of study 1 are summarised in section 4.8.

4.8 CONCLUSION

Study 1 highlighted the type of population attending a primary care clinic in Johannesburg SA, in the early period of HAART initiation, namely women who are part of the workforce and have dependants. It also provided information on the presence of risk factors for IHD in this population. Reduced physical activity levels and the presence of other non-invasive risk factors for IHD, such as increased perceived stress levels, diet low in fruit and vegetables,

elevated BMI and RHR values in the study cohort builds on the body of knowledge related to IHD in PLWHA in SA. These risk factors could possibly be influenced by education and intervention programmes, such as a physical activity modification programme at primary care level. However, social factors such as financial constraints could influence adequate implementation of dietary guidelines in PLWHA in SA. Furthermore, family responsibility or work obligations may influence adherence to exercise programmes.

The study found that the risk of IHD was reduced when considering family history related this condition, as only a few participants reported such a history. Other risk factors for IHD such as smoking were also less prevalent in the study cohort than indicated in international data, and this might be due to population particulars, e.g. females being less likely to smoke than South African men. Diagnosed diabetes and HTN were also less prevalent in the study cohort, but management of reported HTN leaves room for improvement. Even though a low prevalence of these known risk factors for IHD was present in the sample, aggressive management is still of extreme importance to reduce the absolute risk of cardiovascular disease in PLWHA (Lundgren et al., 2008).

This study is the first to report on the physical activity preferences of PLWHA in SA, and provides information specific to the mode of activity. Walking and running were most often reported as means by which participants included exercise in their lives. The study found that participants reported implementing their own exercises, but that those assertions were not adequately reflected in their pedometer physical activity findings. It is therefore suggested that the study cohort would need education regarding an adequate frequency, and possibly the correct intensity level, of physical activity to gain added health benefits and reduce their risk of IHD.

Weight gain and increased BMI were noted in this study as a significant risk factor for IHD, and the parameters associated with an elevated BMI were found to be more extensive in this study than other national data, such as that found by Hurley et al. (2011). The results of this study provide additional South African information to build on the available international data related to overweight and obesity in PLWHA.

Subjective symptoms such as fatigue, SOB and chest pain were reported by some study participants. A review of the explanations of when such symptoms were experienced provided screening information for IHD, and also reinforced the fact that fatigue and SOB were most often experienced when performing physical activity or when an increase in physical activity was required. The influence of these symptoms on physical activity levels should therefore not be ignored, but instead could also be used as self-monitoring methods for participants to evaluate their tolerance for exercise and effort during exercise.

It was disturbing to note that individual participants presented with suspect signs and symptoms (palpitations, sinus tachycardia at rest and chest pain with cardiogenic referral pattern) that had not been identified or managed in standard clinic care. Screening these individual signs and symptoms added clinical importance to the screening process for IHD risk factors in the study cohort.

Chapter 5 consists of an explanation of the methodology, procedures, results and discussion of study 2 of phase 1. The focus of study 2 was to investigate study participants' self-perception and behaviour towards IHD. The information obtained from this study described their knowledge and understanding regarding IHD and their insight into their own risk of IHD.

CHAPTER 5

5. STUDY 2: SELF-PERCEPTION AND BEHAVIOUR TOWARDS IHD

5.1 INTRODUCTION

With IHD becoming an increasing cause for concern in PLWHA, health promotion and prevention of IHD by screening, identifying and treating modifiable risk factors for IHD are becoming important. A factor that might influence individuals' compliance with such prevention strategies is their perception regarding their own risk of IHD. Research indicates that "perceived susceptibility" for a condition is likely to influence preventive health behaviours (Janz and Becker, 1984). Self-risk perception of IHD is often underestimated in the general population (Hart, 2005; Meischke et al., 2000), as well as in PLWHA (Cioe et al., 2013). It is not known if PLWHA in SA perceive themselves at risk of IHD. Study 2 set out to answer this research question.

5.2 STUDY 2

5.2.1 Aim

The aim of study 2 was to determine the nature of the self-perception and behaviour of PLWHA'S in relation to the risk of IHD.

5.3 METHODOLOGY

5.3.1 Study Design

A qualitative study design was chosen. Qualitative inquiry provides the ideal means to describe the complex nature of humans and how individuals perceive their own experiences within a particular social context (Portney and Watkins, 2009). The study perspective was ethnographic: ethnography is the study of attitudes, beliefs and behaviours of a group of people within their cultural environment (Portney and Watkins, 2009).

5.3.2 Sample Size

The sample size depended on when information gathered in the interview process was considered saturated. Saturation was the point at which no new or relevant information emerged. In this study data saturation occurred when 30 study participants completed their interviews.

5.3.3 Study Subjects

Study 2 was conducted simultaneously with the larger study 1 that sought to determine the prevalence of non-invasive risk factors for IHD in PLWHA, as described in chapter 4. Hence an overlap between the two studies, as the first 30 study participants of study one who also consented to participate in study two were interviewed.

5.3.4 Measuring Instruments

The instruments used to gather the qualitative data were the semi-structured interview questionnaire (Appendix 22), flash cards used in the card-sort method (Appendix 23) with poster board for placement, Olympus VN-5500PC digital voice recorder and conventional Nikon camera. The literature review and justification for the use of these measuring instruments are provided in chapter 3: 3.2.2.

5.3.5 Translation Considerations

The questionnaire (Appendix 24) was translated into isiZulu for use in case individuals had difficulty understanding the English questions. The consent form (2) for study 2 was also available in isiZulu (Appendix 25). The translation of the documents was done by Bangula Translation Services as described in chapter4: 4.3.5.

5.3.6 Pilot Study of Study 2

Pilot study 3 was conducted before study 2, in order to evaluate the instruments planned for use in study 2. Details pertaining to this pilot study are presented in section 5.3.6.1.

5.3.6.1 Pilot study 3

5.3.6.1.1 Aim and objectives: Pilot study 3

Aim:

To test the feasibility of the card-sort method applied in the qualitative interviews.

Objectives:

- To determine whether the questions in the semi-structured interview questionnaire were understood by participants.
- To determine whether the sentences and pictures on the flash cards were understood by participants.
- To facilitate training of the researcher to improve her interview skills.
- To evaluate the feasibility of using the method in interviews with PLWHA.

5.3.6.1.2 Study subjects: Pilot study 3

Four individuals were invited to participate: two lay persons and two senior qualitative researchers and academics in the School of Therapeutic Sciences at the University of the Witwatersrand. One researcher declined participation due to other professional obligations.

5.3.6.1.3 **Measuring instruments: Pilot study 3**

The tools used were: the semi-structured questionnaire, flash cards for card-sort technique with poster board for placement and the Olympus VN-5500PC digital voice recorder. The procedure in pilot study 3 and the results are detailed in Appendix 26.

5.3.6.1.4 **Key recommendations made and adopted: Pilot study 3**

The senior qualitative researcher provided the following feedback and suggestions:

1. Adding the card-sort technique to the interview made it interactive and interesting. The number of flash cards included was appropriate (23 with phrases, and one blank), as it allowed the participant to think about what she wanted to select, and the number of cards was not overwhelming. Adding the blank card was also reported to be beneficial as it allowed the participant to add her own contribution to what was considered “living a healthy lifestyle”.

2. A positive interview skill of the researcher was reminding the participant what she had said earlier when she became confused. This was appropriate, as the participant could easily forget what he or she had said previously, and it also demonstrated that the researcher was listening attentively to the conversation.

3. It is important for the researcher to create an informal atmosphere, especially in the particular study population involved. This was essential, as participants might be nervous about giving an ‘incorrect’ answer, or might feel ill-at-ease if they feel uncertain about their answer. They might feel a need to please the researcher in their feedback. Putting a participant at ease, and assuring at the start of the interview that the researcher is interested in his or her thoughts, could overcome this obstacle.

4. It was suggested that the researcher give more time for thought between questions. If participants get ‘stuck’, they could be reassured by eye contact, a nod of the head, and a murmuring sound, e.g. mm... instead of a prompting question. This would show that the researcher was engaged in the conversation, and was giving the participant freedom in the interview. If, after a few minutes, the participant could not produce an answer, a prompting question would give a helpful lead. This would make for an “open” interview rather than one in which the participant was led along.

5. Field notes should be limited during the interview, as excessive note-taking could become a barrier. Better rather to focus on the participant and make eye contact to demonstrate involvement in what is being said. The tape recorder can be used for collecting data.

6. In the card-sort exercise, hand the cards to the participant in a stack and let them shuffle through them, instead of placing them spread out on a table. This would give the participant control, and also help where space is limited.

These comments were implemented in the first interview of a Themba Lethu participant, and worked well. The participant had no difficulty understanding the questions, and also read the English and isiZulu phrases on the flash cards with ease. The same procedure was therefore followed with the remaining participants of the study.

5.4 PROCEDURE

The qualitative interviews were held in the first contact session with the study participants in the private physiotherapy room in Themba Lethu clinic one-on-one. The participant and researcher sat on comfortable office chairs at a table for the interview.

The questionnaire was followed as a guide in the process to keep the questions standardised. The card-sort technique was done at the appropriate time according to the guide. The stack of flash cards was handed to the participant to peruse and select those that they associated with living a healthy lifestyle. The participant then placed them on the poster board in descending order, with what they considered most important to the left, and least important to the right. Thus the cards were ranked according to importance. The participants were allowed to stack cards on the line if they felt them to be equally important. They could also choose as many cards as they liked. A discussion based on their selection and arrangement followed, in line with the questionnaire guide. After this discussion the interview continued, in keeping with the interview questionnaire.

All interviews were tape-recorded for record keeping and accuracy, to allow for verbatim transcription at a later stage. The researcher made some field notes in the interviews on the participant's copy of the questionnaire. A photograph of selected cards on the poster board was taken at the end of the interview to ensure trustworthiness of note-taking and to assist with analysis of card-sort data. Figure 5.1 is an example of a photograph taken of participant's (number 30) selected flash cards.

Figure 5.1: Photograph of Card Selection of Participant Number 30 of Study 2

5.5 ANALYSIS OF TRANSCRIBED DATA

An inductive approach to data analysis was followed, using conventional content analysis (Thomas, 2006; Hsieh and Shannon, 2005). As stated by Thomas (2006: 238): "inductive analysis refers to approaches that primarily use detailed readings of raw data to derive concepts, themes or a model through interpretation made from the raw data by an evaluator or researcher". All interviews were transcribed by the researcher, in full and verbatim, using Microsoft Word 2007. This allowed the researcher to review the collected data. Codes and keywords were identified that had been repeated by study participants, and the content of the transcribed interviews was analysed to identify codes (keywords) for each question. The codes were sorted in table format with the participant number. The frequency of appearance of codes was analysed question-by-question (Smith, 2000). Data analysis thus occurred vertically and then horizontally. To reduce the data, the codes were collapsed, first into subcategories, then categories and, lastly, themes (Thomas, 2006; Smith, 2000).

The cards selected in the card-sort technique were visually presented in diagram format as in the photograph, and field notes made according to what cards were chosen, and, if cards were stacked into piles how many, and where they were placed. The diagram below (Figure 5.2) is an example of this procedure. It represents the flash cards selected in the interview with participant number 30, as in the photograph above (Figure 5.1).

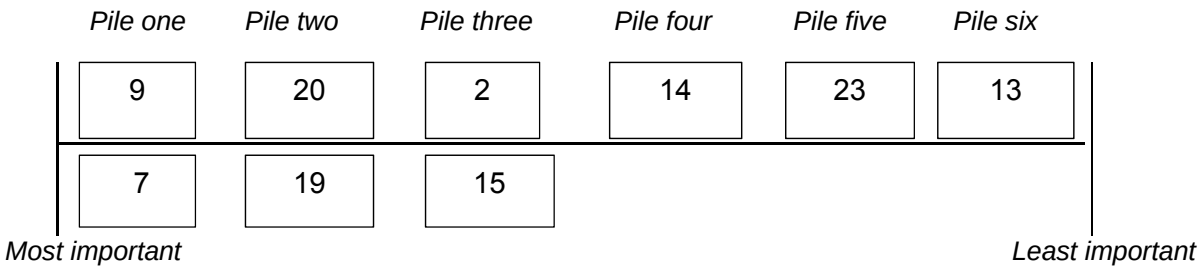


Figure 5.2: Visual Presentation of Diagram Format of Selected Cards

A Microsoft Excel 2007 spread sheet was created to systematically quantify 1) each participant, 2) separate piles created by the participant, and the presence or absence of a unique statement in a particular pile. If a statement was present it was captured as one, and if absent, as zero. The diagram below (Figure 5.3) explains this Microsoft Excel data-capturing procedure for participant 30.

Id	Pile	No of cards in pile	Card 1	Card 2	Card 3	Card 4	Card 5	etc.
30	1	2	0	0	0	0	0	
30	2	2	0	0	0	0	0	
30	3	2	0	1	0	0	0	
30	4	1	0	0	0	0	0	
30	5	1	0	0	0	0	0	
30	6	1	0	0	0	0	0	

Figure 5.3: Microsoft Excel Data-Capturing Procedure

The frequency of occurrence of a statement and the position of each statement on the continuum line (pile number) were then analysed with IBM SPSS 20. The procedure of systematically collapsing and organising cards selected by study participants to enable analysis is supported by Whaley and Longoria (2009).

The participants' demographic and non-invasive risk factors screened were collected from study 1 and analysed by quantitative analysis on SPSS IBM 21. Categorical data are presented as frequencies and percentages. Numerical data are expressed as median (interquartile range) or mean (±SD) dependent on skewness. If the skewness falls outside the +1 to -1 range, findings are presented as median (interquartile range).

5.6 TRUSTWORTHINESS

5.6.1 Credibility

Strategies were implemented throughout the qualitative research process to enhance credibility, as suggested by Patton (1999). The researcher received advice from a senior qualitative researcher to assist her with interview skills in pilot study 3 as preparation for the main study. She also attended qualitative research workshops to improve her understanding of the qualitative research process. In the course of the study three senior

qualitative researchers provided guidance with the analysis process. Triangulation strategies were also implemented to enhance credibility of data-collection and analysis.

a) Methods triangulation

Information such as smoking and diet history collected in study 1 (quantitative study) enhanced and supported some findings of qualitative study 2.

b) Triangulation of sources

Different data-gathering techniques were used: observations with field notes, tape-recordings, card-sort technique, and flash cards selected in the card-sort technique were photographed and compared with field notes. Different data analysis sources enhanced credibility: thematic content analysis findings were enhanced with frequencies of codes and frequencies of flash cards selected in the card-sort activity.

c) Analyst triangulation

The dependability of transcribed interviews was reviewed by a portion of the study sample. The researcher telephoned participants to invite them to a follow-up session, where their transcribed interviews were reviewed. Six participants (20% of the sample) consented to this session. There they listened to their interview, read the transcribed interview, clarified any information and commented on the accuracy of transcribed interviews.

A portion of the transcribed interviews and code analysis was reviewed by a second senior qualitative researcher to allow for member checks. Another researcher analysed six participants' (20% of the sample: participants 5, 10, 15, 20, 25, 30) interviews in line with the procedure stated above. Every fifth interview was selected for sampling to provide the researcher with an evenly distributed sample of interviews for analysis. Two sessions were held between the researcher and the three senior qualitative researchers, where data analysis was reviewed and possible themes suggested.

5.6.2 **Transferability**

The study was conducted in PLWHA in the South African context. A detailed description of the data-collection procedure and analysis process is provided for review. Both these methods are supported by the literature (Whaley and Longoria, 2009; Thomas, 2006; Hsieh and Shannon, 2005; Smith, 2000). Explanatory quotations from the raw data are provided to enhance understanding of participants' viewpoint and background. The reader needs to judge the transferability to other populations and/or situations.

5.6.3 **Dependability**

Transparent coding process and inter-coder verification added to the dependability of the research findings (Thomas, 2006; Patton, 1999).

5.6.4 **Confirmability**

Determining the confirmability of all research findings of this study is difficult, as only one other study has been published related to PLWHA and their perception regarding their risk for IHD. Cioe, Crawford and Stein (2013) conducted a cross-sectional study in a USA cohort, and found that individuals had a fair degree of knowledge related to IHD, but a weak correlation of perceived self-risk to individual estimated risk was noted.

The results of study 2 are presented in section 5.7.

5.7 **RESULTS**

The results of study 2 are presented according to the following sections: demographic characteristics; screening results of risk factors for IHD; participants' self-perception regarding risk of IHD and living a healthy lifestyle; card-sort technique results and themes from content analysis.

5.7.1 **Demographic Characteristics of Study 2 Participants**

The first 30 study participants of study 1 who also consented to participate in study 2 were interviewed. Data saturation occurred when 30 participants were interviewed. The general and HIV demographic characteristics are depicted in Table 5.1, as obtained from study 1.

Table 5.1: Demographic Characteristics of Study 2 Participants (N = 30)

Variable	N	n (%) or Median (Interquartile range)	Normal range
Age (years)	30	36.5 (31.8–45.0)	
Gender ▪ Male ▪ Female	30	 5 (16.7) **25 (83.3)**	
Educational level ▪ None ▪ Primary ▪ Secondary ▪ Post-Secondary	30	 1 (3.3) 5 (16.7) **16 (53.3)** 8 (26.7)	
Employment status ▪ Unemployed ▪ Employed ▪ Self-employed	30	 12 (40.0) **17 (56.7)** 1 (3.3)	
Participants with dependants	30	**26 (86.7)**	
Perception of health status ▪ Average ▪ Good ▪ Excellent	30	 8 (26.7) **17 (56.7)** 5 (16.7)	
Confirmed to have HIV ▪ Before 2005 ▪ 2005 - 2008 ▪ 2009 - 2010	30	 3 (10.0) 6 (20.0) **21 (70.0)**	
HAART categories ▪ Lamivudine, Efavirenz, Tenofovir ▪ Lamivudine, Efavirenz, Stavudine ▪ Other	30	 10 (33.3) **13 (43.3)** 7 (23.3)	
Time on HAART (months)	30	10.5 (7.0–12.0)	
CD_4 count (cells/mm^3)	30	**282 (211.0–357.5)**	600-1500 (Van Dyk, 2008)
Viral load (copies/ml) ▪ < 400	28 *	**26 (86.7)**	

♦ Cells/mm^3 (cells per cubic millimetre of blood), copies/ml (copies of HIV RNA per millilitre of blood)
* Viral load blood results were available for 28 participants.

Most participants were female (n=25; 83.3%), employed (n=17; 56.7%), had a secondary educational level (n=16; 53.3%) and were supporting dependants (n=26; 86.7%). Just over half of participants (n=17; 56.7%) perceived their general health as good. The median time on HAART was 10.5 (7.0–12.0) months, most participants were on a Stavudine-containing regimen (n=13; 43.3%) and confirmed to have HIV in 2009-2010 (n=21; 70%). The median CD_4 count of the sample was less than the suggested normal range for CD_4 count. The majority of participants had a viral load of less than 400 copies/ml. Viral load findings of two participants had not been noted in the hospital records. The IHD risk factor screening results of study 2 participants are presented in section 5.7.2.

5.7.2 Screening Results of Risk Factors for IHD of Study 2 Participants

The screening results of non-invasive risk factors for IHD of study 2 participants are depicted in Table 5.2, as deduced from study 1.

Table 5.2: Non-invasive Risk Factors for IHD of Study 2 Participants (N = 30)

Variable	N	n (%) or Mean (±SD) or Median (Interquartile range)	Normal range
Smokers	30	3 (10)	
History of hypertension	30	3 (10)	
Vegetable and fruit intake ▪ Daily ▪ Weekly	30	 **16 (53.3)** 14 (46.7)	Daily intake (WHO, 2013)
Vegetable and fruit intake daily (three to five) ▪ Yes ▪ No	30	 10 (33.3) **20 (67.3)**	At least five fruit and vegetables combined (WHO, 2013)
Perceived stress level	30	19.6 (±9.1)	75th Percentile (Hamad et al., 2008)
RHR (bpm)	29 *	**82.2 (±13.3**)	Less than 80 (Palatini, 2007)
Blood pressure (mmHg) ▪ SBP ▪ DBP	29 *	 115.8 (106.9–122.4) 74.3 (69.3–81.3)	 Less than 120 Less than 80 (Collins and Dias, 2009)
WC (cm) ▪ Men ▪ Women	29 * 4 25	83.4 (±11.5) 83.4 (±5.9) 83.4 (±12.3)	 Less than 102 Less than 88 (ACSM, 2010)
WHR ▪ Men ▪ Women	29 * 4 25	0.8 (±0.1) 0.9 (±0.1) 0.8 (±0.1)	 Less than 0.95 Less than 0.86 (ACSM, 2010)
BMI (kg/m^2) ▪ Men ▪ Women	29 * 4 25	23.9 (21.5–28.3) 21.9 (21.4–23.1) **25.2 (21.5–28.6)**	18.5 – 24.9 (WHO, 2004)
Physical activity level (steps/day)	29 *	10 087.4 (±4 818.9)	More than 10 000 (ACSM, 2010)
Physical activity categories ▪ Sedentary ▪ Light active ▪ Somewhat active ▪ Active ▪ Very active	29 *	 **3 (10.3)** **7 (24.1)** **7 (24.1)** 5 (17.2) 7 (24.1)	 Less than 5000 5000 – 7499 7500 – 9999 10000 – 12499 More than 12500 (Tudor-Locke and Bassett, 2004)

♦ RHR (resting heart rate), SBP (systolic blood pressure), DBP (diastolic blood pressure), WC (waist circumference), WHR (waist: hip ratio), BMI (body mass index), bpm (beats per minute), mmHg (millimetres mercury), cm (centimetres), kg/m^2 (kilograms per square metre), steps/ day (steps per day).
* One individual did not attend second study 1 session.

The body measurements and physical activity levels of 29 participants were available due to one participant failing to return for his second study 1 appointment, where these data were collected.

Only three individuals (10%) were smokers, and had a known history of HTN. The majority of participants (n=16; 53.3%) were eating fruit and vegetables daily, but were not able to partake in three to five vegetables and fruit combined daily (n=20; 67.3%). The 75th

percentile for perceived stress was 26.3 indicating that the cohort had a moderately high stress level at a mean of 19.6 (±9.1).

The mean RHR was slightly elevated when considering risk of IHD. Women were considered overweight, deduced from an increased BMI value (BMI ≥ 25 kg/m^2).

Waist circumference, WHR and pedometer physical activity step-count mean values were all within the normal ranges. The standard deviations of these parameters, however, indicated that a portion of the sample had abnormal values. Seventeen individuals (58.6%) had a pedometer physical activity level of less than 10 000 steps per day, indicating less-active categories.

5.7.3 Participants' Self-Perception Regarding Risk for IHD (Frequency Data)

The majority of participants (n=15; 50%) did not perceive themselves at risk of developing IHD, as demonstrated in Figure 5.4.

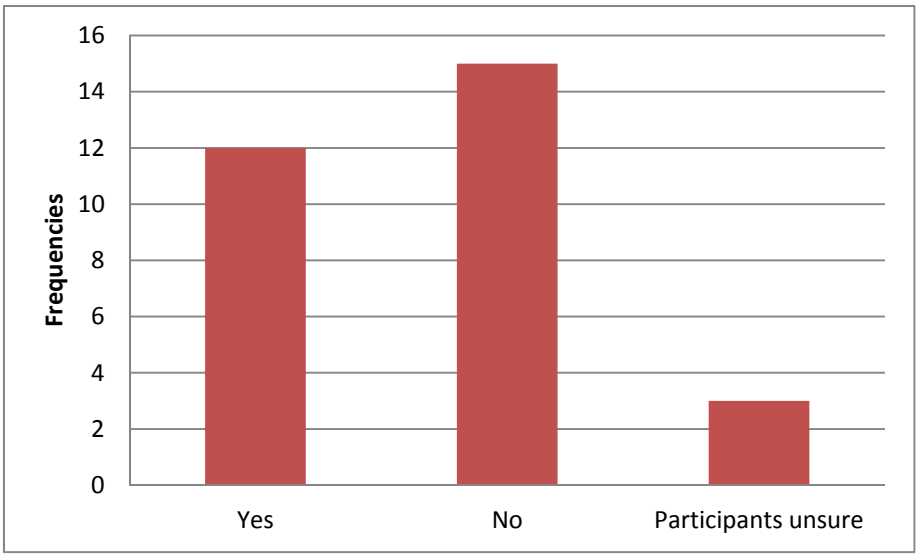


Figure 5.4: Participants' Self-Perception Regarding the Risk of IHD (N = 30)

Twelve participants (40%) did perceive themselves to be at risk of developing IHD, and three (10%) were unsure. Twenty-six individuals (87%) thought one could prevent IHD from occurring. Two (6.6%) considered it unavoidable, and two (6.6%) additional individuals were unsure.

5.7.4 Participants' Self-Perception Regarding Living a Healthy Lifestyle (Frequency Data)

The majority of participants (n=27; 90%) perceived themselves as living a healthy lifestyle, as shown in Figure 5.5.

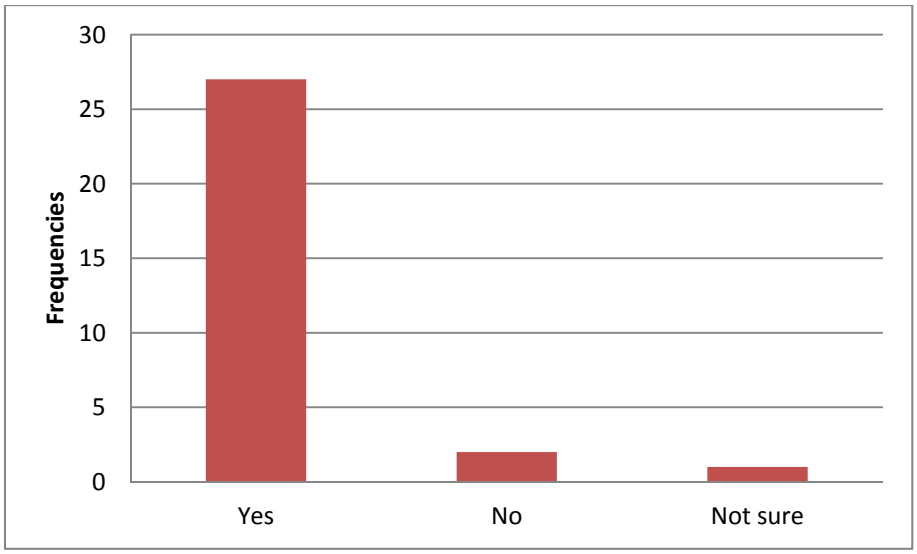


Figure 5.5: Participants' Self-Perception Regarding Living a Healthy Lifestyle (N = 30)

Two participants (6.7%) did not perceive themselves to be living a healthy lifestyle and one (3%) was unsure.

5.7.5 Card-Sort Technique

The card-sort technique results are presented in the following sections: the behaviours and/or components related to living a healthy lifestyle; most important behaviours and/or components related to living a healthy lifestyle, and participants' suggestions regarding behaviours and/or components related to living a healthy lifestyle.

The median number of flash cards selected by participants in the semi-structured interview was 12 (10.0–14.3). The lowest number of cards selected was three, and the highest 17. The participant who selected only three cards was the one who reported no schooling education.

5.7.5.1 Behaviours and/or components related to living a healthy lifestyle

Figure 5.6 is a representation of the frequency of lifestyle behaviours and activities selected in the card-sort technique when components of living a healthy lifestyle were discussed.

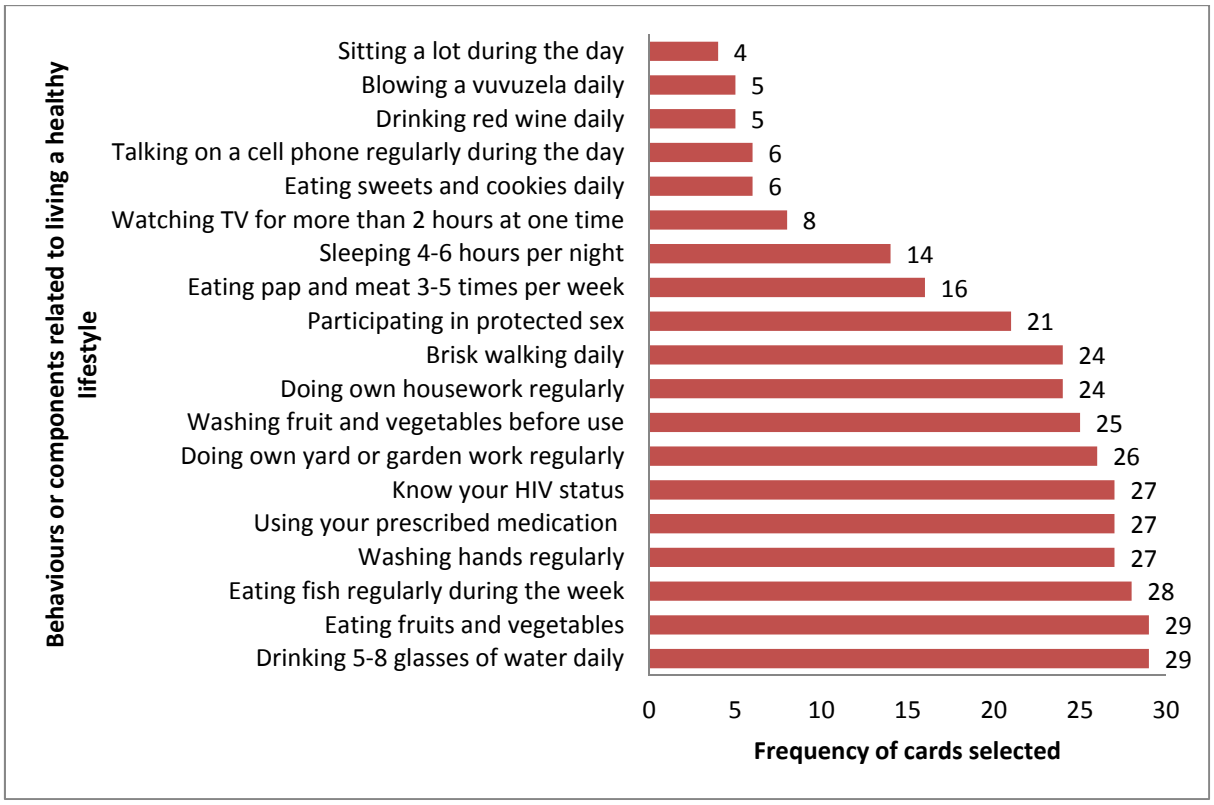


Figure 5.6: Behaviours and/or Components Related to Living a Healthy Lifestyle.

The two most frequently selected cards were card 19: drinking 5 – 8 glasses of water daily and card seven: eating fruit and vegetables daily. Both were selected by 29 participants (96.6%). The second-most frequent card selected was card 23: eating fish regularly during the week, and was selected by 28 participants (93.3%). The third most frequently selected cards were card two: washing hands regularly, card nine: using your prescribed medication and card five: knowing your HIV status. These three cards were selected by 27 participants (90%).

The least-frequently selected card was card 22: sitting a lot during the day. Four participants (13.3%) reckoned this to be part of living a healthy lifestyle, as it allowed them to rest. Interestingly, five participants (16.6%) selected card four: blowing a vuvuzela daily as part of living a healthy lifestyle. A vuvuzela is a plastic horn that makes a monotone note when one blows into the instrument. Participants explained that this behaviour formed part of recreation and socialising, and could also influence one's lung function.

5.7.5.2 Most important behaviours and/or components related to living a healthy lifestyle

In the interview participants stacked their chosen cards from most to least important on a continuous line, and they were allowed to overlap cards into piles if they thought them equally important. The frequency of piles, with number of participants who created them, was as follows: pile one (n=30), pile two (n=30), pile three (n=27), pile four (n=22), pile five (n=17), pile six (n=9), pile seven (n=3) and pile eight (n=2).

Specifics pertaining to pile one will be presented in this chapter, but information related to the other piles is available for review in Appendix 27. Figure 5.7 is a representation of the cards that participants stacked into pile one, indicating that they considered those cards as most important when considering behaviours or activities related to living a healthy lifestyle.

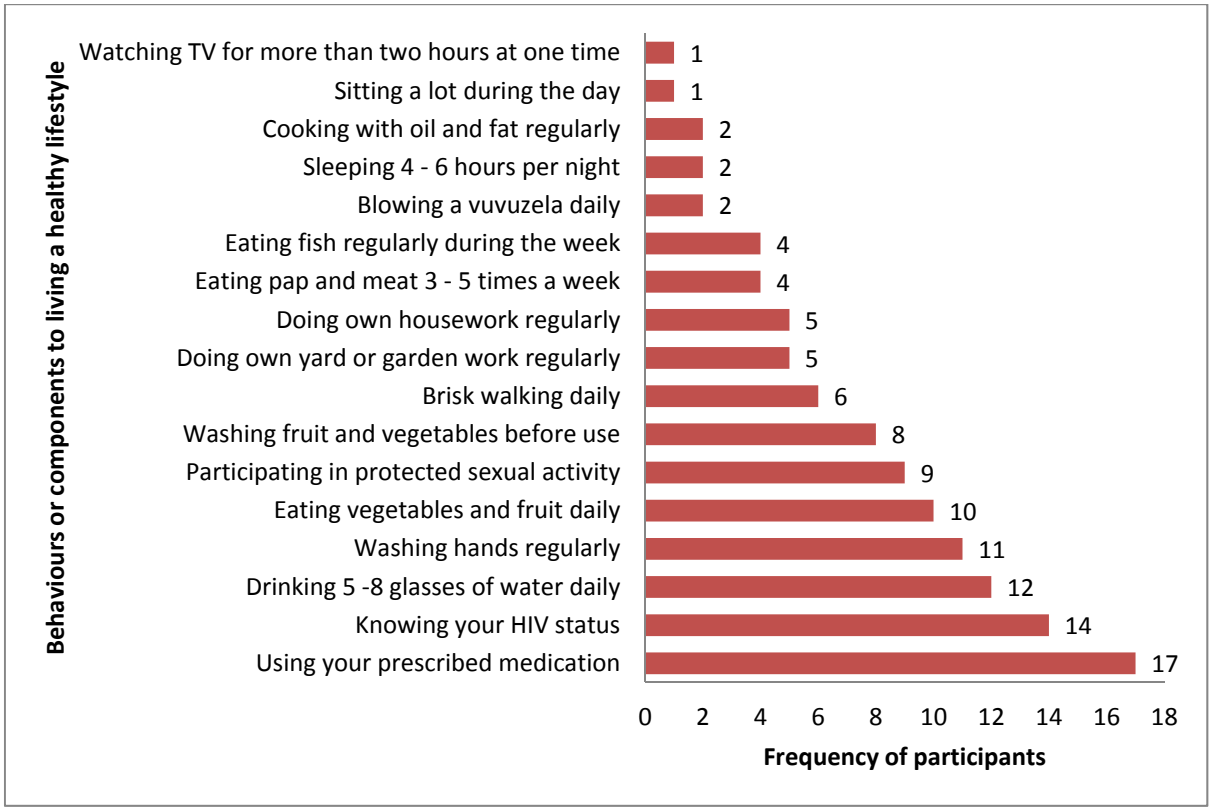


Figure 5.7: Most Important Behaviours and/or Components Related to Living a Healthy Lifestyle (N = 30).

Card nine: using your prescribed medication was selected by 17 participants (56.6%) as the most important component related to living a healthy lifestyle. Secondly, 14 participants (46.6%) selected card five: knowing your HIV status. Interestingly, unhealthy lifestyle components also featured in pile one: sitting frequently (n=1), prolonged television watching (n=1), cooking with oil and fat (n=1) and eating pap and meat 3 – 5 times per week (n=4).

5.7.5.3 Participants' suggestions regarding behaviours and/or components related to living a healthy lifestyle

Participants provided additional information in the blank card discussion concerning what they considered important to live a healthy lifestyle that was not adequately included in the picture flash cards. They could mention more than one factor. Figure 5.8 is a representation of the frequency information regarding their suggestions.

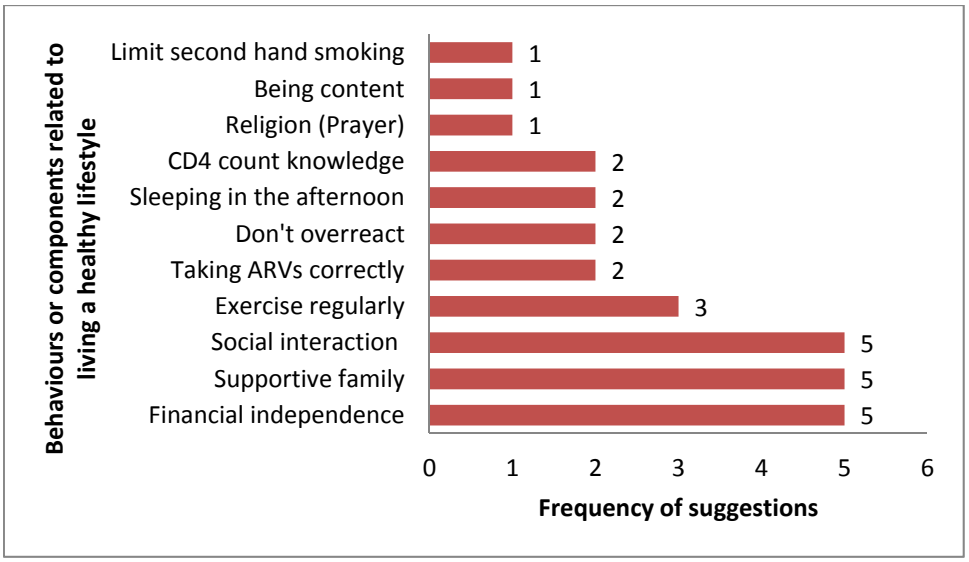


Figure 5.8: Participants' Suggestions Regarding Behaviours and/or Components Related to Living a Healthy Lifestyle.

Six participants (20%) had nothing to add, and 24 (80%) provided additional material. They considered financial independence by being employed (n=5), having a supportive family (n=5) and interacting socially (n=5) as important additional components of a healthy lifestyle.

Section 5.7.6 provides the theme results from the content analysis of the study two interviews.

5.7.6 Themes Identified from Semi-Structured Interviews

Three themes were identified in the course of content analysis of transcribed interviews: knowledge and understanding related to IHD, insight into own risk of IHD and health character in the HIV context.

5.7.6.1 Theme 1: Knowledge and understanding related to IHD

Causes, consequences and prevention strategies for IHD were recognised as categories of participants' knowledge and understanding related to IHD (theme 1). Table 5.3 is a representation of this. Selected quotations to illustrate are added for review.

Table 5.3: Theme 1: Knowledge and Understanding Related to IHD (Causes*).*

Category	Sub-category	Codes/Keywords	Code frequency n (%)	Quotes to illustrate
Causes	Psychological	Stress 'Thinking too much' (brooding, worrying)	13 (43) 7 (23)	*"Mostly thinking, when you are thinking a lot you are not giving your heart a chance to function well. You are most of the time panicking. When you panic a lot, I used to even feel like something is piercing me through the heart, I feel a pain,that means I am panicking a lot. You know when you are relaxing you are just okay you feel even you are calm. When you are thinking a lot you are like the kind of life you are living you are stressed mostly you develop heart disease" (Participant 2: Quote 1).*
	Nutrition	Eating habits Alcohol abuse	16 (53) 3 (10)	*"When you are eating too much fat, the fat clots the heart. Pumping of the heart is not good. When it is very bad your heart can fail" (Participant 11: Quote 2).* *"I have thought a lot that drinking a lot of tea like my dad can cause heart problems. My dad also liked a lot of sweet cookies. Sweets and cold drinks. I think sweet things" (Participant 9: Quote 3).* *"When you are eating mostly fatty things, too much fatty things or drinking too much also. People are drinking too much alcohol you eat less you are going to develop heart disease" (Participant 2: Quote 4).*
	Structure and function	Heart pump abnormal Blood flow abnormal Fatty heart	8 (27) 4 (13) 1 (3)	*"The fat closes the veins and then there is not enough blood going through the heart then the heart stops when the veins are blocked then the heart don't get enough blood and the heart won't pump" (Participant 16: Quote 5).* *"When you have a heart attack then the heart is beating fast" (Participant 27: Quote 6).* *"I don't have a lot of history and maybe your heart with too much fat on it" (Participant 1: Quote 7).*
	Behaviour	Smoking Not exercising Not living healthy	4 (13) 2 (7) 1 (3)	*"It is being inactive number one, not eating fruits, if you think too much and stress a lot you get it. Those are the main things" (Participant 8: Quote 8).*

Category	Sub-category	Codes/Keywords	Code frequency n (%)	Quotes to illustrate
	Emotional	Keeping problems inside Anger Not accepting HIV	3 (10) 1 (3) 1 (3)	*"When one has a lot of problems that you can't solve on your own that you keep on yourself, inside that can cause heart disease" (Participant 6: Quote 9).* *"I think it means it is because they don't accept that they are sick and also don't tell people close to them that they are sick" (Participant 14: Quote 10).* *"Causes of heart disease…like when you talk too much with your heart it cause heart disease. When you take something little like and get so angry every day it causes heart problems. Like you put the pain things in your heart. Like the heart will be affected" (Participant 10: Quote 11).*
	Physical	Heart disease when body big Hypertension Cholesterol Inherited heart disease	1 (3) 1 (3) 1 (3) 1 (3)	*"I think it starts with stress because you will be stressed and stressed etc. and maybe you will start having high blood pressure that will lead you to heart attack" (Participant 3: Quote 12).*

Stress and 'thinking too much' were codes that presented most frequently (n=20; 66%) as causes of IHD. 'Thinking too much' was an frequently-reported concept, and included aspects of worrying, panicking and not allowing the mind to rest, resulting in increased stress levels. Participants explained it as follows: *"It means worrying. When I sit I often worry about how long I will live and have time to spend with my child. And who will look after my child and what sort of life he will have if I am not there" (Participant 9: Quote 13); "If you are thinking too much you can't rest, you can't have a peace, your mind is always busy, and you worry this is what is happening now, you are always worried" (Participant 13: Quote14).*

The second-most common cause of IHD was reported to be nutrition, as reflected by specifics related to diet (n=16; 53%). Third was impaired structure and function of the heart (n=13; 43%). Only a few participants reported the effects of smoking (n=4; 13%) and not being active (n=2; 7%). Emotional factors, such as anger (n=1; 3%), not accepting one's HIV status (n=1; 3%) and keeping problems to themselves (n=3; 10%) were least-often mentioned. A few participants related the causes of IHD to physical changes as a risk factor for IHD (n=4; 12%).

The consequences of IHD were highlighted by participants' knowledge and understanding regarding the signs and symptoms of IHD, and the fact that this disease could be fatal. Table 5.4 is a representation of the knowledge and understanding regarding the consequences of IHD, with selected explanatory quotations added.

Table 5.4: Theme 1: Knowledge and Understanding Related to IHD (Consequences).

Category	Sub-category	Codes/Keywords	Code frequencies n (%)	Quotes to illustrate
Consequences	Signs and symptoms	Chest pain Breathing problems Feeling tired Sweating Swollen feet Collapse Anger Can't talk properly Feel dizzy Feeling weak Losing weight	13 (43) 11 (37) 8 (27) 4 (13) 3 (10) 2 (7) 2 (7) 2 (7) 1 (3) 1 (3) 1 (3)	*"I think swelling because the circulation is not well. Sweating and breathing problems and chest pains most of the time" (Participant 8: Quote 15).* *"Some of them collapse, complaining of pain in the heart and you will see that a person is shrinking, shrinking" (Participant 7: Quote 16).* *"The person won't breathe well. The heart is paining" (Participant 27: Quote 17).* *"Feel numb, tired and sometimes the hearts beats faster" (Participant 20: Quote 18).*
	Mortality	Heart disease can kill	8 (27)	*"If someone is having heart disease they can die from heart disease or if they take care of themselves they can live long. Heart disease is not very nice" (Participant 29: Quote 19).*
	Morbidity	Does not start immediately	1 (3)	*"The little that I understand about heart disease it's a disease that does not start immediately it starts with small things like stress" (Participant 1: Quote 20).*

Participants identified chest pain (n=13; 43%), breathing problems (n=11; 37%) and feeling tired (n=8; 27%) as the most common symptoms of IHD. Signs such as sweating (n=4; 13%), swelling (n=3; 10%) and collapsing (n=2; 7%) were noted to accompany IHD, though to a lesser extent. One participant was aware of the insidious onset of IHD, and a number (n=8; 27%) were aware of the serious nature of IHD and that it could result in death. IHD also elicited emotions of anxiety and nervousness in participants: *"It makes me scared, because the heart is important in our body. So if you have a problem with your heart you have a problem with your life" (Participant 19: Quote 21).*

IHD was viewed as a serious condition, and participants had knowledge and understanding regarding prevention strategies that could influence the risk of its developing. Table 5.5 is a representation of the knowledge and understanding regarding prevention strategies of IHD, with selected explanatory quotations added.

Table 5.5: Theme 1: Knowledge and Understanding Related to IHD (Prevention)

Category	Sub-category	Codes/Keywords	Code frequency n (%)	Quotes to illustrate
Prevention strategy	Lifestyle change	Eating healthy diet Don't stress Exercise Healthy lifestyle Don't smoke Reduce alcohol Sleep enough	14 (47) 7 (23) 6 (20) 2 (7) 2 (7) 1 (3) 1 (3)	*"Yes, if you do all the right things like not eating fatty food not using cooking oil, if you don't smoke if you do your exercises and eat your vegetables and fruit. Healthy balanced life; drink enough water, sleep enough and don't stress too much. You always make sure that you are in the middle and level" (Participant 29: Quote 22).* *"Ja, I do think so reducing fats there are things when we were growing up like eating atcher like chacalekka in my community my culture there is a whole lot of oily stuff that you eat. Not to leave them but to reduce the amount of fat you are using every time" (Participant 1: Quote 23).*
	Coping behaviour	Share problems Don't think too much Don't overreact Forget the past Socialise	2 (7) 2 (7) 2 (7) 1 (3) 1 (3)	*"Yes a person can by not keeping your problems inside always but share with someone" (Participant 6: Quote 24).* *"Prevent…we can't stop problems from happening but you need to take it normally. When things happen it happens but you must go on" (Participant 13: Quote 25).*
	Health-seeking behaviour	Consult a doctor Hospital attendance	1 (3) 1 (3)	*"Yes, they must come to the clinic to the hospital to get treatment. Only the hospital can make the heart disease right… A person can't help themselves they can't do something the hospital must help" (Participant 26: Quote 26).*
	Medical management	Heart operation New heart	2 (7) 1 (3)	*"Yes you can…like an operation to your heart. I don't know anything else that will help" (Participant 10: Quote 27).* *"Yes, a lot of people can go for heart operations and maybe get another heart" (Participant 9: Quote 28).*

Changing one's lifestyle as a means to achieve a balanced and healthy lifestyle was considered essential for preventing IHD. Participants reported following a healthy diet (n=14; 47%); reducing stress levels (n=7; 23%); exercising (n=6; 20%) (less important than diet modification); coping strategies; health-seeking behaviour all as ways of preventing IHD. Then three individuals reported medical management in the form of surgical intervention as the sole way of preventing IHD.

Although participants demonstrated knowledge and understanding regarding components of IHD, it was important to identify whether they were able to apply this knowledge and determine their own risk of IHD in self-assessment. Section 5.7.6.2 provides the results regarding participants' insight into their own risk of IHD.

5.7.6.2 **Theme 2: Insight into own risk of IHD**

Insight into own risk of IHD was identified as theme no. two, with self-perception as its main category. Table 5.6 is a representation of participants' insight into their own risk for IHD findings.

Table 5.6: Theme 2: Insight into Own Risk of IHD

Category	Sub-category	Codes/Keywords	Code frequency n (%)	Quotes to illustrate
Self- perception	Lifestyle	Living a healthy lifestyle Exercise	2 (7) 1 (3)	*"No, at the moment with HIV and the life I have been leading before, it has been a healthy life throughout and I have never thought that I could get heart disease, but in the course of time you are no longer as young and fit as you used to be you can come across a lot of problems and could get heart disease, but at the moment I don't think so" (Participant 28: Quote 29).*
	Coping behaviour	Share problems Take everything as it comes Avoid anything that can cause pain	1 (3) 1 (3) 1 (3)	*"No, because something that can cause a painful heart I try and take away or leave alone" (Participant 21: Quote 30).* *"No because I share my problems always" (Participant 6: Quote 31).*
	HIV influence	Better since ARVs	2 (7)	*"No since I am taking ARVs I am healthy" (Participant 14: Quote 32).*
	Possibility for IHD risk - Behaviour	Diet Stress Thinking too much Lack of exercise Smoking Lack of awareness	5 (17) 2 (7) 2 (7) 2 (7) 1 (3) 1 (3)	*"Sometimes, because of the stress and unhealthy diet and not exercising. I think sometimes I can feel my heart tension that is not normal. Maybe you feel that you are stressed and angry. Anger causes your high blood to go higher and you can even feel that your heart is not klopping normal. You feel that it is beating faster. It feels like you can hold it then you feel the short breath and everything" (Participant 3: Quote 33).*
	Possibility for IHD risk - Physical symptoms	Chest pain Heart beating fast Heart beat abnormal	2 (7) 1 (3) 1 (3)	*"I think so, because when I am worried there is pain straight in the heart. Sometimes I feel weak and the pain goes to my back" (Participant 7: Quote 34).* *"Yes I think so, because sometimes when I am sitting I am scared and I feel my heart is going fast" (Participant 17: Quote 35).*

Fifteen participants (50%) did not perceive themselves at risk of IHD, due to reporting living a healthy lifestyle, exhibiting coping behaviour and reporting that their health had improved since being on HAART. Twelve (40%) perceived a possibility of risk of IHD due to specific behaviours and physical symptoms. Participants linked their own risk for IHD most often to behavioural factors, such as following an unhealthy diet (n=5; 17%), psychological factors, such as stress (n=2; 7%) and "thinking too much" (n=2; 7%). Lack of exercise (n=2; 7%) and smoking (n=1; 3%) were less often cited.

A third, final, theme: health character in the HIV context, was identified in content analysis of the transcribed interviews. It became apparent that when participants were providing information regarding living a healthy lifestyle, they were doing so from their HIV perspective. This data is presented in section 5.7.6.3.

5.7.6.3 **Theme 3: Health character in the HIV context**

Three categories were identified regarding participants' health character in the HIV context: knowledge and understanding regarding HIV, coping with HIV and applications to manage HIV. Table 5.7 is a representation of participants' knowledge and understanding regarding HIV, with selected quotes to illustrate added.

Table 5.7: Theme 3: Health Character in the HIV Context (Knowledge and Understanding regarding HIV)

Category	Sub-category	Codes/Keywords	Code frequency n (%)	Quotes to illustrate
Knowledge and understanding regarding HIV	HIV - Self-care	Protect yourself when having sex Take your treatment Look after self Don't deny that you are ill Know your CD_4 count Can't smoke	7 (23) 4 (13) 4 (13) 1 (3) 1 (3) 1 (3)	*"Live a positive life by taking care of yourself. Protecting yourself when having sex or abstaining. Take care of yourself now that you know you are HIV positive how to protect yourself from getting other infections and all that" (Participant 3: Quote: 36).* *"To live longer that is way I am taking ARVs so that I live longer for my children. I know that the ARVs are helping me to keep the sickness down but not to prolong my life" (Participant 6: Quote 37).*
	HIV - Remission	Immune system Not taking medication	6 (20) 3 (10)	*"Ja, they might have re-infection with the HIV virus and their immune system will be getting weak and they will be prone to getting infections" (Participant: 18: Quote 38).*
	HIV - Co-morbidities	Tuberculosis Mind gets disturbed	5 (17) 1 (3)	*"TB, losing weight, skin can change, some people get a rash or get sores in the mouth" (Participant 22: Quote 39).* *"Especially the mind can get disturbed, losing your mind, not communicating with the people well, sometimes they speak to you and you are not even there. It is not a disease as such, but it becomes a disease if you begin to worry what is going on in your life" (Participant 28: Quote 40).*
	Healthy lifestyle	Diet Exercise Limit stress Don't smoke Don't drink Sleep Don't do drugs Drink water	19 (63) 14 (47) 11 (37) 7 (23) 7 (23) 1 (3) 1 (3) 1 (3)	*"Taking care of themselves, their bodies, trying to give their bodies a fair way of living…we need to eat good food as well there is good food and we also need to exercise, which I believe gives energy it gives the mind clarity to think very clearly" (Participant 1: Quote: 41).* *"Can't smoke or drink when on ARVs; smoke damages the lungs and beer damages the liver; you deteriorate faster and will die faster" (Participant 11: Quote 42).*

Participants' knowledge and understanding about how to manage their health, knowing they were HIV^{+}, was frequently reported when answering what they understood about living a healthy lifestyle. Wearing a condom to protect themselves when having sex (n=7; 23) and adhering to their HAART (n=4; 13%) were important aspects of self-care knowledge. Not taking their HAART medication was known to have detrimental consequences, as it could result in remission and development of co-morbidities. Knowledge concerning the importance of incorporating healthy lifestyle choices to manage HIV was reported.

Coping with HIV was considered an important facet influencing health, and coping beliefs and certain coping behaviours were identified as ways in which they attempted to live a healthy lifestyle. Table 5.8 is a representation of participants' coping with HIV.

Table 5.8: Theme 3: Health Character in the HIV Context (Coping with HIV)

Category	Sub-category	Codes/ Keywords	Code frequency n (%)	Quotes to illustrate
Coping with HIV	Coping beliefs	Supportive family Share with people To be happy Ignore gossip	5 (17%) 3 (10%) 1 (3%) 1 (3%)	*"Okay…like…let me think first…It is important to have support from my family, especially my mother, because in many ways she supported me in my life; if I am sick she was there for me" (Participant 10: Quote 43).*
	Coping behaviour	Watch television Using a cell phone Socialise Sleep Doing yard work Prayer	7 (23%) 4 (13%) 2 (7%) 2 (7%) 2 (7%) 1 (3%)	*"Me at home I can sit and watch TV and then the stress is gone. Sitting and watching TV helps to decrease my stress. If I am thinking about my child, my child passed away of HIV, but when I watch TV I can smile and forget and I can tell myself I must not stress myself" (Participant 13: Quote 44).* *"I enjoy doing yard work. I don't have a lot of flowers in the garden but I enjoy working in the yard. When I do yard work I forget about my problems and physically my body feels relaxed and it feels like my problems are gone. It is a way I handle my stress. Eating sweets and cookies are my best friends. I like eating it and it makes me feel relaxed within me. I can eat a whole bag of cookies or bag of sweets. My favourite is Romany Creams. It gives me the same feeling as if when I work in the garden" (Participant 9: Quote 45).* *"Personally I think prayer. Your religion. In order for me to do all of these things, I feel I can't do them on my own. I pray to God and believe that God will help me to do all the things I have to do" (Participant 8: Quote 46).*

The importance of having a supportive family (n=5; 17%) was considered an essential coping belief, as well as sharing problems with others (n=3, 10%). Certain pastimes, such as watching television (n=7; 23%) as a form of escape; and interacting with others by cell phone (n=4; 13%) were all ways of coping with HIV. Spirituality played an important role in one participant's ability to cope. A healthy lifestyle was often hindered by environmental factors beyond their control. Despite this reality, their ability to take responsibility for their health and self-regulate their behaviour were important components to function. Table 5.9 is a representation of their applications to manage HIV as part of their health character.

Table 5.9: Theme 3: Health Character in the HIV Context (Applications to Manage HIV)

Category	Sub-category	Codes/Keywords	Code frequency n (%)	Quotes to illustrate
Applications to manage HIV	Self-regulation	Adherence to HAART Knowing HIV status Protected sex Control reactions CD_4 count evaluation Don't rush things	17 (56.7) 13 (43.3) 7 (23.3) 2 (6.6) 1 (3) 1 (3)	*"You need to know your HIV status. You, if are living and you don't know your status you don't know where you belong. If you know, you know sometimes some people look healthy, when you ask them if they know their status, they say why should I know my status I am healthy. I don't do these things with men but maybe if you tried once you catch that disease. It is better to know your status and keep it that way. If you know your status, eat healthily and have less stress you will know you will be okay. You know now how you are going to live. If you don't know your status you are living anyhow" (Participant 2: Quote 47).* *"I think to take my medication at the right time. Not to take my medication at any time. If I take my medication at eight o'clock I need to take my medication at the same time. It is very important and healthy" (Participant 14: Quote 48).* *"You have to protect yourself from STI's, HIV and unexpected pregnancies. Sometimes people are throwing the babies in the dustbins because they did not use protection or anything" (Participant 16: Quote 49).* *"You must always know your CD_4 count, how much is the level of your CD_4 count. CD_4 count tells you how much is the virus active in you. The CD_4 count must be 200 and upwards and not less than that. We want it high and level" (Participant 6: Quote 50).*
	Behaviour	Drinking water Exercise Eating vegetables and fruit	10 (33) 9 (30) 7 (23.3) 6 (20)	*"I think I am doing half of it and not a 100% of what I should do. I need to exercise and eat healthy more often. That is the important thing. I can't afford to buy food I should eat. My work is not paying a lot. Such as vegetables and fruits and healthy food that I might need. I would eat anything at the moment*

Category	Sub-category	Codes/Keywords	Code frequency n (%)	Quotes to illustrate
		Washing hands Eating fish Sleep enough Gardening Washing fruit and vegetables Eating pap and meat Time for relaxation	5 (16.7) 3 (10) 3 (10) 2 (6.6) 1 (3) 1 (3)	*because I don't have the income to buy healthy food. Exercising; I am trying by working hard, like cleaning/ scrubbing/ cleaning the floor/ bending/ washing and everything and at least not to sit down but to do something. Just to be active" (Participant 3: Quote 51).* *"Doing your own yard work and housework is important if you have the strength. Some people are too sick and can't do their own house or yard work and just sit. If you can, it is important, and it is part and parcel of exercises, and you will grow your own vegetables in your own yard. The vegetables will be fresh out of your garden, unlike buying vegetables from the market. Because now other people don't have money to buy vegetables because if you have vegetables in your yard you can cook the spinach and cabbage from your yard" (Participant 12: Quote 52).* *"Most of we black people prefer eating pap because we don't have money to buy rice every day and spaghetti or macaroni or buying take-away. It is starch food" (Participant 16: Quote 53).*
	Environment	Job Family	5 (16.7) 3 (10)	*"Yes it is important to have a job so that you will be able to buy food to be able to take your medication" (Participant 25: Quote 54).* *"Fruits I don't eat every day because sometimes we don't have money. Fruits are the same price as vegetables but vegetables you can cook; cabbage you eat today and put it in the fridge and tomorrow again. Sometime you buy five apples or oranges - after two days they start to rot. The vegetables last longer than the fruit" (Participant 30: Quote 55).* *"If I have a job I will buy myself Flora for my heart and olive oil and I would not use normal oil. I can't afford them at the moment and are taking the cheaper option" (Participant 19: Quote 56).* *"I don't have family support. No one knows I am HIV positive. If they know they would not be supportive. They do not like my boyfriend, and said that if he brings me into trouble they will not help me. That is why I don't tell them that I am positive" (Participant 18: Quote 57).* *"I work in Jo-burg, but my house is far away in Kimberley. Sometimes I want to go home because I miss my family, but I need to work to earn money. I would want to see my family more and earn more money to be more financially independent" (Participant 21: Quote 58).*

Knowing their HIV status (n=13; 43.3%) was an important component to self-regulation, as it represented responsible behaviour and facilitated action by adhering to HAART (n=17; 56.7%) and taking responsibility for their health. Unemployment was an environmental factor that prevented participants from living a healthy lifestyle. It had a severe effect on stress levels, diet and, possibly, their adherence to HAART. Family dynamics (being a single parent, non-disclosure to family members or living far from family) were an environmental factor that influenced health character, as it affected their support structure. Participants were applying healthy lifestyle choices in their lives by performing certain behaviours as they were able

Section 5.8 consists of a discussion of the results found in study 2, evaluating participants' self-perception and behaviour towards IHD.

5.8 DISCUSSION

The aim of the study was to determine the nature of the participants' self-perception and behaviour in relation to the risk of IHD. This is said to depend on knowledge and understanding of IHD (Meischke et al., 2000). Participants had fair knowledge and understanding relating to IHD, as they demonstrated positive knowledge of risk factors, signs and symptoms, and prevention strategies for IHD. They also had some understanding regarding the pathophysiology of IHD, as they reported that it could change blood flow and develop due to arteriosclerosis. Only one other published study that investigated the knowledge of risk factors for IHD and self-perception for the risk of developing IHD in PLWHA is available for comparison, namely, that of Cioe, Crawford and Stein (2013).

Cioe, Crawford and Stein evaluated IHD risk factor knowledge and risk perception in a cohort of HIV-infected adults in the USA. A cross-sectional study was done with 130 individuals where risk factor knowledge was assessed with the Heart Disease Fact Questionnaire. The sample achieved a mean value of 19 (±3.5), reflecting a fair knowledge of IHD. The demographics of the study were different from the current study: mean age (48 [±8.4] years), consisted mostly of male patients (62%), had more smokers (56%) and participants had had longer HIV exposure (14.7 years). The current study, being qualitative in nature, provides information regarding perspectives in a South African context of HIV, and highlights social difficulties encountered on a day-to-day basis. Background information regarding social impediments is helpful for planning an intervention to manage specific IHD risk factors. In-depth information is more difficult to collect with quantitative research, and absent from the study conducted by Cioe, Crawford and Stein (2013). Thus the two studies consider the topic (providing information regarding PLWHA's self-perception regarding the

risk for IHD) from different perspectives. Participants in this study demonstrated knowledge of IHD, as evidenced by their understanding of risk factors for IHD.

Participants described causes of IHD in relation to known risk factors for IHD. Stress, diet, HTN, cholesterol, being overweight and a family history of IHD were mentioned. Being overweight was reported as a cause, but by only one individual. The lack of understanding among participants of the causative role that overweight or obesity play in relation to IHD is of concern, considering that the cohort was overweight. Participants did not report being overweight or obese as part of their explanation of why they perceived themselves at risk for IHD. Thus it could imply either that they did not perceive themselves as overweight or that they did not view being overweight as a problem, or both. This finding is in contrast to international data regarding perceptions or beliefs regarding contribution of overweight to IHD risk (Pace et al., 2008).

Pace et al. (2008) reported that African-American individuals in rural areas in Alabama noted that being overweight or obese increased one's chances for IHD by 71.3%. The participants in their study also had knowledge of the link between overweight and obesity with high blood pressure (71.3%), diabetes (71.1%) and cancer (53.5%). In the West Africa region, Ansa, Oyo-Ita and Essien (2007) evaluated the knowledge of risk factors for IHD in a cohort of university staff in Nigeria. The authors reported that smoking (70.6%), alcohol use (52.8%) and obesity (41.6%) were most often reported as risk factors, and sedentary lifestyle as less so (16.6%). Having a post-secondary school educational level in the reported study determined whether individuals were able to note a sedentary lifestyle as a risk factor for IHD. The inverse relationship between education and IHD risk factor knowledge is well reported in the literature (Pace et al., 2008; Potvin, Richard and Edwards, 2000; Avis, Smith and McKinlay, 1989). Literature suggests that lower educational levels reduces one's knowledge of IHD risk factors. Ansa, Oyo-Ita and Essien (2007) also explained that a sedentary job in the African culture is seen as an elevation in social status, and therefore not often associated with IHD risk by the less-educated. Performing jobs involving physical labour can also influence one's perception regarding performing exercise.

Airhihenbuwa et al. (1995) reported that African-Americans believed that, since they performed jobs that involved physical labour, they needed to rest in off-work time and not perform additional exercise. In the current study few participants (n=8; 26.6%) had post-secondary school education that might have influenced their knowledge of the risk of a sedentary lifestyle for IHD. The majority of participants were employed (n=17; 56.7%) and performed work that involved physical labour, e.g. domestic workers or waiters. Lack of

exercise (n=2; 7%) and smoking (n=4; 13%) were mentioned less often than diet and stress as causative factors for IHD. The lower level of reporting of lack of exercise as cause for IHD could be due to participants not knowing the link between IHD and physical inactivity, or possibly to a belief that additional exercise is not necessary because of their active jobs. The objective in this study was not to determine beliefs regarding exercise, and further research is warranted to evaluate this question. The lower number of participants that reporting smoking as harmful is most probably due to the low number of smokers in the cohort (n=3; 10%). Studies have indicated that smokers more often interpret smoking as a risk factor for IHD than non-smokers (Hamarneh et al., 2012; Silagy et al., 1993). This could explain participants' lack of belief of smoking as risk factor for IHD. Participants referred to diet frequently in the interview.

Participants noted that diet plays a significant role in causing IHD, and a change in diet was reported as a prevention strategy for IHD. An unhealthy diet by eating too much or eating a diet high in fat and/or sugary substances was reported to increase one's chances of developing IHD. The importance that participants linked to diet is understandable: firstly, the role that diet plays in the management of HIV has received focus from the national media in SA, due to sensational and controversial information provided by a previous Health Minister (BBC News, 2006). The information provided to PLWHA regarding diet has been updated since then, and education regarding a healthy diet is now often included as part of health programmes at HIV clinics in SA. The HIV clinic that participants frequented advised them to attend the clinic's health and HAART adherence programmes on enrolment to the clinic. These programmes included advice on eating a healthy diet. It is therefore not surprising that participants considered a diet high in fruit and vegetables part of living a healthy lifestyle.

Secondly, national advertising through television media, e.g. Flora margarine campaigns, often advocates low-fat options for a healthy heart. Watching television was reported by individuals as a coping strategy, and seeing these advertisements could have added to their knowledge of the topic. This was illustrated by one participant's explanation which referred specifically to Flora. A noticeable lack of knowledge and understanding relating to salt intake and its relationship to HTN and IHD was exhibited by participants. Three individuals (10%) were known hypertensives, and neither they nor the other participants referred to salt intake in discussions on diet. The finding in the current study could be explained by those of Pace et al. (2008), who noted that participants in their study were more likely to maintain that salt intake had an effect on blood pressure or IHD risk if it was of concern to them, or if they had an educational level greater than high school. Additional

education regarding the effects of a diet high in salt on blood pressure levels, and the consequent risk of developing IHD could be included in health programmes for PLWHA.

Participants' diet was also given as one reason why they perceived themselves at risk for IHD. Disagreement was noted between dietary knowledge and practice. The majority of participants (n=16; 53.3%) were able to partake in daily fruit and vegetable intake, but unable to consume three to five vegetables and fruit combined daily (n=20; 67.3%). Environmental factors such as financial constraints due to unemployment, low salaries or absence of financial support from life-partners were offered as explanations for their dietary choices. Growing own produce was suggested as a solution to overcome these environmental problems, but physical impairment such as lack of strength were noted as hindrances. Participants also opted for buying produce from street vendors or made different dietary choices to limit cost. Dietary practices were therefore partly due to external factors, and not necessarily to lack of knowledge or unwillingness to change behaviour. Individual participants, however, did choose to follow dietary behaviours that put them at risk for IHD, despite knowing that it was unhealthy. IHD is said to develop due to factors that act synergistically, and minor adjustments in one lifestyle risk factor in the presence of others can have a significant effect on overall risk (Silagy et al., 1993). In these individuals, where education regarding diet is not effective, management of their other risk factors for IHD might lower their overall risk.

Psychological factors, such as stress and 'thinking too much' were frequently reported in the interviews as important causative factors for IHD. An inter-relationship between 'thinking too much' and stress were noted in discussions. Worry and panicking were concepts that included it, and were reported to result in stress or to escalate stress levels. The subjects of the worry included their children and what would happen when they are no longer there; finances and employment. Naturally, these aroused high levels of stress. The concept of worry is reported in literature on chronic diseases. Boutain (2001) noted that African-American individuals in Louisiana, living with HTN, often expressed worrying about their family and financial burdens. Worrying about others was also reported by women with IHD, and perceived to exacerbate their disease (Lisk and Grau, 1999). Angus et al. (2007) also noted that stress-talk in women, when evaluating risk for IHD, was often centred on caring for spouses and children, and balancing these with other work responsibilities. Stress in Boudain's (2001) study was linked to participants having to do multiple tasks and confronting prejudice in the workplace and surrounding community.

Prejudice against PLWHA is a reality, and one reason why individuals fear disclosing their status because of the uncertainty of how others might react (Bogart et al., 2013). Social

support, such as support from significant others and others with similar experiences are reported in the literature as aids in managing stress (Thoits, 2011). These stress-management methods (Mkandawire-Valhmu et al., 2013), and also spirituality (Dalmida et al., 2012; Hodge and Roby, 2010), are coping strategies employed in HIV populations. Coping strategies for participants in the current study were: sharing with others, receiving support from family, socializing and prayer. Non-disclosure of status can therefore create a form of isolation where some coping strategies, such as sharing with others, are not possible, and could compound the stress, as described by one participant. Most participants had disclosed their status to family or friends they could trust, and used sharing with others as a form of coping behaviour to manage their stress levels, as well as coping with their HIV status in general.

A number of participants perceived themselves to be at risk of developing IHD. Twelve participants (40%) perceived themselves to be at risk of IHD. This self-perception was due to a combination of behavioural aspects, and also to physical symptoms. When evaluating this perception it is important to remember that the current study consisted mostly of women participants (n=25). Literature suggests that women often underestimate their risk of IHD (Hart, 2005; Legato, Padus and Slaughter, 1997), but are more likely than men to perceive behaviours such as smoking and diet as harmful (Silagy et al., 1993). Stress in women less than 60 years old is also noted to be high, or very high, when evaluating risk perception for IHD, and is a risk factor to be monitored closely (Legato, Padus and Slaughter, 1997). In this regard, it is not surprising that behavioural aspects expressed by participants included an unhealthy diet, stressing too much, smoking and not exercising enough. Preferring a diet high in fat content was one such reason reported, and this could have been related to exposure to culture-specific food from an early age. Literature states that individuals often maintain that self-perceived risk of IHD due to dietary behaviour and dietary practices related to culture are hindrances that need to be overcome when addressing IHD risk (Angus et al., 2009). Insufficient exercise was another reason reported, and they attempted to increase activity during the day if they were not able to perform formal exercise.

Of greater concern were the physical symptoms that a few participants experienced that informed their belief regarding their risk for IHD, including chest pain with referral and perceived alterations in heart rate. Known cardiac symptoms include chest pain, chest pain with referral to upper extremity or jaw or back, and, often, palpitations (Collins and Dias, 2009). Reasons why participants had not acted on their symptoms and requested medical advice could be due to a number of factors. Bodily sensations provide information to the individual, and, depending on one’s previous experiences, a person might or might not act

on these experiences (Corbin, 2003). Corbin (2003) states that individuals are likely to 'wait and see what happens', and if the sensations become more frightening they will then seek medical advice. The Shifting Perspectives Model of chronic illness described by Paterson (2001) could also be used to explain the reluctance to seek medical advice. The Shifting Perspectives Model demonstrates that individuals living with chronic illness, e.g. HIV, continually shift between two states: illness-in-the-foreground or wellness-in-the-foreground. Wellness is determined by comparing the experience, e.g. chest pain, to what is known and understood about the illness and *vice-versa*. Paterson (2001) explains that a perception of threat to one's control is the major factor that will move an individual from a state of wellness-in-the-foreground to illness-in-the-foreground. Study 1, that determined the non-invasive risk factors for IHD, highlighted that participants' medical histories included a number of illnesses. These previous physical experiences could have determined whether they considered their current symptoms frightening or not, and hence influenced their actions. This notion is supported by Meischke et al. (1995), as their study findings indicated that reasons why patients with chest pain delay seeking help were belief that symptoms would go away, or that the symptoms were not severe enough, or that they thought it was due to another illness. Individuals also perceive themselves to be at a greater risk of IHD if they perceive their general health as poor (Meischke et al., 2000). In the current study no participants held this perception, and only eight (26.7%) thought their general health was average. Participants also reported that their health had improved when they initiated HAART, and thus could not come to terms with the idea that they might now be at risk of another threatening disease, IHD.

When contrasting participants' self-perception for risk of IHD to their non-invasive risk factors screened in study 1, some agreement was noted in behavioural risk factors. Actual risk factors present in the study cohort included: not consuming enough daily fruit and vegetables; moderately high stress levels; overweight; raised RHR; not active enough (a portion of the sample); smoking and HTN. The number of participants that viewed their behaviour as reason for increased risk of IHD was less than those presenting with the actual risk factors screened. Cioe, Crawford and Stein (2013) had similar findings. They noted that smoking (56%), pre-hypertension (48.5%) and overweight (BMI 27 ± 5.5 kg/m^2) were traditional risk factors encountered in their Boston cohort of PLWHA. Information relating to perceived risk of IHD was collected by participants using the Perception of Risk of Heart Disease Scale. The total mean score in the authors' sample was 53.1 (±5.9). Estimated risk for IHD was calculated by the FRS. The authors found that estimated and perceived risk for IHD had a weak correlation ($r=0.24$; $p=0.01$) in their study sample. Further education strategies are therefore indicated to assist individuals in seeing the

relationship between their behaviour and risk of IHD, and to assist them in implementing prevention strategies.

An important finding highlighted in the study was that participants did not perceive themselves to be at risk of IHD due to being HIV^+ or using HAART. They were unaware that these factors could put them at risk of developing IHD over time. Their perception regarding HAART usage was positive, as it was seen to make them healthy and not to cause other ailments. Informing individuals of the effects of the virus on the cardiovascular system, and of the effects of different HAART regimens on their risk of IHD could improve adherence to behavioural lifestyle strategies.

Important aspects regarding health character were identified in the course of the study that did not directly inform their self-perception of IHD, but did influence their general behaviour, and are worth mentioning. Participants presented with social difficulties in the form of unemployment, financial constraints and single parenthood. These difficulties were a significant source of stress, but did not prevent them from attempting to improve their health and make the most of their situation. They were actively engaged with their health condition. Participants were HIV^+ and engaged in active management of their disease by attending clinic appointments, using HAART and implementing clinic advice as able. They were also knowledgeable about HIV; knew how to prevent re-infection, what parameters to monitor to evaluate their status, and had an understanding of the co-morbidities that can occur. This level of knowledge about HIV is supported by Mkandawire-Valhmu et al. (2013), as evaluated in a study where the capacity of women living with HIV in low-income areas in Malawi and Kenya were evaluated. A culture of responsible health behaviour was present in participants with regard to their HIV status. Due to the ingrained culture of going to the clinic and seeking medical advice, it is not surprising that visiting the clinic for medical advice and/or having heart surgery were prevention strategies for IHD mentioned by participants. Of concern was that they believed that heart surgery was the only course of action to take when confronted with the possibility of being diagnosed with IHD. Educating individuals on the other avenues available for the prevention of IHD is necessary. The influence of their actions through healthy behaviour should be reinforced, to emphasise to them that their behaviour affects their HIV condition, and also overflows, and can prevent IHD to some extent.

5.9 CONCLUSION

This is the first study to be conducted on PLWHA in a South African population where the nature of participants' self-perception and behaviour in relation to the risk of IHD was investigated. It highlights the status of individuals' perception in a South African context,

where the demographics related to HIV prevalence are different from the rest of the Western world. Women are more afflicted by HIV in the South African region, and internationally women often perceive their risk of IHD to be low. In the current study 40% of participants perceived themselves to be at risk of IHD due to behavioural aspects and physical symptoms. The larger portion of the sample (50%) presented with an optimistic bias due to not perceiving themselves at risk when they presented with risk factors. Three (10%) participants were unsure of their own risk.

Participants presented with positive knowledge about IHD, but this knowledge was not often used when reviewing personal risk. Actual risk factors for IHD were present, and moderate agreement was noted between actual and perceived risk factors.

Responsible health behaviour was noted, as reflected by active involvement in their HIV management and knowledge ability related to their HIV condition. Participants attempted to follow healthy lifestyle choices, but were often hindered by social hindrances. Education strategies regarding how overweight, and a positive HIV status with treatment interventions, influence risk of IHD are required in PLWHA to inform their personal risk perception of IHD.

Chapter 6a consists of an explanation of the development of the education physical activity diary. This was used in the intervention evaluating the effects of an education and home-based walking programme on risk factors for IHD in PLWHA. Details of the intervention are elaborated on in study 4 (chapter 6b).

CHAPTER 6A

6a. STUDY 3: DEVELOPMENT OF THE EDUCATION PHYSICAL ACTIVITY DIARY

6a.1 INTRODUCTION

Education and therapeutic exercise are recognised treatment modalities in physiotherapy practice to improve health. They are used as prevention strategies for medical conditions and to manage known pathologies present in patient populations (Dean, 2009). A suggested method for providing education to assist individuals in changing a specific behaviour - for example, physical inactivity - is through providing information material (Evans, 2013; Whitlock et al., 2002). This chapter outlines the development of the education physical activity diary that was used in the intervention in study 4.

6a.2 STUDY 3

6a.2.1 Aim and Objectives

Aim:

To create an education physical activity diary for use in an education and home-based walking programme to mitigate associated risk factors for IHD in individuals infected by HIV and on HAART.

Objectives:

- To create the education material for the diary.
- To create the self-monitoring tools for the diary.
- To validate the content of the education material for the diary.
- To design and construct the diary.

6a.3 METHODOLOGY

The function of the education physical activity diary was twofold: it provided education material specific to the objectives of the intervention programme of study 4, and it was used as a self-monitoring tool by participants in the intervention programme. The first objective was thus to create the education material to be included.

6a.3.1 Education Material of the Physical Activity Diary

In the course of studies 1 and 2 differences in the level of the study participants' understanding and knowledge of IHD became apparent. The 'knowledge' referred to the risk factors for IHD and why physical activity was important in reducing the risk of IHD. To ensure that all the participants began the intervention with a reasonable baseline understanding of IHD, it was decided to include relevant information in the educational

material. A systematic literature review was undertaken related to IHD: risk factors for IHD; the importance of physical activity; guidelines for physical activity in the general population; and the same, specific to PLWHA. The information obtained laid the groundwork for the education material of sections A and B of the diary. Figure 6a.1 is a representation of the education material for section A.

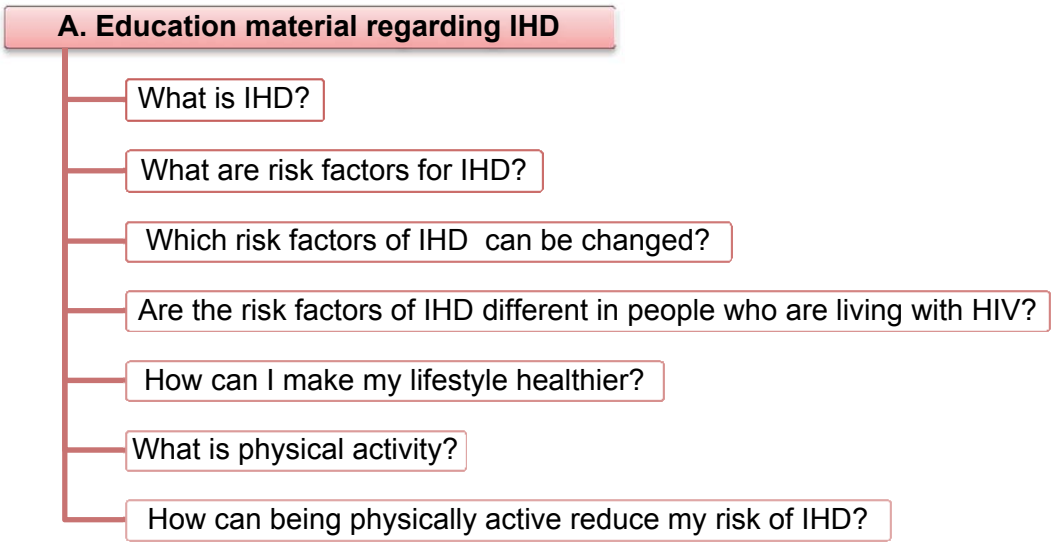


Figure 6a.1: Education Material Regarding IHD Included in the Physical Activity Diary

Figure 6a.2 is a representation of the education material included in section B.

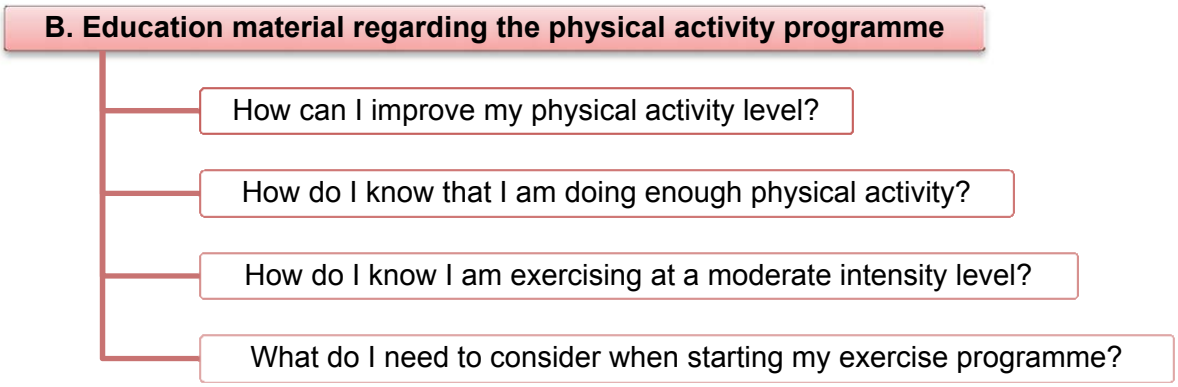


Figure 6a.2: Education Material Regarding the Physical Activity Programme

Warm-up and cool-down exercises were included in the education material. This was to educate participants on a range of motion exercises of specific joints and muscle stretches of targeted muscles before performing a focused walk, as a prevention strategy for injury. The warm-up and cool-down exercises were included in section C. Figure 6a.3 is a representation of the activities included in section C.

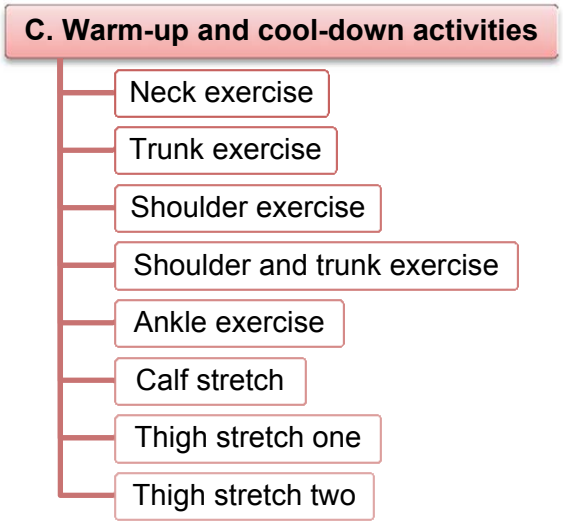


Figure 6a.3: Education Material Regarding Warm-Up and Cool-Down Activities.

Literature indicates that people who are being educated about IHD request information regarding how risk factors influence the heart, recommended normal values of risk factors and recommended duration and frequency of physical activity (Redfern et al., 2006). In addition, space for participants to record their values should be included (Redfern et al., 2006). These recommendations were applied in compiling the education material, and the self-monitoring tools were also included. The second objective was to create the self-monitoring tools to be included in the diary.

6a.3.2 Self-Monitoring Tools of the Physical Activity Diary

The self-monitoring tools consisted of a page where participants could document their assessment results. With the intervention focusing on increasing participants' pedometer physical activity levels incrementally, weekly physical activity tracking sheets were created. These were used for participants to document their pedometer physical activity level daily, and they provided space for comment on how they were feeling that week. The pages also carried the participants' weekly pedometer physical activity prescription, with heart rate intensity levels, for their knowledge and self-monitoring. Sheets for face-to-face sessions with the physiotherapist were created. On these sheets participants' suggestions regarding how to overcome their reported impediments to walking were documented for record and implementation. To remind participants of the function of the intervention, the aim and make-up of the physical activity programme was presented on the front of the dairy, together with a physiotherapy appointment schedule.

6a.3.3 Message Framing of the Education Material of the Physical Activity Diary

The message framing of the material was considered important for its influence on participants' motivation (Gallagher and Updegraff, 2012; Latimer, Brawley and Bassett, 2010). The benefits of being physically active were depicted in a gain-frame message; i.e., a positive, rather than negative cast, e.g. "it improves blood circulation", instead of a loss-frame approach. This followed literature suggesting that gain-frame messages are effective when promoting increased physical activity (Gallagher and Updegraff, 2012; Latimer, Brawley and Bassett, 2010).

With the success of the intervention being dependent on participants' willingness to change their behaviour by self-monitoring and increasing their daily step-count, a behavioural contract was added. Behavioural contracts are said to improve self-confidence regarding ability to perform a particular behaviour when implementing behavioural change interventions (Charlson et al., 2007). These contracts are said to embody the commitment that participants are willing to make when participating in interventions (Charlson et al., 2007). The academic peer review panel that reviewed the diary preferred term "commitment" to "contract" to avoid the suggestion of a legal document. The behavioural commitment document was placed in the front of the diary for participant review. A copy of the "Commitment to Myself" document is available for review in Appendix 28.

6a.3.4 Readability of the Education Material of the Physical Activity Diary

Readability of the material was considered important to ensure comprehension. To ensure readability the following suggestions by Albert and Chadwick (1992) and Jamison (2010) were implemented:

- Sentences were kept short.
- Understandable layman's language was used as much as possible.
- Attempts were made to frame messages according to individuals' environmental context.
- Sentences were written in the active voice.
- Attempts were made to keep the writing personal by using the words "I, me and you".
- Pictures were included to explain the text and to keep readers' interest.
- Clutter was reduced by adequate white space between writing.
- Non-gloss paper was used.
- Bold print was included as a typographical cue to suggest important information.

The readability of the education material was evaluated using the Gunning Fog Index before content validation by an academic peer review panel and a Themba Lethu patient group. In the Gunning Fog index the average sentence length and the number of words of

three syllables or more per 100 words is calculated (Jamison, 2010). The result is then multiplied by 0.4 to get a reading score. A score of between six and ten is considered “easy”, and above 13 requires a reading-level of a first year university student (Jamison, 2010). The score of these pages ranged from 4.8 to 11.4. Recommendations of the academic and patient groups, and also the Gunning Fog Index score, were implemented to improve readability.

The procedure followed to assist with content validation of the education physical activity diary is explained in section 6a.4.

6a.4 PROCEDURE

The procedure of study 3 consisted of content validation of the education material and the steps taken to construct the final version.

6a.4.1 Content Validation of the Education Material of the Physical Activity Diary

The steps taken to ensure the content validity were:

- The education material was developed as explained in section 6a.3.

- Content validity was evaluated by peer review, as recommended by Portney and Watkins (2009). The peer-review panel consisted of eight academics drawn from the Wits Physiotherapy department, selected to include individuals with the following knowledge: conducting clinical research in the public health care sector of SA, cardiopulmonary and HIV academic background, cultural sensitivity and correct English grammar usage. Suggestions made by the panel were implemented. See Appendix 29 for information regarding the suggestions made by the peer-review panel.

- The education material and self-monitoring tools were translated from English into isiZulu by a professional translator, and then back-translated into English by a second professional translator. Translation services were provided by Bangula Translation Services.

- Copies of the English and isiZulu education physical activity diaries were reviewed by a physiotherapist who occasionally worked at the study site and was fluent in English and isiZulu. His suggestions, consisting of minor language changes e.g. changing of particular words and isiZulu spelling corrections, were implemented.

- Copies of the English and isiZulu versions of the diary were then reviewed by five Themba Lethu patients voluntarily while waiting in the clinic queue for their medication. Their suggestions were implemented. Refer to Appendix 30 for a review of the background of the patients and their suggestions. The practice of including patients in the review process is supported in the literature, and is part of the member check to improve validity and credibility (Redfern et al., 2006; Hill and Bird, 2003).

Once the content validation process had been completed the education physical activity diary was constructed.

6a.4.2 Constructing the Education Physical Activity Diary

A graphic designer drew up the lay-out of the English and isiZulu diaries, based on discussions held with the researcher. The lay-out of both formats was reviewed by the researcher a number of times to ensure consistency between them before finalisation. Appendix 31 consists of a selection of pages from the final version.

Figure 6a.4 shows the cover page of the final edition of the education physical activity diary.

Figure 6a.4: Cover Page of the Education Physical Activity Diary

Chapter 6b consists of an explanation of the methodology, procedure, results and discussion related to study 4 of phase 2 of the research project. The aim of this study was to implement and evaluate the effects of the education and home-based walking programme on pedometer physical activity levels and secondary IHD risk-factor outcomes in individuals living with HIV and on HAART in Johannesburg, SA.

CHAPTER 6B

6b. STUDY 4: PHYSICAL ACTIVITY MODIFICATION AS PREVENTION STRATEGY FOR IHD

6b.1 INTRODUCTION

The promotion of adequate physical activity levels by means of physical activity modification methods is supported as a prevention strategy for IHD in PLWHA (Lundgren et al., 2008). Supervised structured exercise is one such method to increase physical activity levels and influence some risk factors for IHD (O'Brien et al., 2010). To date the effects of a predominantly self-monitored home-based education and pedometer walking programme on known modifiable risk factors for IHD are not known. Study 4 set out to investigate the effects of such a programme in PLWHA in a South African context.

The hypothesis statement of study 4 was as follows:

An individualised education and home-based walking programme would influence the associated risk factors of IHD in individuals infected by HIV (on HAART).

6b.2 STUDY 4

Study 4 is the final study of the research project (as set out in section 1.8 in Figure 1.1 of chapter 1), and tests the effects of a physical activity modification programme on selected risk factors for IHD.

6b.2.1 Aim and Objectives

Aim:

To determine the effects of a six-month individualised education and home-based walking programme on the associated risk factors for IHD in individuals infected by HIV, on HAART.

Objectives:

1. To determine levels of the following factors in individuals infected by HIV, on HAART:
   - physical activity
   - perceived stress
   - RHR and blood pressure
   - waist and hip circumference, WHR and BMI
   - Hs-CRP
   - lipid profiles (total cholesterol, HDL, LDL, and TG)
   - glucose

2. To implement an individualised education and home-based walking programme for affected individuals at risk of IHD, and monitor adherence to the programme.

3a. To determine whether an education and home-based walking programme has an effect on the pedometer-determined physical activity level of affected individuals.

3b. To determine whether an education and home-based walking programme has an effect on 6MWT distance, perceived stress level, RHR, blood pressure, WC, WHR, BMI, Hs-CRP, lipid profile and glucose levels.

4. To determine, in affected individuals, whether a correlation exists between Hs-CRP and evaluated related IHD risk markers.

5. To calculate the 10-year relative risk of IHD events in individuals living with HIV, using the Framingham Risk equation, and to evaluate whether an education and home-based walking programme had an effect on that relative risk.

6b.3 METHODOLOGY

6b.3.1 Study Design

A single blind randomised controlled trial was done.

6b.3.2 Sample Size

Information from a systematic review done by Ebrahim and Smith (1998) regarding the estimated change in SBP that occurs during an exercise programme was used as guide for sample size calculation. If the change in SBP is 6 mmHg (±7) with alpha set at 5% and the power at 80%, then the sample calculated using a sample size calculator was estimated at 22 participants for the intervention, and 22 participants acting as controls. To account for loss to follow-up a challenge faced by roll-out HAART centres in South Africa (Cornell et al., 2012) and non-adherence to exercise reported in PLWHA (O'Brien et al., 2010), 20% non-compliance and 20% drop-out rates respectively were selected as precautions for the eventuality of a decreasing sample size as the study progressed. This resulted in the sample used in the study: 42 control and 42 intervention participants.

6b.3.3 Study Subjects

Study 1 participants who were identified as being at risk of developing IHD were invited to continue with study 4.

6b.3.3.1 **Inclusion criteria**

Inclusion rested on the following criteria:

- Those on HAART for six months or more, aged 20 to 65 years, ambulatory without an assistive device and willing to accept randomised group allocation

Plus one or more of the following:

- A pedometer physical activity level of less than 10 000 steps per day
- A BMI value of ≥ 25 kg/m^2
- Increased WC (women ≥ 88cm, men ≥ 102 cm)
- Increased WHR (women ≥ 0.85, men ≥ 0.95)
- Blood pressure values in the high normal range (SBP 130-139 mmHg and DBP 85–89 mmHg) or mild hypertension range (SBP 140-159 mmHg and DBP 90-99 mmHg) (Collins and Dias, 2009)
- A known medical history of diabetes or HTN or dyslipidaemia (and on medical management)

6b.3.3.2 **Exclusion criteria**

The following individuals were excluded from participating:

- If they had moved out of the Gauteng province since the screening process.
- Noted to have a RHR > 100 bpm or blood pressure ≥ 160/ 100 mmHg in the screening process.
- Developed any condition or disease that was life-threatening or could be aggravated by exercise.
- Known acute infections or active AIDS-defining opportunistic illnesses.
- Were pregnant.
- Documented new mental illness.

6b.3.4 **Independent and Dependent Variables**

The independent and dependent variables of the study are documented in Table 6b.1.

Table 6b.1: Independent and Dependent Variables

Independent variable	Risk of IHD
Dependent variables	Primary outcome: Pedometer-determined physical activity levels Secondary outcomes: Perceived stress levels, 6MWT distance, RHR, blood pressure, BMI, WC, WHR, Hs-CRP, lipid profile and glucose levels, FRS.

6b.3.5 **Measuring Instruments**

Table 6b.2 is a representation of the measuring instruments used in the study. The literature review and justification for the use of these measuring instruments is provided in chapter 3: sections 3.2.1 and 3.2.3.

Table 6b.2: Measuring Instruments

Outcomes	**Measuring instruments**
Demographics	Demographic questionnaire (2) (Appendix 32)
Physical activity level	Yamax SW200 pedometer with physical activity log sheet (Appendix 14), pedometer accuracy test (Appendix 15), 6MWT evaluation form (Appendix 33), Standardised instruction in the 6MWT (Appendix 34), Borg scale (Appendix 35), two cones, two stools, Rolson measuring wheel, clipboard, pens.
Perceived stress level	PSS – 10 (Appendix 10)
Hs-CRP level, lipid profile and glucose level	Laboratory analysis of overnight fasting venous blood samples performed by Contract Laboratory Services.
Blood sampling equipment	Gloves, adjustable arm tourniquet, alcohol swabs, vacutainer needles, vacutainer holders, bar-coded grey glucose tube, bar-coded yellow serum-separating tube, cotton wool, plaster and medical sharps bin.
Body measurement equipment	9550 Onyx II Nonin finger probe pulse oximeter, Micro Health Stadiometer, Simple Choice electronic portable scale, non-stretch tape measure, Microlife BP A100 automated blood pressure sphygmomanometer, phase 2 evaluation form (Appendix 36).
IHD risk score	FRS tables (Appendix 37)
Adherence to exercise	Face-to-face session with physiotherapist contact session sheets (Appendix 38), photographed copies of Weekly Physical Activity Tracking Sheets in physical activity education diary (Appendix 39), Education physical activity diary, Post-Intervention Questionnaire (Appendix 40).

6b.3.6 **Randomisation Process**

The participants were randomised into either an intervention or control group with simple randomisation procedure using a Microsoft Excel randomisation formula to ensure chance allocation to groups (Schulz and Grimes, 2002). The randomisation process was done by a postgraduate academic, not directly involved with the project. The only restriction placed on the simple randomisation process was that the two groups (control and intervention groups) needed to consist of 42 individuals each. Refer to Appendix 41 for the randomisation list.

Concealment from group allocation was achieved by the same academic placing allocations in sequentially numbered envelopes to reduce selection bias (Viera and Bangdiwala, 2007; Schultz and Grimes, 2002). A fourth research assistant was recruited for the study, whose responsibilities were to perform all assessments with participants. She was blinded to group allocation to limit assessment bias.

6b.3.7 Training of Research Assistants

In the randomised controlled trial, the fourth research assistant did all baseline, six- and 12-month assessments. She was a qualified physiotherapist with an MSc degree in cardiopulmonary physiotherapy with basic cardiac life support certification. She was trained by the researcher over two sessions before the study in the measuring instruments and equipment to be used. In a third session she was oriented to the study site. A qualified nursing sister who specialised in phlebotomy did all blood sampling procedures. She was oriented regarding the aim of the study, the assessment procedures to be carried out, and blood sampling kits.

6b.3.8 Pilot Study of Study 4

Pilot study 4 was conducted before the study to evaluate the intra-rater reliability of the research assistant when assessing PLWHA. Details of this pilot study are presented in section 6b.3.8.

6b.3.8.1 Aims and objectives: Pilot study 4

Aim 1:

To determine the research assistant's intra-rater reliability for vital signs, anthropometric measurements and pedometer accuracy testing in individuals that were HIV^+ (on HAART) and at increased risk for IHD, as determined in study 1.

Objectives of aim 1:

1. To determine the research assistant's intra-rater reliability when assessing, in affected individuals (on HAART) and at increased risk for IHD, as determined by study 1:
   - vital signs: RHR and blood pressure.
   - anthropometric measurements: WC, hip circumference, height and weight.
   - accuracy of the Yamax SW200 pedometer

Aim 2:

To determine, in affected individuals (on HAART) and at increased risk of IHD as determined by study 1:

- the functional exercise capacity with the 6MWT
- whether a statistically significant difference in distance walked was noted between the first and second 6MWT trial.

6b.3.8.2 **Study subjects: Pilot study 4**

The participants in study 1 with an increased risk of IHD as determined by non-invasive risk factor evaluation were invited to continue with study 4, and included in pilot study 4.

6b.3.8.3 **Sample size: Pilot study 4**

The sample size of the pilot study (n = 8) was calculated at 10% of the sample size of study 4 (n = 84) (Hertzog, 2008). The pilot study thus consisted of the first eight participants of study 4 who were willing to stay longer at their first assessment session to allow for two 6MWT trials. The procedure and results from pilot study 4 with a short conclusion are available for review in Appendix 42. Key recommendations from the findings are outlined in section 6b.3.8.4.

6b.3.8.4 **Key recommendations: Pilot study 4**

Pilot study 4 found that the intra-rater reliability of the research assistant was good to excellent when evaluating participants' body measurements, except for the heart rate and blood pressure measurements performed on participants' left arms. The intra-rater reliability when assessing RHR using the left arm was r=0.79 (p=0.02), SBP using the left arm was r=0.70 (p=0.05) and DBP was r=0.61 (p=0.11). Because of the weaker correlation noted with RHR and blood pressure assessments using the left arm, it was suggested that she encourage participants to relax their upper limb and sit quietly a bit longer before the start of the assessments. This suggestion was implemented and changed the correlations of RHR to r=0.96 (p<0.00), SBP to r=0.90 (p<0.00) and DBP to r=0.89 (p<0.00).

The pedometer accuracy test findings between actual counted steps and pedometer-counted steps were r=0.66 (p=0.77) when the research assistant performed this procedure. All intra-rater reliability findings were very similar to the findings of the researcher's intra-rater reliability, as detailed in pilot study 2. It thus indicated that she followed the assessment procedure effectively, and that the equipment was giving reproducible results.

In functional exercise testing with the 6MWT no adverse side-effects occurred, as assessed with objective cardiovascular parameters, perceived breathlessness and fatigue. The median distance walked in the first 6MWT trial was 539.30 (490.03–572.80) meters and in the second trial 527.20 (489.48–588.40) meters. The correlation between the first and second 6MWT trials was excellent (r=0.95; p<0.00), and no statistically significant differences in distance walked between the

two attempts were noted (p=0.88). Due to the 6MWT finding and the difficulty regarding participants' ability to attend appointments as noted in study 1, only one 6MWT trial was done per participant in the remaining assessment periods of study 4. The procedure followed in study 4 is detailed in section 6b.4.

6b.4 PROCEDURE

Assessments in the study were done at baseline, six and 12 months by the research assistant. Each assessment time-slot consisted of two sessions per participant, resulting in two appointments per month. Figure 6b.1 is a flow diagram depicting the assessment activities performed.

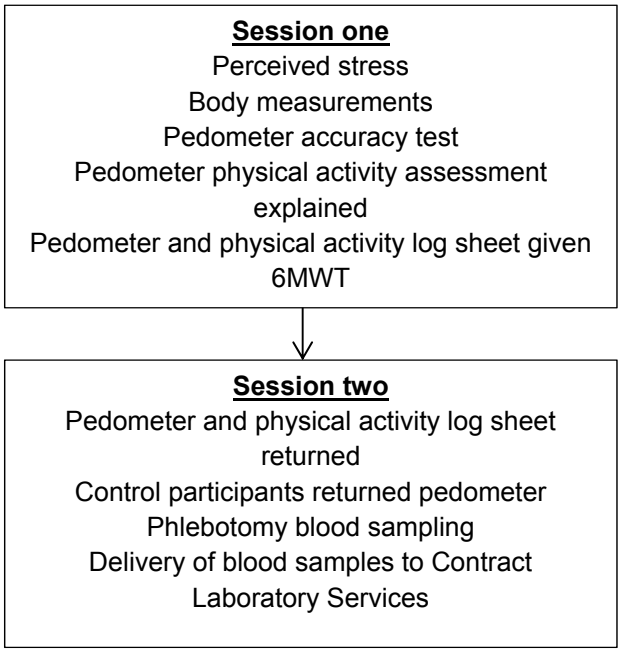


Figure 6b.1: Flow Diagram of Activities Conducted in Assessment Sessions

A. Baseline assessment

The first session with the research assistant was scheduled for each participant at the physiotherapy room in Themba Lethu clinic. If research appointment dates coincided with regular clinic appointments, the "runner" kept participants' place in the clinic queue to allow the research assistant to do their assessments.

At the first session information about participants' demographic details using demographic questionnaire (2) was taken. Parameters depicted in Figure 6b.1 were evaluated. The assessment procedures followed to evaluate body measurements, pedometer accuracy testing and 6MWT are available for review in Appendix 43. On completion of session one the researcher reminded the participants that the blood sampling procedure would be performed at the second session by a nursing sister who

specialised in phlebotomy. They also were given a verbal and written information reminder regarding the blood tests to be done (Appendix 44). Latest CD_4, viral load and liver function test results of participants were obtained from the clinic's electronic National Health Laboratory database system.

Pedometer physical activity assessment

In the period between the first and second assessment sessions each participant had to wear the pedometer for seven consecutive days and document her/his daily step-count on the physical activity log sheet when removing the pedometer in the evening. The second appointment was scheduled approximately eight to 14 days after the first. This was assessed at the beginning of the study, as a time lapse occurred between study 1 and 4.

The day before their second appointment a reminder SMS was sent to each participant of their physiotherapy appointment the next day, and that the fasting blood tests would be done. Participants did not have to respond to this message. If they did not have a cell phone, they were phoned on their land line. If they did not arrive for their second session, the researcher phoned them to enquire about the reason, and rescheduled the appointment. A maximum of two additionally-scheduled appointments was allowed throughout the study, before a participant was considered "lost to follow-up".

Phlebotomy blood sampling collection

At the second baseline assessment session all participants were introduced to the phlebotomist. They were asked to expose their arm and sit comfortably on an office chair at the blood sampling set-up station. The bar-coded glucose and serum-separating tubes were labelled with the participant's study code and initials.

Blood sampling was done through a venepuncture procedure at the median cubital vein. Immediately afterwards the tubes were gently mixed by inverting, as requested by Contract Laboratory Services. Each participant received a small fruit juice and savoury snack after the procedure. The nurse followed general infection control principles when performing the blood sampling procedure as suggested by the Program for Appropriate Technology in Health (2005). She:

- wore a lab coat
- washed her hands frequently
- wore latex gloves and changed gloves between patients
- disinfected the skin with alcohol wipes before blood sampling
- covered the puncture site with cotton wool and plaster following needle removal

- disposed of items in appropriate containers, e.g. medical sharps bin, medical and general waste bins

Contract Laboratory Service's requisition form (Appendix 45), containing the following information, was filled in following blood sampling: blood analysis to be done; the participant's study number, initials, age and gender; date and time of collection of blood sample and bar-coded sticker identical to that on the collection tubes. Bar-coded labels attached to the evacuation tubes, and relevant requisition form allowed for identification of equipment associated with each participant by both the laboratory and the researcher. The requisition form was signed by the phlebotomist and placed with the blood sample tubes in the individualised research kits for transport to the laboratory. Refer to Appendix 46 for a photograph of a study test kit and phlebotomy set-up station.

Quality control of blood samples following sampling

In the course of the study the blood sampling kits containing the blood sample tubes remained in the care of the researcher until she handed it over to the laboratory technicians. She transported the kits to Contract Laboratory Services directly on the same day. The time from sampling to delivery was well within that allowed for stability of specimens, as recommended by the laboratory. The results for electronic reports of the laboratory analysis were sent to the researcher within 24 hours. Hardcopy reports were received a few days later, and filed in the researcher's office for safekeeping and data-capturing.

Laboratory analysis of phlebotomy collected blood samples

Laboratory analysis of blood samples was carried out at Contract Laboratory Services, at the main chemistry laboratory in Johannesburg. Samples were analysed in order of receipt and on day of arrival at the laboratory. The analysis was conducted using the Roche/Hitachi Cobas C system (Roche Diagnostics, Mannheim, Germany) using the following tests:

- Fasting glucose level was enzymatically measured on a cobas c 501 analyser using the Glucose HK, Gen.3 test.
- Total cholesterol level was enzymatically measured on a cobas c 501 analyser using the Cholesterol Gen.2 test.
- HDL level was enzymatically measured on a cobas c 501 analyser using the HDL-Cholesterol plus 3rd generation test.
- Triglycerides were enzymatically measured on a cobas c 501 analyser using the Triglycerides test.

- High-sensitivity C-reactive protein was measured using the particle-enhanced immunoturbidimetric assay test principle on a cobas c /501 analyser, using the Cardiac C-Reactive Protein (Latex) High Sensitive test.

The Friedewald equation was used to calculate LDL, using the Disa laboratory computer system of Contract Laboratory Services. The Friedewald equation is: LDL = total cholesterol – HDL – (triglycerides/5). Details pertaining to the quality assurance strategies in place at the laboratory are outlined in chapter 3: section 3.2.3.

Management of randomisation of participants: Control and intervention group

At completion of blood sampling it was explained to participants that they had been allocated to the intervention or control group according to a computer-generated list, and that the researcher had not arranged membership of either group. At this time the specific participant coded envelope was opened to determine group allocation. If the participant was allocated to the control group the pedometer was returned, and they received feedback regarding their first assessment session findings. They were informed about management of the control group for the period between baseline and six-month assessments. They were telephonically contacted once per month to maintain contact and to determine whether any health or social (e.g. moved out of Gauteng province) changes had occurred. They continued with their normal Themba Lethu clinic management that included routine doctor consultations, nursing staff assessment of vital signs and collection of antiretroviral therapy from the clinic pharmacy. They did not receive any physiotherapy service during the study except scheduled research assessments. In the final monthly telephone call they were informed about the six-month assessment, and appointments were scheduled.

Participants in the intervention group received feedback regarding their first assessment session findings. They kept the pedometer and received an education physical activity diary. Then the intervention programme was initiated. The researcher conducted it, and they continued with their normal Themba Lethu clinic management at the same time. Refer to Appendix 47 for a detailed description of the intervention programme.

Monthly face-to-face sessions were held with each intervention participant and the researcher at the clinic. Attempts were made to schedule the research sessions to coincide with monthly clinic visits. In these sessions body measurements were taken to determine whether any physical changes had occurred. Adherence to individualised pedometer walking programmes was evaluated by checking whether participants had achieved their weekly pedometer step-count goals in the previous month. They were

asked to mention any obstacles to exercise they might have encountered. The researcher made suggestions for possibly overcoming these barriers to improve walking activity. The researcher used the "face-to-face contact sheet" to document the assessment findings and the discussions of the monthly session for her records. The assessment findings, barriers and suggestions to be implemented were documented on the "face-to-face session with physiotherapist" sheets in each participant's physical activity diary for their record and self-monitoring. Each participant gave verbal consent for photographing their notes made in their physical activity diary in these sessions, for analysis at a later stage. None of the participants withheld this consent.

For each monthly appointment the researcher sent a reminder SMS the day before. Participants who did not attend were contacted telephonically to find out the reason, and the appointment was rescheduled. The intervention participants attended monthly face-to-face sessions with the researcher, and received monthly SMS prompts in the baseline-to-six-month period to encourage adherence to the programme. Refer to Appendix 48 for a review of the SMS prompts. At the final face-to-face session the participants were reminded about the approaching six-month assessment, and appointments were scheduled. Figure 6b.2 is a representation of the contacts made between the researcher and participants.

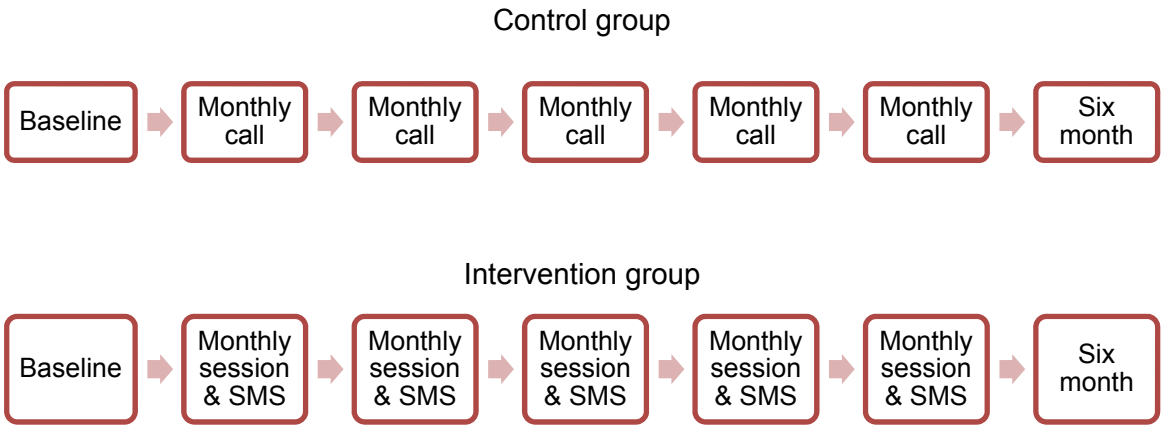


Figure 6b.2: Contact Sequence of Control and Intervention Group Management

B. **Six month assessment**

When the six-month assessments were scheduled participants were informed that the research assistant should not be informed about their group allocation, as she should remain blinded. They were therefore instructed to conceal their pedometer until they were seated in the research room. The researcher had a private consultation with each participant in the research room for five minutes before the assessment with the

research assistant. In this time control participants received a pedometer that was positioned at the waist and reset to zero. Intervention participants were instructed to keep their physical education diary in their bag or handbag, to prevent the research assistant accidentally finding out their group allocation. Their pedometer position was reviewed and reset to zero. These precautions were taken to ensure that the research assistant remained blinded to participants' group allocation. The assessment procedure was followed in the same manner as with the baseline assessments.

At the second assessment session, following blood sampling, intervention participants were requested to continue with their exercise programme in the six- to 12- month period. Both control and intervention participants were informed that the researcher would only contact participants again in the month before the 12 month appointment dates. If participants had any queries regarding their six month assessment findings they were responded to accordingly.

C. **Twelve month assessment**

In the six to 12 month period neither the researcher nor assistants had any contact with study participants. This was to determine participants' adherence to the physical activity programme with no motivation from the researcher. In this period the intervention participants still had their pedometers and education physical activity diaries for use while continuing with their individualised programme. Control participants continued with standard clinic care. In the month preceding the twelve month assessment control and intervention participants alike were contacted telephonically by the researcher to schedule appointments. The day before their appointments they were sent a reminder SMS.

At the last assessment session all pedometers and physical activity diaries were returned to the researcher. The intervention participants completed the post-intervention questionnaire, providing information regarding their adherence to the exercise programme over the six- and 12-month periods. Participants' queries regarding their 12th month assessment findings were answered. The participants were thanked for their participation in the research project at their final assessment session. The statistical analysis performed in the study is detailed in section 6b.5.

6b.5 STATISTICAL ANALYSIS

The data analysis was performed with the assistance of a bio-statistician using STATA 12.0 (StataCorp, 2011), IBM SPSS 21 (IBM Corp, 2012) and IBM SPSS 22 (IBM Corp, 2013). Intention-to-treat (ITT) analysis was selected as the primary analysis method of the study

and a confirmatory per protocol analysis was done. Intention-to-treat was selected as the primary analysis to ensure that the original random group allocation effect would be maintained, as suggested by Gupta (2011). A strategy to prevent any loss of data was to systematically follow up all participants, as set out in the procedure in section 6b.4.2 (White et al., 2011).

In the course of the study a number of participants dropped out. Explanations (provided in the results section) ensured that the missing data could be considered “missing completely at random” (European Medicines Agency, 2010). These “missing completely at random” data were managed by imputing the “last observation carried forward” of the particular individual (European Medicines Agency, 2010). An exception to this occurred in the case of three participants not returning for their second baseline assessment. Their missing baseline blood results were managed by imputing the mean value of the cohort’s results (European Medicines Agency, 2010). One of those three participants sent a friend to return her pedometer and baseline physical activity log sheet for use in data analysis. The two remaining individuals’ missing baseline pedometer data were managed by using their study 1 findings as a source for this data to be imputed (European Medicines Agency, 2010). Any absences of participants’ clinic viral load and/or liver function test results that were not available in the National Health Laboratory database were handled by imputing the mean value of the cohort’s specific results. These strategies ensured a complete data set for ITT analysis.

Evaluation of randomisation process

Data were evaluated for normal distribution. The randomisation procedure (baseline characteristics of the control and intervention groups) was evaluated with a two sample/ independent t-test or Wilcoxon rank–sum (Mann–Whitney) test for non-normally distributed continuous data. Categorical data were evaluated with the Pearson Chi Square test. A p–value less than 0.05 was considered statistically significant. Baseline characteristics of the intervention and control participants are presented as means (±SD) and frequencies with percentages. With few numbers in some categorical data, demographic categories were collapsed in analysis. Employment and self-employment both reflected a state considered employed, and so were collapsed. The last two categories of gross monthly income were collapsed to represent participants that earned more than R5 000 per month. Marital status categories were collapsed according to similar support structures, and housing according to similar house sizes. Lastly, transportation was collapsed into walking or wheeled transportation.

Evaluation of within-group management effect on IHD risk factors

The within-group mean changes in risk factors assessed, at the different assessment periods, were determined with repeated measures ANOVA. Results are presented as means (±SE), p-values and 95% CI in table format.

Evaluation of between-group management effect on IHD risk factors

The between-group management effect on IHD risk factors assessed, at the different assessment periods, were determined with repeated measures ANCOVA with baseline findings as co-variates. Findings of the ANCOVA analysis are presented as adjusted means due to co-variate inclusion (±SE) and between-group effect output (df, F, p-value, partial eta-squared) in table format.

Secondly, the study was of longitudinal nature, and to evaluate the associations of interaction effect between treatment (control or intervention group management) and time on the variables of interest, the generalised estimation equation (GEE) approach was used for between-group analyses. Three assessment intervals existed: baseline (84 individuals), six (84 individuals) and 12 months (84 individuals), totalling 252 assessments. To facilitate GEE the wide Microsoft spread-sheet format was altered to a long format, so that observations totalling 252 should be noted. The correlation structure selected in the GEE model was the exchangeable option, as this takes time into account (Ghisletta and Spini, 2004), with the identity link function due to data being continuous (Ma, Mazumdar and Memtsoudis, 2012). Due to skewness of the pedometer physical activity level data, these data were log-transformed for statistical analysis when adjusting for the secondary outcomes in the univariate and multivariate logistic regression model. A mixed effects model (MEM) analysis was added to provide information regarding the between-group individual participant changes (within participant effect) over time following GEE analysis. A wide-format data sheet was also used with MEM. Findings from the univariate logistic regression analysis in the GEE and MEM models are presented as log-transformed coefficients of mean change, 95% confidence intervals. To illustrate if changes were significant a p–value less than 0.05 was considered statistically significant.

The univariate logistic regression analysis was followed by multivariate logistic regression analysis to evaluate how the dependent variables reacted in the presence of others. The dependent variables that fulfilled a p–value less than 0.1 were added to the multivariate logistic regression model. A goodness-to-fit test was performed using Cook's Distance to identify any outliers in the pedometer physical activity data that could influence analysis before multiple regression analysis. To limit the effect of these outliers on the multiple regression analysis a restriction of less than +2 and more than –2 standardised residuals

were implemented to the MEM model. This restriction resulted in a reduction of observations from 252 to 240, as 12 observations fell outside the set parameters. A restriction of more than -3 and less than 11 was applied to the GEE model. This restriction reduced the observations from 252 to 249, as three observations fell outside the set parameters. Findings of the multiple regression analysis are reported with and without restriction using log-transformed coefficients of mean change, 95% confidence intervals and p–values. A p–value less than 0.05 was considered statistically significant. Refer to Appendix 49 for graphical illustration of the goodness-to-fit testing.

Evaluation of relationship between hs-CRP and evaluated IHD risk markers

Linear correlation with the Pearson correlation coefficient was used to consider the relationship between Hs-CRP and evaluated IHD risk markers at baseline and with univariate logistic regression in MEM to highlight if within individual findings differed. Due to skewness of the Hs-CRP data these data were log-transformed for statistical analysis.

Evaluation of participant adherence to the education and home-based walking programme

Statistical analysis to monitor adherence to the education and home-based walking programme was conducted in two ways: firstly, adherence to the programme in the baseline to six month period was done by the researcher partly using IBM SPSS 21 (IBM Corp, 2012) using descriptive analysis. Adherence to the programme was evaluated by firstly determining their monthly attendance of face-to-face sessions, and, secondly, establishing whether they achieved their weekly pedometer step-count goals per month. These data are presented as frequencies and percentages. Reasons for non-adherence to face-to-face sessions as explained telephonically by participants are given for review.

The barriers to, and enablers of, participants' achieving their weekly pedometer step-count goals were determined following a content review of the researcher's field notes recorded on participants' monthly "face-to-face session with physiotherapist" sheets. Keywords were identified on each sheet. To collapse the data, the keywords were collapsed into monthly keywords, then to monthly categories and finally to prominent overall categories. The photographed weekly physical activity tracking sheets of participants' diaries and returned diaries were reviewed for their explanatory quotes for categories determined.

Secondly, adherence to the programme during the six to 12 month interval was partly explained by the Anova analysis, as noted in change of pedometer physical activity level findings over time. Findings from the post-intervention questionnaire provided additional input regarding adherence to the programme. The following facets of adherence were collected from the questionnaire:

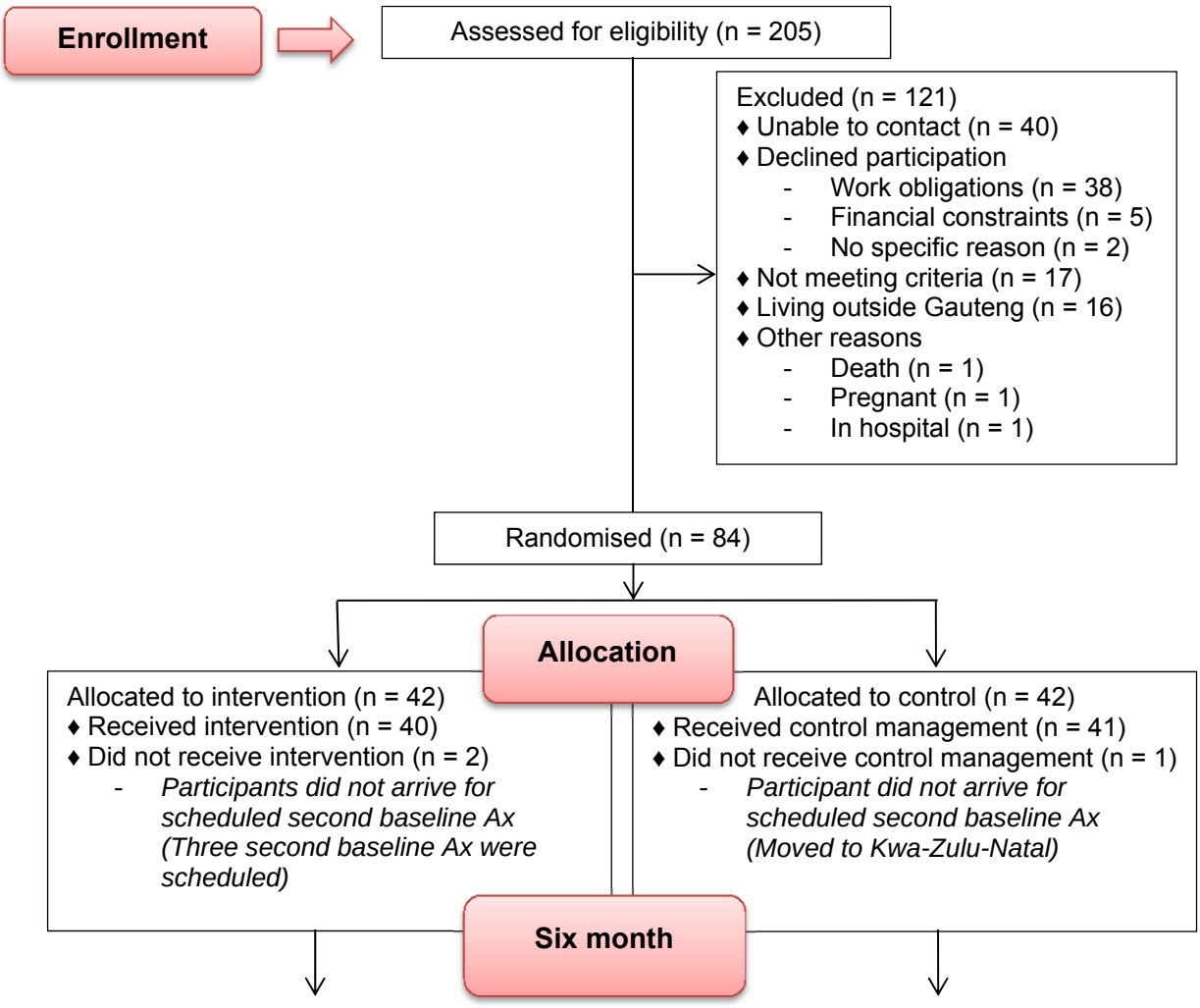
- Whether participants used the pedometer in the six to 12 month period.
- The frequency per week that participants performed a focus walk.
- Whether participants documented their pedometer step-count as an aid for self-monitoring.
- Whether participants performed the warm-up and cool-down activities regularly.
- How often participants performed the warm-up and cool-down activities.

This information is presented as frequencies and percentages in table format following IBM SPSS 21 analysis done by the researcher.

The results of Study 4 are presented in section 6b.6.

6b.6 RESULTS

The ITT analysis findings are presented for review in the results section. Figure 6b.3 is a consort diagram showing the participants' flow throughout the study.



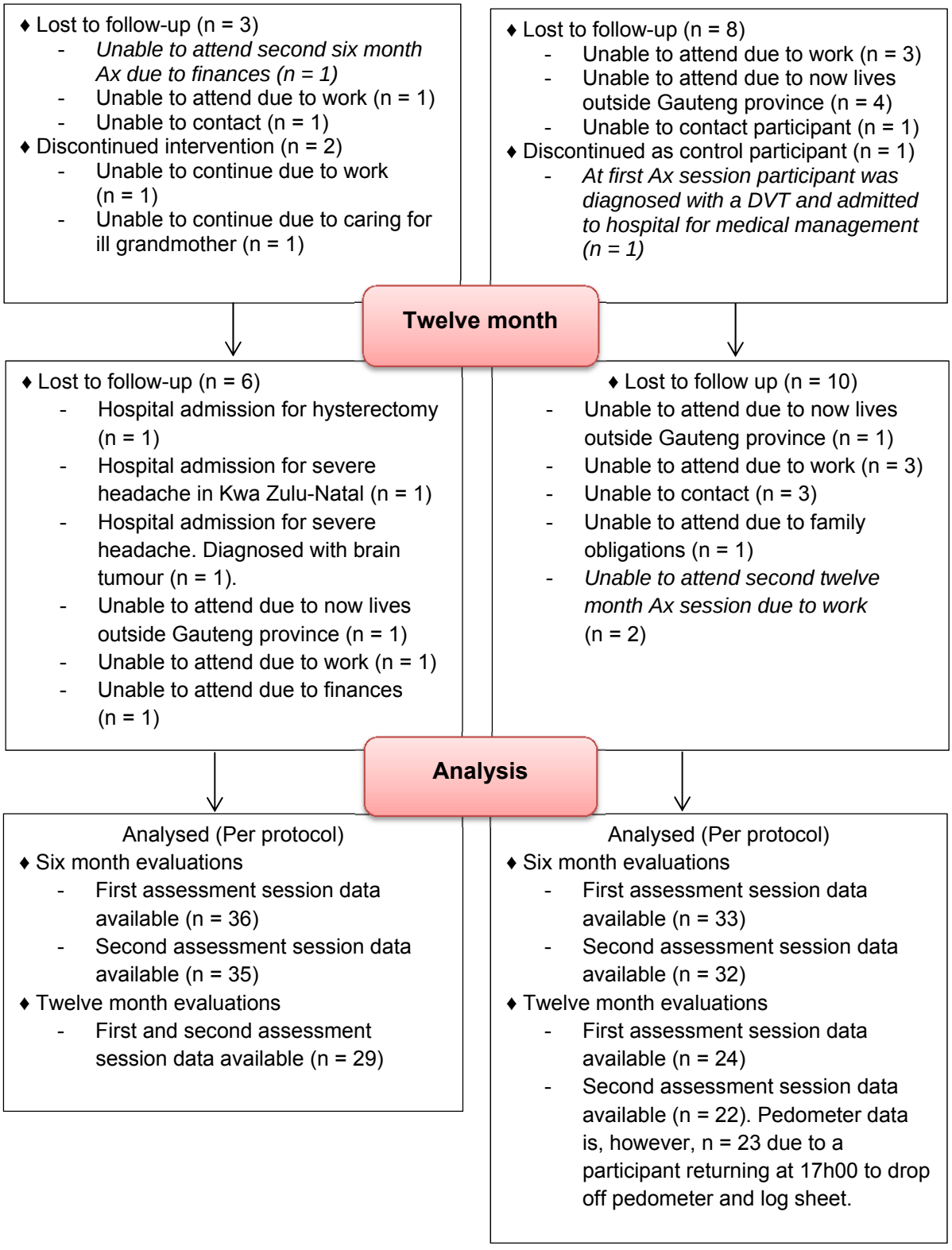


Figure 6b.3: Consort Diagram of the Study Participants Followed Up from 2012 to 2013

6b.6.1 **Baseline Characteristics of the Study Participants (N = 84).**

Tables 6b.3 – 6b.9 provide the results of the baseline levels for the socio-demographic profile, HIV-related clinical markers and IHD risk factors evaluated in the study. The

difference between the levels reported for the control and intervention groups were also tested and the p-values are presented for review. No significant between-group differences were noted. The socio-demographic profile is presented in Table 6b.3.

Table 6b.3: Socio-Demographic Profile of PLWHA (on HAART) (N = 84)

Variable	n	Intervention Group Mean (±SD) or n (%)	Control Group Mean (±SD) or n (%)	p-value
Age	42	38.7 (±8.9)	39.4 (±9.6)	0.7
Gender	42			
▪ Male		7 (16.7)	11 (26.2)	0.3
▪ Female		**35 (83.3)**	**31 (73.8)**	
Employment status	42			
▪ Unemployed		17 (40.5)	13 (30.9)	0.3
▪ Employed and self-employed		**19 (45.2)**	**26 (61.9)**	
▪ Retired and other		6 (14.29)	3 (7.1)	
Gross monthly income	42			
▪ Less than R500		**19 (45.2)**	**13 (30.9)**	0.3
▪ R501 – R1000		7 (16.7)	9 (21.4)	
▪ R1001 – R2000		6 (14.3)	9 (21.4)	
▪ R2001 – R5000		9 (21.4)	6 (14.3)	
▪ More than R5000		1 (2.4)	5 (11.9)	
Marital status	42			
▪ Single/ Widowed		**23 (54.8)**	**26 (61.9)**	0.8
▪ Married/ Cohabiting		12 (28.6)	10 (23.8)	
▪ Divorced/ Separated		7 (16.7)	6 (14.3)	
Housing environment	42			
▪ Share a space/ Shack		10 (23.8)	11 (26.2)	0.4
• RDP house/ hostel/ flat		9 (21.4)	6 (14.3)	
• Town/ residential house		**15 (35.7)**	11 (26.2)	
• Other		8 (19.1)	**14 (33.3)**	
Transportation	42			
▪ Walking		17 (40.5)	**21 (50)**	0.4
▪ Wheeled transport		**25 (59.5)**	21 (50)	

♦ R (rands), RDP (Reconstruction and Development).

The majority of participants were female (control [n=31; 73.8%] and intervention group [n=35; 83.3%]), employed (control [n=6; 61.9%] and intervention group [n=19; 45.2%]) and earned less than R500 per month (control [n=13; 30.9%] and intervention group [n=19; 45.2%]). Most participants fell in the single/widowed marital status category (control [n=26; 61.9%] and intervention group [n=23; 54.8%]). Intervention participants lived mostly in a townhouse or a residential house (n=15; 35.7%) and control participants in a room attached to a residential house (n=14; 33.3%), as demonstrated by the “other” category. Control participants mostly used walking (n=21; 50%) and intervention participants wheeled devices (n=25; 59.5%) as transportation methods. Fifteen (35.7%) intervention participants and nine (21.4%) control participants received a government child grant. Other sources of income included earnings from doing volunteer work, financial assistance from family members, pension and interest from investments.

Table 6b.4 summarises the HIV-related clinical markers of participants.

Table 6b.4: HIV-Related Clinical Markers of PLWHA (on HAART) (N = 84)

Variable	n	Intervention Group Mean (±SD) or n (%)	Control Group Mean (±SD) or n (%)	p-value	Normal range
Immune parameters	42				
▪ CD_4 count (cells/mm^3)		**340.3 (±132.4)**	**347.1 (±172.3)**	0.8	600-1500
- n (%): six month		29 (69)	23 (54.8)		(Van Dyk, 2008)
▪ Viral load (copies/ml)		**10 140 (±42 525.9)**	**2 793.9 (±15 252.2)**	0.8	
- <400		35 (83.3)	35 (83.3)		
- n (%): six month		35 (83.3)	32 (76.2)		
Liver function parameters (U/L)	42				
▪ Single ALT		26.3 (±15.5)	37.8 (±47.6)	0.3	7 – 56
- n (%): six month		28 (66.7)	25 (59.5)		(Gowda et al.,2009)
▪ Full liver function ALT		29.1 (±8.7)	33.2 (±24.9)	0.9	7 – 56
▪ Full liver function AST		30.5 (±5.2)	32.7 (±10.7)	0.8	0 – 35
▪ Full liver function GGT		56.4 (±20.6)	63.4 (±52.8)	0.7	9 – 85
- n (%): six month		1 (2.4)	1 (2.4)		(Gowda et al., 2009)
HAART exposure	42				
▪ TDF, EFV, 3TC		**26 (61.9)**	**32 (76.2)**	0.2	
▪ Other		16 (38.1)	10 (23.81)		
- 3TC, EFV, Stavudine		9 (21.4)	5 (11.9)		
- 3TC, TDF, Nevirapine		4 (9.5)	4 (9.5)		
- 3TC, Stavudine, Nevirapine		1 (2.4)	0 (0)		
- 3TC,Alluvia, Saquinavir		0 (0)	1 (2.4)		
- 3TC, TDF, Alluvia		2 (4.8)	0 (0)		

♦ Cells/mm^3 (cells per cubic millimeters of blood), copies/ml (copies of HIV RNA in milliliters of blood), U/L (units per liter), AST (aspartate transaminase), ALT (alanine transaminase), GGT (gamma glutamyl transpeptidase), TDF (tenofovir), EFV (efivarenz), 3TC (lamivudine).

The control and intervention groups' CD_4 counts were both below the suggested normal range for this value. The mean viral load findings were elevated but the majority of the sample had findings less than 400 copies/ml. Liver function results were within normal suggested ranges. More than 50% of the participants had a CD_4, viral load or single ALT test done in the preceding six months. Only two participants had had a full liver function analysis review in the six months preceding the programme.

A secondary analysis was conducted on CD_4 count and viral load findings of only the results of tests done in the clinic in the preceding six months. Findings were as follows: CD_4 count (control group: 365.3 [±169.5] cells/mm^3 and intervention group: 352.9 [±121.7] cells/mm^3) and viral load (control group: 3 435.7 [±17 459.2] copies/ml and intervention group: 9 882.6 [±45 269.2] copies/ml). In this analysis the CD_4 count improved slightly. There were still no statistically significant differences between the control and intervention groups' CD_4 count (p=0.9) or viral load findings (p=0.8).

The first-line South African HAART regimen (Tenofovir, Lamivudine, Efivarenz) was in use by 61.9% (n=26) of intervention and 72.2% (n=32) of control group participants (Department of Health, 2013). One control and two intervention group participants were on

a protease inhibitor-containing regimen. The remaining participants were on a HAART regimen containing two nucleoside reverse transcriptase inhibitors and one non-nucleoside reverse transcriptase inhibitor. Table 6b.5 contains the baseline physical activity level information.

Table 6b.5: Baseline Physical Activity Level of PLWHA (on HAART) (N = 84)

Variable	n	Intervention Group Mean (±SD) or n (%)	Control Group Mean (±SD) or n (%)	p-value	Normal range
Pedometer physical activity level, steps/day	42	**6 888.1 (±2 925.8)**	**8 102.7 (±5 395.6)**	0.8	More than 10 000 (ACSM, 2010)
6MWT distance, m	42	**540.7 (±71.6)**	**547.8 (±56.9)**	0.6	571 (±90) (Casanova et al., 2011)
Predicted 6MWT distance, m	42	690.6 (±36.5)	695.7 (±41.0)	0.5	868.8 – (age $_{years}$ x 2.99) – (sex $_{men = 0; women = 1}$ x 74.7). (Gibbons et al., 2001)
% Predicted 6MWT distance achieved	42	**78.2 (±8.8)**	**78.1 (±7.7)**	1.0	Distance walked/predicted distance x 100 More than 82% of predicted is normal range. (Troosters, Gosselink and Decramer, 1999).

♦ Steps/day (steps per day), m (meters), 6MWT (six-minute walk test).

Both groups' pedometer physical activity levels were less than 10 000 steps per day. Both groups achieved less than 82% of their predicted 6MWT distance, indicating a reduced functional exercise tolerance level. The 6MWT distance was less in both groups compared to the proposed normal mean distance for healthy individuals. Table 6b.6 is a representation of the smoking, HTN and diabetes mellitus history. Prevalence of these modifiable risk factors for IHD was low.

Table 6b.6: Baseline smoking, HTN and diabetes history of PLWHA (on HAART) (N = 84)

Variable	n	Intervention Group n (%)	Control Group n (%)	p - value
Smokers	42	4 (9.5)	5 (11.9)	1.0
History of hypertension	42	5 (11.9)	4 (9.5)	1.0
History of diabetes mellitus	42	0 (0)	1 (2.4)	1.0

Table 6b.7 consists of the baseline information related to perceived stress levels and body measurements.

Table 6b.7: Baseline Perceived Stress Levels and Body Measurements of PLWHA (on HAART) (N = 84)

Variable	n	Intervention Group Mean (±SD)	Control Group Mean (±SD)	p - value	Normal range
Perceived stress level	42	20.1 (±6.7)	20.1 (±6.4)	0.9	Normative values not available. 75th percentile for cohort = 24
Resting heart rate, bpm	42	**80.8 (±11.6)**	77.2 (±10.7)	0.1	Less than 80 (Palatini, 2007)
Blood pressure, mmHg ▪ SBP ▪ DBP	42	 **121.3 (±10.5)** 79.4 (±8.1)	 **120.1 (±12.8)** 78.2 (±8.6)	 0.6 0.5	 Less than 120 Less than 80 (Collins and Dias, 2009)
Body mass index, kg/m^2	42	**25.9 (±4.0)**	**25.4 (±6.5)**	0.9	18.5 – 24.9 (WHO, 2004)
Waist circumference, cm - Men* - Women**	42	81.3 (±7.5) 78.0 (±8.9) 81.9 (±7.1)	79.8 (±12.6) 77.4 (±10.4) 80.7 (±13.3)	0.5	Less than 102 Less than 88 (ACSM, 2010)
Waist: hip ratio - Men* - Women**	42	0.8 (±0.1) 0.8 (±0.1) 0.8 (±0.1)	0.8 (±0.1) 0.8 (±0.1) 0.8 (±0.1)	0.5	Less than 0.95 Less than 0.86 (ACSM, 2010)

♦ Bpm (beats per minute), mmHg (millimeters mercury), cm (centimeters), kg/m^2 (kilograms per square meter), m (meters)

* Control group men (n=11; 26.2%) and intervention group men (n=7; 16.7%).

** Control group women (n=31; 73.8%) and intervention group women (n=35; 83.3%).

The mean RHR of the intervention group was slightly elevated when considering risk for IHD. Blood pressure findings for both groups were within the pre-hypertension range (systolic blood pressure: 120–139 mmHg; diastolic blood pressure: 80–89 mmHg) (Collins and Dias, 2009). Both groups were overweight (mean BMI > 25 kg/m^2, but less than 30 kg/m^2) (WHO, 2004). The mean WC and WHR results were normal, but when considering the standard deviations, individual women in the control and intervention groups had above-normal WC readings. Both groups' perceived stress levels were moderately high when taking into account the 75th percentile for perceived stress being a score of 24 out of 40. Table 6b.8 is a representation of the baseline results of the biochemical IHD risk factors assessed. The National Cholesterol Education Programme, Adult Treatment Panel III Guidelines (George et al., 2009; NCEP ATP-III, 2002) were used as guide in interpretation of the lipid profile and glucose results.

Table 6b.8: Baseline biochemical risk factors for IHD of PLWHA (on HAART) (N = 84)

Variable	n	Intervention Group Mean (±SD)	Control Group Mean (±SD)	p-value	Normal range
Glucose level, mmol/l	42	4.8 (±0.7)	5.1 (±1.8)	0.5	< 5.6 (NCEP, 2002)
Lipid profile, mmol/l	42				
▪ Total cholesterol		4.3 (±0.8)	4.3 (±1.1)	0.9	< 5.0
▪ HDL		1.4 (±0.5)	1.4 (±0.4)	1.0	> 1.0
- Men*		1.1 (±0.6)	1.2 (±0.2)		> 1.3
- Women**		1.5 (±0.6)	1.5 (±0.4)		< 3.0
▪ LDL		2.5 (±0.7)	2.5 (±0.8)	0.6	< 1.7
▪ TG		1.0 (±0.5)	1.0 (±0.4)	0.5	(NCEP, 2002)
Inflammatory parameter, mg/l	42				
▪ Hs-CRP		**8.6 (±8.4)**	**5.4 (±6.6)**	0.05	Low risk < 1.0 Moderate risk 1.0–3.0 High risk > 3.0 (Pearson et al, 2003)

♦ Mmol/l (millimoles per litre), mg/l (milligrams per litre).

* Control group men (n=11; 26.2%) and intervention group men (n=7; 16.7%).

** Control group women (n=31; 73.8%) and intervention group women (n=35; 83.3%).

The mean glucose and lipid profile results were within normal ranges. If one takes into account the standard deviations, abnormal results were found in the glucose level of individual control participants. The mean glucose level in the control group might have been higher, as one individual had known diabetes mellitus. This was confirmed by secondary glucose analysis omitting this individual's data. The findings then were: mean glucose level 4.8 (±0.1) mmol/l, and no statistically significant differences were noted between the groups (p=0.6). In terms of the standard deviations of total cholesterol, HDL and LDL, individual control and intervention participants had abnormal findings.

The mean Hs-CRP in both groups was above 3.0 mg/l, indicating a high risk of IHD (Pearson et al., 2003). The randomisation process indicated that a significant difference between the control and intervention group regarding Hs-CRP was borderline, as the p–value was 0.05. Fifteen participants (control group [n=4] and intervention group [n=11]) had Hs-CRP values above 10 mg/l, indicating a possible active inflammatory process (Pearson et al., 2003). A secondary analysis without these 15 participants' Hs-CRP findings indicated that participants were still at an increased risk of IHD. The Hs-CRP result in the control group was then 3.9 (±3.9) mg/l and in the intervention group 5.2 (±5.4) mg/l. No statistically significant differences were observed between the control and intervention group regarding Hs-CRP (p=0.3).

Results showing the effect of the physical activity modification programme on pedometer-determined physical activity levels are reported in section 6b.6.2.

6b.6.2 Pedometer Physical Activity Level Change Over Time in PLWHA (on HAART)

Table 6b.9a is a representation of the within-group change in pedometer physical activity levels over time calculated by repeated measures ANOVA. The change in mean represents the change from baseline.

Table 6b.9a: Within-Group Pedometer Physical Activity Level Change Over Time in PLWHA (on HAART) (N = 84)

	Control Group	Intervention Group
Baseline steps/day, mean (±SE)	8 102.67 (±832.56)	6 888.13 (±451.46)
Change at six months, mean (±SE)	1 123.41 (±422.12)	5 935.37 (±2 186.47)
Change at six months, 95% CI	69.71 – 2 177.11	477.52 – 11 393.22
Change at six months, p-value	**0.03***	**0.03***
Change at 12 months, mean (±SE)	817.34 (±500.86)	3 809.96 (±2 041.44)
Change at 12 months, 95% CI	-432.87 – 2 067.62	-1 285.86 – 8 905.78
Change at 12 months, p-value	0.33	0.21

* The within-group pedometer physical activity levels increased significantly from baseline at the six month assessment period in the control and intervention groups. The increase was however more in the intervention group and they exceeded the aim of the programme: 3 000 steps above baseline finding.

The increase in pedometer physical activity levels was not significant from baseline at the 12 month assessment period in the control and intervention groups. Both groups were however still more active than what they were at baseline. The intervention group was still clinically significant at this time point as the group still exceeded the aim of the programme.

Table 6b.9b is a representation of the between-group effect on pedometer physical activity levels after 12 months of physical activity modification expressed with baseline value as co-variate using ANCOVA.

Table 6b.9b: Between-group effect on pedometer physical activity levels after 12 months of physical activity modification (N = 84)

	† Mean (±SE)	95% CI	Between-Group Effect
Control group (six months), steps/day	8 667.44 (±1 596.35)	5 490.60 – 11 844.28	$F(1,80)=0.48$, $p=0.49$, $n_p^2=0.01$
Control group (12 months), steps/day	8 395.06 (±1 511.73)	5 386.62 – 11 403.50	
Intervention group (six months), steps/day	13 718.34 (±1 620.71)	10 493.02 – 16 943.66	
Intervention group (12 months), steps/day	11 385.25 (±1 534.80)	8 330.90 – 14 439.60	

† Co-variate appearing in the model is evaluated at the following value: pedometer physical activity level (baseline) = 7495.39 steps/ day.

No statistically significant between-group effect occurred in pedometer physical activity level. The adjusted mean values at the six and 12 month assessment periods where however higher in the intervention than the control group and represented the “active” category (> 10 000 steps/ day).

6b.6.3 Effect of the Physical Activity Modification Programme on Risk Factors for IHD in PLWHA (on HAART)

The effect of the physical activity modification programme on risk factors for IHD was evaluated by repeated measures ANCOVA and secondly the GEE and MEM analysis. The results of the between-group differences are presented in section 6b.6.3.1, and within-group differences in section 6b.6.3.2.

6b.6.3.1 Between-group differences of the effect of the physical activity modification programme

Table 6b.10 is a representation of the between-group effect on 6MWT and perceived stress expressed respectively with baseline values as co-variates using ANCOVA.

Table 6b.10: Between-Group Effect on 6MWT and Perceived Stress after 12 Months of Physical Activity Modification (N = 84)

	† Mean (±SE)	95% CI	Between-Group Effect
6MWT distance			***F*(1,80)=7.83, p=0.01, n_p^2=0.09***
Control group (six months), m	543.78 (±6.62)	530.60 - 556.96	
Control group (12 months), m	541.89 (±7.73)	526.53 - 557.27	
Intervention group (six months), m	562.30 (±6.62)	549.13 - 575.47	
Intervention group (12 months), m	554.78 (±7.72)	539.42 - 570.14	
Perceived stress			*F*(1,80)=0.26, p=0.61, n_p^2=0.00
Control group (six months)	18.18 (±0.96)	16.27 - 20.10	
Control group (12 months)	19.16 (±0.88)	17.42 - 20.90	
Intervention group (six months)	18.36 (±0.96)	16.44 - 20.28	
Intervention group (12 months)	18.01 (±0.88)	16.26 - 19.75	

† Co-variates appearing in the model are evaluated at the following values: baseline SMWT = 544.26m and perceived stress = 20.13.♦ M (meters)

* A statistically significant between-group effect occurred in 6MWT distance as demonstrated by the higher adjusted mean findings in the intervention group at six and 12 months compared to baseline co-variate. The 6MWT distance in the control group lowered progressively at each time point.

No statistically significant between-group effect occurred in perceived stress levels but the adjusted mean findings at six and twelve months progressively lowered in the intervention group compared to control findings.

Table 6b.11 is a representation of the between-group effect on clinical physiological measures expressed with baseline values as co-variates using ANCOVA.

Table 6b.11: Between-group Effect on Physiological Measures after 12 Months of Physical Activity Modification (N = 84)

	† Mean (±SE)	95% CI	Between-Group Effect
Resting heart rate			*F*(1,80)=1.14, p=0.29, n_p^2=0.01
Control group (six months), bpm	78.39 (±1.40)	75.61 - 81.17	
Control group (12 months), bpm	78.90 (±1.23)	76.46 - 81.35	
Intervention group (six months), bpm	78.48 (±1.39)	75.71 - 81.25	
Intervention group (12 months), bpm	78.45 (±1.23)	76.01 - 80.89	
SBP			*F*(1,80)=2.22, p=0.14, n_p^2=0.03
Control group (six months), mmHg	116.26 (±1.35)	113.58 - 118.94	
Control group (12 months), mmHg	118.82 (±1.29)	116.26 - 121.38	
Intervention group (six months), mmHg	115.74 (±1.35)	113.06 - 118.43	
Intervention group (12 months), mmHg	118.20 (±1.29)	115.64 - 120.76	
DBP			*F*(1,80)=1.31, p=0.26, n_p^2=0.02
Control group (six months), mmHg	76.14 (±1.03)	74.09 - 78.18	
Control group (12 months), mmHg	77.61 (±1.05)	75.51 - 79.71	
Intervention group (six months), mmHg	76.79 (±1.03)	74.75 - 78.85	
Intervention group (12 months), mmHg	77.82 (±1.05)	75.72 - 79.91	

† Co-variates appearing in the model are evaluated at the following values: baseline resting heart rate =78.99 bpm, SBP = 120.70 mmHg and DBP = 78.79 mmHg. ♦ Bpm (beats per minute) and mmHg (millimeters mercury).

No statistically significant between-group effect occurred in resting heart rate, systolic and diastolic blood pressure.

Table 6b.12 is a representation of the between-group effect on anthropometric measures with baseline values as co-variates using ANCOVA.

Table 6b.12: Between-Group Effect on Anthropometric Measures after 12 Months of Physical Activity Modification (N = 84)

	† Mean (±SE)	95% CI	Between-Group Effect
Weight			*F*(1,80)=2.39, p=0.13, n_p^2=0.03
Control group (six months), kg	70.35 (±0.49)	69.37 - 71.34	
Control group (12 months), kg	70.95 (±0.66)	69.63 - 72.27	
Intervention group (six months), kg	70.55 (±0.49)	69.57 - 71.54	
Intervention group (12 months), kg	71.08 (±0.66)	69.76 - 72.39	
Body mass index			*F*(1,80)=0.95, p=0.33, n_p^2=0.01
Control group (six months), kg/m^2	26.53 (±0.21)	26.11 - 26.94	
Control group (12 months), kg/m^2	27.04 (±0.29)	26.44 - 27.63	
Intervention group (six months), kg/m^2	26.48 (±0.21)	26.06 - 26.90	
Intervention group (12 months), kg/m^2	27.18 (±0.30)	26.58 - 27.78	
Waist circumference			*F*(1,80)=2.89, p=0.09, n_p^2=0.04
Control group (six months), cm	79.60 (±0.64)	78.32 - 80.89	
Control group (12 months), cm	80.62 (±0.62)	79.39 - 81.84	
Intervention group (six months), cm	80.09 (±0.65)	78.81 - 81.38	
Intervention group (12 months), cm	81.02 (±0.62)	79.79 - 82.25	
Hip circumference			***F*(1,80)=13.86, p<0.00, n_p^2=0.15***
Control group (six months), cm	103.37 (±0.58)	102.21 - 104.53	
Control group (12 months), cm	103.39 (±0.59)	102.21 - 104.59	
Intervention group (six months), cm	104.14 (±0.58)	102.98 - 105.29	
Intervention group (12 months), cm	104.48 (±0.59)	103.29 - 105.67	
Waist: hip ratio			***F*(1,80)=32.35, p<0.00, n_p^2=0.29***
Control group (six months)	0.77 (±0.01)	0.76 - 0.79	
Control group (12 months)	0.78 (±0.01)	0.77 - 0.80	
Intervention group (six months)	0.77 (±0.01)	0.76 - 0.79	
Intervention group (12 months)	0.78 (±0.01)	0.77 - 0.79	

† Co-variates appearing in the model are evaluated at the following values: baseline weight = 70.01 kg, body mass index = 25.62 kg/m^2, waist circumference = 80.55 cm, hip circumference = 103.77 cm and waist: hip ratio = 0.78. ♦ Kg (kilogram), kg/m^2 (kilograms per square meter), cm (centimetres).

No statistically significant between-group effect occurred in weight, BMI and WC. Slight increases in these parameters occurred overtime when reviewing the adjusted mean values.

* A significant between-group effect occurred in hip circumference due to the intervention group's hip circumference increasing slightly more than the control group.

* A significant between-group effect occurred in waist: hip ratio due to the intervention group's waist: hip ratio reducing slightly more than the control group.

Table 6b.13 is a representation of the between-group effect on biochemical measures with baseline values as co-variates using ANCOVA.

Table 6b.13: Between-Group Effect on Biochemical Measures After 12 Months of Physical Activity Modification (N = 84)

	† Mean (±SE)	95% CI	Between-subject effect
Glucose			***F*(1,80)=15.56, p<0.00, n_p^2=0.16***
Control group (six months), mmol/l	4.89 (±0.07)	4.75 - 5.04	
Control group (12 months), mmol/l	4.81 (±0.07)	4.66 - 4.96	
Intervention group (six months) mmol/l	4.72 (±0.08)	4.57 - 4.87	
Intervention group (12 months), mmol/l	4.74 (±0.08)	4.59 - 4.89	
Total cholesterol			*F*(1,80)=2.68, p=0.11, n_p^2=0.03
Control group (six months), mmol/l	4.23 (±0.10)	4.03 - 4.43	
Control group (12 months), mmol/l	4.13 (±0.08)	3.97 - 4.28	
Intervention group (six months), mmol/l	4.32 (±0.10)	4.12 - 4.52	
Intervention group (12 months), mmol/l	4.30 (±0.08)	4.15 - 4.45	
High density lipoprotein			***F*(1,80)=7.71, p=0.01, n_p^2=0.09***
Control group (six months), mmol/l	1.39 (±0.04)	1.32 - 1.46	
Control group (12 months), mmol/l	1.43 (±0.04)	1.35 - 1.50	
Intervention group (six months), mmol/l	1.45 (±0.04)	1.38 - 1.53	
Intervention group (12 months), mmol/l	1.50 (±0.04)	1.43 - 1.58	
Low density lipoprotein			*F*(1,80)=0.32, p=0.57, n_p^2=0.00
Control group (six months), mmol/l	2.38 (±0.06)	2.26 - 2.50	
Control group (12 months), mmol/l	2.26 (±0.06)	2.14 - 2.38	
Intervention group (six months), mmol/l	2.52 (±0.06)	2.39 - 2.64	
Intervention group (12 months), mmol/l	2.35 (±0.06)	2.23 - 2.47	
Triglycerides			*F*(1,80)=0.46, p=0.50, n_p^2=0.01
Control group (six months), mmol/l	1.06 (±0.04)	0.98 - 1.14	
Control group (12 months), mmol/l	1.04 (±0.05)	0.93 - 1.14	
Intervention group (six months), mmol/l	0.99 (±0.04)	0.91 - 1.06	
Intervention group (12 months), mmol/l	1.01 (±0.05)	0.91 - 1.12	
High sensitivity-CRP			*F*(1,80)=3.16, p=0.08, n_p^2=0.04
Control group (six months), mg/l	7.25 (±0.78)	5.71 - 8.79	
Control group (12 months), mg/l	6.68 (±0.85)	4.50 - 8.37	
Intervention group (six months), mg/l	7.23 (±0.77)	5.71 - 8.76	
Intervention group (12 months), mg/l	8.26 (±0.84)	6.59 - 9.93	

† Co-variates appearing in the model are evaluated at the following values: baseline glucose = 4.95 mmol/l, total cholesterol = 4.33 mmol/l, HDL = 1.41 mmol/l, LDL = 2.49 mmol/l, triglycerides = 1.00 mmol/l and Hs-CRP = 7.01 mg/l. ♦ Mmol/l (millimoles per litre) and mg/l (milligrams per litre).

No significant between-group effect occurred in total cholesterol, LDL, triglycerides and Hs-CRP.

* A significant between-group effect occurred in HDL due to the adjusted mean values in the intervention group increased progressively more overtime than the control group.

* A significant between-group effect occurred in glucose level as indicated by lower adjusted mean values (95% CI) in the intervention group compared to the control group.

Tables 6b.14–6b.27 provide information regarding the pedometer physical activity level changes with interaction effect (time and treatment) when adjusting for secondary outcomes, as assessed in the log-transformed model with univariate logistic regression analysis performed in GEE and MEM. The univariate analysis was followed by multivariate logistic regression analysis to evaluate how the dependent variables reacted in the presence of others. The multivariate logistic regression also consisted of a log-transformed model. Table 6b.28 provides information regarding the multiple regression analysis of GEE and MEM, with specific restrictions applied as indicated by the goodness-to-fit evaluations. Table 6b.29 provides the information without the restrictions applied.

Table 6b.14: Physical Activity Levels Adjusted for Perceived Stress Level in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
• Baseline	9.16 (8.91 – 9.40)		PSL	9.14 (8.88 – 9.39)		PSL
• Six months	0.11 (-0.03 – 0.24)	0.11	-0.02 (-0.03 - -0.01)	0.11 (-0.12 – 0.33)	0.35	-0.02 (-0.02 - -0.01)
• Twelve months	0.08 (-0.05 – 0.21)	0.30	**<0.00** *	0.08 (-0.15 – 0.30)	0.50	**<0.00** *
Intervention group						
• Baseline	-0.10 (-0.33 – 0.12)	0.36		-0.10 (-0.33 – 0.12)	0.36	
• Six months	0.35 (0.13 – 0.58)	**<0.00** *		0.35 (0.13 – 0.58)	**<0.00** *	
• Twelve months	0.19 (-0.04 – 0.41)	0.10		0.19 (-0.04 – 0.42)	0.09	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), Coef. (coefficient), Rx (treatment), MEM (mixed effects model), PSL (perceived stress level).

* Significance noted in physical activity levels when adjusted for perceived stress level at six months: intervention group versus baseline control group (GEE and MEM). A significant association between the interaction and perceived stress levels at group (GEE) and individual level (MEM) were also observed.

Table 6b.15: Physical Activity Levels Adjusted for 6MWT Distance in PLWHA (on HAART) (Observations = 252).

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	8.17 (7.56 – 8.78)		6MWT distance	7.96 (7.41 – 8.51)		6MWT distance
▪ Six months	0.14 (0.00 – 0.27)	**0.04***	0.00 (0.00 – 0.00)	0.14 (-0.09 – 0.36)	0.23	0.00 (0.00 – 0.00)
▪ Twelve months	0.09 (-0.04 – 0.23)	0.17	**0.03***	0.09 (-0.13 – 0.32)	0.41	**<0.00***
Intervention group						
▪ Baseline	-0.10 (-0.32 – 0.13)	0.41		-0.09 (-0.32 – 0.13)	0.42	
▪ Six months	0.37 (0.14 – 0.59)	**<0.00***		0.36 (0.14 – 0.58)	**<0.00***	
▪ Twelve months	0.22 (-0.01 – 0.44)	0.06		0.21 (-0.01 – 0.44)	0.06	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), Coef. (coefficient), Rx (treatment), MEM (mixed effects model), 6MWT (six minute walk test).

* Significance noted in physical activity levels when adjusted for 6MWT at six months control group (GEE) and at six months intervention group versus baseline control group (GEE and MEM). A significant association was also noted between the interaction and 6MWT distance at group (GEE) and individual level (MEM).

Table 6b.16: Physical Activity Levels Adjusted for RHR in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE Variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM Variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	8.97 (8.46 – 9.48)		RHR	8.88 (8.39 – 9.37)		RHR
▪ Six months	0.14 (0.00 – 0.27)	0.04	-0.00 (-0.01 – 0.01)	0.14 (-0.09 – 0.36)	0.24	-0.00 (-0.01 – 0.01)
▪ Twelve months	0.09 (-0.04 – 0.22)	0.18	0.61	0.09 (-0.14 – 0.32)	0.43	0.87
Intervention group						
▪ Baseline	-0.10 (-0.33 – 0.13)	0.40		-0.10 (-0.33 – 0.13)	0.38	
▪ Six months	0.38 (0.16 – 0.61)	**<0.00***		0.38 (0.15 – 0.61)	**<0.00***	
▪ Twelve months	0.23 (-0.00 – 0.46)	0.05		0.22 (-0.01 – 0.45)	0.05	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), Coef. (coefficient), Rx (treatment), MEM (mixed effects model), RHR (Resting heart rate).

* Significance noted in physical activity level when adjusting for RHR at six months intervention group compared to control group in the GEE and MEM.

Table 6b.17: Physical Activity Levels Adjusted for SBP in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log - PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE Variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM Variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	9.18 (8.44 – 9.91)		SBP	9.20 (8.52 – 9.87)		SBP
▪ Six months	0.12 (-0.01 – 0.26)	0.07	-0.00 (-0.01 – 0.00)	0.12 (-0.10 – 0.35)	0.29	-0.00 (-0.00 – 0.00)
▪ Twelve months	0.09 (-0.05 – 0.21)	0.20	0.35	0.09 (-0.14 – 0.31)	0.46	0.29
Intervention group						
▪ Baseline	-0.10 (-0.33 – 0.13)	0.39		-0.10 (-0.33 – 0.13)	0.39	
▪ Six months	0.37 (0.14 – 0.59)	**<0.00***		0.37 (0.14 – 0.59)	**<0.00***	
▪ Twelve months	0.22 (-0.01 – 0.45)	0.06		0.22 (-0.01 – 0.45)	0.06	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), Coef. (coefficient), Rx (treatment), MEM (mixed effects model), SBP (systolic blood pressure).

* Significance noted in physical activity level when adjusting for SBP at six months intervention group compared to baseline control in the GEE and MEM.

Table 6b.18: Physical Activity Levels Adjusted for DBP in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE Variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM Variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	9.16 (8.53 – 9.79)		DBP	9.14 (8.52 – 9.76)		DBP
▪ Six months	0.13 (-0.01 – 0.26)	0.06	-0.00 (-0.01 – 0.00)	0.13 (-0.10 – 0.36)	0.28	-0.00 (-0.01 – 0.00)
▪ Twelve months	0.09 (-0.05 – 0.22)	0.20	0.31	0.09 (-0.14 – 0.32)	0.45	0.33
Intervention group						
▪ Baseline	-0.10 (-0.33 – 0.13)	0.39		-0.10 (-0.33 – 0.13)	0.39	
▪ Six months	0.38 (0.15 – 0.60)	**<0.00***		0.38 (0.15 – 0.61)	**<0.00***	
▪ Twelve months	0.22 (-0.01 – 0.45)	0.05		0.22 (-0.01 – 0.45)	0.05	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), Coef. (coefficient), Rx (treatment), MEM (mixed effects model), DBP (diastolic blood pressure).

* Significance noted in physical activity levels when adjusting for DBP at the six months intervention group baseline control in the GEE and MEM.

Table 6b.19: Physical Activity Levels Adjusted for Weight in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	9.36 (8.89 – 9.83)		Weight	9.33 (8.99 – 9.67)		Weight
▪ Six months	0.14 (0.01 – 0.27)	**0.04***	-0.01 (-0.01 - -0.00)	0.14 (-0.08 – 0.36)	0.22	-0.01 (-0.01 - -0.00)
▪ Twelve months	0.10 (-0.03 – 0.23)	0.15	**0.02***	0.10 (-0.13 – 0.32)	0.39	**<0.00***
Intervention group						
▪ Baseline	-0.10 (-0.33 – 0.12)	0.37		-0.10 (-0.33 – 0.12)	0.37	
▪ Six months	0.39 (0.16 – 0.61)	**<0.00***		0.39 (0.16 – 0.61)	**<0.00***	
▪ Twelve months	0.23 (0.01 – 0.46)	**0.04****		0.23 (0.00 – 0.45)	**0.04****	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), Coef. (coefficient), Rx (treatment), MEM (mixed effects model).

* Significance noted in physical activity levels when adjusted for weight at six months for control group (GEE) and intervention group versus baseline control (GEE and MEM). A significant association between the interaction and weight was also noted at group (GEE) and individual level (MEM).

** Significance noted in physical activity levels when adjusted for weight (GEE and MEM) at 12 months intervention group versus baseline control.

Table 6b.20: Physical Activity Levels Adjusted for BMI in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	9.23 (8.79 – 9.67)		BMI	9.29 (8.96 – 9.62)		BMI
▪ Six months	0.15 (0.02 – 0.28)	**0.03***	-0.02 (-0.03 – 0.00)	0.15 (-0.07 -0.38)	0.18	-0.02 (-0.03 - -0.01)
▪ Twelve months	0.11 (-0.02 – 0.25)	0.10	0.06	0.12 (-0.11 – 0.34)	0.31	**<0.00***
Intervention group						
▪ Baseline	-0.10 (-0.32 – 0.13)	0.40		-0.10 (-0.32 – 0.13)	0.41	
▪ Six months	0.40 (0.18 – 0.63)	**<0.00***		0.41 (0.18 – 0.63)	**<0.00***	
▪ Twelve months	0.25 (0.03 – 0.48)	**0.03****		0.26 (0.04 – 0.48)	**0.02****	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), Coef. (coefficient), Rx (treatment), MEM (mixed effects model), BMI (body mass index).

* Significance noted in physical activity levels when adjusted for BMI at six months control (GEE) and intervention group (GEE and MEM) versus baseline control. A significant association between the interaction and BMI was also noted at individual level (MEM).

** Significance noted in physical activity levels when adjusted for BMI (GEE and MEM) at 12 months intervention group versus baseline control.

Table 6b.21: Physical Activity Levels Adjusted for WC in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	9.58 (8.91 – 10.26)		WC	9.72 (9.21 – 10.23)		WC
▪ Six months	0.13 (-0.01 – 0.26)	0.06	-0.01 (-0.02 - -0.00)	0.13 (-0.10 – 0.35)	0.27	-0.01 (-0.02 - -0.01)
▪ Twelve months	0.09 (-0.04 – 0.22)	0.18	**0.03***	0.09 (-0.13 – 0.31)	0.42	**<0.00***
Intervention group						
▪ Baseline	-0.09 (-0.31 – 0.13)	0.43		-0.09 (-0.31 – 0.13)	0.44	
▪ Six months	0.39 (0.16 – 0.61)	**<0.00***		0.39 (0.17 – 0.61)	**<0.00***	
▪ Twelve months	0.24 (0.02 – 0.46)	**0.04****		0.24 (0.02 – 0.47)	**0.03****	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), Coef. (coefficient), Rx (treatment), MEM (mixed effects model), WC (waist circumference).

* Significance noted in physical activity levels when adjusted for WC at six months intervention group versus baseline control (GEE and MEM). A significant association between the interaction and WC was noted at group (GEE) and individual level (MEM).

** Significance noted in physical activity levels when adjusted for WC at 12 months intervention group versus baseline control (GEE and MEM).

Table 6b.22: Physical Activity Levels Adjusted for WHR in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	9.00 (8.22 – 9.78)		WHR	9.11 (8.40 – 9.82)		WHR
▪ Six months	0.14 (0.00 – 0.27)	0.05	-0.21 (-1.19 – 0.78)	0.13 (-0.09 – 0.36)	0.25	-0.35 (-1.23 – 0.54)
▪ Twelve months	0.09 (-0.04 – 0.22)	0.18	0.68	0.09 (-0.14 – 0.32)	0.43	0.44
Intervention group						
▪ Baseline	-0.10 (-0.33 – 0.13)	0.39		-0.10 (-0.33 – 0.13)	0.40	
▪ Six months	0.38 (0.15 – 0.61)	**<0.00***		0.38 (0.15 – 0.61)	**<0.00***	
▪ Twelve months	0.22 (-0.00 – 0.45)	0.05		0.22 (-0.00 – 0.45)	0.05	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), CI (confidence interval), Rx (treatment), MEM (mixed effects model), WHR (waist: hip ratio).

* Significance noted in physical activity level when adjusted for WHR at six months intervention group versus baseline control (GEE or MEM).

Table 6b.23: Physical Activity Levels Adjusted for Glucose in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	8.94 (8.55 – 9.33)		Glucose	8.95 (8.60 – 9.30)		Glucose
▪ Six months	0.13 (0.00 – 0.27	0.05	-0.02 (-0.09 – 0.05)	0.13 (-0.09 – 0.36)	0.25	-0.02 (-0.08 – 0.04)
▪ Twelve months	0.09 (-0.05 – 0.22)	0.20	0.59	0.09 (-0.14 – 0.32)	0.46	0.48
Intervention group						
▪ Baseline	-0.11 (-0.34 – 0.12)	0.35		-0.11 (-0.34 – 0.12)	0.35	
▪ Six months	0.37 (0.14 – 0.60)	**<0.00***		0.37 (0.14 – 0.60)	**<0.00***	
▪ Twelve months	0.21 (-0.02 – 0.44)	0.07		0.21 (-0.02 – 0.44)	0.07	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), Coef. (coefficient), Rx (treatment), MEM (mixed effects model).

* Significance noted in physical activity levels when adjusted for glucose level at six months intervention group versus baseline control (GEE or MEM).

Table 6b.24: Physical Activity Levels Adjusted for Total Cholesterol in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	9.06 (8.68 – 9.43)		TC	9.31 (8.97 – 9.64)		TC
▪ Six months	0.13 (-0.00 – 0.27)	0.05	-0.05 (-0.13 – 0.03)	0.13 (-0.10 – 0.35)	0.27	-0.11 (-0.18 - -0.04)
▪ Twelve months	0.08 (-0.05 – 0.22)	0.24	0.22	0.07 (-0.16 – 0.29)	0.55	**<0.00 ***
Intervention group						
▪ Baseline	-0.11 (-0.33 – 0.12)			-0.11 (-0.33 – 0.12)	0.35	
▪ Six months	0.38 (0.15 – 0.60)	**<0.00***		0.38 (0.15 – 0.60)	**<0.00***	
▪ Twelve months	0.22 (-0.00 – 0.44)	0.06		0.22 (-0.01 – 0.44)	0.06	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), CI (confidence interval), Rx (treatment), MEM (mixed effects model), TC (total cholesterol).

* Significance noted in physical activity levels when adjusted for total cholesterol at six months intervention group versus baseline control (GEE and MEM). A significant association was also noted between the interaction and total cholesterol at individual level (MEM).

Table 6b.25: Physical Activity Levels Adjusted for HDL and LDL Levels in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	8.88 (8.57 – 9.19)		HDL	8.95 (8.66 – 9.23)		HDL
▪ Six months	0.14 (0.00 – 0.27)	0.05	-0.03 (-0.22 – 0.16)	0.14 (-0.09 – 0.36)	0.25	-0.07 (-0.24 – 0.09)
▪ Twelve months	0.09 (-0.04 – 0.22)	0.18	0.78	0.09 (-0.14 – 0.32)	0.43	0.38
Intervention group						
▪ Baseline	-0.10 (-0.33 – 0.13)	0.37		-0.10 (-0.33 – 0.13)	0.38	
▪ Six months	0.38 (0.15 – 0.61)	**<0.00***		0.38 (0.16 – 0.61)	**<0.00***	
▪ Twelve months	0.22 (-0.00 – 0.45)	0.05		0.23 (0.00 – 0.46)	0.05	
Control group						
▪ Baseline	8.95 (8.63 – 9.27)		LDL	9.11 (8.83 – 9.38)		LDL
▪ Six months	0.13 (-0.00 – 0.27)	0.05	-0.04 (-0.15 – 0.07)	0.13 (-0.10 – 0.35)	0.28	-0.11 (-0.19 - -0.02)
▪ Twelve months	0.08 (-0.06 – 0.22)	0.24	0.44	0.07 (-0.16 – 0.29)	0.57	**0.02***
Intervention group						
▪ Baseline	-0.11 (-0.33 – 0.12)	0.35		-0.11 (-0.33 – 0.11)	0.33	
▪ Six months	0.39 (0.15 – 0.61)	**<0.00***		0.38 (0.15 – 0.60)	**<0.00***	
▪ Twelve months	0.21 (-0.01 – 0.44)	0.06		0.20 (-0.03 – 0.43)	0.08	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), Coef. (coefficient), Rx (treatment), MEM (mixed effects model), HDL (high density lipoprotein), LDL (low density lipoprotein).

* Significance noted in physical activity levels when adjusted for HDL and LDL respectively at six months intervention group versus baseline control group (GEE and MEM). A significant association between the interaction and LDL was also noted at individual level (MEM).

Table 6b.26: Physical activity Levels Adjusted for TG in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	8.97 (8.74 – 9.20)		TG	9.06 (8.84 – 9.28)		TG
▪ Six months	0.14 (0.01 – 0.28)	0.04	-0.13 (-0.29 – 0.04)	0.15 (-0.08 – 0.37)	0.19	-0.21 (-0.36 - -0.07)
▪ Twelve months	0.09 (-0.04 – 0.23)	0.16	0.13	0.10 (-0.13 – 0.32)	0.39	**<0.00***
Intervention group						
▪ Baseline	-0.11 (-0.34 – 0.12)	0.34		-0.11 (-0.34 – 0.11)	0.32	
▪ Six months	0.37 (0.15 – 0.60)	**<0.00***		0.37 (0.14 – 0.59)	**<0.00***	
▪ Twelve months	0.21 (-0.01 – 0.44)	0.06		0.22 (-0.01 – 0.44)	0.06	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), Coef. (coefficient), Rx (treatment), MEM (mixed effects model), TG (triglycerides).

* Significance noted in physical activity levels when adjusted for TG at six months intervention group versus baseline control group (GEE and MEM). A significant association between the interaction and TG was also noted at individual level (MEM).

Table 6b.27: Physical Activity Levels Adjusted for Hs-CRP in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	8.87 (8.70 – 9.05)		hs-CRP	8.89 (8.73 – 9.06)		hs-CRP
▪ Six months	0.14 (0.00 – 0.27)	**0.04***	-0.01 (-0.01 – 0.01)	0.14 (-0.08 – 0.37)	0.22	-0.01 (-0.02 - -0.00)
▪ Twelve months	0.09 (-0.04 – 0.23)	0.18	0.31	0.09 (-0.13 – 0.32)	0.42	**0.04***
Intervention group						
▪ Baseline	-0.09 (-0.32 – 0.14)	0.45		-0.07 (-0.30 – 0.15)	0.53	
▪ Six months	0.39 (0.17 – 0.62)	**<0.00***		0.41 (0.18 – 0.63)	**<0.00***	
▪ Twelve months	0.24 (0.00 – 0.47)	0.41		0.26 (0.03 – 0.48)	**0.03****	

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), CI (confidence interval), Rx (treatment), MEM (mixed effects model), Hs–CRP (high sensitivity C-reactive protein).

* Significance noted in physical activity levels when adjusted for Hs-CRP at six months control (GEE) and intervention group (GEE and MEM) versus baseline control group. A significant association between the interaction and Hs-CRP was also noted at individual level (MEM).

** Significance noted in physical activity levels when adjusted for Hs-CRP at twelve months intervention group versus baseline control group (MEM).

Table 6b.28: Physical Activity Levels Adjusted for Perceived Stress Levels, BMI, LDL and TG in PLWHA (on HAART) with Restrictions Applied (GEE and MEM)

Group and Ax period	♦GEE Log-PA Coef. of mean change (95% CI)	♦GEE Log-PA p-value	♦GEE variables (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	♦♦MEM Log-PA Coef. of mean change (95% CI)	♦♦MEM Log-PA p-value	♦♦MEM variables (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	9.78 (9.28 – 10.28)		PSL	9.96 (9.59 – 10.33)		PSL
▪ Six months	0.13 (0.01 – 0.25)	**0.04***	-0.01 (-0.02 - -0.01)	0.09 (-0.08 – 0.27)	0.31	-0.02 (-0.02 - -0.009)
• Twelve months	0.10 (-0.03 – 0.22)	0.13	**<0.00 ***	0.08 (-0.10 – 0.25)	0.40	**<0.00 ****
Intervention group						
▪ Baseline	-0.12 (-0.32 – 0.08)	0.26	BMI	-0.06 (-0.06 – 0.09)	0.53	BMI
▪ Six months	0.32 (0.12 – 0.52)	**<0.00***	-0.02 (-0.03 - -0.002)	0.24 (0.24 – 0.09)	**0.01****	-0.01 (-0.02 - -0.01)
▪ Twelve months	0.16 (-0.04 – 0.37)	0.11	**0.02 ***	0.14 (0.14 – 0.09)	0.11	**<0.00 ****
			LDL			LDL
			-0.04 (-0.14 – 0.06)			-0.10 (-0.18 - -0.03)
			0.41			**0.01 ****
			TG			TG
			-0.15 (-0.30 – 0.002)			-0.17 (-0.29 - -0.1)
			0.05			**0.01 ****

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity level), Coef. (coefficient), Rx (treatment), MEM (mixed effects model), PSL (perceived stress level), BMI (body mass index), LDL (low density lipoprotein), TG (triglycerides).

♦ GEE observations = 249 ♦♦ MEM observations = 240

* Significance noted in physical activity levels when adjusted for perceived stress level, BMI, LDL and TG at six month control and intervention group versus baseline control (GEE). A significant association between the interaction and perceived stress levels ($p < 0.00$) and BMI ($p = 0.02$) was still highlighted in the multiple regression analysis at group level (GEE).

** Significance noted when adjusted for perceived stress level, BMI, LDL and TG at six month intervention group versus baseline control (MEM). A significant association between the interaction and perceived stress levels ($p < 0.00$), BMI ($p < 0.00$), LDL ($p = 0.01$) and TG ($p = 0.01$) was still highlighted with the multiple regression analysis at individual level (MEM).

Table 6b.29: Physical Activity Levels Adjusted for Perceived Stress Levels, BMI, LDL and TG in PLWHA (on HAART) without Restrictions Applied (GEE and MEM) (observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE Variables (Time and Rx effect) Lof-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM variables (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	9.78 (9.24 – 10.32)		PSL	10.02 (9.57 – 10.46)		PSL
▪ Six months	0.12 (-0.02 – 0.25)	0.08	-0.02 (-0.03 - -0.01)	0.11 (-0.10 – 0.33)	0.31	-0.02 (-0.03 - -0.01)
▪ Twelve months	0.09 (-0.05 – 0.22)	0.21	**<0.00 ***	0.07 (-0.14 – 0.29)	0.51	**<0.00 ****
Intervention group						
▪ Baseline	-0.11 (-0.32 – 0.11)	0.34	BMI	-0.11 (-0.33 – 0.10)	0.30	BMI
▪ Six months	0.36 (0.15 – 0.58)	**<0.00***	-0.02 (-0.03 – 0.001)	0.36 (0.14 – 0.57)	**<0.00****	-0.02 (-0.03 - -0.004)
▪ Twelve months	0.20 (-0.02 – 0.42)	0.07	0.07	0.19 (-0.03 – 0.41)	0.09	**0.01 ****
			LDL			LDL
			-0.05 (-0.16 – 0.06)			-0.11 (-0.20 - -0.02)
			0.35			**0.02 ****
			TG			TG
			-0.11 (-0.27 – 0.05)			-0.16 (-0.30 - -0.02)
			0.17			**0.03 ****

♦ Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity level), Rx (treatment), MEM (mixed effects model), PSL (perceived stress level), BMI (body mass index), LDL (low density lipoprotein), TG (triglycerides).

* Significance noted in physical activity levels when adjusted for perceived stress level, BMI, LDL and TG at six month intervention group versus baseline control (GEE). A significant association between the interaction and perceived stress level ($p < 0.00$) was still observed in the multiple regression analysis at group level (GEE).

** Significance noted in physical activity levels when adjusted for perceived stress level, BMI, LDL and TG at six month Intervention group versus baseline control (MEM). A significant association between the interaction and perceived stress level ($p < 0.00$), BMI ($p = 0.01$), LDL ($p = 0.02$) and triglycerides ($p = 0.03$) were still observed in the multiple regression analysis at individual level (MEM).

Section 6b.6.3.2 consists of the ANOVA findings related to the within-group changes on the secondary outcomes assessed that occurred in the control and intervention group in the physical activity modification period.

6b.6.3.2 **Within-group differences of the effect of the physical activity modification programme**

Table 6b.30 represents the control group's findings of the secondary outcomes assessed with repeated measures ANOVA. The mean change reported is the change from baseline.

Table 6b.30 Risk Factor Changes within the Control Group in the Year of Physical Activity Modification (N = 42)

	Baseline (Mean [±SE])	Mean change six months (Mean [±SE])	Mean change six months (95% CI)	Mean change six months (p-value)	Mean change 12 months (Mean [±SE])	Mean change 12 months (95% CI)	Mean change 12 months (p-value)
6MWT distance, m	547.82 (±8.77)	-0.41 (±5.66)	-14.53 - 13.72	1.00	-2.15 (±4.83)	-14.21 - 9.91	1.00
Perceived stress	20.14 (±0.99)	-1.95 (±1.14)	-4.80 - 0.89	0.28	-0.98 (±1.00)	-3.48 - 1.53	1.00
Physiological measures							
RHR, bpm	77.17 (±1.65)	-0.14 (±1.32)	-3.43 - 3.14	1.00	0.38 (±1.22)	-2.66 - 3.41	1.00
SBP, mmHg	120.11 (±1.98)	-4.24 (±1.58)	-8.18 - -0.31	**0.03***	-1.71 (±1.49)	-5.42 - 1.99	0.77
DBP, mmHg	78.21 (±1.34)	-2.45 (±1.19)	-5.41 - 0.52	0.14	-0.94 (±1.15)	-3.82 - 1.94	1.00
Anthropometric measures							
Weight, kg	69.92 (±2.89)	0.34 (±0.41)	-0.67 - 1.35	1.00	0.94 (±0.58)	-0.51 - 2.37	0.34
BMI, kg/m^2	25.36 (±1.00)	0.89 (±0.19)	0.41 - 1.37	**<0.00***	1.39 (±2.51)	0.77 - 2.02	**<0.00***
WC, cm	79.83 (±1.94)	-0.94 (±0.52)	-2.24 - 0.36	0.23	0.03 (±0.51)	-1.25 - 1.31	1.00
HC, cm	103.51 (±2.46)	-0.41 (±0.50)	-1.67 - 0.84	1.00	-0.39 (±0.49)	-1.62 - 0.85	1.00
Waist: hip ratio	0.77 (±0.01)	-0.01 (±0.01)	-0.02 - 0.01	0.56	0.00 (±0.00)	-0.01 - 0.01	1.00
Biochemical measures							
Glucose, mmol/l	5.10 (±0.27)	-0.12 (±0.15)	-0.49 - 0.24	1.00	-0.18 (±0.10)	-0.43 - 0.06	0.21
TC, mmol/l	4.35 (±0.16)	-0.10 (±0.08)	-0.31 - 0.11	0.70	-0.21 (±0.08)	-0.40 - -0.01	**0.04***
HDL, mmol/l	1.41 (±0.06)	-0.02 (±0.03)	-0.09 - 0.05	1.00	0.01 (±0.03)	-0.07 - 0.09	1.00
LDL, mmol/l	2.53 (±0.13)	-0.11 (±0.07)	-0.28 - 0.06	0.34	-0.24 (±0.07)	-0.39 - -0.07	**<0.00***
TG, mmol/l	1.02 (±0.07)	0.06 (±0.04)	-0.04 - 0.15	0.43	0.03 (±0.05)	-0.10 - 0.16	1.00
Hs-CRP, mg/l	5.45 (±1.02)	0.57 (±0.60)	-0.93 - 2.08	1.00	0.21 (±0.59)	-1.28 - 1.70	1.00

♦ 6MWT (six-minute walk test), RHR (resting heart rate), SBP (systolic blood pressure), DBP (diastolic blood pressure), BMI (body mass index), WC (waist circumference), HC (hip circumference), TC (total cholesterol), HDL (high density lipoprotein), LDL (low density lipoprotein), TG (triglycerides), Hs-CRP (high sensitivity C-reactive protein).

* A significant within-group change occurred in SBP at six months compared to baseline due to a reduction in SBP. The 12 month finding was still lower than the baseline value but it was not significant.

* A significant within-group change occurred in BMI at six and 12 months compared to baseline respectively due to an increase in BMI.

* A significant within-group change occurred at 12 months in total cholesterol and LDL compared to baseline due to a reduction in these two parameters respectively.

A reduction in 6MWT distance, perceived stress, diastolic blood pressure, hip circumference and glucose level occurred at each assessment time point when compared to baseline findings respectively. These changes were however not statistically significant.

Table 6b.31 represents the intervention group's findings of the secondary outcomes assessed with repeated measures ANOVA. The mean change reported is the change from baseline.

Table 6b.31: Risk factor Changes within the Intervention Group in the Year of Physical Activity Modification (N = 42)

	Baseline (Mean [±SE])	Mean change six months (Mean [±SE])	Mean change six months (95% CI)	Mean change six months (p-value)	Mean change 12 months (Mean [±SE])	Mean change 12 months (95% CI)	Mean change 12 months (p-value)
6MWT distance, m	540.69 (±11.05)	19.55 (±8.66)	-2.07 - 41.17	0.09	11.71 (±10.32)	-14.05 - 37.48	0.79
Perceived stress	20.12 (±1.03)	-1.76 (±1.02)	-4.30 - 0.78	0.27	-2.12 (±1.01)	-4.63 - 0.39	0.12
Physiological measures							
RHR, bpm	80.79 (±1.79)	-1.36 (±1.69)	-5.58 - 2.85	1.00	-1.18 (±1.39)	-4.67 - 2.31	1.00
SBP, mmHg	121.29 (±1.62)	-5.07 (±1.26)	-8.22 - -1.91	**<0.00***	-2.52 (±1.17)	-5.44 - 0.41	0.11
DBP, mmHg	79.36 (±1.25)	-2.13 (±0.98)	-4.57 - 0.31	0.11	-1.05 (±1.07)	-3.73 - 1.62	0.99
Anthropometric measures							
Weight, kg	70.10 (±1.39)	0.54 (±0.57)	-0.88 - 1.96	1.00	1.06 (±0.75)	-0.81 - 2.93	0.49
BMI, kg/m^2	25.88 (±0.62)	0.87 (±0.23)	0.29 - 1.45	**<0.00***	1.56 (±0.35)	0.69 - 2.42	**<0.00***
WC, cm	81.26 (±1.14)	-0.54 (±0.75)	-2.40 - 1.33	1.00	0.38 (±0.71)	-1.40 - 2.16	1.00
HC, cm	104.02 (±1.52)	0.33 (±0.69)	-1.39 - 2.05	1.00	0.65 (±0.78)	-1.31 - 2.60	1.00
Waist: hip ratio	0.78 (±0.02)	-0.01 (±0.01)	-0.04 - 0.02	1.00	-0.01 (±0.01)	-0.04 - 0.02	1.00
Biochemical measures							
Glucose, mmol/l	4.81 (±0.11)	-0.13 (±0.11)	-0.39 - 0.13	0.68	-0.11 (±0.12)	-0.40 - 0.19	1.00
TC, mmol/l	4.31 (±0.13)	-0.01 (±0.12)	-0.31 - 0.29	1.00	-0.02 (±0.09)	-0.24 - 0.19	1.00
HDL, mmol/l	1.42 (±0.08)	0.04 (±0.05)	-0.09 - 0.17	1.00	0.09 (±0.05)	-0.05 - 0.22	0.34
LDL, mmol/l	2.45 (±0.10)	0.04 (±0.06)	-0.11 - 0.18	1.00	-0.13 (±0.07)	-0.29 - 0.04	0.21
TG, mmol/l	0.98 (±0.08)	-0.01 (±0.05)	-0.13 - 0.11	1.00	0.02 (±0.06)	-0.12 - 0.16	1.00
Hs-CRP, mg/l	8.58 (±1.29)	-0.43 (±1.04)	-3.02 - 2.16	1.00	0.31 (±1.29)	-2.93 - 3.55	1.00

♦ 6MWT (six-minute walk test), RHR (resting heart rate), SBP (systolic blood pressure), DBP (diastolic blood pressure), BMI (body mass index), WC (waist circumference), HC (hip circumference), TC (total cholesterol), HDL (high density lipoprotein), LDL (low density lipoprotein), TG (triglycerides), Hs-CRP (high sensitivity C-reactive protein).

* A significant within-group change occurred in SBP at six months compared to baseline due to a reduction in SBP. The 12 month finding was still lower than the baseline value and more so when compared to the within-group control findings but it was not statistically significant.

* A significant within-group change occurred in BMI at six and 12 months compared to baseline respectively due to an increase in BMI.

An increase in 6MWT distance occurred at six and 12 month compared to baseline but a reduction was noted at 12 months compared to the six months findings. Findings for these increases in 6MWT distance were however not statistically significant.

A progressive reduction in perceived stress was noted at each assessment period when compared to baseline findings. These reductions were however not statistically significant.

A reduction in RHR, DBP, WHR, glucose and total cholesterol levels occurred at each assessment time point when compared to baseline findings respectively. These changes were however not significant. In all of these parameters except WHR and total cholesterol a greater reduction was noted at the six month period.

A progressive increase in HDL was noted at each assessment period when compared to baseline findings. These changes were however not statistically significant.

Section 6b.6.4 provides the results concerning the effect of the physical activity modification programme on the FRS.

6b.6.4 Effect of the Physical Activity Modification Programme on Framingham Risk Score in PLWHA (on HAART)

Table 6b.32 provides information regarding the baseline FRS of participants.

Table 6b.32: Baseline FRS of PLWHA (on HAART) (N = 84)

Variable	n	Intervention Group Mean (±SD)	n	Control Group Mean (±SD)	p-value
Framingham Risk Score points	42	2.5 (±6.5)	42	3.3 (±6.5)	0.5
- Men*		4.1 (±5.6)		4.1 (±8.3)	
- Women**		2.1 (±6.7)		3.1 (±5.9)	

* Men: control group (n=11) and intervention group (n=7)

**Women: control group (n=31) and intervention group (n=35)

The FRS points were slightly higher in the control than the intervention group. This might be due to the control group participants being slightly older and having more smokers.

The men in the control and intervention groups had a mean FRS of 4.1 points, that is, equal to a 1% 10-year risk of IHD (Blom, 2011). The women in the control (3.1 [±5.9]) and intervention (2.1 [±6.7]) groups had a mean FRS of less than nine points, also indicating a 1% 10-year risk for IHD (Blom, 2011). With a 10-year risk of IHD of less than 3%, the study cohort had a low risk of IHD when using only the FRS as guide (Klug et al., 2012).

To evaluate whether the physical activity modification programme had an effect on the FRS, repeated measures ANCOVA was performed to evaluate between-group effect and repeated measures ANOVA for within-group effect. The between-group result is presented in Table 6b.33 and within-group result in Table 6b.34.

Table 6b.33: Between-group effect on FRS after 12 months of physical activity modification (N = 84)

	† Mean (±SE)	**95% CI**		**† Mean (±SE)**	**95% CI**	**Between-subject effect**
Control group (six months)	2.11 (±0.49)	1.147 - 3.08	Intervention group (six months)	2.48 (±0.49)	1.51 - 3.44	$F(1,80) = 0.09$, $p=0.78$, $n_p^2=0.00$
Control group (12 months)	1.97 (±0.53)	0.92 - 3.02	Intervention group (12 months)	1.94 (±0.53)	0.90 - 2.99	

† Co-variate appearing in the model is evaluated at the following value: baseline FRS = 2.89.

No significant between-group effect was observed in FRS after 12 months of physical activity modification. The adjusted mean values of both the control and intervention groups decreased overtime.

Table 6b.34: Within-Group Effect on FRS after 12 Months of Physical Activity Modification (N = 84)

	Baseline (Mean [±SE])	Mean change six months (Mean [±SE])	Mean change six months (95% CI)	Mean change six months (p-value)	Mean change 12 months (Mean [±SE])	Mean change 12 months (95% CI)	Mean change 12 months (p-value)
Control group	3.33 (±1.00)	-0.86 (±0.60)	-2.36 - 0.65	0.49	-1.00 (±0.61)	-2.52 - 0.52	0.32
Intervention group	2.45 (±1.00)	-0.38 (±0.36)	-1.27 - 0.51	0.88	-0.86 (±0.49)	-2.09 - 0.37	0.27

No significant within-group effect was observed in the control and intervention groups after 12 months of physical activity modification. The mean change increased progressively at each assessment period when compared to baseline findings in the control and intervention group respectively.

Table 6b.35 provides the results of the pedometer physical activity levels when adjusting for the FRS with the interaction effect (time and treatment effect), as assessed in the log-transformed model with univariate logistic regression analysis performed in GEE and MEM.

Table 6b.35: Physical Activity Levels Adjusted for FRS in PLWHA (on HAART) (Observations = 252)

Group and Ax period	GEE Log-PA Coef. of mean change (95% CI)	GEE Log-PA p-value	GEE variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value	MEM Log-PA Coef. of mean change (95% CI)	MEM Log-PA p-value	MEM variable (Time and Rx effect) Log-adjusted Coef. of mean change (95% CI) p-value
Control group						
▪ Baseline	8.88 (8.72 – 9.05)		FRS	8.90 (8.74 – 9.06)		FRS
▪ Six months	0.13 (-0.01 – 0.26)	0.07	-0.01	0.12 (-0.10 – 0.34)	0.29	-0.02
▪ Twelve months	0.08 (-0.06 – 0.21)	0.25	(-0.03 – 0.00)	0.07 (-0.15 – 0.29)	0.52	(-0.03 - -0.01)
Intervention group			0.05			**<0.00***
▪ Baseline	-0.12 (-0.34 – 0.11)	0.31		-0.12 (-0.34 – 0.10)	0.29	
▪ Six months	0.36 (0.14 – 0.59)	**<0.00***		0.36 (0.13 – 0.58)	**<0.00***	
▪ Twelve months	0.19 (-0.02 – 0.42)	0.08		0.19 (-0.03 – 0.41)	0.09	

♦ Abbreviations: Ax (assessment), GEE (generalised estimation equation), Log–PA (log-transformed pedometer physical activity levels), Coef. (coefficient), Rx (treatment), MEM (mixed effects model), FRS (Framingham Risk Score).

* Significance noted in the physical activity levels when adjusted for the FRS at six months intervention group versus baseline control group (GEE and MEM). The association between FRS and the interaction was borderline at group-level (GEE), with a p-value of 0.05.

A statistically significant association was observed between the interaction and the FRS at individual-level (MEM).

Section 6b.6.5 provides the results concerning the inflammatory marker (hs-CRP) correlations with IHD risk markers evaluated.

6b.6.5 Inflammatory Marker (Hs-CRP) Correlations with IHD Risk Markers Evaluated

This objective was met with the Pearson correlation coefficient and univariate logistic regression in MEM to highlight within individual findings. Table 6b.36 provides information regarding the linear correlations between log-transformed Hs-CRP and IHD risk markers assessed at baseline.

Table 6b.36: Baseline IHD Risk Marker Correlations with Log-Transformed Hs-CRP in PLWHA (on HAART) (N = 84)

Variable	n	r-value	p-value	MEM Coefficient	95% CI	p-value
Perceived stress level	84	0.23	**0.03***	0.04	0.004 – 0.08	**0.03***
Physical activity level	84					
▪ Pedometer physical activity		-0.06	0.58	0.00	-0.00 – 0.00	0.57
▪ 6MWT distance		-0.12	0.26	-0.00	-0.01 – 0.00	0.25
Physiological measures	84					
▪ Resting heart rate		0.13	0.23	0.01	-0.01 – 0.04	0.22
▪ Systolic blood pressure		0.13	0.23	0.01	-0.01 – 0.03	0.22
▪ Diastolic blood pressure		0.15	0.17	0.02	-0.01 – 0.05	0.16
Anthropometric measures	84					
▪ Weight		0.28	**0.01***	0.02	0.01 – 0.04	**0.01***
▪ BMI		0.35	**<0.00***	0.07	0.03 – 0.12	**<0.00***
▪ Waist circumference		0.28	**0.01***	0.03	0.06 – 0.36	**0.01***
▪ Hip circumference		0.28	**0.01***	0.02	0.01 – 0.04	**0.01**
▪ Waist: hip ratio		0.01	0.96	0.07	-2.87 – 3.00	0.96
Biochemical measures	84					
▪ Glucose		0.12	0.29	0.09	-0.08 – 0.28	0.28
▪ Total cholesterol		0.06	0.58	0.08	-0.19 – 0.34	0.57
▪ HDL		0.11	0.32	0.29	-0.27 – 0.85	0.31
▪ LDL		0.03	0.82	0.04	-0.29 – 0.37	0.81
▪ Triglycerides		-0.01	0.94	-0.02	-0.55 – 0.51	0.94
Framingham Risk Score	84	0.06	0.59	0.01	-0.03 – 0.05	0.59

♦ 6MWT (six-minute walk test), BMI (body mass index), HDL (high density lipoprotein), LDL (low density lipoprotein), MEM (mixed effects model).

* A statistically significant association was observed between perceived stress levels, weight, BMI, waist and hip circumference and Hs-CRP at baseline.

The following section consists of the results pertaining to objective 3 of the study that focused on the evaluation of participants' adherence to the intervention programme.

6b.6.6 Adherence to the Education and Home-Based Walking Programme in PLWHA (on HAART)

The results regarding participants' adherence to the education and home-based walking programme are presented, firstly according to the baseline to six month timeframe, and then the six to 12 month timeframe below.

6b.6.6.1 Adherence to the physical activity modification programme (baseline to six month interval)

Forty-two participants were randomised into the intervention group. Two of them did not receive the intervention programme because they did not return for their second baseline assessment (despite a number of attempts to reach them). Two additional participants dropped out at the start of the intervention: one moved to Zimbabwe to care for an ailing family member, and the second did not attend her first session despite a number of attempts to contact her. Adherence analysis of the baseline to six month interval was therefore calculated on the remaining intervention group participants (n=38). Table 6b.37 consists of information regarding the monthly adherence of participants to the intervention programme.

Table 6b.37: Adherence to the Physical Activity Modification Programme (Baseline to Six Months Interval)

Variable	n	Session One n (%)	Session Two n (%)	Session Three n (%)	Session Four n (%)	Session Five n (%)
Attendance of sessions	38	37 (97.4)	36 (94.7)	36 (94.7)	36 (94.7)	34 (89.5)
Achieved pedometer goal	38	14 (36.8)	26 (68.4)	28 (73.7)	28 (73.7)	20 (52.6)
Identified barriers	38	26 (68.4)	15 (39.5)	9 (23.7)	9 (23.7)	14 (36.8)
Physical complaints	38	22 (57.9)	9 (23.7)	9 (23.7)	5 (13.2)	9 (23.7)
Psychological complaints	38	7 (18.4)	11 (28.9)	6 (15.8)	4 (10.5)	7 (18.4)
Implemented strategies	38	25 (65.8)	34 (89.5)	30 (78.9)	34 (89.5)	28 (73.7)

Monthly contact sessions were not 100%-attended in the baseline to six month period. Reasons included financial constraints, work obligations and being out of Gauteng province in a specific month. Another participant dropped out at session two due to work obligations.

The lowest achievement of monthly pedometer step-count goals was noted in the first month. This was due to the highest percentage of participants experiencing barriers such as physical complaints. More participants achieved their monthly pedometer step-count goals at sessions two to four. The frequency of reports of barriers such as physical and/or psychological complaints decreased as the programme progressed. At session five a drop in the percentage of participants achieving their monthly pedometer step-count goal was again noted.

From content analysis the barriers preventing participants from achieving their monthly pedometer step-count goals and enablers could be grouped into two broad categories: individual and contextual factors.

Table 6b.38 outlines the individual, and Table 6b.39 the contextual factors that influenced ability to adhere to the physical activity modification programme in the baseline to six month period.

Table 6b.38: Individual Barriers Influencing Participants' Adherence to the Physical Activity Modification Programme (Baseline to Six Month Interval)

Sub-category	Keywords/Key phrases	Explanatory quotation/Information given in monthly sessions.
Physical complaints	Respiratory ailments	*"My day was not well and I had a rough day. My head was paining and I had flu"* (Participant 30: Quote 1).
	Intestinal tract ailments	*"I was not feeling good. My stomach was very sore"* (Participant 5: Quote 2).
	Dermatological ailments	*"Thursday too tired, my lower body itches (forgot about allergy)"* (Participant 36: Quote 3).
	Low energy levels	*"I was so weak, I feel like sleeping because of tiredness"* (Participant 57: Quote 4).
Psychological complaints	Poor motivation	*"My spirit was down. I just felt tired. Even my body was not okay. I just felt sick and I had stress"* (Participant 6: Quote 5).
	Worrying about family	*"I was sad for that my mother is sick and I may lose her…I did not put my pedometer"* (Participant 5: Quote 6). *"I was worried because my daughter was sick since giving birth. She never stops bleeding and she is feeling very weak"* (Photograph 23: Quote 7).
	Stress	*"I didn't experience any problems, only pressure from the college. Just had a lot on my mind that kept me occupied"* (Participant 64: Quote 8).
Family responsibility	Being the primary care giver	*"I was not feeling good as my son was sick, so I could not cope. But even though I did try my best"* (Photograph 4: Quote 9).
	Travelling to family members	*"I was working very hard at home in Eastern Cape preparing for the funeral"* (Participant 29: Quote 10).
	Significant family events	*"I did not have the chance/time to do my road works, because on Tuesday I lost my granddad"* (Participant 84: Quote 11).

Table 6b.39: Contextual Barriers Influencing Participants' Adherence to the Physical Activity Modification Programme (Baseline to Six Month Interval).

Sub-category	Keywords/ Key phrases	Explanatory QUOTATION/Information GIVEN in Monthly Sessions
Workplace	Sedentary job	*"The week was challenging in that I was working shifts and I have to sit on a chair the whole shift and I then go home with transport"* (Participant 50: Quote 12).
	Change in working hours or working activity	*"Tired after I was doing the housework and working in the shop the whole weekend"* (Participant 29: Quote 13).
Time of year	Christmas	*"I could not reach my daily step-count because of Christmas things"* (Participant 9: Quote 14).
Physical environment	Weather	*"It was not easy this week because it was very cold"* (Photograph 229: Quote 15). *"I am fine the weather is the problem"* (Participant 9: Quote 16). *"The rain made it so hard for me"* (Participant 42: Quote 17). *"Tuesday and Wednesday my legs got swollen because of the heat and they were not painful. Very lazy I think because of the heat temperature"* (Photograph 678: Quote 18).
Social environment	Domestic abuse	*"I was physically abused so I couldn't do anything. I did nothing as I was not feeling well this week"* (Participant 6: Quote 19).
	Incidences of crime	No explanatory quotes noted, but information disclosed to researcher in discussion. One participant assaulted while walking home from wedding. One mugged and assaulted while walking in community. Handbag with diary and pedometer stolen in the incident. Burglary at participant's home in which clothing with pedometer stolen.

Table 6b.40 outlines the individual enablers that assisted participants to achieve their step-count goals in the programme.

Table 6b.40: Individual Enablers Enhancing Participants' Adherence to the Physical Activity Modification Programme (Baseline to Six Month Interval)

Sub-category	Keywords/Key phrases	Explanatory quotation/Information given in monthly sessions.
Family and friends involvement	Motivation Active participation Support and encouragement	*"My husband helps me with walking. I was very happy and everything was going my way"* (Photograph 38: Quote 18). *"In the morning I walk a long distance with my child"* (Participant 5: Quote 19). Family motivate participants not to sit too long and to go for walks so pedometers can register steps mentioned in discussions. Walking with friends and neighbours reported in discussions. Friends and family members attended monthly sessions with participants.
Family responsibility	Primary care giver duty	Walking children to school and back a means of increasing step count mentioned in monthly discussions.
Religion	Church worship	*"We went to church and we danced a lot. I was feeling good"* (Photograph 317: Quote 20).
Home	Housework	Participants reported doing own housework as means of increasing step-counts.
	Indoor exercise	Participants reported doing indoor exercises when it was raining outside.
Dedicated walking	Allocated time	Participants allocated a time for walking after work and altered walking time to suit weather, e.g. early in morning before it becoming hot.
	Walking bouts	Participants reported doing short bouts of walking in morning and afternoon and including it in daily activity.

Table 6.41 outlines the contextual enablers that assisted participants to achieve their step-count goals in the programme.

Table 6b.41: Contextual Enablers Enhancing Participants' Adherence to the Physical Activity Modification Programme

Sub-category	Keywords/Key phrases	Explanatory quotation/Information given in monthly sessions.
Environment	Rural community	*"We go for long distance to fetch water and wood"* (Photograph 314: Quote 20).
	Community environment	*"After the ups and downs of the past weeks, I decided to go for a long walk to church and to gym. I felt good, happy and relief"* (Participant 6: Quote 21). *"I was walking around the field about 20 minutes"* (Participant 5: Quote 22).
Workplace logistics	Transportation to work	Walking to work as transportation reported in discussions.
	Increased activity at work	Participants reported when very busy at work it was easy to attain step count goal.

Section 6b.6.6.2 provides information regarding intervention participants' adherence to the education and home-based walking programme in the six to 12 month interval, during which neither the researcher nor research assistants had any contact with participants.

6b.6.6.2 Adherence to the education and home-based walking programme (six to 12 month interval)

Twenty-nine intervention participants attended the twelve month assessment and completed a post-intervention questionnaire.

Fourteen (48.3%) of the 29 intervention participants signed the behavioural contract at the start of the programme and fifteen participants (51.7%) did not. Reasons for not signing were that participants felt it was not important (n=3; 20%) or forgot to sign (n=12; 80%).

All the intervention participants (n=29; 100%) felt that wearing the pedometer motivated them to increase their physical activity level, and would advise others to use a pedometer if they too wished to increase their activity levels.

They all found the monthly contact sessions in the baseline to six month period beneficial. They enjoyed the programme overall, and would recommend the programme to others.

Information from the post-intervention questionnaire provides explanations for their adherence to the education and home-based walking programme in the six and 12 month period. Table 6b.42 is a representation of this adherence information supplied.

Table 6b.42: Adherence to the Physical Activity Modification Programme (Six to 12 Month Interval)

Variable	n (%)
Participants who used the pedometer in this period	
▪ No	8 (27.6)
▪ Yes	21 (72.4)
Frequency of pedometer use and walking programme execution	
▪ One to three times per week	5 (17.2)
▪ Four times per week	4 (13.8)
▪ Five times per week	4 (13.8)
▪ Daily usage of pedometer	6 (20.7)
▪ Infrequent use of pedometer	2 (6.9)
▪ Unable to use the pedometer due to equipment problems	1 (3.4)
▪ Non-adherence to pedometer usage	7 (24.1)
Pedometer step-count documentation in their diary in this period	
▪ No	10 (34.5)
▪ Yes	19 (65.5)
Participants who performed the warm-up and cool-down exercises regularly	
▪ No	6 (20.7)
▪ Yes	23 (79.3)
Performance frequency of warm-up and cool-down exercises	
▪ Daily	13 (44.8)
▪ Weekly	14 (48.3)
▪ Monthly	2 (6.9)
Participants who did not encounter programme difficulties in this period	
▪ No	5 (17.2)
▪ Yes	24 (82.8)

Eight (27.6%) participants did not continue with the pedometer-based walking programme in the six to 12 month interval. One of them could not do so as it fell to the floor and broke. The remaining participants who continued with the pedometer-based walking programme did so at varying frequencies per week. The majority (n=19; 65.5%) continued to document their pedometer step-count in their education physical activity diary. Those who used the pedometer and did the walking programme, but did not document their pedometer step-counts, explained that they no longer had pages left in their diaries to use. The majority (n=23; 79.3%) continued with the warm-up and cool-down exercises and did these exercises mostly (n=14; 48.3%) weekly. Nine (31%) participants found palpating their pulse rate difficult and 12 (41.4%) did not monitor their pulse rate during exercise, but rather evaluated their breathing and/or ability to speak as means to monitor their exercise level.

Appendix 50 provides information regarding what information participants found most helpful in the monthly education sessions, as well as what they enjoyed most about the whole education and home-based walking programme.

6b.6.7 Medication Changes During the Study

At the 12 month assessment control and intervention participants were asked whether they had been started on additional medication or whether their current medication had been changed during the study. The following changes were reported, and could have influenced participants' assessment findings:

- One control participant who had diabetes mellitus reported that his daily dose of Glucophage had been reduced.
- One intervention participant reported that her Statin dose had been reduced.
- Two control participants had been initiated on Statin therapy.

The medication of participants who had known hypertension did not change in the course of the physical activity modification period, and no-one was initiated on antihypertensive medication.

Regarding HAART, all participants reported that they had used their medication as instructed by the clinic, but six reported that their medication had been changed in the course of the physical activity modification period.

Section 6b.7 consists of a discussion of the results of the study, and is structured in the following way in relation to the objectives:

- Risk of IHD among PLWHA (on HAART).
- Effect of the education and home-based walking programme on the FRS of PLWHA (on HAART).
- Effect of the education and home-based walking programme on behavioural risk factors for IHD among PLWHA (on HAART).
- Effect of the education and home-based walking programme on clinical risk factors of IHD among PLWHA (on HAART).
- Effect of the education and home-based walking programme on biochemical risk factors of IHD among PLWHA (on HAART).
- Adherence to the education and home-based walking programme among PLWHA (on HAART).

6b.7 DISCUSSION

The primary aim of study 4 was to implement a home-based pedometer physical activity modification programme in PLWHA at primary care level, as prevention strategy for IHD, and to evaluate the effects of that programme. The participants of the study were screened for the presence of risk factors of IHD in study 1 and included in the study if they had one or more risk factors of IHD present. The causes of cardiovascular disease are multifactorial, and risk factors are said to act together to increase overall risk (Silagy et al., 1993). Because of this interplay of risk factors, small adjustments in one, e.g. physical inactivity in the presence of the others, could possibly reduce the overall risk of IHD significantly (Sliagy et al., 1993). The aim was thus to look at the effects of the physical activity programme on pedometer physical activity level, and also to observe whether any changes occurred in secondary known modifiable risk factors for IHD. Findings would therefore shed light on whether a home-based pedometer physical activity modification programme would be able to influence a range of IHD risk factors, and, if so, could contribute to designing a low-cost programme to be implemented at primary care level.

6b.7.1 Risk for IHD among PLWHA (on HAART)

The FRS indicated that participants were at a low 10-year relative risk of IHD. This finding contrasted to findings reported by Cioe, Crawford and Stein (2013), where the risk of IHD was evaluated in a HIV population in Rhode Island, USA. The mean FRS in the authors' study was 7.9 (±6.0), with 67%, 21% and 12% of study participants scoring in the low-, moderate- and high-risk categories respectively. The higher mean score and presence of individuals in the moderate- to high-risk categories could have been due to a number of reasons:

Firstly, the authors' sample consisted mostly of men (n=81; 62.3%), smokers (n=73; 56.2%) and relatively older individuals (47.9 [±8.4] years of age). The Framingham risk equation incorporates gender, age, smoking status, SBP, total cholesterol and HDL to calculate an individual's score (Blom, 2011). A positive smoking status and advancing age result in higher scores when evaluating risk of IHD. Our study cohort, on the other hand, consisted mostly of women (n=66; 78.6%), non-smokers (n=75; 89.3%) and was a fairly young population (intervention group 38.7 [±8.9] years and control group 39.4 [±9.6] years). These differences might well have resulted in lower FRS.

Secondly, PLWHA on HAART are said to have an increased risk of IHD, but the relative risk is reported to be stable up to eight years of treatment (Obel et al., 2007). The risk of IHD is also thought to increase when individuals are on a protease inhibitor-containing regimen, such as lopinavir-ritonavir (Worm et al., 2010). The population in Cioe, Crawford

and Stein's study (2013) had been living with HIV for 14.6 (±7.9) years since diagnosis, and 41.5% (n=54) of them were on a protease inhibitor-based antiretroviral regimen. In the current study time since diagnosis and length of HAART was much less, and only three individuals were on a protease inhibitor regimen. These additional differences could have resulted in the lower mean FRS, due to HAART having had less time to influence cholesterol profile. HAART is known to alter cholesterol profile unfavourably, with a protease inhibitor having the largest effect on the different parameters (Friis-Møller et al., 2003).

Lastly, the mean SBP, total cholesterol and HDL levels of the control and intervention groups were normal, and would therefore have had minimal influence on the FRS. When considering the relative risk of IHD it should be noted that risk factors that were more pronounced in the sample are generally not included in the FRS when assessing risk. Risk factors that were more pronounced were increased stress levels, BMI, physical inactivity and elevated Hs-CRP levels. It is thus understandable that the 10-year risk of IHD according to the FRS in the study cohort was low. The FRS is the recommended risk scoring system in the South African context, since it is a validated tool for a developing country and a multi-ethnic population (Klug, 2012). The Reynolds Risk Score might be suggested as an alternative IHD risk scoring system, as it incorporates hs-CRP (Ridker et al., 2007). The Reynolds Risk Score could also be beneficial in the South African HIV population where prevalence is higher among women, as it was developed for women, and has been validated in a multi-ethnic female population (Cook et al., 2012). A concern with this scoring system, however, would be that it was developed for women 45 years and older (Ridker et al., 2007). It can therefore not be used in younger women, where HIV prevalence is reported to be higher in the South African context (Stats SA, 2013). The need for an HIV-specific risk prediction tool that includes inflammatory parameters has been suggested as a means of improving IHD risk assessment in PLWHA (D'Angostino, 2012). Such a scoring system, incorporating Hs-CRP findings, could provide different relative risk results.

The Hs-CRP level of the sample was elevated, the control group having a mean of 5.4 (±6.6) mg/l and intervention group a mean of 8.6 (±8.4) mg/l at baseline (high risk of IHD: Hs-CRP > 3 mg/l). The secondary analysis, excluding the 15 individuals with the Hs-CRP values above 10 mg/l, still resulted in mean baseline values higher than 3 mg/l. A number of factors might have contributed to the elevated Hs-CRP value: an elevated CRP value is reported to indicate HIV disease progression, as it is linked with poorer immune parameters and inflammatory processes. Chaudhary et al. (2008) and Lau et al. (2006) both reported an inverse relationship between CD_4 count and CRP values. Chaudhary et al. (2008)

reported that CRP results were highest where CD_4 counts were less than 200 cells/mm^3, and the authors considered it probably related to disease progression. Lau et al. (2006) likewise noted a positive relationship between increased viral load and CRP findings. They also found a progressive increase in CRP values over time regardless of whether individuals progressed to AIDS. Noursadeghi and Miller (2005) also considered that the higher CRP values in PLWHA without intercurrent infections could indicate a sustained inflammatory response as a specific consequence of HIV infection. This finding is significant when one considers the relationship between chronic inflammation and the risk of IHD development over time. The findings with regard to the association of CD_4 count and viral load with Hs-CRP in our study were, however, different from the literature (Chaudhary et al., 2008; Lau et al., 2006).

In the current study the correlation at baseline between CD_4 count and Hs-CRP was r=0.11 (p=0.31), and between viral load and Hs-CRP was r=-0.12 (p=0.27), indicating no statistically significant relationship. The direction of the correlations, however, suggests that improved immune parameters could relate to higher Hs-CRP values. This finding, of no relationship between Hs-CRP and immune parameters, is supported by Guimaraes et al. (2008), as assessed when they evaluated cardiovascular and HIV infection factors. They reported that Hs-CRP was associated with traditional risk factors for IHD: WC (p=004), WHR (p<0.001), SBP (p=0.05), DBP (p=0.03), glucose (p<0.001), TG (p=0.001) and total cholesterol (p=0.01). In the current study a positive association between Hs-CRP and the following IHD risk factors were found: perceived stress levels, weight, BMI, waist and hip circumference.

A positive association is known to exist between CRP values and anthropometric measures. Yudkin et al. (1999) noted that positive relationships exist between BMI, WHR and CRP respectively in healthy subjects. The association between WHR and CRP was supported by Dolan et al. (2005) when evaluating cardiovascular disease risk parameters in HIV-infected women compared to non-infected women. The authors noted that HIV-infected women had higher CRP values than non-infected women, but among all participants a strong association was found with WHR. Guimaraes et al. (2008) also reported that hs-CRP values were higher in PLWHA on HAART than HAART-naïve patients. The authors also confirmed the relationship between Hs-CRP and waist: hip ratio and, in addition, WC.

An Hs-CRP above 3 mg/l is reported to indicate a high risk of IHD in the general population, due to the presence of chronic inflammation (Pearson et al., 2003). In the general population the risk ratio for IHD per one SD higher log-CRP concentration is 1.44 (1.32–1.57) when adjusted for age, gender and conventional risk factors for IHD (Emerging Risk

Factors Collaboration, 2010). This increased risk of IHD with elevated Hs-CRP values is supported in an HIV population, as demonstrated by De Luca et al. (2013). These authors found that an Hs-CRP > 3 mg/l was independently associated with cardiovascular disease risk (De Luca et al., 2013). Triant, Meigs and Grinspoon (2009) also demonstrated that a raised CRP value and a positive HIV status were independently associated with AMI. The authors reported that the risk of AMI is increased four-fold in patients with HIV and an elevated CRP value when compared to patients without HIV infection and a normal CRP value. It can therefore be suggested that the study 4 cohort, with their elevated Hs-CRP values, is at an increased risk of IHD due to the presence of inflammation.

The effect of the education and home-based walking programme on the FRS of PLWHA (on HAART) is discussed in section 6b.7.2.

6b.7.2 Effects of the Education and Home-Based Walking Programme on the Framingham Risk Score of PLWHA (on HAART)

The mean change in the FRS from baseline reduced progressively during the study in the control (six months: -0.86 [±0.60] and 12 months: -1.00 [±0.61]) and intervention groups (six months: -0.38 [±0.36] and 12 months: -0.86 [±0.49]). A significant between-group effect was however not observed ($p=0.78$). In the log-transformed univariate model a statistically significant ($p<0.00$) inverse association was noted between the interaction (time and treatment effect) and the FRS at the six month interval in individual intervention participants, compared to baseline control findings (MEM analysis). In the GEE analysis this association was noted to be borderline ($p=0.05$). An inverse association was therefore found between the education and home-based walking programme and FRS at the six month period.

Literature regarding the effect of exercise on FRS in a HIV population is not available, and so information regarding such programmes in a general population is presented. Tully et al. (2005) conducted a 12-week pedometer walking programme in physically inactive individuals. Participants were given a pedometer with a diary and phoned every two weeks for motivation. The aim was to walk for 30 minutes five times per week. The authors found a significant decrease in the 10-year risk estimate for IHD based on SBP in both the intervention ($p=0.032$) and in the control groups ($p<0.00$). No between-group differences were noted. The authors used the FRS, but in analysis only the effect on blood pressure was used to evaluate effect. If the same type of analysis was done in the current study, similar results might have been found considering the significant within-group changes that occurred in the SBP in both the intervention and control groups.

On the other hand, Meikle et al. (2013) evaluated the effect of exercise in the Healthy Heart programme, as conducted at a prevention clinic in Vancouver, Canada. Individuals were referred to this clinic for preventative or secondary management of IHD. The study consisted of a retrospective chart review of a large sample (n=300) who attended the clinic six-monthly over a period of 4.9 years. The authors found that a significant reduction in RHR and FRS occurred if individuals were compliant with exercise suggestions and increased their frequency of performing 30 minutes of exercise per week. Resting heart rate in compliant individuals decreased by 5.9 bpm compared to 0.3 bpm in the “no exercise change” group. A reduction of 15.7% to 13.4% was observed in the 10-year FRS. Similarly, Richardson et al. (2008) found a reduction of 13.1% to 12.3% in the 10-year FRS in a 12-month community behavioural intervention, consisting of smoking cessation, exercise and diet changes. Both these studies had higher mean baseline FRS results and a larger scope for improvement than the current study.

Section 6b.7.3 consists of a discussion of the effects of the education and home-based walking programme on the behavioural risk factors assessed in the study.

6b.7.3 Effects of the Education and Home-Based Walking Programme on Behavioural Risk Factors for IHD among PLWHA (on HAART)

This study is the first to provide information regarding the effects of a home-based education and pedometer physical activity programme on IHD risk factors in PLWHA on HAART. The effects of the education and home-based walking programme on the following behavioural risk factors for IHD will be discussed in this section: pedometer-determined physical activity, 6MWT distance and perceived stress levels.

The education and home-based walking programme resulted in statistically significant (p=0.03) within-group increases in pedometer-determined physical activity levels in the control (mean change: 1 123.41 [±422.12] steps/day) and intervention (mean change: 5 935.37 [±2 186.47] steps/day) groups at the six month assessment period. No statistically significant changes were however observed at the 12 month assessment period: control group (mean change: 817 [±500.86]; p=0.33) and intervention group (mean change: 3 809.96 [±2 041.44]; p=0.21). The change in the intervention group at this time point was however still clinically significant as the change in step count from baseline exceeded the aim of the programme: 3 000 steps from baseline value. No statistically significant between-group change (p=0.49) occurred during the programme as assessed with the repeated measure ANCOVA.

No published information regarding the effects of a pedometer walking programme in PLWHA is available, and findings from studies conducted in a general population are therefore presented for comparison. Access to a pedometer while performing a walking programme is reported to be effective in increasing ambulation physical activity levels. In a systematic review Bravata et al. (2007) found that pedometer use was associated with significant increases in physical activity levels. The magnitude of step-count change differed between the various clinical trials, but ranged from 395 to 5 066 steps per day. Including a step-count goal or step diary were key motivating factors in clinical trials. In trials where participants received a specific goal, e.g. walk more than 10 000 steps per day, or an individualised step goal, significant increases in physical activity levels occurred. Trials in which this was absent showed no statistically significant change in physical activity level from baseline (Bravata et al., 2007). Musto et al. (2010) likewise found that implementing a step-count goal in sedentary overweight women where the goal was to increase incrementally resulted in significant changes in pedometer-determined step-counts. The incremental step-count programme implemented in the authors' study was an increase of 10% of baseline step-count weekly. The authors observed a change of 5 646 (± 1 328) steps per day in intervention participants over their 12-week physical activity programme. In the current study the intervention group improved their step count more than the control group. This increase in pedometer-determined step-count at six months could therefore be the result of having had an individualised incremental step-count goal combined with the step diary, as supported by Musto et al. (2010) and Bravata et al. (2007). The beneficial effect of receiving the education material and its motivating effect on increasing physical activity levels should also not be excluded.

Vallance et al. (2007) evaluated the effects of different motivation methods for promoting physical activity amongst breast cancer survivors over a 12-week programme. The clinical trial had four management arms: individuals who received standard verbal recommendation to perform 30 minutes of moderate activity per week; those who received printed education material regarding breast cancer; those who received a pedometer, and, lastly, those who received printed material and a pedometer. The physical activity time increase from baseline to the 12-week assessment per group was: standard advice, 30 minutes per week; printed material, 70 minutes per week; pedometer, 89 minutes per week and the combined group, 87 minutes per week. Receiving education material compared to standard advice more than doubled the effect, but was less effective than combining the education material with a pedometer. It is, however, interesting that providing a pedometer was the most effective in increasing physical activity levels. The influence of the education physical activity diary combined with the pedometer would thus also have contributed to the increase in pedometer step-count observed in the current study.

Conflicting information is available regarding the effectiveness of physical activity counselling as a means of motivating individuals to increase their physical activity level. This counselling is supported in literature as a means of improving health by promoting an increase in physical activity levels (American College of Sports Medicine, 2014; Williams, 2013; Hawk, 2010). Bravata et al. (2007), however, found that it did not result in an increase in participants' pedometer steps per day. The authors reported that this could have been due to the different counselling methods used in the clinical trials included in the systematic review. Similarly, Eden et al. (2002) reported that there was inconclusive evidence regarding the effect of physical activity counselling when provided by a patient's primary care clinician (nurse practitioner, nurse, physician or physician's assistant). In this review studies involving pedometers were not included, and the counselling was done in different ways. Counselling sessions differed with regard to time, number of sessions and whether education material was provided. Frerichs et al. (2012), on the other hand, indicated that counselling patients effectively regarding changing lifestyle behaviour is possible. The authors conducted a systematic review, analysing seven clinical trials that focused on lifestyle behavioural change in terms of physical activity and/or diet, or both aspects combined. The authors noted that the counselling performed by physiotherapists had an influence in the short term on outcomes. In addition, Fitzsimons et al. (2012) evaluated the effect of two approaches to delivering a pedometer-based activity programme on physical activity levels in low-active Scottish men and women over a 12 month period. One included physical activity counselling, while the other did not. The authors found that the group that received physical activity counselling had higher physical activity levels, and more of these participants had achieved their step-count goals at the 12 month period. The differences were, however, not statistically significant. In the current study physical activity levels, as determined with the pedometer, increased significantly from baseline to six months, but a drop in activity was noted in the six- to 12 month period. In that period the motivational aspects related to the counselling sessions and SMS prompts were absent. The effect on behaviour regarding physical activity level related to these components of the intervention cannot, therefore, be dismissed as ineffective.

Despite the decreased pedometer-determined step-count of the intervention participants from the six-month interval, they nevertheless logged more steps per day than the control group. Considering that they were less active than the control group at baseline, they subsequently improved their pedometer physical activity level by 3 809.96 (±2 041.44) steps per day from baseline to 12 months. These additional steps would correspond to an estimated 38 minutes of additional walking per day at 12 months, assuming that they walked at a moderate intensity level of 100 step.min^{-1} (Marshall et al., 2009). The increased step-count was of clinical value, as they were accumulating in excess of 30 minutes of

walking per day, as recommended by the public health physical activity guidelines (Haskell et al., 2007). The pedometer physical activity category of the intervention group also improved over time when considering their increase in step-count. The mean baseline step-count was 6 888.1 (± 2 925.8) steps per day ("light active") and, with the additional steps at 12 months, the intervention group progressed to "active", with a daily step-count of above 10 000 steps per day (Tudor-Locke and Bassett, 2004). The inclusion of the pedometer in this period and the education received in the earlier part of the intervention, therefore, continued to motivate participants to becoming more physically active than they had been at baseline.

It is interesting to note that control participants' pedometer-determined steps per day also increased from baseline to six months followed by a small drop in steps per day in the six- to 12 month period, despite not having a pedometer or education physical activity diary. At six months the control participants accrued an additional 1 123.41 (±422.12) steps per day that would correspond to an estimated 11 minutes of additional walking per day. That increase could be of clinical value. The control group's management consisted of phoning participants once a month in the baseline to six month assessment period. In these calls they were asked about their general health and whether they were still within the Gauteng province. They received no advice regarding exercise or how to increase their physical activity levels. Merely knowing that they were participating in a clinical trial where physical activity was being assessed, besides participating in the assessments and receiving the monthly phone calls, could have raised their awareness of their activity level, and motivated them to improve. This suggestion regarding how participating in assessment in clinical trials could influence control participants to increase their physical activity level is supported by Sheedy et al. (2000) and Frerichs et al. (2012). A reduction in the control participants' steps per day occurred between the six to 12 month assessments. This is an important finding in that it supports motivational contact, whether face-to-face or by telephone has potential for influencing individuals' physical activity levels as found in the intervention group.

Results for the intervention group from baseline to 12 months show an increase in the mean distance walked in the 6MWT. By comparison the control group's results indicated a decrease in the same period. The between-group changes in 6MWT were statistically significant ($p=0.01$) and the programme therefore resulted in an improved physical function capacity in the intervention group. Similarly, Serwe et al. (2011) found a significant increase in 6MWT distance in an eight-week pedometer walking programme when participants not infected with HIV were encouraged to accumulate 30 minutes of walking per day. Established minimal clinically important difference for the 6MWT is not available for PLWHA but 6MWT findings from another study are available for comparison. Dolan et al. (2006)

noted a significant improvement in 6MWT distance ($p<0.00$) of 34 (±11) meters in their intervention group. The authors evaluated the effects of a supervised home-based exercise programme in women living with HIV in Boston, USA. The programme involved home visits to participants three times per week where strengthening, flexibility and aerobic exercises were performed over 16 weeks. It is important to note that the cohort of Dolan et al. (2006) had more room for improvement in 6MWT distance than the current study, as their baseline findings were: intervention group, 489 (±20) meters and control group, 474 (±14) meters, compared to the current study's 6MWT findings of: intervention group, 540 (±71.6) meters and control group, 547.8 (±56.9) meters. The lower 6MWT distance baseline finding in Dolan et al.'s study (2006) could be due to their cohort consisting of a slightly older population (intervention group, 43 [±2 years] and control group, 40 [±2 years]). In addition, study participants also had a higher BMI baseline value (intervention group, 29.3 [±1.4] kg/m^2 and control group, 28.6 [±1.6] kg/m^2) than the current study. The effect of age and BMI on predicted 6MWT distance is well-reported in the literature (Troosters, Gosselink and Decramer, 1999; Enright and Sherrill, 1998). Even though the mean change in the current study was smaller, the improvement in 6MWT distance brought the intervention group closer to the predicted normal value for healthy individuals (571 [±90] m) (Casanova et al., 2011).

In addition, the log-transformed univariate model showed a positive association between 6MWT distance and the interaction (time and treatment) at six months for both control and intervention groups: at group level (GEE), and at six months intervention group at individual level (MEM). Therefore the increased pedometer physical activity levels at six months were associated with an increase in 6MWT distance. This positive association indicates that the potential for an increase in 6MWT distance and improved functional exercise tolerance level was possible, especially in the intervention group, as demonstrated by GEE and MEM analysis. The education and pedometer walking programme could therefore be a means of improving functional exercise tolerance in PLWHA.

In study 1 the moderately high perceived stress levels in participants were of concern. Stress was also a reason for study 2 participants perceiving themselves to be at risk of developing IHD. A statistically significant association ($p=0.03$) between Hs-CRP and perceived stress was observed at baseline, and, considering the association reported to exist between Hs-CRP and IHD, this finding was of concern. Assessing the effect of the education and home-based walking programme on perceived stress levels of participants was therefore an important objective, as stress was a recurring theme throughout the research project.

The within-group analysis indicated that a reduction in perceived stress levels occurred in the control (six months: mean change -1.95 [±1.14] and 12 months: -0.98 [±1.00]) and intervention (six months: mean change -1.76 [±1.02] and 12 months: -2.12 [±1.01]) groups overtime but progressively more so in the intervention group. No significant ($p=0.61$) between-group effect was however noted. However, a statistically significant inverse relationship ($p<0.00$) between perceived stress level and pedometer-determined physical activity at the six-month interval was observed in the intervention group at both group (GEE) and also individual levels (MEM), compared to the baseline control group in the log-transformed univariate analysis. This inverse relationship was confirmed in the multivariate logistic regression analysis. It shows that, as the physical activity level in the intervention group improved, perceived stress declined. This relationship was not observed in the control group.

The reduced stress association observed in the intervention programme at this sixth month stage could have been due to the combined effects of the exercise programme and the physical activity counselling sessions. The counselling most probably provided a supportive environment for participants. Perceived support was also reported in the post-intervention questionnaire. The importance of a support structure was highlighted in study 2 as a coping mechanism for participants. The physical activity counselling sessions could therefore have indirectly improved participants' coping behaviour, and resulted in additional stress reduction. There is no literature on the effects of a pedometer walking programme on perceived stress levels in either the general or HIV population. Two study protocols, however, have been published: one in a general population consisting of university staff (Ainsworth et al., 2012) and another in PLWHA (Jaggers et al., 2013). Comparison with this study's findings will be possible when findings from those studies become available. Likewise, no information with regard to the effect of a structured exercise programme on stress reduction in PLWHA has been published. Studies done in PLWHA indicate that exercise is beneficial in improving certain parameters, including psychological components. These psychological parameters are: an improvement in quality of life (Ogalha et al., 2011; Mutimura et al., 2008), improvement in life satisfaction (Gomes et al., 2010), improvement in self-efficacy (Fillipas et al., 2006) and reduction in symptoms of depression (Neidig, Smith and Brashers, 2003). Neidig, Smith and Brashers (2003) in addition to determining the effect of exercise on depressive symptoms, assessed their cohort's stress levels with the PSS-4. The outcome of their intervention was however not assessed according to the PSS-4 and changes in PSS-4 between the exercise and control groups also not reported on. The current study thus builds on the body of knowledge of the beneficial effects of exercise on psychological parameters that present in PLWHA.

The effects of the education and home-based walking programme on the clinical risk factors for IHD assessed are discussed in section 6b.7.4.

6b.7.4 Effects of the Education and Home-Based Walking Programme on Clinical Risk Factors for IHD among PLWHA (on HAART)

The clinical risk factors for IHD assessed in the study were RHR, blood pressure and the anthropometric measures (weight, BMI, WC and WHR).

No statistically significant changes in RHR and DBP were observed between the control and intervention groups. The within-group changes did however indicate a slight reduction in these parameters overtime with more pronounced changes occurring in the intervention group. The education and home-based walking programme did not influence these parameters significantly. The study's findings regarding DBP were similar to those of Dolan et al. (2006) that evaluated the effects of a structured home-based exercise programme in women living with HIV. The authors likewise noted no statistically significant (p=0.21) changes in DBP (intervention group: -3 [±2] mmHg and control group: -2 [±2] mmHg) in their study participants in the 16 week programme. The RHR findings were in contrast to Ogalha et al. (2011) who evaluated the effect of aerobic exercise and counselling on diet and physical activity in PLWHA. Authors observed a significant change in their intervention group (pre-: 74.09 [±7.09] bpm and post-intervention: 70.30 [±6.44] bpm; p=0.001). In this study intervention participants were encouraged to perform one hour of aerobic activity such as walking, cycling or running at least three times per week. The greater change in RHR in their study could have been due to the higher activity time and possibly greater intensity-level than the current study.

In the current study a significant reduction in SBP was noted in the within-group analysis in both the control (mean change: -4.24 [±1.58] mmHg; p=0.03) and intervention (mean change: -5.07 [±1.26] mmHg; p<0.00) groups at the six month assessment period. These mean change results are similar to findings from Tully et al. (2007) in which participants performed a walking programme 30 minutes/ three times a week (SBP reduction: 4.51 [±8.77] mmHg) compared to five times a week (SBP reduction: 6.00 [±9.72] mmHg). It is in contrast to findings from Dolan et al. (2006) where authors noted an increase of 1 (±4) mmHg in intervention and 3 (±4) mmHg in control groups' SBP readings. In the current study, the changes in SBP at 12 months were not significant in either group but their SBP findings at this time point was still lower than baseline and more so in the intervention group. The between-group effect was however not significant for SBP (p=0.14).

Conflicting findings are given in the literature related to pedometer programmes and the effect on cardiovascular parameters. Iwane et al. (2000) indicated that blood pressure of hypertensive patients could be lowered from 149 (±2.7)/ 98.5 (±1.4) mmHg to 139.1 (±2.0)/ 90.1 (±1.9) mmHg if they walked 13 510 (±837) steps per day for 12 weeks. Musto et al. (2010) indicated that an incremental 12-week programme conducted in the general population with 10 000 steps per day as an aim could have a significant within-group reduction in intervention participants' RHR. The reduction in RHR recorded in that study was 2.8 (±3.5) bpm. This was, however, not the case in the between-group comparison of the authors. On the other hand, Serwe et al. (2011) found no statistically significant changes in SBP or RHR when women performed short (10 minutes three times per day) or long (30 minutes) bouts of walking per day. The authors did, however, notice a significant decrease in DBP in the group that performed short bouts of walking. In addition, Gray et al. (2009) and Baker et al. (2008) noted no significant change in blood pressure in a 12-week pedometer-based walking programme where the aim was to accumulate 3 000 steps daily. The differences in findings among studies could be due to length of programmes, participants' adherence, and whether participants were evaluating parameters to ensure a moderate-intensity walking pattern, such as heart rate or breathlessness during walking bouts.

An increased BMI was highlighted in study 1 as a risk factor. It was therefore important to evaluate whether the education and home-based walking programme could influence weight and BMI.

The mean weight and BMI of the control and intervention groups increased between each assessment period with BMI changes being significant. The between-group analysis showed no significant effect in either weight ($p=0.13$) or BMI ($p=0.33$). This finding is similar to Dolan et al. (2006), who found no statistically significant change ($p=0.34$) in BMI when women living with HIV participated in a structured home-based exercise and resistance programme. The mean changes observed in the authors' study were as follows: intervention group an increase of 0.4 (±0.2) kg/m^2 and control group a reduction of 0.1 (±0.4) kg/m^2. Similarly, Ogalha et al. (2011) noted no significant ($p=0.06$) change in BMI in their PLWHA intervention group when performing one hour of aerobic exercises three times per week.

In the current study the log-transformed physical activity model indicated a significant inverse relationship between weight and BMI with the physical activity modification programme respectively. The relationship was observed in the intervention group at six and 12 months at group- (GEE) and individual level (MEM), and also in the control group at six

months (GEE). The association between BMI and the interaction (time and treatment effect) was confirmed in multivariate analysis. The interaction could possibly lead to weight loss, even though this was not observed in either the control or intervention groups. This is in keeping with the literature concerning the effect of pedometer-based walking programmes on weight loss in the general population. Richardson et al. (2008) demonstrated in a meta-analysis that the range of weight change in such programmes was +0.30 to -3.70 kg. The authors suggested that the average participant in such a programme could expect to lose about one kg without implementing dietary change. Musto et al. (2010) also reported a modest weight reduction of 0.8 (±1.0) kg and a reduction of 0.3 (±0.4) kg/m^2 in BMI, in their incremental 12-week pedometer-based walking programme with sedentary, overweight women. Serwe et al. (2011), on the other hand, found no change in either weight or BMI of their study participants in an eight-week pedometer walking programme. Weight loss in pedometer-based walking programmes is therefore expected to be modest.

Encouraging more than 12 000 steps per day might have resulted in actual weight loss, thereby influencing BMI. Tudor-Locke et al. (2008) reported that taking more than 12 000 steps per day is associated with a healthy body-weight category of BMI < 25 kg/m^2 in a general population. Adding dietary counselling to the current physical activity programme might have further enhanced weight loss in PLWHA at primary care level. The current format of the education and home-based walking programme might therefore be suggested as a means to maintaining PLWHA's weight and BMI at a stable level, instead of reducing it significantly over the longer term.

Central obesity was evaluated by WC and WHR measurements. The within-group analysis indicated that WC decreased in the control and intervention groups at the six month assessment period compared to baseline. At 12 months, both groups however had an increase in WC when compared to their baseline findings. The within-group and between-group effect on WC were not significant. This was in contrast to findings from Dolan et al. (2006) as authors noted a significant between-group effect (p=0.03). The authors noted that their intervention group had a reduction of 1 (±0.6) cm and their control group an increase of 1.5 (±1.0) cm after their 16 week supervised home-based programme. Similarly, Mutimura et al. (2008) found a significant between-group effect in WC (p<0.0001) when PLWHA attended a centre-based supervised aerobic and strengthening programme. The authors noted that their intervention group reduced their WC by 7.13 (±4.4) cm and their control group's WC increased by 0.03 (±10.7) cm. It therefore seems that programmes that include direct supervision and include exercises that strengthen the abdominal wall (Mutimura et al., 2008) will have a larger effect on WC in PLWHA.

With regards to WHR changes, the intervention group had a reduction in WHR at the six month period and this reduction was maintained at the 12 month assessment. In comparison, the control group's WHR had a reduction at six months but then at 12 months they had an increase in WHR when compared to their baseline finding. The within-group changes were not statistically significant but the differences led to a statistically significant between-group effect ($p<0.00$). Waist: hip ratio changes in the intervention group in the current study was less than that noted by Mutimura et al. (2008): reduction of 0.10 (±0.1). This might have been due to the current study not including strengthening exercises that could have resulted in greater weight loss at the waist of participants as was done by Mutimura et al. (2008).

The current study's findings are supported by Baker et al. (2008) with regards to effect on WC not being significant. They implemented a 12-week pedometer walking programme at community level with an accumulation of 3 000 steps as a goal. Central obesity parameters recorded in Baker' study (2008) were as follows: WC in intervention group (pre-: 89.5 [±12.6] cm to post-intervention: 89.9 [±12.6] cm) and control group (pre-: 90.4 [±14.6] cm to post-intervention: 91.1 [±15.6] cm). Additionally the authors findings regarding WHR changes were: intervention group (pre-: 0.82 [±0.08] to post-intervention: 0.83 [±0.08]) and control group (pre-: 0.82 [±0.09] to post-intervention: 0.82 [±0.09]). Gray et al. (2009), who also implemented a 12-week pedometer walking programme with an accumulated 3 000 steps as a goal, had similar findings to Baker et al. (2008), but contrasting findings to the current study. The authors found no significant changes in WHR as reflected by the following findings: intervention group (pre-: 0.81 [±0.08] to post-intervention: 0.81 [±0.08]) and control group (pre-: 0.82 [±0.10] to post-intervention: 0.82 [±0.09]). In contrast, Tully et al. (2007) found significant changes in WC of study participants in a pedometer-based walking programme. Participants had to walk briskly for 30 minutes three or five days/week, document their steps, time walked and breathlessness in their activity diary. Contact with participants was also made every two weeks. The changes in WC that Tully et al. found was as follows: three times per week (reduction of 2.63 [±4.05] cm; $p<0.001$) and five times per week (reduction of 2.48 [±4.20] cm; $p<0.001$). No significant changes in WHR were however noted by Tully et al. (2007). The increased contact and self-monitoring of the parameters recorded in participants' diaries could have influenced their findings. Additionally, having participants walk 30 minutes from the beginning of the programme could have contributed to their results.

In the current study an inverse, statistically significant, association in WC and the interaction at the six and 12 month intervals of the intervention group compared to the baseline control group findings was found in the log-transformed model. The beneficial

effects of supervised structured exercise programmes, consisting of aerobic and resistance training, on abdominal obesity in PLWHA have been well documented. Such programmes were found to be effective in reducing WC (Mutimura et al., 2008; Dolan et al., 2006) and WHR (Mutimura et al., 2008). The current study thus adds to the body of knowledge related to the effect of exercise on WC in PLWHA. It also possibly provides an alternative method for influencing WC in PLWHA, by implementing an activity programme that requires fewer man-hours to implement, as it promotes self-management.

The effects of the education and home-based walking programme on the biochemical risk factors for IHD evaluated in the study are discussed in section 6b.7.5 below.

6b.7.5 Effects of the Education and Home-Based Walking Programme on Biochemical Risk Factors of IHD among PLHV (on HAART)

The biochemical risk factors for IHD assessed in the study consisted of glucose, lipid profile (total cholesterol, HDL, LDL and TG) and Hs-CRP. A statistically significant within-group change occurred in total cholesterol ($p=0.04$) and LDL ($p<0.00$) in the control group at the 12 month assessment when compared to their baseline findings. The initiation of Statin therapy in two control participants in the course of the investigation period might have contributed to the within-group changes noted in these lipid profile markers in the control group. Statins are recommended drugs for the management of hypercholesterolaemia, as they are known to lower total cholesterol and LDL levels (NCEP ATP-III, 2002). No statistically significant changes occurred in biochemical markers assessed in the intervention group.

The education and home-based walking programme had no statistically significant between-group effect on total cholesterol, LDL, TG and Hs-CRP. A significant between-group effect was observed in glucose ($p<0.00$) and HDL ($p=0.01$) respectively. The log-transformed physical activity model indicated a statistically significant between-group association between the interaction (time and treatment) and total cholesterol, LDL and TG respectively at the six month interval for the intervention group compared to baseline control group findings. This was, however, shown with the MEM analysis, indicating an association between the interaction (time and intervention management) and these parameters in individual intervention participants, compared to individual control participants. With further multivariate logistic regression analysis a statistically significant inverse association between the interaction (time and treatment effect) and LDL and TG was still observed in MEM analysis. The physical activity modification programme, therefore, is possibly an effective method for addressing these risk factors in PLWHA at

individual level. The effect of the education and home-based walking programme on lipid profiles might be explained by considering the baseline lipid profile results.

The mean total cholesterol, HDL, LDL and TG results of both the intervention and control groups were within normal limits at baseline, according to the Adult Treatment Panel III Guidelines of the National Cholesterol Education Programme (2002). Abnormal values in total cholesterol, HDL and LDL must have been present in individual control and intervention participants when one considers the standard deviations of these results. As a result, improvement in these parameters might be reflected in the MEM analysis. Even if favourable changes had occurred in individuals with normal lipid profile values, the finding is still of benefit, considering the known variable degree of dyslipidaemia that is said to develop in PLWHA on HAART (Grinspoon and Carr, 2005). The minimal change in lipid profile can also be explained in terms of the energy expenditure elicited by the walking programme which may have been suboptimum.

Research indicates that exercise can influence lipid profile favourably, though only when a particular exercise threshold is reached. This threshold is the accumulation of 24 to 32 kilometres of brisk walking or jogging per week, that results in an energy expenditure of 1 200 to 2 200 kilocalories per week (Durstine et al., 2001). Walking 2 000 steps is said to result in an energy expenditure of 100 kilocalories (Thompson et al., 2008). It is thus possible that the intervention group did not meet the energy expenditure required to facilitate a marked change in the lipid profile. An increased intensity, by walking more than the stipulated 3 000 steps per day above their baseline level, might therefore have had a more favourable response than the one observed. Combining dietary advice with the walking programme might also produce more favourable results in lipid profile.

The current study's results are supported by pedometer-based walking programme literature. Bravata et al. (2007), in a systematic review of effects of pedometer-based walking programmes, found no statistically significant changes in glucose level and lipid profiles in the trials under review. The authors suggested that this might be due to normative values at baseline. Musto et al. (2010) also found no statistically significant between-group or within-group changes in TG or HDL values when an incremental 10 000 steps per day programme was implemented in sedentary overweight women for 12-weeks. The authors suggested that their findings might be due to participants not reaching an adequate energy expenditure level in the intervention. Bell et al. (2010), however, found a statistically significant change in TG and glucose level in an incremental 10 000 steps per day programme when they performed the programme for seven days per week over a six month period. They found no significant changes in total cholesterol, HDL or LDL. Baker et

al. (2008) found no significant changes in total cholesterol or HDL in a 12-week walking programme where participants had to incrementally increase their step count with 3 000 steps. Gray et al. (2009) also found no significant changes in glucose level in a 12-week walking programme where participants increased their step count by 3 000 steps. On the other hand, Tully et al. (2007) noted a significant change in log-transformed TG in a 12-week walking programme when participants performed a 30 minute walk three times per week. Results therefore vary depending on length of trial, pedometer prescription (incremental step increase, or 10 000 steps, or time length of walk), and the number of days walking is performed (e.g. daily or three times per week).

This study showed elevated Hs-CRP values in the sample at baseline, and it was therefore important to assess whether the education and home-based walking programme could influence this parameter. No significant between-group or within-group changes occurred in hs-CRP in the investigation period. This might have been due to the close relationship observed between anthropometric measures and Hs-CRP. If a significant change in anthropometric measures had occurred, it might have resulted in reduced Hs-CRP. In the MEM model a significant inverse association between the interaction (time and treatment effect) and Hs-CRP and the intervention group at six and 12 months compared to baseline control findings was observed. The interaction thus has the potential to decrease Hs-CRP, even though no significant change in the Hs-CRP was observed in the current study.

Published findings regarding the effect of a pedometer-based walking programme on hs-CRP are limited. One such study was found: Gray et al. (2009) conducted a 12-week community pedometer-based walking programme in individuals that perceived themselves as not meeting public health physical activity recommendations. Participants were randomised to control and intervention groups, and control participants were asked to continue with their normal activity during the programme. The intervention participants received a pedometer and physical activity counselling formulated to assist them in increasing their step-count by 3 000 steps per day on at least five days of the week. They were asked to perform brisk walking during the programme. The authors found no significant between- or within-group changes in weight, BMI, body fat, WHR, blood pressure, glucose, insulin, Hs-CRP, IL-6, soluble IL-6 receptor, TNF-α, soluble TNF receptor I or II following the programme. Certain secondary outcomes (body fat, blood pressure, WHR, glucose and insulin) were within normal ranges, and the programme would therefore have had minimal effect on these parameters. The authors did, however, indicate that the intervention group increased their pedometer-determined physical activity levels significantly ($p<0.001$), increasing it by 3 300 (± 2 215) steps per day over the 12 week period. It could be suggested that their results in the secondary outcomes might have been

significant if their intervention period had extended over a longer timeframe or the pedometer step-count goal had been higher.

Conflicting findings regarding the effect of exercise on CRP are seen in general exercise studies conducted in less-active individuals. Some authors noted no change in CRP values in exercise programmes with sedentary overweight men and women (Stewart et al., 2009; Campbell et al., 2008). The length of the interventions were six and 12 months respectively. Other authors reported a reduction in CRP values in an exercise programme with less-active individuals (Campbell et al., 2009; Viera et al., 2009). The authors did note that this result was related to a significant reduction in trunk fat (Viera et al., 2009) if individuals were obese or had an abnormal WC value at baseline (Campbell et al., 2009). In addition, Selvin, Paynter and Elinger (2007), in a systematic review, reported weight-loss associated with a reduction in CRP value when lifestyle and surgical interventions were evaluated. The authors reported that a reduction of one kg of weight produced an estimated reduction of 0.13 mg/l in CRP results. Findings with regard to Hs-CRP in the current study could thus be explained by the study sample not being obese and not having abnormal WC values at initiation, as well as no change in weight over time.

The last objective of the study was to monitor and evaluate participants' adherence to the education and home-based walking programme. Discussion of this follows, Section 6b.7.6, below.

6b.7.6 Adherence to the Education and Home-Based Walking Programme among PLHV (on HAART)

The final objective of the study was to monitor adherence to the intervention in the baseline-to-six month interval, and identify the barriers and enablers that influenced adherence to the programme. A second interest was to identify whether and how participants continued with the intervention in the six- to 12 month interval, being reliant solely on what they had learned earlier, and equipped with a pedometer for self-monitoring. Adherence is defined as taking one's medication and other interventions, e.g. exercising correctly, as prescribed in the programme (Reda and Biadgilign, 2012). Others, discussing exercise programmes in the HIV sector, defined adherence more leniently, as attending 50% of exercise sessions (O'Brien et al., 2010). Adherence in pedometer literature is usually defined as the number of days walked as a percentage of the total number of days prescribed (Serwe et al., 2011; Tully et al., 2007). In the current study adherence was assessed by attendance of face-to-face sessions and whether participants achieved their walking aim each week during the preceding month.

The monthly adherence to attendance of face-to-face sessions with the researcher at the clinic ranged between 89.5%-97.4%. This high attendance was possible because it was only monthly, and efforts were made to schedule the sessions to coincide with regular clinic visits. This was done because study 1 highlighted that loss to follow-up was due to difficulty in attending sessions because of work obligations and/or financial constraints. It is difficult to compare the attendance data with other exercise studies in the HIV sector, as they were structured in such a way that individuals had to attend a number of sessions per week, thus requiring greater determination. This might explain the slightly lower attendance rate of exercise sessions (82.2%) in Mutimura et al.s' (2008) study, conducting a six-month intervention. Petroczi et al. (2010) had a lower attendance of exercise sessions, with only 12 of a sample of 22 attending more than eight of 20 sessions in a 10-week period. In a four-month home-based exercise programme conducted by Dolan et al. (2006), 96% of intervention participants completed exercise sessions. It is again difficult to compare Mutimura et al. (2008) with Dolan et al. (2006), as participants in the former had to make their own way to a fitness centre, whereas in the latter a physical therapist did home visits with participants. The higher adherence to attendance of exercise sessions in the latter study can be assumed to be the result of participants not having had to make any effort. Considering the degree of variation of exercise attendance across the studies, the current study's structure, relying on only a monthly session by encouraging self-management, could be an option to consider when planning an exercise programme in PLWHA.

Reasons for non-attendance of monthly sessions were financial, work obligations and participants travelling outside Gauteng Province in a particular month. Social difficulties such as financial constraints preventing visits to a clinic are reported as one of the reasons why individuals in Africa are often unable to adhere to HAART (Reda and Biadgilign, 2012). Withdrawal from exercise studies in the HIV sector is often due to inability to attend as a result of work obligations and travelling to a different province (O'Brien et al., 2010). The reasons reported in the current study are thus known in the literature as obstacles that could present when implementing an intervention in PLWHA.

Even though participants attended only monthly sessions in the baseline to six month interval, more dedication was required from them to follow their individualised walking programme between these sessions. Chao and Foy (2000) report that home-based physical activity programmes pose unique challenges compared to structured centre-based programmes. Participants have to decide when and where to perform the physical activity, and depend on self-motivation to carry it through. Less decision-making is required by participants in a structured centre-based programme. The difficulties encountered with the

home-based walking programme became apparent when reviewing participants' achievement of the prescribed pedometer step-count.

Participants' individualised weekly step-count goal was assessed at the face-to-face sessions. Adherence to their individualised prescribed walking programme was determined in terms of achieving each week's prescription in the course of a month by reviewing participants' notations in their diaries. Individuals that achieved their pedometer prescription ranged between 36.8%-73.7% in the baseline to six month interval. In a study conducted by Serwe et al. (2011) adherence to prescribed pedometer walking ranged between 69% and 80%. In addition, Tully et al. (2007) reported adherence to their pedometer walking programmes as ranging between 82.6% and 89.3%. The study conducted by Serwe et al. (2011) was eight weeks long, and that of Tully et al. (2007) 12 weeks. Both research groups calculated each day achieved as a percentage of the prescribed walking programme. This way of calculating adherence was possible in their respective studies as participants in Serwe's study handed in their pedometer log-sheets every week for evaluation. In Tully's study, dairies were collected every second week and a new one issued to participants. This was not possible in the current study as participants used their diaries throughout the project and only attended monthly sessions with the researcher. Therefore the way the authors calculated adherence would account for the higher adherence levels than those as calculated in the current study.

During the first month the lowest percentage of individuals achieved their step-count goal, and this was attributed to the high number who experienced physical complaints (n=22: 57.9%) during this time. It was winter at the start of the intervention, and respiratory ailments were often reported by intervention as well as control participants in the earlier part of the programme. Over time more intervention participants achieved their weekly step-count goal. In the second and fourth visits 68.4%-73.7% adhered to their step-count prescription, well above the suggested 50% reported by O'Brien et al. (2010). It is also well above adherence findings reported by Meikle et al. (2009), as evaluated in the Healthy Heart programme conducted at a prevention clinic in Vancouver, Canada. They reported that only 50% of individuals adhered to exercise suggestions, despite repeated messages regarding the importance of regular exercise. This increased adherence to exercise prescription in the current study could be explained in part by findings from Escolar-Reina et al. (2010). They noted that patients were more likely to adhere to a home-based back and neck exercise programme if the healthcare provider provided facts about the disease and gave feedback regarding progress and reminders to exercise. Considering that the education and home-based walking programme of this study included these components, it may explain the increased adherence. A slight drop in achievement of pedometer step-

count goal was observed in the last month (n=20; 52.6%). At this time the frequency of the pedometer step-count goal was increased to five times per week, and this might have contributed to the lower level of achievement. Tully et al. (2007) reported that when individuals performed walking three times per week their adherence to a pedometer-based walking programme was higher (89.3%) than those walking five times per week (82.6%). In addition, the fifth contact session in the current study occurred in December, when participants were busy preparing for vacation and Christmas. It being summer, deterrents such as higher temperatures and thunderstorms were faced. Both these factors could have contributed to the lower adherence.

Literature suggests that exercise prescription guidelines do not influence adherence to physical activity programmes. In a systematic review evaluating the characteristics of physical activity guidelines in randomised trials and their effect on adherence, the authors suggested that frequency, intensity, duration or mode of exercise played no role (Rhodes, Warburton and Murray, 2009), whereas personality, social and environmental factors played a larger role. An environmental barrier that influenced participants' adherence to their pedometer step-count prescription was often reported to be the weather.

Weather was identified by participants as a barrier to achieving their weekly pedometer step-count goal. Cold weather was reported early in the programme, and later on hot weather with increased rainfall. Weather conditions had an impact, as they walked outdoors to increase their step-count. Owing to financial factors they lacked access to an exercise facility where they could walk indoors. A large proportion of the intervention group were unemployed (n=17; 40.5%) and most (n=19: 45.2%) who were employed earned very little (less than R500 per month). The environment, therefore, presented itself as a barrier throughout the programme to a varying extent. Adverse weather conditions are reported as a barrier to regular exercise in the literature (Chan and Tudor-Locke, 2008; Serour et al., 2007). The study conducted by Serour et al. (2007) was done in Kuwait where a hot climate is a formidable obstacle. In contrast, Chan and Tudor-Locke (2008) noted snowfall as a challenge to following a community pedometer-based programme in North America.

Two social environmental barriers highlighted in the study were domestic abuse and crime. Street-robbery is said to primarily affect poorer people in SA, and usually occurs when individuals are walking to buses, taxi ranks and train stations (Africa Check, 2013). Considering that participants used walking to the taxi rank or to work as a means of increasing their step-count, this information is of concern. Two intervention participants experienced such events in the baseline to six month interval. During the street robbery they were also assaulted, which resulted in superficial bruises and muscle tenderness that

were self-managed. One intervention participant and one control participant were burgled at home, and pedometers stolen. In the case of the control group participant, this occurred after her seven-day physical activity period at the baseline assessment. In the intervention group participant it occurred during the intervention, and an additional pedometer was issued to him. Lastly, one intervention group participant suffered domestic abuse from her life partner, and prevented a repeat by moving in with her mother. This influence of domestic abuse and crime on the home-based physical activity programme was not anticipated, but became a factor to be reckoned with when implementing home-based physical activity programmes.

Individual barriers, such as physical or psychological, were often reported in the baseline to six month interval as factors influencing adherence to their exercise prescription. Physical complaints were presented to varying degrees during the programme, and were often linked to the weather: respiratory ailments in cold weather, and lower energy levels or skin allergies in the hot weather. Psychological barriers such as poor motivation, stress and worry about family members were also reported as influencing their adherence. Major life events such as loss of family members occurred in the intervention period. These identified barriers are mentioned in exercise adherence literature: stress and physical ailments (Serour et al., 2007) and major life events (White et al., 2005). Even though participants experienced individual and contextual challenges that influenced their adherence, they implemented strategies to increase their adherence to the home-based walking programme.

A prominent enabler assisting participants in adhering to their walking programme and achieving their step-count prescription was support and encouragement from family members and friends. This was reflected by the interest that friends and family members showed by occasionally attending monthly sessions with intervention participants. They also influenced motivation by actively participating with the participants' walking sessions in the community. The importance of the support of family and friends in physical activity programmes is highlighted in literature. Tierney et al. (2011) reported that patients with heart failure are more likely to adhere to exercise programmes when there is a measure of encouragement to exercise from family, friends and professionals. White et al. (2005) reiterated that this social support is especially important for women in the initiation part of a programme, as it creates a bonding experience. The wider community health effect of participants' involving friends and family members with their programme should not be ignored. It could have indirectly raised their friends and family members' awareness of their own activity levels, thereby prompting them to participate. White et al. (2005) reported that

support from family and friends play a smaller role in long-term maintenance of physical activity levels.

The secondary adherence objective of the study was to evaluate whether participants continued with the physical activity programme in the six to 12 month interval. Dropout rates in pedometer walking programmes vary in the literature: in an eight-week programme, 12% (Serwe et al., 2011); in twelve-week programmes, 8% (Musto et al., 2010); 27% (Gray et al., 2009); 19% (Baker et al., 2008); 12% (Tully et al., 2007); in a six-month programme, 20% (Zoelliner et al., 2010), and in 12-month programmes, 39% (Fitzsimons et al., 2012) and 77% (Chan and Tudor-Locke, 2008). The dropout rates in these studies referred to individuals not attending final assessment. In the current study 36 intervention and 33 control participants participated in the six month assessment, indicating a dropout rate of 18% (n=15) of the study sample as a whole at six months. At the twelve month assessment 29 intervention and 23 control participants completed the 12 month assessment. The dropout rate of the original 84 study participants was, therefore, 38% (n=32). The six month dropout rate was lower than Zoelliner et al. (2010) in their study of a cohort of disadvantaged African-American adults in the USA. The 12 month dropout rate was also lower than Chan and Tudor-Locke (2008) and Fitzsimons et al. (2012). Findings from the 29 intervention participants at the 12 month assessment provide information regarding their adherence to the programme between the six and 12 month interval.

A decline in pedometer-determined physical activity occurred in the six to 12 month interval, but the intervention group's activity level was still greater than at baseline. The reduction in pedometer step-count from the six to 12 month assessments in the current study could be explained by the way in which participants performed the home-based walking programme in this period. A variation in the number of times per week that participants wore the pedometer to enable them to self-monitor their step-count was identified. Chan and Tudor-Locke (2008) provide similar findings regarding adherence to a 12 month pedometer community programme. The programme initiated by the authors was called the First Step Programme, and aimed to promote walking in individuals living with type two diabetes. The authors reported that 68% of those that completed the 12-month programme reported wearing their pedometers (either sometimes or always). Despite this infrequent use of pedometers, pedometer steps per day were still higher at the 12 month assessment compared to baseline. The authors reported that other parameters, assessed earlier in their study, had returned to baseline values at the 12 month assessment, e.g. general health, as assessed with the SF-20. Similarly, Fitzsimons et al. (2012) examined the effects of two approaches to delivering a pedometer-based programme, one including physical activity consultations and the other without, on physical activity levels in low-active Scottish men

and women over a 12 month period. The authors reported an increase in pedometer step-count from baseline in both groups, and maintained over the intervention period. In addition, they indicated that the quality of life of study participants improved in the 12 month period, but that no significant changes were noted in weight, BMI, waist and hip circumference or WHR respectively. The pedometer in the current study and in those of Chan and Tudor-Locke (2008) and Fitzsimons et al. (2012) was thus a tool that assisted with raising the awareness of physical activity levels in study participants.

A further reason for lower adherence to the walking programme might have been the absence of motivational support compared to that received in the baseline and six month period. Participants reported they found the face-to-face sessions and SMS prompts beneficial to their motivation to exercise. The absence of these components in the six to 12 month period could thus have explained why participants wore the pedometer less frequently in the latter period.

Nineteen of the 29 intervention participants that completed the 12 month assessment (65.5%) in the current study continued documenting their pedometer step-count in their education diary as means to continue with self-monitoring. Reasons why some did not do so were that they no longer had pages left to use in their diaries. It can therefore be recommended that ample space for documentation be included in physical activity diaries in future. The stretches and range of motion exercises taught to participants were continued by more participants (n=23; 79.3%) in this period in comparison to the walking. It might be simply that they required less time and effort to perform.

Even though participants used the pedometer to varying degrees, 21 of the 29 intervention participants that completed the 12 month assessment continued being mindful of their physical activity level throughout the intervention. Thus, 50% of the original intervention group continued with self-monitoring their physical activity level as a means of improving their health 12 months following initiation of the programme.

The conclusion of the study is presented in section 6b.8.

6b.8 CONCLUSION

Study 4 was successful in raising awareness of physical activity levels in both the control and intervention groups, as participants' pedometer-determined step-count increased from baseline. It was however of clinical value in the intervention group, due to the group exceeding the step count aim of the programme, that being 3 000 steps above baseline at each assessment point. Translating the step count into time, would amount to

approximately 30 minutes of added walking per day. The group therefore reached the Public Health recommendations for physical activity. The guidelines also state that persons, who wish to further improve their personal fitness, reduce risk for chronic diseases and disabilities, will likely benefit by exceeding the minimum recommended amount of physical activity. This added benefit was seen in the secondary outcomes assessed.

The education and home-based walking programme was effective in reducing risk factors for IHD, in particular, improving physical function capacity (6MWT distance), reducing waist: hip ratio, decreasing glucose and increasing HDL level as evaluated in between-group analysis. In addition, the programme lowered SBP in both groups, but more so in the intervention group. The largest effect was noted at the six month assessment period as this with-in group change was statistically significant. Multivariate analysis indicated an inverse association between the interaction (time and treatment effect) and perceived stress levels and BMI in the control and intervention groups at six months at group level (GEE). Similarly, the associations were noted between the interaction (time and treatment effect) and perceived stress levels, BMI, LDL and TG in the intervention group at six months at individual level (MEM). The interaction, consisting of an education and home-based walking programme performed over time, therefore has the potential to reduce these risk factors for IHD in PLWHA.

Intervention participants' attendance of physical activity counselling sessions was good, at greater than 75%, and adherence to their pedometer step-count prescription in the baseline to six month interval was average, at more than 50%. Individual and contextual barriers, however, influenced adherence to the physical activity programme. The influence of crime and domestic abuse were highlighted as factors to consider when introducing future such programmes in Johannesburg, SA. Social support in the form of encouragement, motivation and participation of friends and family was noted as an important enabler that assisted intervention participants to adhere to their programme.

When reviewing the feedback given by intervention participants (Appendix 50) regarding what they found most helpful in the programme, it contains positive feedback regarding all aspects of the programme. Participants viewed the programme as an exercise programme as noted by their responses on the post-intervention questionnaire. They reported that the knowledge that they gained by doing the progamme was of benefit e.g. importance of exercise. In addition, performing the walking programme was of social benefit as they made new friends in the community while walking and enjoyed walking with friends and family. It had physical benefits as some reported losing weight, becoming more flexible, having less respiratory symptoms and being less tired. It also had psychological benefits as it helped

individual participants to manage their stress levels. Having the contact sessions provided motivation and receiving the SMS prompts made them feel someone cared about how they were fairing. Lastly, having access to a pedometer and being able to self-monitor their steps was noted as a beneficial aspect of the programme.

Although a decline in physical activity levels was observed in both the control and intervention groups in the six to 12 month period, their respective activity levels were nonetheless higher than at baseline. The drop suggests that the motivational components in the management of the groups influenced physical activity levels in the baseline to six month interval, and hence the lower levels at 12 months. A second factor influencing the intervention group's activity level at the 12 month assessment was the variation in how participants adhered to the pedometer-based walking programme.

The MEM analysis included in the study was beneficial in highlighting associations between the interaction (time and treatment) and secondary outcomes not apparent when reviewing mean group changes as reflected by the GEE analysis. Individuals often perceive/ experience symptoms differently e.g. perceived stress. It thus allowed for assessment of the effect of the interaction within individuals. Including both MEM and GEE analysis when evaluating the effect of a behavioural intervention is therefore recommended to improve interpretation of findings.

The IHD risk according to the FRS was low, as the equation does not include pertinent risk factors present in the study population, e.g. Hs-CRP. The study highlighted that elevated hs-CRP values were present in the study cohort, indicating inflammation: a cause for concern, considering the link between IHD and chronic inflammation over time. The need for a validated IHD prediction equation that includes this inflammatory component, and which could be used in a younger population (less than 45 years), is therefore apparent. This inflammatory marker was positively associated with perceived stress levels and anthropometric parameters (weight, BMI, waist and hip circumference and WHR). An inverse association between Hs-CRP and the interaction (time and treatment) was observed in univariate analysis in the GEE and MEM models. This association highlights that the education and home-based walking programme could potentially be an effective method for reducing this inflammatory risk factor for IHD.

Chapter 7 consists of the conclusion to the study as a whole, including limitations and recommendations identified in the course of the research project.

CHAPTER 7

7. CONCLUSION, LIMITATIONS AND RECOMMENDATIONS

7.1 CONCLUSION

The research project was beneficial in highlighting the presence of risk factors for IHD in PLWHA (on HAART) attending an outpatient HIV clinic in Johannesburg, SA. It also contributes to the known literature related to the socio-demographic profile of those individuals. In addition, the project provided information regarding the effects of an education and home-based pedometer walking programme on physical activity levels and additional risk factors for IHD.

The project highlighted that socio-demographic factors of PLWHA in SA, such as unemployment or low-income employment (less than R500 per month: ± 50 US dollars) are impediments. Exacerbating factors were that participants were often supporting dependants, and were single. This situation contributed to increased perceived stress levels, as well as influencing their dietary choices. Most participants reported eating fruit and vegetables weekly, though few were able to consume three to five vegetables and fruit combined daily. In addition, most participants reported that they were unable to eat fish every week. Diet therefore increased their risk of IHD. A number of participants also perceived themselves at risk of IHD due to their perceived stress levels, and knew that they were following an unhealthy diet and not doing enough exercise. Education strategies regarding a healthy diet on its own would therefore not solve the problem of participants' dietary choices, as financial constraints play a significant role.

International literature suggests that PLWHA are at increased risk of IHD due to the higher prevalence of smoking (Saves et al., 2003). The current study highlighted that smoking in the evaluated study cohort was not as prevalent. This might have been due to the group consisting mostly of women, as fewer women in the study reported smoking than the men. In the general population of SA smoking is also less common among women than men (Peer et al., 2009). Physical inactivity, perceived stress levels and participants being overweight were more prevalent risk factors in this study cohort.

Most participants in study 1 took fewer than 10 000 steps per day, and were thus not active (Tudor-Locke and Bassett, 2004). Participants tried to include some form of exercise in their lives, and the preferred mode of activity reported was walking and running. In the study wheeled transportation was used more frequently than walking as a means of getting around, and the homes of the majority of study participants also constituted a smaller living

environment. Both these factors are social components that would influence physical activity level in an urban environment, as they tend to reduce the amount of normal walking.

The beneficial effect of the education and home-based pedometer walking programme on physical activity level was a positive outcome of the research project. Prominent factors enhancing adherence to the physical activity programme were support and encouragement from friends and family. Barriers to adherence to the physical activity modification often included physical and psychological complaints. In the South African context HIV prevalence is high (±5.26 million in 2013 [Stats SA, 2013]) and the number of practising physiotherapists are low (practising physiotherapist estimated at n=6 328 [World Confederation of Physical Therapist News, 2014]). This physical activity modification programme could therefore be an effective means of implementing a self-management programme to enhance physical activity levels. Participants enjoyed using the pedometer, and found it useful in tracking their walking throughout the project. Issuing a pedometer to individuals attending an HIV clinic and education regarding a healthy step-count could be a simple and effective means to promote activity and enhance health in ambulatory PLWHA.

Stress was a theme that permeated the entire research project. Participants perceived themselves to be at risk of IHD due to stress and ‘thinking too much’, e.g., worrying. Stress was also reported to be a barrier to adhering to the physical activity modification programme. High-sensitivity CRP was found to correlate with perceived stress levels. The positive effect that the education and home-based pedometer walking programme had on the perceived stress levels of participants was therefore significant in managing this risk factor.

In the physical activity modification programme the mean weight and BMI of participants increased very slightly between assessments periods. The programme thus did not bring about significant change in these parameters. The log-transformed analysis did, however, indicate a significant inverse association between the interaction at the different stages and these parameters. The programme as it was conducted can therefore be recommended as a means to enhance physical activity in PLWHA while maintaining these parameters constant, with the potential for weight reduction. Since weight gain can develop over time due to HAART (Hurley et al., 2011), a higher step-count goal might be required to achieve a further weight-loss effect with the addition of dietary counselling and combined resisted exercise.

Study 2 highlighted that participants had an optimistic bias concerning their risk of IHD when self-perception of the risk was evaluated. Participants presented with knowledge and

understanding regarding IHD, but often did not apply it to evaluate their own risk. A discrepancy between self-perception of IHD risk and status of risk factors assessed in participants was apparent. The study highlighted that participants were unaware of the link between risk of IHD and being HIV^+, or HAART exposure and risk of IHD. A positive finding of study 2 was the participants' understanding of their HIV status and their role involved in managing the disease. This characteristic of responsibility might have influenced intervention participants' adherence to the physical activity modification programme.

An elevated level of chronic inflammation (Hs-CRP) was identified in the study cohort as a risk factor for IHD. The relationship between Hs-CRP and assessed IHD risk factors included anthropometric measures and perceived stress levels. Due to the high Hs-CRP results, the study cohort could be considered at a high risk of IHD. By contrast, the FRS put the study cohort at a low risk. This conflicting finding indicates that a prediction equation applicable to PLWHA of all ages that includes an inflammatory component is required. The programme did not produce a significant change in Hs-CRP, and this might be due to the absence of significant change in weight and BMI. The log-transformed univariate model did, however, indicate an inverse association between the interaction and Hs-CRP at the different stages when compared to baseline control findings. There is, therefore, the potential to influence this parameter by physical activity if an increased change in anthropometric measures can be achieved.

The physical activity modification programme resulted in significant reduction in SBP in both groups in the within-group analysis with higher reductions noted in the intervention group. Hypertension was a risk factor highlighted in the INTERHEART Africa study as more prominent in the black African group (Steyn et al., 2005). Additional literature suggests that prevalence of HTN in women is twice that of men for Black Africans, Coloured and Indian/Asian individuals in SA, as assessed in a nationwide survey (Hasumi and Jacobsen, 2012). Considering that HIV is more prevalent among women (Stats SA, 2013) and black Africans (Shisana et al., 2014) in SA, this effect on SBP is important. The education and home-based pedometer walking programme is an effective method to influence this prominent risk factor, and thus significant in the South African context.

The study highlighted that contact between the healthcare practitioner and participant is important to bring about the greatest change in physical activity. When this contact is no longer present a decline in activity level occurs. To prevent this decline from occurring when programmes end, innovative methods are required to still encourage and motivate individuals to keep being active. Such strategies could be telephone calls and SMS prompts to encourage and motivate individuals. Adherence group classes every three

months could be an alternative to discuss individuals' challenges and implement additional forms of exercise that individuals can continue with at home. Participants in the current study emphasized that receiving support is an important enabler to activity. Support structures in the community but also in healthcare would be required to enhance and promote being active and more so staying active.

In 2010 O'Brien et al. presented key research priorities requiring attention in HIV. The authors created The Framework of HIV and Rehabilitation Research, and included the research priorities presented in Figure 7.1:

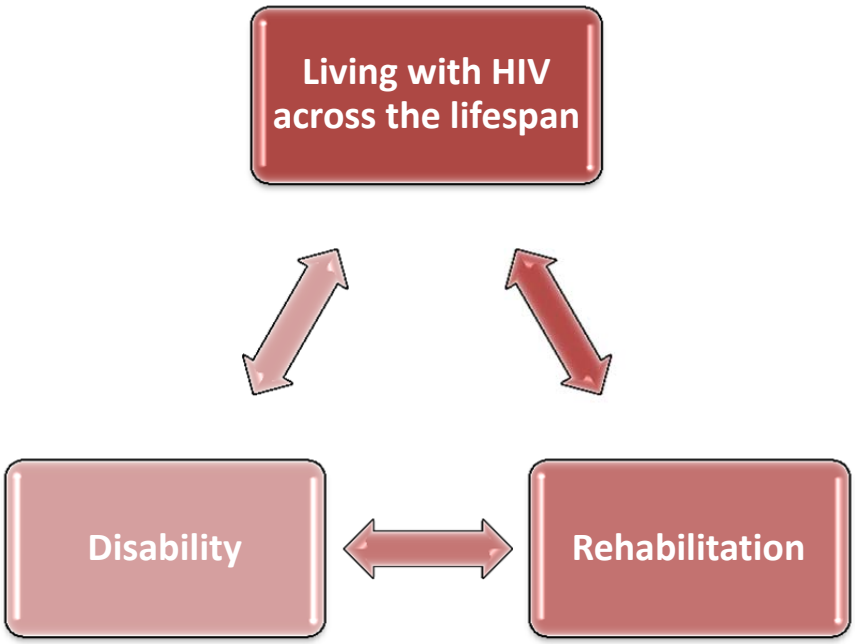


Figure 7.1: Key Research Priorities in HIV and Rehabilitation

The current research project contributes to knowledge related to "Living with HIV across the lifespan", as it provides information regarding the risk factors for IHD in PLWHA in the South African context as a means of highlighting concurrent health conditions. In addition it includes information regarding PLWHA self-perception for the risk of IHD. It also contributes to the body of knowledge related to "Rehabilitation", as it provides information regarding the effects of an education and home-based pedometer walking programme in PLWHA as a prevention and management strategy for IHD. Lastly, it highlights environmental and personal factors present in PLWHA in SA that could influence all three research priorities.

Section 7.2 contains information regarding the limitations identified in the research project.

7.2 LIMITATIONS

The research project was structured in such a way as to focus on assessing risk factors for IHD and implement a physical activity modification programme to manage that risk. Therefore the focus when reviewing diet was limited to fruit, vegetable and fish consumption. The content of the general diet, and diet on a larger scale were not investigated. Moreover, the focus on physical activity was related specifically to walking, as walking is often given as an example for increasing activity level. Other aspects of activity, e.g. upper limb function when performing tasks, cannot be monitored by a pedometer. These additional aspects of activity contribute to general activity on a larger scale. Thus it needs to be noted that the findings in the current research project provide information only on walking, and not overall physical activity levels, as would be assessed by a more comprehensive review of activities of daily living.

Gathering data on pedometer step-count was dependent on participants wearing the instrument as instructed, and documenting the daily step-count in their physical activity log sheet. In addition, collecting data on smoking status, alcohol consumption and whether participants performed exercise (study 1) were also dependent on participants' truthfulness. A margin of error in self-reporting could have occurred.

The physical activity modification period of study 4 was a year, and a progressive increase in dropout rate occurred over that time. Attempts were made to follow up all participants, but this was not possible due to individual participants' financial constraints, work obligations, moving out of Gauteng province and not being able to contact individuals.

During study 4 all participants continued with standard clinic management that included visiting medical doctors, having vital signs assessed by nursing staff and collecting HAART from the pharmacy. Participants could thus possibly have received information regarding diet and exercise from other medical practitioners or from the general media, and this might have influenced their activity level.

Lastly, study 4 indicated that participants' Hs-CRP results were above 3 mg/l, indicating an increased risk of IHD. Unknown to the researcher at the start of the study, CRP levels are reported to fluctuate in women of child-bearing age, dependent on the phase of their menstrual cycle. Gaskins et al. (2012) reported that more women were classified as being at high risk of IHD (Hs-CRP > 3 mg/l) in menses than other phases of the cycle. Both control and intervention groups consisted mostly of women, and the mean age corresponded to the child-bearing age. Particulars regarding whether participants were having their menses at the time of Hs-CRP blood sampling were not collected in the study.

Information regarding irregular menses or possible change in menses was also not collected during the study. Attempting to schedule appointments according to phase of menstrual cycle would have been problematic, as assessments were dependent on availability of research assistants. This confounding variable might therefore have influenced participants' Hs-CRP findings.

Section 7.3 contains recommendations for future projects.

7.3 RECOMMENDATIONS

The research project highlighted several areas where research is still needed:

- Evaluate physical activity levels in PLWHA longitudinally at different time points when on HAART. At each time point additional parameters could be evaluated to investigate what might be influencing individuals' activity level. Such outcome parameters could be socio-demographic, biomedical, therapeutic or person-specific factors. In the South African context pulmonary TB co-infection in PLWHA is high (Van Dyk, 2008). A project investigating activity parameters in PLWHA with TB co-infection would be valuable. In addition, PLWHA are prone to COPD (Morris et al., 2011) and another project could investigate COPD-like changes and their influence on activity parameters. Rehabilitation intervention studies could link into these studies.

- The cost implications of rolling out the pedometer physical activity modification programme in SA needs to be determined to inform translation of such a programme into the community.

- The current research project cohort could be followed up longitudinally for a longer period to determine whether participants continue to implement their new knowledge regarding trying to be active. Individuals implementing this knowledge could be compared to those who do not, and could highlight additional adherence factors. In addition, one could evaluate retention of this knowledge.

- In the research project a number of participants were lost to follow-up. Data collected from these participants could be compared to those who completed the project, and findings could highlight possible adherence impediments.

- The study highlighted that participants found the pedometer beneficial in self-monitoring their activity level, and that it assisted in improving their walking activity level. Including this device in current HAART initiation group education management on its own, and

assessing the effect on activity level without the additional monthly sessions, could be beneficial.

- The project focused on assessing the physical activity levels of PLWHA on HAART at an outpatient clinic. Additional rehabilitative research is needed specific to PLWHA in an acute-care setting.

- PLWHA are at an increased risk of IHD, and secondary management of IHD includes angioplasty or coronary artery bypass graft surgery. Research is needed to investigate the rehabilitative outcomes in acute care and post-hospital discharge following angioplasty or coronary artery bypass graft surgery.

- The research project focused on walking activity, as this is recommended as a means of increasing physical activity as a prevention strategy for IHD. Further research could investigate a wider scope of physical activity.

- Study 1 provided information regarding participants' mode of preferences when performing physical activity. Additional research could provide information on format, location and social setting.

- Important avenues to be investigated in PLWHA in the South African context are individuals' perceptions regarding exercise, obesity and stress.

- Study 1 highlighted that participants were at an increased risk of IHD due to low daily intake of vegetables and fruit. Additional research is needed with regard to general diet, specifically its content, to identify whether individuals are consuming enough macro- and micronutrients. In addition, the research needs to focus on factors influencing diet, so that appropriate management strategies can be formulated and implemented.

- The project highlighted that increased perceived stress levels, physical inactivity and overweight/obesity presented as risk factors for IHD, requiring management in PLWHA. It would be beneficial to conduct a comparative study in individuals not infected with HIV to determine whether these factors apply more to PLWHA or are of more general concern in SA.

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APPENDIX 1

ETHICAL CLEARANCE CERTIFICATE OF THE RESEARCH PROJECT

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Ms Ronel Roos

CLEARANCE CERTIFICATE	**M10238**
PROJECT	Risk Factors and the Effect of Physical Activity Modification for Ischemic Heart Disease in Individuals Living with HIV
INVESTIGATORS	Ms Ronel Roos.
DEPARTMENT	Phsyiotherapy Department
DATE CONSIDERED	26/02/2010
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 23/03/2010 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr H Myezwa

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

APPENDIX 2

TITLE APPROVAL LETTER OF THE RESEARCH PROJECT

Faculty of Health Sciences
Medical School, 7 York Road, Parktown, 2193
Fax: (011) 717-2119
Tel: (011) 717-2745

Reference: Ms Tania Van Leeve
E-mail: tania.vanleeve@wits.ac.za
03 June 2010
Person No: 516037
PAG

Ms R Roos
Fairway Gardens No. 15
12 St Michael Street
1449
South Africa

Dear Ms Roos

Doctor of Philosophy: Approval of Title

We have pleasure in advising that your proposal entitled "*Risk factors and the effect of physical activity modification for ischemic heart disease in individuals living with HIV.*" has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

APPENDIX 3

CLINICAL SITE APPROVAL LETTER

Clinical HIV Research Unit, Department of Medicine

Helen Joseph Hospital, Themba Lethu Clinic, Perth Road, Westdene, Johannesburg 2092, South Africa
Postnet Suite 176, Private Bag X2600, Houghton 2041, South Africa • Tel: +27 11 276-8800 • Fax: +27 11 482-2130

07 July 2010

Dr NL Hlongwane
Senior Superintendent
Helen Joseph Hospital
Perth Road
Westdene

By Hand

Dear Dr Hlongwane

RE: Ronel Roos: ETHICS REF NO: M10238

"Risk factors and the effect of physical activity modification for ischemic heart disease in individuals living with HIV."

This letter serves to confirm that Ronel Roos is a Physiotherapy Lecturer, PhD Student (first year), Physiotherapy Department, University of the Witwatersrand and wishes to conducted research study here at Helen Joseph Hospital

The research has already been approved by the Human Research Ethics Committee (University of the Witwatersrand) under protocol M10238.

As the proposed study is purely research and will not impact on the hospital in anyway.

Yours sincerely,

Naida

Mrs Marlene Naidoo
Regulatory Manager
Clinical HIV Research Unit
Themba Lethu Clinic
Helen Joseph Hospital
Perth Road, Westdene, Johannesburg
Tel: +27 11 276 8809

APPENDIX 4

INFORMATION DOCUMENT (ENGLISH)

Study Title: Risk factors and the effect of physical activity modification for ischemic heart disease in individuals living with HIV.

Good Day,

My name is Ronel Roos. I am a physiotherapy lecturer at the University of the Witwatersrand. I am doing research on heart disease in individuals with an HIV positive status. Research is just a way to learn the answer to specific questions. In this specific study we want to see if there is a risk of heart disease in individuals with an HIV positive status and if an education and exercise program will help to lessen this risk. I am therefore asking/ inviting you to participate in this research study.

What does the study involve?
Individuals with an HIV positive status attending the Themba Lethu Clinic at Helen Joseph Hospital are invited to participate in this research study. The study will consist of two parts.

Part One

In part one, I will evaluate your risk of heart disease by evaluating your heart rate, blood pressure, weight, waist circumference and waist: hip ratio. You will also be asked to complete two questionnaires. The first questionnaire will ask you about general information such as age, date of birth, smoking history, HIV history and general symptoms that you experience etc. The second questionnaire will ask information about the amount of stress you experience in your life. We will also evaluate your physical activity level with a pedometer (small calculator) that counts the number of steps you take per day. You will be asked to wear this small calculator during the day for a week. During this part of the study I will also conduct an interview with you to see what you understand about living a healthy lifestyle and risk factors of heart disease. I will also ask you to look at specific cards and select important cards that you think explains the concept of living a healthy lifestyle during this interview. This interview will also be tape recorded so that I will be able to interpret it at a later stage. These tape recordings will be kept for a period of five years in a safe place and after five years it will be destroyed. Part one will consist of two consultation sessions of approximately an hour in duration.
Part Two

People from part one of the study who have an increased risk of heart disease and on a specific antiretroviral regime will be invited to participate in the second part of the study. The second part of the study will again consist of two consultation sessions: an evaluation session and an education session. During the evaluation session a research assistant will reassess your heart rate, blood pressure, weight, waist circumference and waist: hip ratio as well as your level of stress. The amount of steps you take per day will again be measured by the pedometer. This is necessary because the values might be different since part one. A blood test will also be needed at this time to evaluate your glucose, cholesterol and inflammatory heart marker levels. The blood sampling procedure will be done by a laboratory nurse and approximately four teaspoons of blood will be drawn. There might be some physical discomfort during the blood sampling procedure.

People participating in part two will then be assigned to either a control or intervention group. This means that some people will receive an education-exercise program from me and some will not. The participants who do not receive a program will continue with the standard clinical management. When the study is completed and if the intervention worked, the control participants will be educated regarding the intervention if they are interested. Every month I will phone these participants to find out how they are doing. The people that do receive the education-exercise program from me will be asked to try and do this for twelve months at their own pace. Every month we will meet at Helen Joseph hospital to monitor your progress and I will send a reminder SMS to you every two weeks to encourage you to exercise. After six months a consultation session at Helen Joseph will take place with all participants of the study to establish how you are coping and to evaluate all the parameters tested at the initiation of the study. The following six months will require you to exercise on your own without any contact from the researcher or research assistant. After a year we will need to do the whole evaluation procedure again to see how your body responded over time. All consultation sessions will be done at Helen Joseph Hospital and you will be reimbursed for your travel expenses at R50 a session.

What are the benefits to the participants?

If you participate in the research study you will be able to find out if you are at risk of heart disease and could be educated on how you can lessen the risk. If you are selected as one of the education-exercise participants the year exercise program could lessen your risk for heart disease. The participants will be given information on the study while involved in the project and when results are available. Participation in this research study is voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation in this research study at any time.

Are there any risks involved in participation in the study?

There are no risks involved to you while participating in the intervention. Taking medication such as anti-retroviral therapy, could involve some risks but if the researcher or research assistant notice any deterioration in health status while you are participating in the study she will refer you to a medical practitioner at Themba Lethu clinic.

Will information be handled as confidential?

Efforts will be made to keep personal information confidential. If you have any further questions regarding the research study you can contact me, *Ronel Roos* at the following contact number: 011 7173723 during office hours.

If you wish to report any complaints/problems regarding the research study you can contact Anisa Keshav at The Human Research Ethics Committee of the University of Witwatersrand on telephone number 011 7171234.

APPENDIX 5

CONSENT FORM 1 (ENGLISH)

Title of Study: Risk factors and the effect of physical activity modification for ischemic heart disease in individuals living with HIV.

Informed Consent

- I hereby confirm that I have been informed by the researcher, Ronel Roos or her research assistant about the nature, conduct, benefits and risks of this study
- I have also received, read and understood the above written information document regarding the research study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by Ronel Roos or on her behalf.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

PARTICIPANT:

Printed Name	Signature / Mark or Thumbprint	Date and Time

I, Ronel Roos or research assistant, herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

RESEARCHER/ RESEARCH ASSISTANT:

Printed Name	Signature	Date and Time

APPENDIX 6

CONSENT FORM 2 (ENGLISH)

Title of the study: Risk factors and the effect of physical activity modification for ischemic heart disease in individuals living with HIV.

Informed Consent form: Semi-structured interview

- I hereby confirm that I was informed by the researcher, Ronel Roos or her research assistant that the semi-structured interview of phase one of this study will be tape recorded to enable transcription following the interview.
- I hereby confirm that I was informed by the researcher, Ronel Roos or her research assistant that these tape recordings will be kept in a safe place and locked away for five years following the completion of the study. After a period of five years these tapes will be destroyed.

PARTICIPANT:

Printed Name Signature/ Mark or Thumbprint Date and Time

I, Ronel Roos or research assistant, herewith confirms that the above participant has been fully informed about the nature of the semi-structured interview.

RESEARCHER/ RESEARCH ASSISTANT

Printed Name Signature Date and Time

APPENDIX 7

CODING FORM

Participant's Code:

Title of study: Risk factors and the effect of physical activity modification for ischemic heart disease in individuals living with HIV.

Name : ……..……
Physical address:
……..
……..
……..

Postal address:
……..
……..
……..

Home telephone number : ……..
Work telephone number : ……..
Cell phone number : ……..

APPENDIX 8

DEPARTMENT OF HEALTH CLINICAL TRIAL REGISTRATION INFORMATION

From: confirmation@sanrr.co.za
Sent: 04 May 2012 08:23 AM
To: Ronel Roos
Subject: National Ethics Application #: 2982

Dear Ronel Roos

Your Application, "Risk factors and the effect of physical activity modification for ischemic heart disease in individuals living with HIV.", Protocal # "M10238" has been assigned the following unique DOH Trial Number: "DOH-27-0512-3982".

Kind regards,
Department of Health

APPENDIX 9

COHEN'S PERCEIVED STRESS SCALE – 10 (PERMISSION LETTER)

From: Sheldon Cohen [mailto:scohen@andrew.cmu.edu]
Sent: 01 December 2009 02:38 PM
To: Ronel Roos
Subject: RE: Perceived Stress Scale: PhD

Ronel, You have my permission to use the PSS in your study. You can find information on the PSS on our website: www.psy.cmu.edu/~scohen click on scales on the front page. Best of luck with your work. Sheldon Cohen

---

From: Ronel Roos [mailto:Ronel.Roos@wits.ac.za]
Sent: Tuesday, December 01, 2009 4:49 AM
To: scohen@cmu.edu
Subject: Perceived Stress Scale: PhD

Dear Dr. Cohen,

My name is Ronel Roos and I am a physiotherapy lecturer and potential PhD candidate at the University of the Witwatersrand in Johannesburg, South Africa.

I am planning to do my PhD in the HIV research arena.

As part of my study I would like to use your "Cohen's Perceived Stress Scale" to evaluate the participants' perceived stress levels.

I am thus writing to you in order to obtain permission to use your "Cohen's Perceived Stress Scale" as assessment tool in my study.

It would be highly appreciated if this could be made possible.

Sincerely,
Ronel Roos
(Physiotherapy Lecturer)

APPENDIX 10

COHEN'S PERCEIVED STRESS SCALE – 10

Participant's Code: **Date:**

Items and instructions for Perceived Stress Scale

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate *how often* you felt or thought a certain way. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer each question fairly quickly. For each question choose from the following alternatives and then *tick the appropriate box*

0. Never	1. Almost Never	2. Sometimes	3. Fairly often	4. Very often

---

1. In the last month, how often have you been upset because of something that happened unexpectedly?

0. Never	1. Almost Never	2. Sometimes	3. Fairly often	4. Very often

2. In the last month, how often have you felt that you were unable to control the important things in your life?

0. Never	1. Almost Never	2. Sometimes	3. Fairly often	4. Very often

3. In the last month, how often have you felt nervous and "stressed"?

0. Never	1. Almost Never	2. Sometimes	3. Fairly often	4. Very often

4. In the last month, how often have you felt confident about your ability to handle your personal problems?

0. Never	1. Almost Never	2. Sometimes	3. Fairly often	4. Very often

5. In the last month, how often have you felt that things were going your way?

0. Never	1. Almost Never	2. Sometimes	3. Fairly often	4. Very often

6. In the last month, how often have you found that you could not cope with all things that you had to do?

0. Never	1. Almost Never	2. Sometimes	3. Fairly often	4. Very often

7. In the last month, how often have you been able to control irritations in your life?

0. Never	1. Almost Never	2. Sometimes	3. Fairly often	4. Very often

8. In the last month, how often have you felt that you were on top of things?

0. Never	1. Almost Never	2. Sometimes	3. Fairly often	4. Very often

9. In the last month, how often have you been angered because of things that were outside of your control?

0. Never	1. Almost Never	2. Sometimes	3. Fairly often	4. Very often

10. In the last month, how often have you felt difficulties were piling up so high you could not overcome them?

0. Never	1. Almost Never	2. Sometimes	3. Fairly often	4. Very often

APPENDIX 11

CONTRACT LABORATORY SERVICES ACCREDITATION WITH THE SOUTH AFRICAN NATIONAL ACCREDITATION BOARD

sanas
South African National Accreditation System

CERTIFICATE OF ACCREDITATION

In terms of section 22(2) (b) of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 (Act 19 of 2006), read with sections 23(1), (2) and (3) of the said Act, I hereby certify that:-

NATIONAL HEALTH LABORATORY SERVICE (NHLS)
CONTRACT LABORATORY SERVICES
Co reg no: 1997/015443/07
Practice no: 5204240

Facility Accreditation Number: **M0074**

is a South African National Accreditation System accredited laboratory provided that all SANAS conditions and requirements are complied with

This certificate is valid as per the scope as stated in the accompanying schedule of accreditation, Annexure "A", bearing the above accreditation number for

MEDICAL TESTING LABORATORY
CHEMISTRY, HAEMATOLOGY, MICROBIOLOGY, MOLECULAR BIOLOGY, SEROLOGY AND TUBERCULOSIS

The facility is accredited in accordance with the recognised International Standard

ISO 15189:2007

The accreditation demonstrates technical competency for a defined scope and the operation of a laboratory quality management system

While this certificate remains valid, the Accredited Facility named above is authorised to use the relevant SANAS accreditation symbol to issue facility reports and/or certificates

Mr R Josias
Chief Executive Officer

Effective Date: 01 July 2009
Certificate Expires: 30 June 2013

APPENDIX 12

DEMOGRAPHIC QUESTIONNAIRE (1)

Demographic Questionnaire (1) **Participant's Code:**

1. Date of Birth:	**2. Gender:** Male □ Female □
3. Dependents: Yes □ No □	Age of dependents:
4. Education level: No education □ Primary School □ Secondary School □ Post Secondary School □	**5. Occupation:**
6. Past Medical History:	**7. Past Surgical History:**
8. Current medications (*Participant*) _____ _____ _____ _____ _____ _____ _____ _____	**9. Drug History** (*Participants File*) _____ _____ _____ _____ _____ _____ _____ _____

10. Recreational activities

10.1. Do you participate in any formal sport activity? *(tick the relevant box)*

Yes	No

If you do, what sport do you play?

10.2. Do you do any exercises on your own?

Yes	No

If you do, what type of exercise do you do?

11. Smoking History *(tick the relevant box)*

11.1 Do you smoke?

Yes	No

11.2 If no, have you ever smoked?

Yes	No

11.3 If yes, did you smoke in the last 12 months?

Yes	No

11.4 How many cigarettes do you smoke per day?

0-5	5-10	10-20	More than 20

11.5 How many years have you smoked?

0-5	5-10	10-20	More than 20

11.6 If you stopped smoking, why did you stop?

12. HIV History

12.1 When were you diagnosed as being HIV positive?

12.2 How long have you been taking antiretroviral therapy?

12.3 How would you rate your current health status? *(Tick the relevant box)*

Excellent	Good	Average	Poor

12.4 Do you feel that your body shape has changed in the last six months?

Yes	No

If it did change, how did your body shape change?

12.5 Do you feel that you have gained weight in the last six months?

Yes	No

12.6 Do you feel that you have lost weight in the last six months?

Yes	No

13. General Symptoms *(tick the relevant box)*

13.1 Is there a history of heart disease in your family?

Yes	No

If there is a history of heart disease in your family, did it involve your parents or grandparents?

Yes	No

13.2 Do you often feel short of breath?

Yes	No

If you do, when do you often feel short of breath?

13.3 Do you often feel tired or fatigued?

Yes	No

If you do, when do you often feel tired or fatigued?

13.4 Have you ever experienced chest pain?

Yes	No

If you have, where on your chest did you have chest pain?

What were you doing when you experienced chest pain?

How many minutes did the chest pain remain?

What did you do for the chest pain to subside?

14. Dietary evaluation *(tick the relevant box)*

14.1 How often do you drink alcoholic beverages?

Daily	weekly	monthly	I do not drink

14.2 How many alcoholic beverages do you drink per day?

None	0-2	More than 5	More than 10

14.3 How often do you eat fish in a week?

I do not eat fish	I do not eat fish every week	Once a week	More than two times a week

14.4 Do you eat vegetables and/or fruit?

Yes	No

14.5 How often do you eat vegetables and/or fruit?

Daily	Weekly	I do not eat vegetables or fruit

14.6 Do you eat 3-5 vegetables and/or fruit per day?

Yes	No	I do not eat vegetables or fruit

Thank you for completing this information!

Have a good day!

APPENDIX 13

PHASE 1 EVALUATION FORM

Participant Code: **Date:**

MEASUREMENTS	
Vital Signs: Heart rate: *HR 1:* *HR 2:* *Average HR:* Blood pressure: *Right SBP:* *Right DBP:* *Left SBP:* *Left DBP:* *Average SBP:* *Average DBP:* Respiratory rate:	Anthropometric measure: Height: Weight: Waist circumference: Hip circumference: *Placement during hip circumference*
Waist: Hip ratio	Body Mass Index: (*kg/m²)*
Pedometer results Steps per day: Steps per seven days:	
EXISTING DATA FROM PARTICIPANT'S CLINIC FILE	
Liver Function Data *(Participants clinical captured data)* • Date of latest full LFD data • Date of latest AST/ALT data	 _____ _____
Latest full LFD results AST: ALT: GGT:	Latest AST/ALT results AST: ALT:
Viral load • Date of latest results. _____ • Results: _____	CD4 count • Date of latest results. _____ • Results: _____
Latest HIV testing date:	

APPENDIX 14

PEDOMETER ACTIVITY WALKING LOG (ENGLISH)

Participant Code: **Date:**

Dear Participant,

Remember at this phase of the study we want to evaluate the number of steps you take during the day. We are able to evaluate this by using the pedometer (step counter) supplied to you. There are a few things to remember during this process and they are as follows:

- The time period for assessment is *seven days*. At the end of each day when going to bed, document the pedometer readings on the table provided. The seven days should be consecutive days.

- The pedometer should be worn during the day, from getting up in the morning until going to bed at night. The pedometer should not be worn when sleeping, showering, bathing or washing one self.

- The pedometer should be placed at the waist at mid-thigh level e.g. clipped to a belt or waistband of skirt or pants. Wear it on the same side of your body every day.

- The pedometer is an electronic devise. Please do not let the pedometer get wet, don't throw or drop the pedometer and keep the pedometer away from young children.

Day	Date	Pedometer Count	Activity Time
Saturday			
Sunday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

Please bring this paper filled in as requested to your next appointment. Thank you!

APPENDIX 15

PEDOMETER ACCURACY SHEET

QUICK PEDOMETER VALIDATION TEST

Participant's Code:	
Pedometer type:	
Pedometer number:	
Date:	
Distance measured:	10 meters
Number of steps counted in distance:	
Pedometer step count in distance:	
Stride length: Distance divided by number of steps counted.	

Instruction for measuring stride:

1. Measure a distance of 10 meters using a tape measure.
2. By starting with both feet behind the starting point count how many steps it takes you to walk 10 meters (try and walk at a normal fast pace).

Position of pedometer:

1. Position on belt or waistband, in the midline of the thigh.
2. Pedometer's writing should be level (horizontal) with no tilting of pedometer.

APPENDIX 16

INFORMATION DOCUMENT (ISIZULU)

Idokumende Lemfomesheni

Isihloko Salolu Cubungulo: Amaphuzu amathuba engozi (risk factors) kanye nomthelela wokushintshwa komnyakazo womzimba mayelana nesifo senhliziyo se-*ischemia* (ukushoda kwezinhlayiya zegazi ezibomvu endaweni ethile emzimbeni) kubantu abaphila ne-HIV.

Sawubona,

Igama lami wuRonel Roos. Ngiwumfundisi we-*physiotherapy* (ukwelashwa ngokunyakazisa umzimba) eNyuvesi yaseWitwatersrand. Ngenza ucwaningo ngesifo senhliziyo kubantu abane-HIV. Ucwaningo lumane luyindlela yokuthola impendulo emibuzweni ethile ekhethekile. Kulolu cubungulo ngokukhethelile sifuna ukubona ukuthi likhona yini ithuba lengozi yokuphathwa yisifo senhliziyo kubantu abane-HIV nanokuthi uhlelo lokufundiswa nokuvocavoca umzimba lungasiza yini ekwehliseni leli thuba lengozi. Ngakho-ke ngiyakucela/ngiyakumema ukuba ubambe iqhaza kulolu cubungulo locwaningo.

Lolu cubungulo lubizelani?

Abantu abane-HIV abahamba uMtholampilo iThemba Lethu eSibhedlela iHelen Joseph bamenywa ukuba babambe iqhaza kulolu cubungulo locwaningo.

Ingxenye Yokuqala

Kungxenye yokuqala, ngizokala ithuba lakho lokubanjwa yisifo senhliziyo ngokukala ukushaya kwenhliziyo, umfutho wegazi, isisindo, umjikelezo wokhalo kanye nesilinganiso sokhalo: inqulu (waist: hip ratio). Uzocelwa futhi ukuba ugcwalise izinhla zemibuzo ezimbili (questionnaires). Uhla lwemibuzo lokuqala luzokubuza ngemfomesheni ejwayelekile njengobudala, usuku lokuzalwa, umlando wokubhema, umlando we-HIV kanye nezimpawu ezivamile ozilindele, njl. Olwesibili uhlaka lwemibuzo luzobuza imfomesheni ngobungako bokucindezeleka (stress) obhekana nabo ekuphileni kwakho. Sizokala futhi iqophelo lomnyakazo wakho womzimba nge-*pedometer* (umshini wokubala omncanyana) obala izinyathelo ozithathayo ngosuku. Uzocelwa ukuba ulokhu unalo mshini wokubala kuwe phakathi nosuku isikhathi esiyiviki. Kule ngxenye yocubungulo ngizobuye ngibe nengxoxiswano nawe ukuze ngibone ukuthi ukuqonda kanjani ukuphila ngendlela enempilo kanye namaphuzu ethuba lokubanjwa yisifo senhliziyo. Futhi kule ngxoxiswano ngizokucela ukuba ubheke amakhadi akhethekile bese ukhetha lawo makhadi ocabanga ukuthi achaza umqondo wokuphila ngendlela enempilo. Futhi le ngxoxiswano izoqoshwa ngetheyiphu ukuze ngikwazi ukuyihlaziya kamuva. Le miqopho yetheyiphu izogcinwa inkathi eyiminyaka emihlanu endaweni ephephile bese kuthi emva kweminyaka emihlanu ibhujiswe. Ingxenye yokuqala izohlanganisa iziwombe ze-*consultation* ezimbili ezicishe zibe yihora sisinye.

Ingxenye Yesibili

Labo bantu abakungxenye yokuqala yalolu cubungulo abanethuba elithe xaxa lokubanjwa yisifo senhliziyo futhi abasonyangweni lwe-*antiretroviral* bazomenyelwa kungxenye yesibili yalolu cubungulo. Ingxenye yesibili yocubungulo nayo izoba neziwombe ezimbili ze-*consultation*:

isiwombe sokukala kanye nesiwombe sokufundisa. Ngenkathi siqhubeka isiwombe umsizi wocwaningo uzophinda akale busha ukushaya kwenhliziyo yakho, umfutho wegazi, isisindo somzimba, isilinganiso sokhalo: inqulu kanye neqophelo lakho lokucindezeleka. Inani lezinyathelo ozithatha ngosuku lizophinda likalwe yi-*pedometer*. Loku kubalulekile ngoba amanani kungenzeka asehlukile ukusuka kungxenye yokuqala. Futhi ngalesi sikhathi kuzodingeka ukuhlolwa kwegazi ukuze kukalwe iglukhosi, ikholesteroli kanye namaqophelo okuphawula inhliziyo enezilonda zokugula. Inqubo yesampula legazi izokwenziwa wunesi waselebhu futhi kuzothathwa cishe amathesipuni amane egazi. Kungase kube khonyana ukungaphatheki kahle ngenkathi kwenziwa inqubo yesampula legazi.

Abantu ababamba iqhaza kungxenye yesibili bazobe sebabelwa eqenjini eligcinwa linjalo noma okwenziwa kulo ushintsho. Loku kusho ukuthi abantu abathile bazothola kimi uhlelo lokufundiswa kuthi abanye bangalutholi. Labo abangatholi hlelo bazoqhubeka benakekelwa ngendlela ejwayelekile yezokwelapha (clinical management). Lapho lolu cubungulo seluphothuliwe futhi noshintsho olwenziwe eqenjini lusebenzile, ababambi-qhaza beqembu eligcinwe linjalo nabo bazofundiswa ngoshintsho oluye lwenziwa uma bethanda. Njalo ngenyanga ngizobafonela laba bambi-qhaza ukubabuza ukuthi kuhamba kanjani. Labo bantu abathola kimi uhlelo lokufundiswa bazocelwa ukuba bazame ukukwenza loku izinyanga eziyi-12 ngesivinini sabo. Njalo ngenyanga sizohlangana esibhedlela iHelen Joseph ukuze ngiqaphe intuthuko yenu futhi ngizokuthumelela i-SMS njalo emavikini amabili yokukukhumbuza ukuba unyakazise umzimba. Emva kwezinyanga eziyi-6 kuzoba khona isiwombe se-*consultation* eHelen Joseph nabo bonke ababambi-qhaza balolu cubungulo ukuze kutholwe ukuthi niqhuba kanjani nanokukala imininingwane eye yahlolwa lapho kuqaliswa lolu cubungulo. Izinyanga eziyi-6 ezilandelayo zizobizela ukuba wena uzinyakazisele umzimba ngaphandle kokuthintwa wumcwaningi noma umsizi wocwaningo. Emva konyaka kuzodingeka siyiphinde yonke le nqubo yokukala futhi ukuze sibone ukuthi umzimba wakho uye wasabela kanjani. Zonke iziwombe ze-*consultation* zizokwenzelwa eSibhedlela iHelen Joseph futhi uzobuyiselwa izindleko zakho zokugibela kube yi-R50 isiwombe ngasinye.

<u>Ziyini izinzuzo kubababambi-qhaza?</u>

Uma ubamba iqhaza kulolu cubungulo locwaningo uzokwazi ukuthola ukuthi usethubeni yini lokubanjwa yisifo senhliziyo futhi ungase ufundiswe ngokuthi ungalinciphisa kanjani ithuba lale ngozi. Uma ukhethwa njengomunye wababambi-qhaza bohlelo lokufundiswa lolu hlelo lonyaka lungase lunciphisa ithuba lakho lokubanjwa yisifo senhliziyo. Ababambi-qhaza bazonikwa imfomesheni ngalolu cubungulo ngenkathi bekuleli projeke lapho imiphumela isitholakala. Ukubamba iqhaza kulolu pahando locwaningo kungokokuzithandela, ukwala ukubamba iqhaza akuzukuhambisanba nasijeziso noma ukulahlekelwa yizinzuzo ovele unelungelo lazo, futhi ungase uyeke ukuqhubeka nalolu cubungulo nokubamba iqhaza kulolu cubungulo noma nini.

<u>Ingabe akhona amathuba engozi ekubambeni iqhaza kulolu cubungulo?</u>

Akukho mathuba engozi kuwe ngenkathi ubambe iqhaza kulolu nyango lokuhlola. Ukuthatha imishanguzo enjengonyango lwe-*antiretroviral*, kungase kuhilele amathuba athile engozi kodwa uma umcwaningi noma umsizi wocwaningo eqaphela ukwehla kwesimo sempilo ngenkathi ubambe iqhaza uzokukhomba kudokotela wokwelapha emtholampilo iThemba Lethu.

Ingabe imfomesheni izophathwa njengeyisifuba?

Kuzokwenziwa imizamo yokugcina imfomesheni yomuntu siqu iyisifuba. Uma useneminye imibuzo mayelana nalolu cubungulo locwaningo, ungangithinta mina, *Ronel Roos*, kule namba yokuxhumana elandelayo: 011 7173723 ngesikhathi somsebenzi.

Uma ufisa ukubika noma yiziphi izikhalo/ izinkinga ngokuphathelene nalolu cubungulo locwaningo ungathinta u-Anisa Keshav e-Human Research Ethics Committee yeNyuvesi yaseWitwatersrand kunamba yocingo u-011 7171234.

APPENDIX 17

CONSENT FORM 1 (ISIZULU)

Isihloko Salolu Cubungulo: Amaphuzu amathuba engozi (risk factors) kanye nomthelela wokushintshwa komnyakazo womzimba mayelana nesifo senhliziyo se-*ischemia* (ukushoda kwezinhlayiya zegazi ezibomvu endaweni ethile emzimbeni) kubantu abaphila ne-HIV.

Imvume Emva Kokuchazelwa

- Ngaloku ngiyaqinisekisa ukuthi ngazisiwe wumcubunguli, uRonel Roos noma umsizi wakhe wocwaningo, ngobunjalo, indlela yokuziphatha, izinzuzo kanye namathuba engozi kwalolu cubungulo (study).
- Futhi ngilitholile, ngalifunda ngaliqonda iphepha lemfomesheni ebhalwe ngenhla mayelana nalolu cubungulo locwaningo.
- Ngiyaqaphela ukuthi imiphumela yalolu cubungulo, kuhlanganise imininingwane yomuntu siqu ngobulili bami, ubudala, usuku lokuzalwa, amanishiyeli kanye nopopolo (diagnosis) kuzoproseswa ngaphandle kokudalula igama lami kufakwe embikweni wocubungulo.
- Ngokwezindingeko zalolu cwaningo, ngiyakuvuma ukuthi imininingwane (data) eqoqwe ngesikhathi salolu cubungulo iproseswe kusistimu yekhompuyutha wuRonel Roos noma egameni lakhe.
- Nginakho, kunoma yiliphi iqophelo, futhi ngaphandle kokulimala ngandlela thize, ukuhoxisa imvume yami kanye nokubamba iqhaza kulolu cubungulo.
- Ngibé nalo ithuba elanele lokubuza imibuzo futhi (ngokuzithandela) ngazisa obala ukuthi ngizimisele ukuhlanganyela kulolu cubungulo.

UMBAMBI-QHAZA:

Igama Eliprintiwe	Isiginesha / Uphawu noma Isithupha	Usuku Nesikhathi

Mina, Ronel Roos noma umsizi wocwaningo, ngaloku ngiqinisekisa ukuthi lo mbambi-qhaza ongenhla uye waziswa ngokugcwele ngobunjalo, indlela yokuziphatha kanye namathuba engozi alolu cubungulo olungenhla.

UMCWANINGI / UMSIZI WOCWANINGO:

Igama Eliprintiwe	Isiginesha	Usuku Nesikhathi

APPENDIX 18

DEMOGRAPHIC QUESTIONNAIRE (1) (ISIZULU)

Uhla Lwemibuzo Lwedemografi **Ikhodi Lombambi-qhaza:**

1. Usuku Lokuzalwa:	**2. Ubulili:** Isilisa □ Isifazane □
3. Abondliwayo: Yebo □ Cha □	Ubudala babondliwayo:
4. Iqophelo lemfundo: Akukho mfundo □ Isikole Sabaqalayo □ Isikole semfundo yesibili □ Ngaphezu kwesikole semfundo yesibili □	**5. Umsebenzi owenzayo:**
6. Umlando Wokwelashwa:	**7. Umlando Wokuhlinzwa:**
8. Imishanguzo yanjengamanje (*Umbambi-qhaza*) _____ _____ _____ _____ _____ _____ _____ _____	**9. Umlando wezidakamizwa** (*Ifayela Lombambi-qhaza*) _____ _____ _____ _____ _____ _____ _____ _____

10. Izenzo zokuzilibazisa

10.1. Ingabe imidlalo ehleliwe (formal) ohlanganyela kuyo? *(Qhwisha ibhokisi okuyilonalona)*

Yebo	Cha

Uma udlala, mdlalo muni owudlalayo?

10.2. Ingabe uyazijimela ngokwakho?

Yebo	Cha

Uma ujima, wenza nhloboni yokuzivocavoca?

11. Umlando Wokubhema *(Qhwisha ibhokisi okuyilonalona)*

11.1 Ingabe uyabhema?

Yebo	Cha

11.2 Uma ungabhemi, ingabe wake wabhema?

Yebo	Cha

11.3 Uma ubhema, ingabe uke wabhema kulezi zinyanga eziyi-12 ezidlule?

Yebo	Cha

11.4 Ubhema osikilidi abangaki ngosuku?

0-5	5-10	10-20	Ngaphezu kuka-20

11.5 Usebheme iminyaka emingaki?

0-5	5-10	10-20	Ngaphezu kuka-20

11.6 Uma ngabe uyekile ukubhema, wayekelani?

12. Umlando we-HIV

12.1 Wapotsholwa watholakala nini ukuthi une-HIV?

12.2 Side kangakanani isikhathi uthola unyango lwe-*antiretroviral*?

12.3 Ungasibeka kuphi isimo sakho sempilo? *(Qhwisha ibhokisi okuyilonalona)*

Sihle kakhulu	Sihle	Silingene nje	Sibi

12.4 Ingabe unomuzwa wokuthi isakheko somzimba wakho sishintshile kulezi zinyanga ezi-6 ezidlule?

Yebo	Cha

Uma sishintshile, sishintshe kanjani isakheko sakho somzimba?

12.5 Ingabe unomuzwa wokuthi uye wakhuluphala kulezi zinyanga ezi-6 ezidlule?

Yebo	Cha

12.6 Ingabe unomuzwa wokuthi uye wehla ngesisindo kulezi zinyanga ezi-6 ezidlule?

Yebo	Cha

13. Izimpawu Ezijwayelekile *(Qhwisha ibhokisi okuyilonalona)*

13.1 Ingabe bakhona abake baba nesifo senhliziyo emndenini wakini?

Yebo	Cha

Uma bekhona abake baba nesifo senhliziyo emndenini wakini, ingabe kwakukubazali bakho noma komkhulu nogogo?

Yebo	Cha

13.2 Ingabe uvamile ukuphelelwa wumoya?

Yebo	Cha

Uma kunjalo, uvame ukuphelelwa nini wumoya?

13.3 Ingabe uvamile ukuzizwa ukhathele noma ucobekile?

Yebo	Cha

Uma kunjalo, uvame ukuzizwa nini ukhathele noma ucobekile?

13.5 Ingabe wake wezwa ubuhlungu esifubeni?

Yebo	Cha

Uma kunjalo, kumaphi esifubeni lapho wezwa khona ubuhlungu?

Wawenzani ngesikhathi uzwa ubuhlungu esifubeni?

Lobu buhlungu esifubeni bathatha imizuzu emingaki?

Yini owayenza ukuze budambe lobu buhlungu esifubeni?

14. Ukuhlolwa kwesimo sokudla *(Qhwisha ibhokisi okuyilonalona)*

14.1 Uvame kangakanani ukuphuza uphuzo oludakayo?

Njalo ngosuku	Njalo ngeviki	Njalo ngenyanga	Angiphuzi

14.2 Uphuza iziphuzo ezidakayo ezingaki ngosuku?

Azikho	0-2	Ngaphezu kuka-5	Ngaphezu kuka-10

14.3 Uvame ukuwudla kangaki ufishi ngeviki?

Angiwudli ufishi	Angidli ufishi onke amaviki.	Kanye ngeviki	Ngaphezu kwakabili ngeviki

14.4 Ingabe uyawadla amaveji noma izithelo?

Yebo	Cha

14.5 Uvame kangakanani ukudla amaveji noma izithelo?

Njalo ngosuku	Njalo ngeviki	Angiwadli amaveji noma izithelo

14.6 ingabe udla amaveji ayi-3-5 noma izithelo ngosuku?

Yebo	Cha	Angiwadli amaveji noma izithelo

Siyabonga ngokugcwalisa kwakho le mfomesheni!

Ube nosuku oluhle!

APPENDIX 19

PEDOMETER ACTIVITY WALKING LOG (ISIZULU)

Ikhodi Lombambi-qhaza: **Usuku:**

Mbambi-qhaza othandekayo

Khumbula ukuthi kulesi sigaba socubungulo sifuna ukukala inani lezinyathelo ozithathayo phakathi nosuku. Loku sikwazi ukukukala ngokusebenzisa i-*pedometer* (isibali-zinyathelo) esiyinikwa nguwe. Kunezinto ezimbalwa zokukhunjulwa phakathi nale nqubo futhi yilezi ezilandelayo:

- Ubude benkathi yokukala *yizinsuku eziyi-7.* Ekupheleni kosuku ngalunye lapho usuyolala, bhala phansi ama-*reading* e-*pedometer* kuthebula elihlinzekiwe. Lezi zinsuku eziyi-7 kufanele kube ngezilandelanalayo.

- I-*pedometer* kufanele ibe semzimbeni, ukusuka ekuvukeni ekuseni kuze kube yisikhathi sokuyolala ebusuku. I-*pedometer* akufanele ibe semzimbeni lapho umuntu elele, eseshaweni, esebhavini noma egeza.

- I-*pedometer* kufanele ibekwe okhalweni iqondane nemaphakathi lethanga, okuwukuthi ipaqekwe ebhandeni noma endaweni yebhande lasokhalweni yesiketi noma ibhulukwe. Ifake ohlangothini olufanayo lomzimba nsuku zonke.

- I-*pedometer* iyithuluzi lelektroniki. Siza ugweme ukuba i-*pedometer* ibe manzi, ungayiphonsi noma uyiwise i-*pedometer* futhi gcina i-*pedometer* ikude nezingane ezincane.

Usuku lweviki	**Usuku**	**Isibalo se-*Pedometer***	**Isikhathi Somnyakazo**
Mgqibelo			
Sonto			
Msombuluko			
Lwesibili			
Lwesithathu			
Lwesine			
Lwesihlanu			
Mgqibelo			
Sonto			
Msombuluko			
Lwesibili			
Lwesithathu			
Lwesine			
Lwesihlanu			

*Ucelwa ukuba uze naleli phepha ligcwalisiwe lapho uza ku-*appointment *yakho elandelayo.*

Siyabonga!

APPENDIX 20

PILOT STUDY 1

Procedure

Participants were educated regarding the two pedometers and how to keep a physical activity log. An accuracy test of the pedometers used in the study was done with each participant. Accuracy was determined by demarcating a 10 meter distance in a corridor of the physiotherapy department and participants were instructed to wear each of the pedometers respectively on the right side of the body. The participants walked at a comfortable normal pace over the 10 meters, starting with the right leg and counting the number of steps taken. The researcher also counted the steps taken and was positioned at a distance behind the participant so that the walking speed would not be influenced. The counted steps were evaluated against the pedometer reading and recorded on a pedometer accuracy sheet (Appendix 15). During the course of the pilot study 1 four of each pedometer model was used to provide a representative pedometer sample. This procedure of including more than one pedometer of a specific model when evaluating pedometers is supported by Schneider et al. (2004).

Participants were given the following instructions:

- to wear the pedometer for seven consecutive days from getting up in the morning until going to bed at night. It was requested that the SW200 should be worn on the left and the CW600 on the right side of the body. This particular body placement, if the SW200 is to be used as the criterion, is supported by Schneider et al. (2004). Pedometer placement was standardised by placing it on the belt or waistband, in the midline of the thigh, consistent with the manufacturer's recommendations (Yamax, 2010).

- to continue with their normal daily routine as this study focused on everyday physical activity.

- to document their steps per day (SW200 and CW600) and physical activity time (CW600) on the physical activity log at night when removing the two pedometers.

Statistical analysis

Data collected were captured in Microsoft Excel 2007 spread sheets. Analyses were performed using Windows Microsoft 2007 Excel and SPSS version 18. An alpha of $p \leq 0.05$ was used to denote statistical significance. Means and standard deviations were used to demonstrate average steps per day as well as physical activity time data of the study sample. The student t-test was used to determine whether the pedometer-estimated steps were significantly different from the actual steps taken during the accuracy test as well as to assess the differences between steps counted with the two pedometers. The Pearson correlation coefficient was used to assess the association with regards to reliability between the two pedometers during physical activity assessment over the seven day assessment period as the data were normally distributed. The association between the counted steps and pedometer steps of the 12 individuals during the pedometer accuracy test were evaluated with the Spearman's correlation coefficient as the data were not normally distributed. Accuracy of agreement between the two pedometers was evaluated using the Bland-Altman method and presented as a Bland-Altman plot.

Results

The sample consisted of 10 women (83.30%) and two men (16.70%). One participant in the sample of twelve did not record data for consecutive days and this subject's information was therefore not included during the data analysis of physical activity levels but included during pedometer accuracy analysis. Table 20.1 outlines the physical activity results of pilot study 1.

Table 20.1: Physical activity level results of pilot study 1 (n = 11)

Variable	n	SW 200	CW 600
Mean (±SD) physical activity time			
▪ sample	11	*This model does not reflect activity time.*	74 (±34) min
▪ men	2		86 (±34) min
▪ women	9		71 (±34) min
Mean step count per day			
▪ sample	11	7 749 (±3 970)	7 603 (±3 947)
▪ men	2	9 314 (±3 429)	8 597 (±3 503)
▪ women	9	7 401 (±4 023)	7 382 (±4 031)

♦ m (meters), min (minutes)

There was no statistically significant difference between the pedometer-estimated steps and actual counted steps for the accuracy tests (SW200: p=0.29; CW600: p=0.26). A higher correlation was observed between pedometer-estimated steps and actual counted steps during the accuracy test with the SW200 pedometer (r=0.96, p<0.00) compared to the CW600 pedometer (r=0.82, p<0.00). The results during the accuracy test of the SW200 were as follows (n=12): mean counted steps 14.83 (±2.16) and mean pedometer steps 14.75 (±2.34). The results during the accuracy test of the CW600 were as follows (n=12): mean counted steps 15.08 (±1.93) and mean pedometer steps 15.33 (±2.23). The difference between the mean counted steps and mean pedometer steps of the SW200 and CW600 respectively was as follows; SW200 tended to underestimate by 0.5% and the CW600 tended to overestimate by 1.02%.

No statistically significant difference (p=0.13) was noted between the two pedometers with step count evaluation during everyday physical activities in this sample. The Pearson correlation coefficient between the SW200 and CW600 pedometers concerning step count was r=0.96 (p=0.00) as depicted in Figure 20.1.

It is important to note that one participant's individualised data resulted in a correlation of r=0.52 that slightly affected the scatter plot. The SW200 pedometer reading was significantly (p<0.00) lower than the CW600 reading in her case.

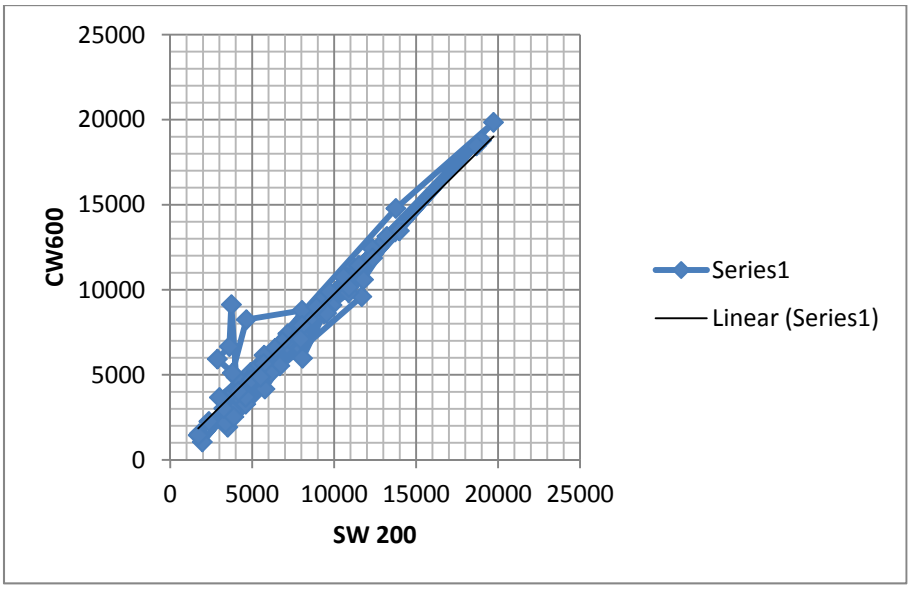


Figure 20.1: Scatter Plot of Pearson Correlation Coefficient Between SW200 and CW600 Pedometer Models (r=0.96).

Figure 20.2 displays the Bland-Altman plot depicting the difference in steps detected between the CW600 and SW200 (CW600 steps per day minus SW200 steps per day). The mean step count difference in steps detected between the two pedometers was 146 (±24) (SW200 > CW600).

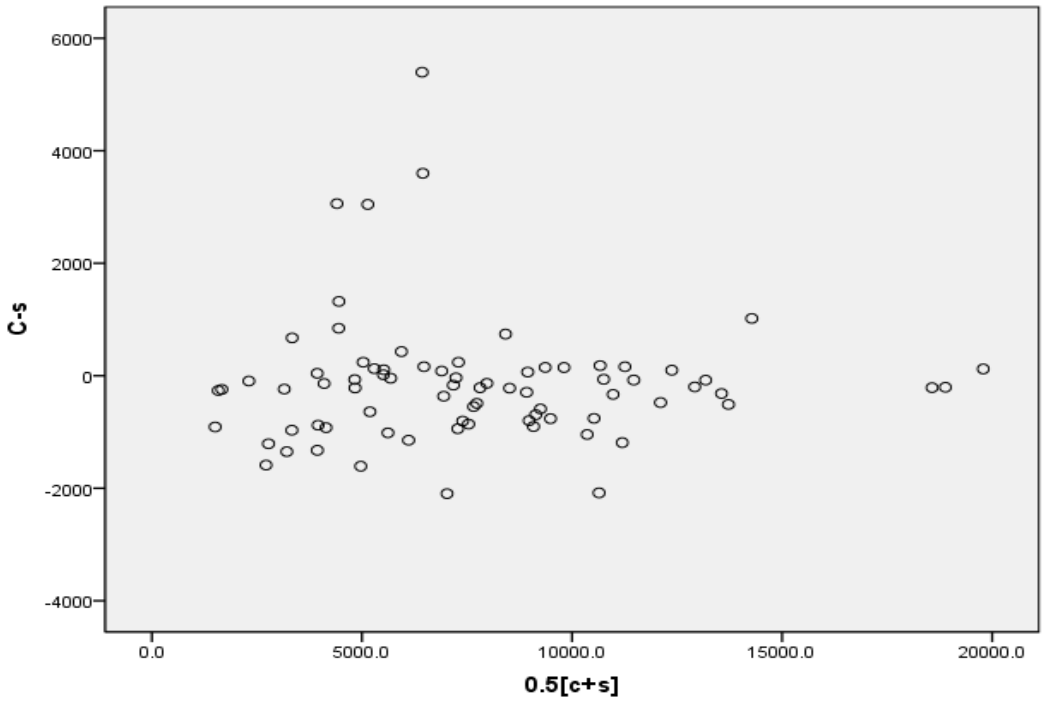


Figure 20.2: Bland-Altman Plot of Difference Between CW600 and SW200 is Drawn Against the Mean of CW600 and SW200.

In 52 of the 77 days data sets analysed, the CW600 detected fewer steps per day than the "gold standard" SW200 pedometer. The CW600 pedometer tended to underestimate step count during everyday physical activity assessment in study participants.

Discussion

The primary purpose of this pilot study was to determine the accuracy and reliability between the Yamax CW600 and Yamax SW200 pedometers during everyday physical activity assessment. Pilot study 1 found that there was no statistically significant difference in step count registered with the SW200 and CW600 Yamax pedometer models. The Pearson correlation coefficient suggested a very strong linear relationship between the two models and intra-model reliability was established. However, closer inspection of the data revealed a notable lack of agreement in steps detected between the two pedometers as evident by the Bland-Altman plot (Figure 20.2). When reviewing the Bland-Altman plot it was clear that an obvious pattern was present; the CW600 pedometer regularly underestimated step count per day. Good agreement between instruments is revealed with a Bland-Altman plot when no discernible pattern can be observed (Myles, 2007; Bland and Altman 1999). The mean difference in steps detected by the CW600 and the SW200 was within an acceptable range. A cause for concern was that the CW600 underestimated steps counted in the majority of the 77 data set days. Cumulatively, these data suggested that one instrument's step output might not be easily substituted for the other if an absolute number of steps taken was desired such as for research purposes. However the high correlation between the two pedometers does support the interchangeability of the two instruments with regards to steps taken if only relative values are required and not absolute.

It is important to elaborate on one participant's lower correlation finding and this can be done in the following way. This participant reported left sided lower back pain during the course of the study period at completion of data collection. It is however important to note that during the accuracy test of the pedometers during this particular participant's evaluation, she did however not complain of any back symptoms and was walking at a similar pace as the other participants. The effects specific to one's lifestyle activity on pedometer reading is not known e.g. carrying a child on one's hip or back while wearing a pedometer. Lifestyle events might have affected the pedometer readings as the participant had a small child that she often carried on her hip. It might be suggested in future that participants with small children not carry them on their hips when physical activity assessment with a waist worn pedometer is being carried out as this might influence research findings.

Challenges identified during pilot study 1

1) Ladies might only wear dresses as clothing. The researcher should ensure that she has a belt available to secure at a participant's waist to enable placement of the pedometer during the pedometer accuracy test in future studies related to the research project. Alternative suggestions should be given to ladies if they only wear dresses e.g. ensure you wear a dress with a secure fitting belt or wear pedometer on cycling shorts (tights) under dress during physical activity assessment in future studies.

2) Lifestyle events could possibly affect accuracy of pedometer findings when participants wear waist worn pedometers and carry a small child on their hip or back during physical activity assessment. This is a very important factor to be aware of, as African women in South Africa often carry their small child on their back firmly secured with a blanket. This practice could result in the child dislodging the pedometer or bumping the pedometer leading to inaccurate step count findings. Women of other ethnic origin in South Africa also commonly carry their small child on their hip. This could also influence pedometer findings. It should therefore be suggested to women with small children to refrain from carrying their child in this manner during the seven day physical activity assessment in future studies.

3) Participants reported often looking for their physical activity log sheet. The researcher decided to add a bright colourful outer cover to the physical activity log to increase visibility of this document during future studies.

4) During explanation of the pedometers at the start of the pilot study, the researcher had to repeat the workings of the CW600 pedometer a number of times before participants understood it as this particular pedometer had more functions. It was thus concluded that the SW200 was easier to understand compared to the CW600.

Conclusion

The intra-model and inter-model reliability of the Yamax SW200 and Yamax CW600 pedometers indicate a close relationship when assessing step count and it can be suggested that these pedometers are suitable for everyday physical activity assessment. Due to the limited agreement/accuracy between the instruments one instrument's steps data may not be easily substituted for the other. The population of the pilot study consisted of individuals with tertiary education and the researcher anticipated that participants in the future studies of the research project would not have such a high educational level. It was therefore concluded that the SW200 should be used as it was easier understood by pilot study participants compared to the CW600. The Yamax SW200 therefore seemed to be more appropriate for research purposes if only steps per day were evaluated in a specific study. It was therefore decided to use the Yamax SW200 pedometer during the rest of the PhD research project studies.

APPENDIX 21

PILOT STUDY 2

Procedure

The procedure that was followed in pilot study 2, was the same as the procedure explained in chapter 4 section 4.4 of study 1. The only differences in the procedure of pilot study 2 were as follows:

- A face-to-face interview for the participant with the researcher was scheduled at the physiotherapy room in the clinic following informed consent received. This was necessary as the "runner" (research assistant three) was not yet part of the research project.

- Participants' information pertaining to CD_4 count, viral load and liver function tests were collected from their clinic files only as the researcher had not yet received permission to access the clinic's National Health Laboratory database.

- The verbal cues given to participants at the pedometer accuracy test was walk at a normal comfortable pace over the 10 meter distance starting with the right leg.

- Two readings of each parameter being assessed were done to allow for reliability assessment.

- During these sessions, if an individual had difficulty understanding information an interpreter (Themba Lethu clinic employee; counselor) was asked to translate for the researcher. The translator was instructed to translate word for word or as close as possible dependent on vernacular word availability.

Statistical analysis

Data collected during pilot study two was captured in Microsoft Excel 2007 spread sheets. Statistical analysis was performed using Microsoft Windows Excel 2007 and IMB SPSS version 20. Data was evaluated for normal distribution. The sample size was small (24 individuals) and variability existed between normal distributions of variables. It was therefore decided to use Spearman's correlation coefficient to evaluate the intra-rater reliability of the pedometer during accuracy testing and researcher reliability during assessment procedures. Physical activity and body measurement findings are represented as medians (interquartile range) and physical activity categories as frequencies and percentages. The percentage difference between mean pedometer counted steps and actual counted steps are reported as part of pedometer accuracy evaluation. Reactivity (Clemes and Parker, 2008): a change in normal behaviour as a result of having to wear a pedometer between first and last day of pedometer wear was assessed with a student t-test. Level of significance was set with alpha at $p \leq 0.05$. The internal consistency of the PSS-10 was evaluated with a Cronbach alpha test.

Results

The pilot study consisted of 22 women (92%) and two men (0.08%) with a median age of 36.50 (30.25–44.25) years. All participants attended both assessment sessions resulting in a 100% adherence rate of attendance. Most participants reported it was enjoyable seeing how their pedometer step counts differed from day to day and no specific problems related to wearing the

pedometer were reported. Table 21.1 is a representation of the body measurements (vital signs and anthropometric measurements) observed in participants.

Table 21.1: Results of the Body Measurements of Participants (n = 24).

Variable	n	Median	Interquartile range
Resting heart rate (bpm)	24	79.75	74.13 – 87.69
Systolic blood pressure (mmHg)	24	112.88	106.00 – 120.44
Diastolic blood pressure (mmHg)	24	74.25	68.94 – 80.38
Weight (kg)	24	66.25	58.00 – 70.58
Height (cm)	24	160.50	158.25 – 163.75
Body mass index (kg/m^2)	24	23.26	21.29 – 27.92
Waist circumference (cm) ▪ Men ▪ Women	24 2 22	80.50 83.25 80.50	73.13 – 89.50 77.00 – 83.25 72.88 – 89.50
Hip circumference (cm)	24	102.25	96.13 – 109.50
Waist: hip ratio ▪ Men ▪ Women	24 2 22	0.80 0.85 0.80	0.72 – 0.86 0.80 – 0.85 0.71 – 0.85

♦ bpm (beats per minute), mmHg (millimeters mercury), kg (kilograms), cm (centimetres), kg/m^2 (kilograms per meters squared).

All median values were within normal levels when reviewing the body measurements of the sample. The median pedometer step count finding of the sample was 9 367.14 (5 299.32–14 876.21) steps per day with men (18 442.57 [16 032.14–20 853]) being more active than women (8 360.43 [5 166.96–12 488.29]). The median physical activity category of the sample as a whole was the “somewhat active” category.

The participant frequencies according to the pedometer categories were as follows: “sedentary”, 4 (16.7%); “light active”, 6 (25%); “somewhat active”, 4 (16.7%); “active”, 3 (12.5%) and “very active”, 7 (29.2%). Thus 14 individuals fell into the less than active categories (less than 10 000 steps per day).

The intra-rater reliability of the pedometer during the accuracy test was r=0.59 (p=0.03). The mean actual counted steps during the accuracy test was 15.63 (±1.76) and the mean pedometer measured steps during the accuracy test was 15 (±1.93). The percentage difference between these two measurements was 0.04%. The researcher did notice that the instruction “walk at a normal comfortable pace” resulted in a slower walking pace when compared to pilot study 1 participants’ response.

No significant reactivity was noted between the first and last day of pedometer data collection (p=0.40). This indicated that participants did not change their physical activity behaviour due to wearing a pedometer and documenting their findings of the physical activity log sheet. Table 21.2 is a representation of the intra-rater reliability of the researcher when conducting body measurement (vital signs and anthropometric) assessment in pilot study 2 participants with study instrumentation.

Table 21.2: Results of the Intra-Rater Reliability of the Researcher (n = 24).

Variable	n	r – value	p – value
Heart rate one (bpm)	24	0.92	<0.00
Heart rate two (bpm)	24	0.93	<0.00
Systolic blood pressure one (mmHg)	24	0.90	<0.00
Systolic blood pressure two (mmHg)	24	0.88	<0.00
Diastolic blood pressure one (mmHg)	24	0.82	<0.00
Diastolic blood pressure two (mmHg)	24	0.90	<0.00
Height (cm)	24	0.99	<0.00
Weight (kg)	24	1.00	<0.00
Waist circumference (cm)	24	0.99	<0.00
Hip circumference (cm)	24	0.99	<0.00

♦ bpm (beats per minute), mmHg (millimeters mercury), kg (kilograms), cm (centimetres).

The intra-rater reliability of the researcher when conducting body measurement assessment of study participants in pilot study 2 with the specific instruments were all significant and fell into the "good to excellent" association category of Portney and Watkins (2009). This indicated that the method and procedure that was followed during assessments were reliable.

No specific challenges were identified when participants completed the demographic questionnaire one and the PSS-10 except that a counselor assisted with translation when one pilot study 2 individuals were interviewed. The only modification that was made to the demographic questionnaire was to question 14.3 that stated "How often do you eat fish in a week? The answers that participants could choose from initially were "I do not eat fish" or "Once a week" and lastly "More than two times per week". An additional option of "I do not eat fish every week" was added to the demographic questionnaire one following the pilot study two. During the pilot study it became apparent that participants could enjoy eating fish but due to personal reasons e.g. finances might not be able to afford to buy fish every week to eat it.

The median perceived stress level of the sample was 20 (14.00–25.75) with women reporting higher stress levels (20 [12.50–26.50]) than men (19 [14-19]). The reliability statistics as per Cronbach's Alpha analysis of the PSS-10 when assessing perceived stress levels in pilot study 2 participants was 0.82. The item-total statistics of the PSS-10 is presented in Table 21.3.

Table 21.3: Item-Total Statistics of PSS-10 in Pilot Study 2

PSS-10 Questions	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Squared multiple correlation	Cronbach's Alpha if item deleted
Question 1	16.96	67.43	0.32	0.49	0.83
Question 2	17.23	68.20	0.26	0.22	0.83
Question 3	17.42	59.65	0.76	0.68	0.78
Question 4	18.13	64.20	0.51	0.37	0.81
Question 5	17.63	61.55	0.56	0.61	0.80
Question 6	17.08	69.21	0.24	0.38	0.83
Question 7	17.67	62.93	0.58	0.53	0.80
Question 8	17.54	58.52	0.65	0.52	0.79
Question 9	17.25	64.02	0.58	0.61	0.80
Question 10	17.21	58.17	0.69	0.75	0.79

The item-total statistics of the PSS-10 maintain a Cronbach's Alpha value 0.70 to 0.90. It can therefore be concluded that the scale has strong internal consistency as supported by Portney and Watkins (2009).

Challenges identified during pilot study 2

A number of challenges were identified during the course of pilot study 2. These challenges were mostly related to logistical matters in the clinic and scheduling appointments for participants. The following is a brief outline of the challenges encountered:

1) When participants were attending the clinic due to reasons not pertaining to the study, it was not possible to test participants on the same day. Participants often supplied the following reasons: they would be tired following queuing, often finishing late for primary reason attending the clinic on the specific day and/or did not plan to attend the physiotherapy session as well. The need for a specific separate appointment for physiotherapy then became apparent but resulted in additional challenges.

2) Participants were subsequently phoned to schedule an appointment with the researcher. A number of cell phone telephone numbers were no longer in use. The clinic reported that they had the same problem and said that patients often bought new SIM-cards instead of doing top-up on existing numbers due to cost. It was less expensive to buy a new SIM-card with added phone time compared to keeping the existing number and buying airtime. If participants did not attend three scheduled first visits appointments, their consent form was filed in the lost to follow-up (post recruitment file).

3) Financial constraints amongst study participants were evident as the unemployment rate was high. This posed some challenges concerning scheduling appointments and adherence to appointments. The researcher did reimburse the participants their travel expenses but participants had to firstly have enough finances to pay for public transport to get to the clinic.

4) Acquiring the participant's file for review was often difficult, due to being in use somewhere in the clinic. The researcher therefore had to rely on subjective feedback from participants when reviewing the inclusion and exclusion criteria related to the study. Information found regarding participants' blood results in clinic files were often absent or very old (older than a year). Following a discussion with the medical manager and nursing manager of Themba Lethu clinic they reported that results are not always printed from the National Health Laboratory database system but viewed electronically.

5) The cue used during the accuracy test: "walk at a normal comfortable pace" resulted in a slower walking pace compared to pilot study one participants. This finding was of benefit as it highlighting the importance of tailoring the cue to the specific study population. The cue during the accuracy test was changed to: "walk at a normal fast pace as if you are trying to catch a taxi" for the remainder of study one.

6) Three of the female participants of pilot study two only wore dresses. This created some challenges concerning doing an accuracy test and placement of the pedometer during physical activity assessment. It was partly overcome by using a belt during accuracy testing in the clinic. Fortunately, these three women always wore lycra cycling shorts underneath their dresses. It was subsequently requested that the pedometer should be worn on these shorts during evaluation periods underneath their dresses.

7) One participant in the pilot study requested that a translator should assist during explanation of her study findings to improve her understanding. A nurse working in Themba Lethu clinic helped with this activity.

8) To overcome some of the challenges mentioned above a third research assistant was employed to function as "runner/place keeper" in the queue. This facilitated testing of participants on the day that informed consent was obtained. After informed consent was received, the researcher took the participant out of the queue, the runner stepped into the clinic queue and kept the participant's place. This strategy assisted in lessening drop-out rates following gaining informed consent from eligible participants. This research assistant also assisted with translation when the need arose creating more stability.

Conclusions

Pilot study 2 indicated that the researcher conducted reliable assessments when evaluating vital signs and anthropometric measurements in study participants with the chosen instruments. The internal consistency of the PSS-10 was demonstrated when evaluating perceived stress levels in individuals living with HIV. Accuracy testing of the Yamax SW200 pedometer in the study population revealed that cues needed to be changed to be more socially context specific during the accuracy test. The method of collecting pedometer step count findings (participants wearing the pedometer and documenting their own findings in the evening) were reliable as participants did not alter their walking behaviour when the first and last day of assessment were compared. This method of collecting step count findings were therefore continued in the rest of the research project. The pilot study found that the sample as a whole were "somewhat" active. However, more than half of the sample took less than 10 000 steps and had scope for improvement. All participants enjoyed wearing the Yamax SW200 pedometer and gave positive feedback regarding this activity.

APPENDIX 22

SEMI-STRUCTURED INTERVIEW QUESTIONNAIRE (ENGLISH)

Phase one: Semi-structured interview **Participant's Code:**

1. What do you understand by "living a healthy lifestyle"?

   _____
   _____
   _____

2. What complications or diseases can develop when one is not "living a healthy lifestyle"?

   _____
   _____
   _____

3. Can you look at the cards spread out in front of you and choose cards you would associate with a person who is "living a healthy lifestyle"?

   Please place these cards in front of you on the table.

   _____
   _____
   _____

   Now, would you please organize those cards you chose in order that you think is of priory and tell me what is most important and least important?

   _____
   _____
   _____

   Why are the cards you have chosen important to you?

   _____
   _____
   _____

4. Are you "living a healthy lifestyle"?

   _____
   _____
   _____

   If yes what are you already doing right in your life and if no why?

   _____
   _____
   _____

Can you tell me what is preventing you from saying that you are "living a healthy lifestyle" that you still need to improve on?

_____
_____
_____

Which elements can you improve on?

_____
_____
_____

5. What do you know about ischemic heart disease or heart disease?

_____
_____
_____

6. What does a person with ischemic heart disease complain of?

_____
_____
_____

7. Is there anyone in your family who has heart disease and what is your relation to that person?

_____
_____
_____

8. What do you think causes ischemic heart disease?

_____
_____
_____

9. Do you think ischemic heart disease and "living a healthy lifestyle" are related?

_____
_____
_____

If yes, why? And if no, why not?

_____
_____
_____

10. *Do you think that a person can prevent heart disease from occurring in his life?*

_____
_____
_____

If yes, why? And if no, why not?

_____
_____
_____

11. Do you consider yourself at risk of ischemic heart disease?

If yes, why? And if no, why not?

_____
_____
_____

Thank you very much for participating in this interview!

APPENDIX 23

CARD SORT FLASH CARDS

CARD 1

- SMOKING.
- **UKUBHEMA.**

CARD 4

- BLOWING A VUVUZELA DAILY.
- **UKUSHAYA IVUVUZELA NSUKUZONKE.**

CARD 2

- WASHING HANDS REGULARLY.
- **UKUHLANZA IZANDLA NJALO.**

CARD 5

- KNOWING YOUR HIV STATUS.
- **UKWAZI NGESIMO SAKHO KUGCIWANE LESANDULELA NGCULAZI.**

CARD 3

- TALKING ON A CELL PHONE REGULARLY DURING THE DAY.
- **UKUKHULUMA KUMAKHALA EKHUKHWINI NJALO OSUKWINI.**

CARD 6

- PARTICIPATING IN PROTECTED SEXUAL ACTIVITY.
- **UKUZIBANDAKAN YA OCANSINI OLUPHEPHILE.**

CARD 7

- EATING FRUITS AND VEGETABLES DAILY.
- **UKUDLA IZITHELO KANYE NEMIFINO NSUKUZONKE.**

CARD 8

- DRINKING RED WINE DAILY.
- **UKUPHUZA IWAYINI ELIBOMVU NSUKUZONKE.**

CARD 9

- USING YOUR PRESCRIBED MEDICATION.
- **UKUSEBENZISA IMITHI OBHALELWE YONA.**

CARD 10

- WATCHING TV FOR MORE THAN 2 HOURS AT ONE TIME.
- **UKUBUKA UMABONAKUDE ISIKHATHI ESINGAPHEZU KWAMAHORA AMABILI.**

CARD 11

- EATING PAP AND MEAT 3-5 TIMES A WEEK.
- **UKUDLA IPAPA NENYAMA IZIKHATHI EZINTATHU KUYA KWEZINHLANU NGESONTO.**

CARD 12

- DOING OWN HOUSEWORK REGULARLY.
- **UKWENZA UMSEBENZI WASENDLINI NJALO.**

CARD 13

- DOING OWN YARD OR GARDEN WORK REGULARLY.
- **UKWENZA UMSEBENZI WEGCEKE NOMA INGADI NJALO.**

CARD 14

- BRISK WALKING DAILY.
- **UKUHAMBA NGOKUSHESHA NSUKUZONKE.**

CARD 15

- SLEEPING 4-6 HOURS PER NIGHT.
- **UKULALA AMAHORA AMANE KUYA KWAYISITHUPHA NGOBUSUKU.**

CARD 16

- FEELING STRESSED OFTEN.
- **UKUZIZWA UKHATHAZEKILE KANINGI.**

CARD 17

- EATING SWEETS AND COOKIES DAILY.
- **UKUDLA AMASWIDI NAMAKHEKHE NSUKUZONKE.**

CARD 18

- MULTIPLE SEXUAL PARTNERS.
- **ABANGANI ABANINGI BOCANSI.**

CARD 19

- DRINKING 5-8 GLASSES OF WATER DAILY.
- **UKUPHUZA IZINGILAZI ZAMANZI EZINHLANU KUYA KWEYIZISHIYAGALOM BILI NSUKUZONKE.**

CARD 20

- WASHING FRUIT AND VEGETABLES BEFORE USE.
- **UKUHLANZA IZITHELO NEMIFINO NGAPHAMBI KOKUZISEBENZISA.**

CARD 21

- COOKING WITH OIL AND FAT REGULARLY.
- **UKUPHEKA NJALO NGOWOYELA NANGAMAFUTHA**

CARD 22

- SITTING A LOT DURING THE DAY.
- **UKUHLALA KAKHULU OSUKWINI.**

CARD 23

- EATING FISH REGULARLY DURING THE WEEK.
- **UKUDLA INHLANZI NJALO MAPHAKATHI NESONTO.**

CARD 24

APPENDIX 24

SEMI-STRUCTURED INTERVIEW QUESTIONNAIRE (ISIZULU)

<u>Isiwombe sokugala: Ingxoxiswano enohlakana</u> **<u>Ikhodi Lombambi-ghaza:</u>**

1. Wena ucabanga ukuthi kuyini “ukuphila ngendlela enempilo”?

   _____
   _____
   _____

2. Nkinga zini noma izifo ezingadaleka uma umuntu engakwenzi “ukuphila ngendlela enempilo”?

   _____
   _____
   _____

3. Ingabe ungabheka amakhadi achaywe phambi kwakho bese ukhetha amakhadi ongawahlobanisa nomuntu owenza “ukuphila ngendlela enempilo”?

   Ucelwa ukuba ubeke la makhadi phambi kwakho phezu kwetafula.

   _____
   _____
   _____

   Manje-ke, ingabe ungawahlela lawo makhadi owakhethayo uwalandelanise ngendlela ocabanga ukuthi abaluleke ngayo futhi ungitshele ukuthi yikuphi okubaluleke kakhulu nokubaluleke kancane kunako konke?

   _____
   _____
   _____

   Kungani la makhadi owakhethile ebalulekile kuwe?

   _____
   _____
   _____

4. Ingabe wena uyakwenza “ukuphila ngendlela enempilo”?

   _____
   _____
   _____

   Uma kunjalo, yini kakade oyenza kahle ekuphileni kwakho futhi uma kungenjalo kungani?

   _____
   _____
   _____

Ungangitshela ukuthi yini ekuvimba ungakwazi ukuthi uyakwenza "ukuphila ngendlela enempilo"?

_____
_____
_____

Yiziphi izici ongathuthukisa kuzo?

_____
_____
_____

5. Wazini ngesifo senhliziyo se-*ischemia* noma isifo senhliziyo?

_____
_____
_____

6. Umuntu onesifo senhliziyo se-*ischemia* uyaye akhale ngani?

_____
_____
_____

7. Is there anyone in your family who has heart disease and what is your relation to that person?

_____
_____
_____

8. Wena ucabanga ukuthi yini ebanga isifo senhliziyo se-*ischemia*?

_____
_____
_____

9. Ingabe wena ucabanga ukuthi isifo senhliziyo se-*ischemia* kanye "nokuphila ukuphila okunempilo" kuhlobene?

_____
_____
_____

Uma kunjalo, kungani kunjalo? Uma kungenjalo, kungani kungenjalo?

_____
_____
_____

10 Ingabe wena ucabanga ukuthi umuntu unako ukuvimba isifo senhliziyo singenzeki ekuphileni kwakhe?

_____
_____
_____

Uma kunjalo, kungani kunjalo? Uma kungenjalo, kungani kungenjalo?

_____
_____
_____

11. Ingabe uzibona usethubeni lengozi yokubanjwa yisifo senhliziyo se-*ischemia*?

Uma kunjalo, kungani kunjalo? Uma kungenjalo, kungani kungenjalo?

_____
_____
_____

Sibonga kakhulu ngokubamba kwakho iqhaza kule ngxoxiswano!

APPENDIX 25

CONSENT FORM 2 (ISIZULU)

Isihloko Salolu Cubungulo: Amaphuzu amathuba engozi (risk factors) kanye nomthelela wokushintshwa komnyakazo womzimba mayelana nesifo senhliziyo se-*ischemia* (ukushoda kwezinhlayiya zegazi ezibomvu endaweni ethile emzimbeni) kubantu abaphila ne-HIV.

Ifomu Lemvume Emva Kokuchazelwa: Ingxoxiswano Enohlakana

- Ngaloku ngiyaqinisekisa ukuthi ngazisiwe wumcubunguli, uRonel Roos noma umsizi wakhe wocwaningo ukuthi le ngxoxiswano ethe ukuba nohlaka yesiwombe sokuqala salolu cubungulo izoqoshwa ngebhande ukuze kwenzeke ukubhaleka okushiwo ngezwi emva kwale ngxoxiswano.

- Ngaloku ngiyaqinisekisa ukuthi ngazisiwe wumcubunguli, uRonel Roos noma umsizi wakhe wocwaningo ukuthi lemiqopho yebhande izogcinwa endaweni ephephile futhi ikhiyelwe iminyaka emihlanu emva kokuphothulwa kwalolu cubungulo. Emva kweminyaka emihlanu la mabhande azobhujiswa.

UMBAMBI-QHAZA:

Igama Eliprintiwe	Isiginesha / Uphawu noma Isithupha	Usuku Nesikhathi

Mina, Ronel Roos noma umsizi wocwaningo, ngaloku ngiqinisekisa ukuthi lo mbambi-qhaza ongenhla uye waziswa ngokugcwele ngobunjalo bale ngxoxiswano enohlakana.

UMCWANINGI / UMSIZI WOCWANINGO:

Igama Eliprintiwe	Isiginesha	Usuku Nesikhathi

APPENDIX 26

PILOT STUDY 3

Procedure

The interviews of the two lay persons were conducted separately in a private room at their home and with the qualitative researcher in a quiet tutorial room in the researcher's department. The aims and objectives of the pilot study were again explained to study participants. The interview was conducted using the semi-structured interview questionnaire and card sort technique. All interviews were tape recorded.

Following the interviews the participants were asked if the questions posed to them were easy to understand and the qualitative researcher was also asked to make suggestions on how the researcher should adapt her interview skills. Interviews were first conducted with the lay persons to assist with practise of the flow of the interview, using the tape recorder and practising interview skills. The third interview was then held with the qualitative researcher for review and academic feedback. The skills learned through the interviews above were then evaluated during the first qualitative interview with an individual living with HIV at Themba Lethu clinic. No additional adjustment needed to be made to interview sessions.

Results

The interviews were conducted with pilot study 3 participants using the selected instruments and procedures. No problems were experienced with the tape recorder during the separate interviews and recordings made were audible and clear. The questions on the semi-structured questionnaire and phrases on the flash cards were understood by all study participants.

The sequence of the interview followed the semi-structured interview questionnaire lay-out. The procedure concerning the card sort technique in the pilot study were as follows: cards were spread in front of participants on a table; they could then select cards that they deemed appropriate; the remaining non-selected cards were then removed from participants' view; participants then grouped the cards from most important to least important on a continuous line and they were able to overlap or stack cards if they thought the significance of cards were similar.

APPENDIX 27

CARD SORT TECHNIQUE (ADDITIONAL ANALYSIS)

Figure 27.1 is a representation of the cards that participants stacked into pile two on the continuous line during their interview therefore indicating that they deemed those cards as the second most important components of living a healthy lifestyle.

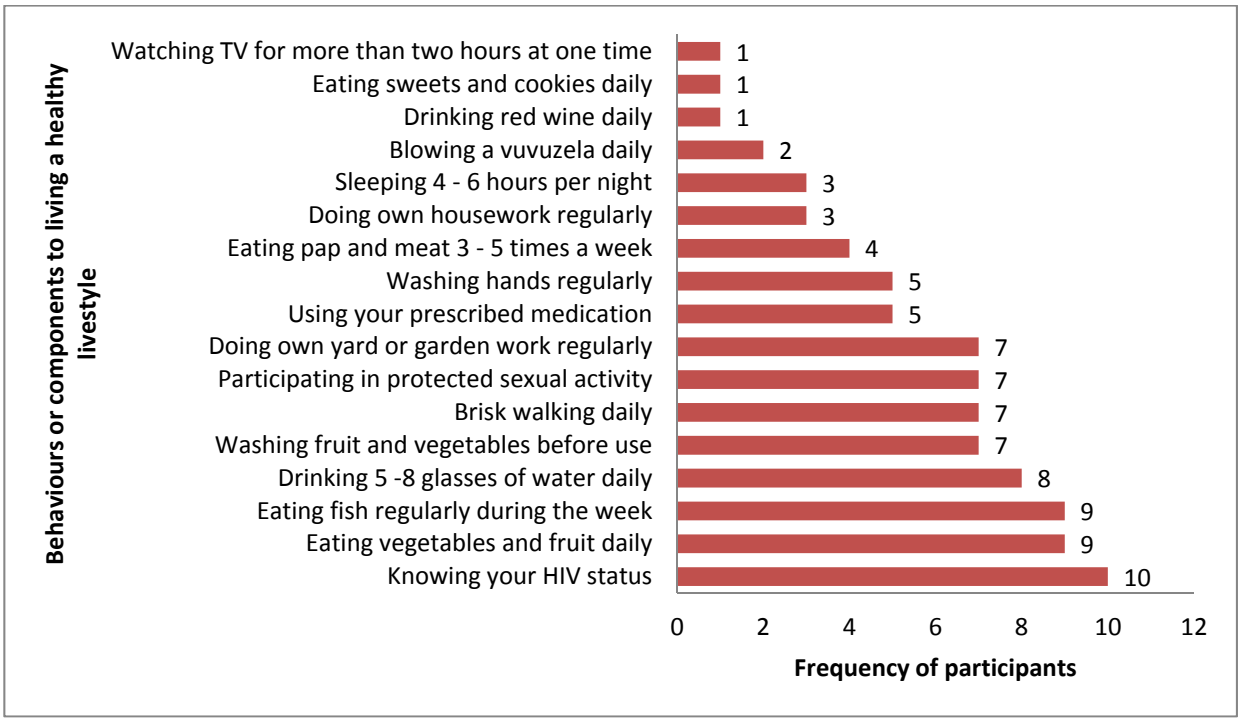


Figure 27.1: Second Most Important Behaviours or Components Related to Living a Healthy Lifestyle (n = 30)

Figure 27.2 is a representation of the cards that participants stacked into pile three on the continuous line during their interview therefore indicating that they deemed those cards as third most important components of living a healthy lifestyle. Twenty seven individuals made three piles during the interviews.

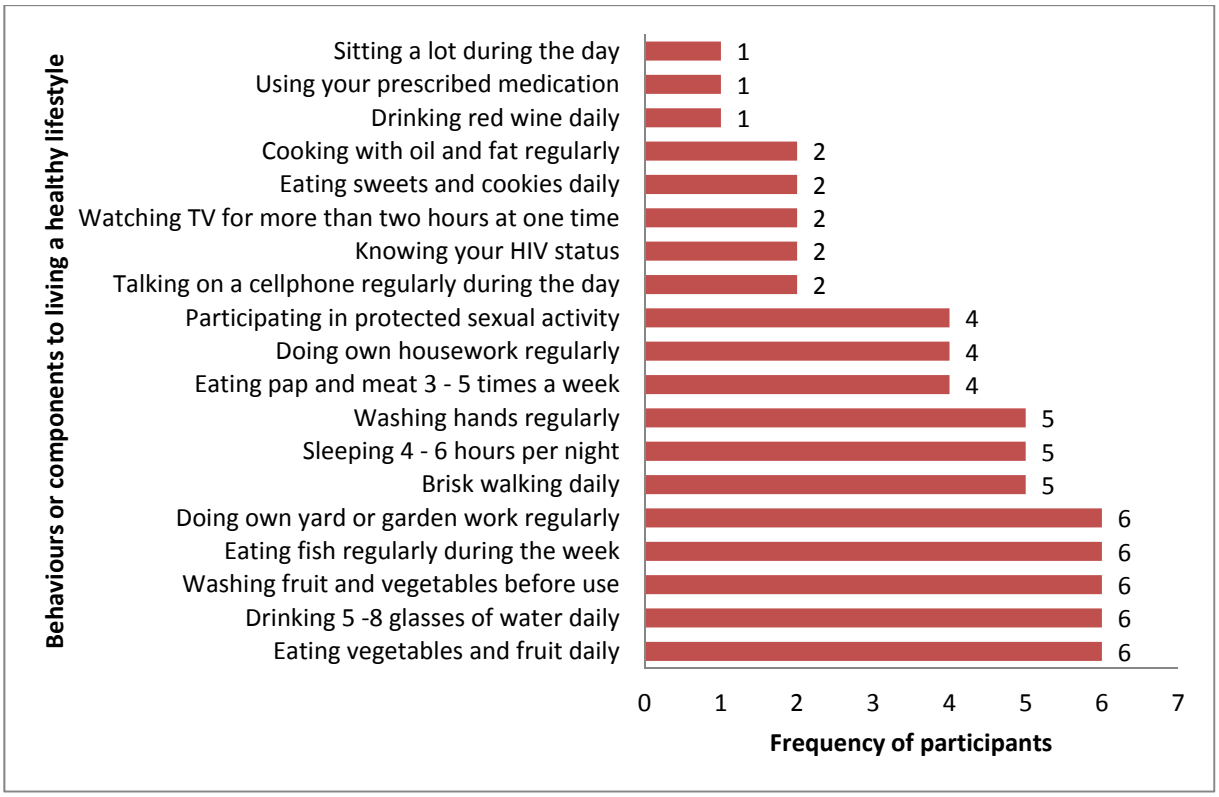


Figure 27.2: Third Most Important Behaviours or Components Related to Living a Healthy Lifestyle (n = 27)

Figure 27.3 is a representation of the cards that participants stacked into the fourth pile on the continuous line during their interview therefore indicating that they deemed those cards as fourth most important components of living a healthy lifestyle. Twenty two individuals made four piles during their interviews.

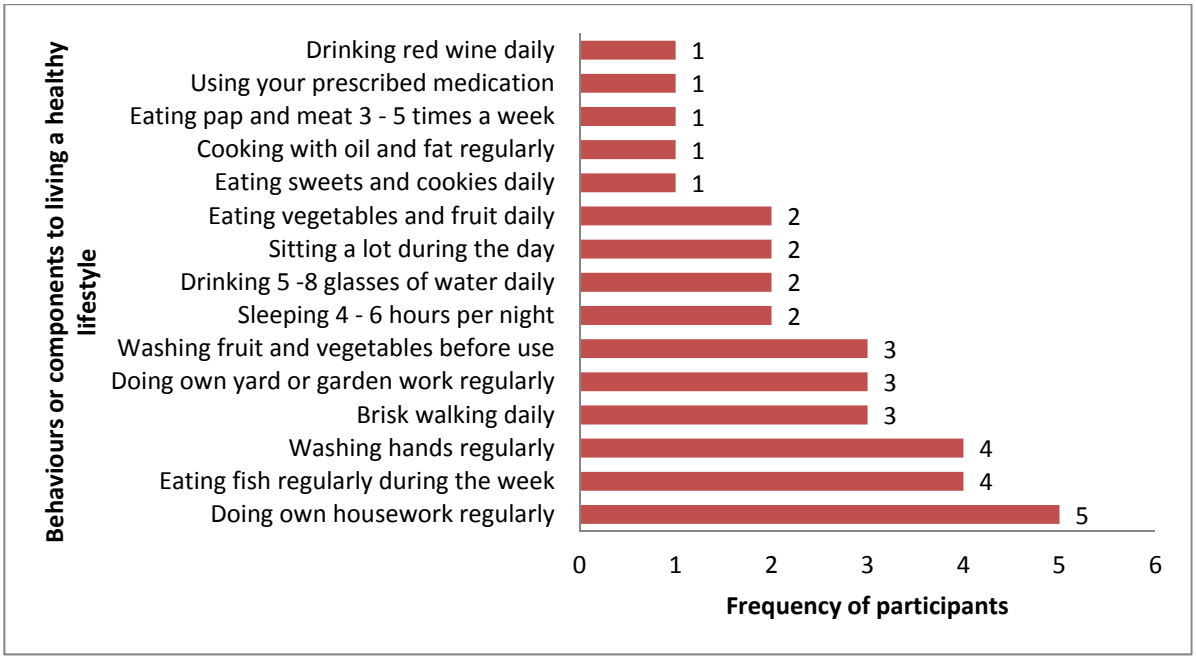


Figure 27.3: Fourth Most important behaviours or components related to living a Healthy Lifestyle (n = 22)

Figure 27.4 is a representation of the cards that participants stacked into the fifth pile on the continuous line during their interview therefore indicating that they deemed those cards as fifth most important components of living a healthy lifestyle. Seventeen individuals made five piles during their interviews.

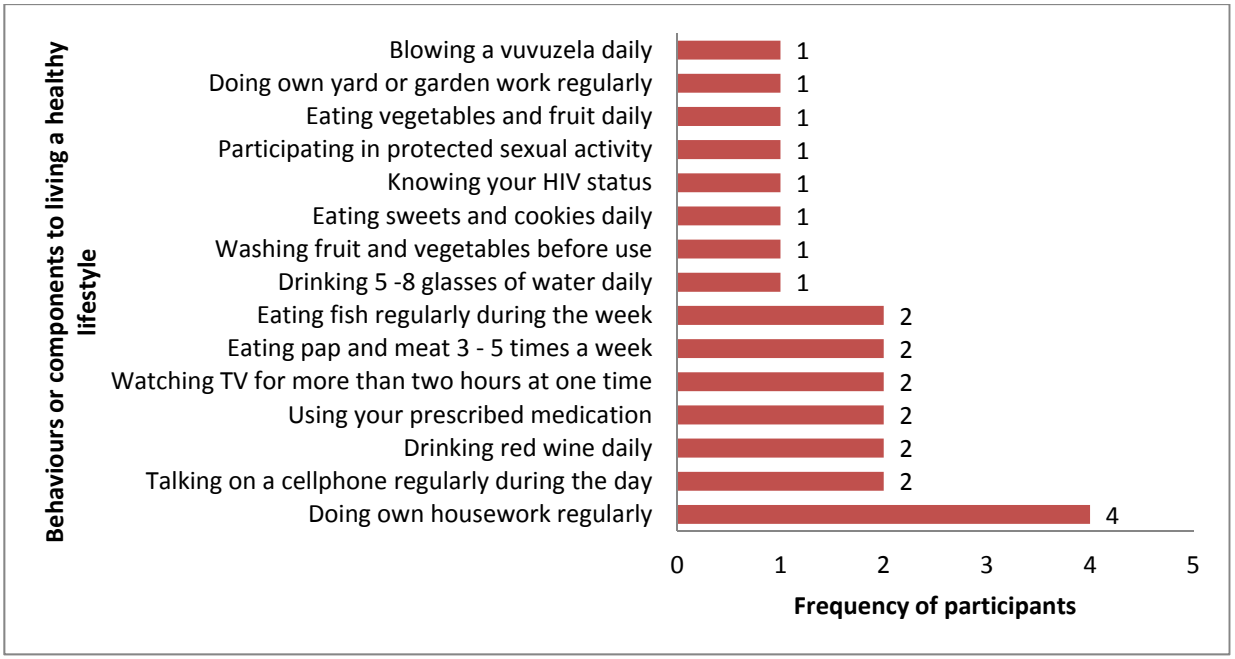


Figure 27.4: Fifth Most Important Behaviours or Components Related to Living a Healthy Lifestyle (n = 17)

Figure 27.5 is a representation of the cards that participants stacked into the sixth pile on the continuous line during their interview therefore indicating that they deemed those cards as sixth most important components of living a healthy lifestyle. Nine individuals made sixth piles during their interviews.

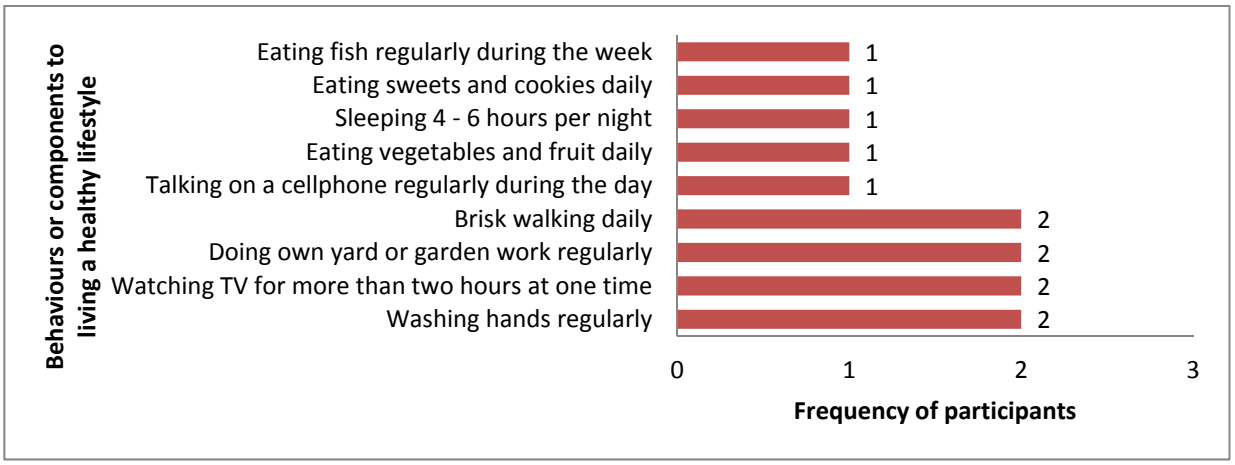


Figure 27.5: Sixth Most Important Behaviours or Components Related to Living a Healthy Lifestyle (n = 9)

Figure 27.6 is a representation of the cards that participants stacked into the seventh pile on the continuous line during their interview therefore indicating that they deemed those cards as second least important components of living a healthy lifestyle. Three individuals made seven piles during their interviews.

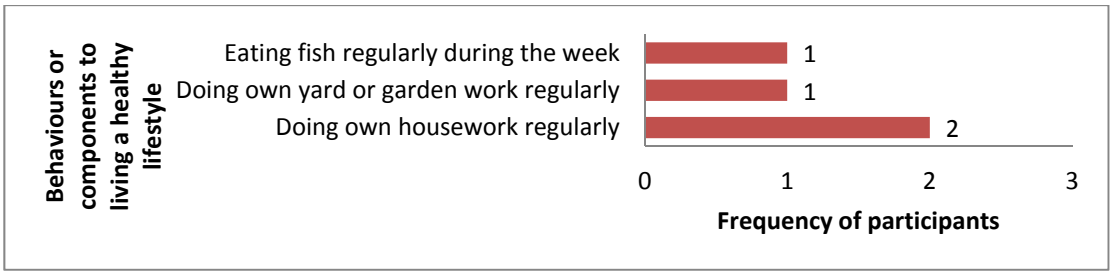


Figure 27.6: Second Least Important Behaviours or Components Related to Living a Healthy Lifestyle (n = 3)

Figure 27.7 is a representation of the cards that participants stacked into the eight pile on the continuous line during their interview therefore indicating that they deemed those cards as least important components of living a healthy lifestyle. Two individuals made eight piles during their interviews.

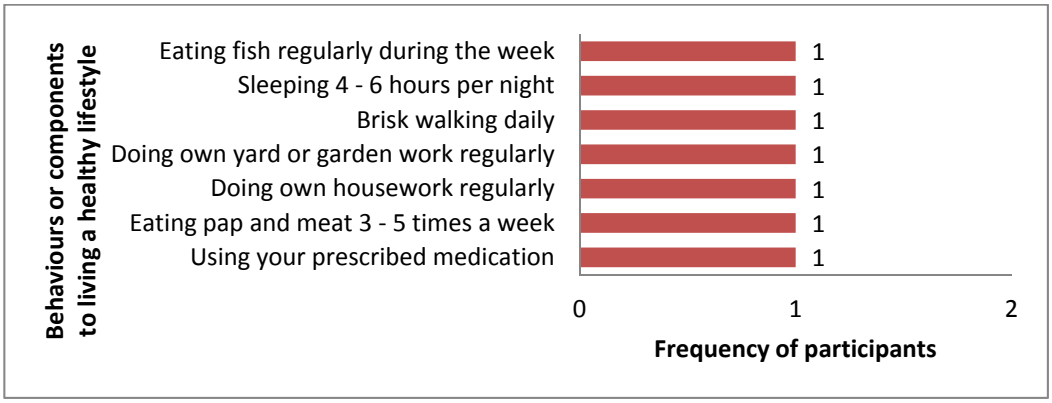


Figure 27.7: Least Important Behaviours or Components Related to Living a Healthy Lifestyle (n = 2)

APPENDIX 28

"COMMITMENT TO MYSELF" DOCUMENT

Figure 28.1 is a copy of the behavioural contract included in the education physical activity diary.

This physical activity diary belongs to:

.....

COMMITMENT TO MYSELF

- I understand that I am participating in this programme to improve my physical activity level and in doing so trying to improve my health status.
- I understand that it is important for me to actively participate in this programme as I am helping myself to live a healthy way of living.
- I will try to do my utmost best to follow my individualized walking programme and use the pedometer (step counter calculator) as instructed.
- I will try to achieve my walking step goals and use this "physical activity diary" to motivate me during the programme.
- If I am unable to meet my walking step goals, I will write down possible reasons why I could not achieve them in this diary. I understand that this will help my physiotherapist and me, to modify my walking programme so that I can achieve my walking step goals in the future.
- I am signing this form to show my commitment to this programme.

....

Signature **Date**

Figure 28.1: Commitment to Myself Document Included in the Education Physical Activity Diary

APPENDIX 29

EDUCATION PHYSICAL ACTIVITY DIARY: PHYSIOTHERAPY PEER-REVIEW PANEL FEEDBACK

The following suggestions were made by the academic peer-review panel that assisted with establishing the content validity of the education physical activity diary used in study 3:

- Grammatical errors were highlighted for correction.

- A number of suggestions were made regarding simplifying words throughout the document to improve understanding. Below is a table consisting of a few examples of such words or phrases.

Table 29.1: Suggestions for Simplifying Words

Initial wording	Suggested changes to be implemented
Modifiable risk factors	Change to "controllable risk factors" as it implies that an individual has some form of control over the risk factor.
Muscles are strengthened	Muscles become stronger
Muscle endurance	Muscles will not tire as quickly
Joint flexible	Joint move easier
Stay positive	Change to "stay motivated" as positive may reflect on HIV status.
Glucose	Sugar level
Cholesterol	Fatty deposits
Calories	Energy
Brisk pace	Brisk/ fast walk
Lifestyle	Way of living

- Suggestions were made regarding the order of the sections in the booklet and to add a heading to break some of the education material e.g. "What is physical activity?"

- The panel suggested adding the researcher's telephone contact details to the education physical activity diary in case a participant needed to inform the researcher about a change in their contact details and/or inability to attend appointments.

- The behavioural contract was initially worded as "Contract with myself" and the peer-review panel suggested changing it to "Commitment to myself" as the word contract implied a legal document and agreement.
- It was suggested that photographs be added to demonstrate the gentle exercises and to use different shapes and sized models as well as pictures to explain some of the education material. Local and contextual photographs were suggested e.g. adding a picture of the clinic or sign of the clinic.

- It was suggested to define certain terms that were used e.g. brisk walk. It was subsequently explained with regards to walking pattern: “A brisk/ fast walk is when you walk with big steps and is also swinging your arms to give you a bit more speed as if you are trying to catch a taxi”. When explaining brisk walking as an example of a moderate intensity activity level it was related more to a feeling of breathing faster and heart beating faster when doing a focussed walk.

- Adding additional words to text were suggested to improve understanding of certain concepts e.g. when describing moderate intensity adding the word medium and also adding “not too fast and not too slow”.

- The initial format had “toi-toi” as an example on how to improve one’s physical activity level. The panel suggested removing this as “toi-toi” dancing is only performed at political rallies and/or strikes in South Africa. It was suggested to rather use dancing, dancing lifting knees up high or running on the spot to explain the same activity without the political implications.

- Then suggestions were made to improve safety when participants were walking in their communities e.g. “If you can, walk with friends in a group” and/or “If you are worried about traffic when walking, remember you can walk around a soccer or sports field in your neighbourhood” and/or “Be safe when walking outdoors”.

The suggestions made by the academic peer-review panel were reviewed and implemented as appropriately prior to review by the physiotherapy clinician and a Themba Lethu patient group. Adding photographs and pictures were done during the design phase of the diary.

APPENDIX 30

EDUCATION PHYSICAL ACTIVITY DIARY: THEMBA LETHU CLINIC PATIENT GROUP FEEDBACK

Procedure of patient review of education physical activity diary

Individuals attending Themba Lethu clinic as patients were approached while they were sitting queuing at the pharmacy in the clinic to ask if they were willing to participate in the review of the education material to be added in the diary. Information pertaining to the research project as set out in the information document was verbally explained to participants to give them an understanding regarding the planned use of the diary. Willing participants were asked which format they would prefer to review: the English or the isiZulu format. A copy of the selected format was then given to each participant. They were requested to read the document and write any questions or comments on the document. A short discussion regarding the comments and questions written were held with each participant respectively following their review. Participants were asked a few demographic detail questions and their demographic feedback was recorded on their individual copies of the education physical activity diary that they reviewed. The researcher compiled the participants' feedback in a Microsoft Word document for review and use during the finalisation of the education physical activity diary. Participants' demographic details were analysed with IBM SPSS 21 following Microsoft Excel 2010 data capture.

Demographic details of patient group

Five female individuals attending Themba Lethu clinic as patients agreed to participate in the review of the education physical activity diary and provide feedback regarding its content. The home languages of participants were as follows: participant one (isiZulu and Sotho), participant two (isiZulu), participant three (isiZulu), participant four (isiZulu) and participant five (isiZulu). All participants reported that they were also able to speak English. Three (60%) participants requested an English format and two (40%) an isiZulu format for review. The demographic details of individuals are provided in the Table 31.1below.

Table 30.1: Demographic Details of Themba Lethu Patient Group

Variable	n	Median (Interquartile range) or n (%)
Age (years)	5	29 (22 – 34)
Education level • Primary school education • Secondary school education • Post-secondary school education	5	 1 (20%) 2 (40%) 2 (40%)
Time attending Themba Lethu clinic (years)	5	3 (1.5 – 5)
Time since diagnosed as HIV^+ (years)	5	6 (3.5 – 9)
Time on HAART (years)	5	5 (1.7 – 5)

General suggestions made by participants

Participants made the following general suggestions:

- Participants suggested the use of pictures in the diary especially at the gentle exercise section and at the paragraph explaining how to palpate their pulse rate to improve understanding.
- Participants suggested printing a small booklet that one could easily carry around in one's handbag.
- A space in the book to be able to record information was suggested. This space was suggested at the end of the book for note taking.
- A suggestion was made to have a section in the book where participants could make notes on how they felt and how they were exercising e.g. how many times they exercised per week.

Specific suggestions from participants

Participants made the following suggestions regarding queries they had when reviewing the diary:

- They did not know what a pedometer was and suggested explaining the device. A notation from one participant was as follows: "not well explained; what it is? Is it a gadget? Or schedule?"
- A participant suggested renaming the gentle exercise section. Her suggestion was as follows: "maybe you should say stretch or warm-up exercises".
- One participant highlighted the following words as difficult to understand: cholesterol level, narrowing, arteriosclerosis, alternating, quadriceps muscle,
- buttocks.

Participants also made notations regarding things they would like to be explained to them. A few examples are provided below for review.

"Uncontrollable risk factors; gender and age" – During the discussion with the researcher the participant explained she is not sure how gender and age can be a risk factor for IHD and wanted it explained. The relationship between age and gender were subsequently explained to this participant.

"If taking medication, and cholesterol affected, how can you control cholesterol to be stable and with your diet" – The participant reported that her cholesterol was high and she was on medication to lower her cholesterol level. She wanted to know what food will have a beneficial effect on lowering her cholesterol level. A low-fat diet with high fruit and vegetable intake was explained to her but it was also suggested that she speak with the dietician in Themba Lethu clinic regarding more specifics.

"Signs of chronic inflammation and how to prevent it" – She asked if one can see when one has chronic inflammation. It was explained to her that it can be evaluated by a blood test e.g. hs-CRP.

Conclusion

All participants wanted to take the information home with them but the researcher had to explain that the information was not yet finalised and being used in the research project at that time. Participants reported that reading the different copies were not difficult and they found the reading informative. One participant noted the following at the end of the booklet: “Informative – well written and interesting”. The suggestions made by participants were implemented during the finalisation of the diary prior to graphic designing the education physical activity diary. These changes included:

- Making the diary an A5 size to easily fit into a handbag.
- Adding illustrations, graphics and photographs.
- Adding the self-monitoring tools e.g. weekly pedometer physical activity tracking sheets.
- The “gentle exercise” section was renamed to “warm-up and cool-down” activities.
- A picture of a pedometer and words such as step counter were added.
- Initially the quadriceps stretch exercise was worded “anterior thigh stretch (quadriceps muscle stretch)” this was subsequently changed to only state “thigh stretch one”.
- Specific words were changed e.g. buttocks to bum and terms were more defined for improved understanding.

APPENDIX 31

EXAMPLE PAGES FROM THE EDUCATION PHYSICAL ACTIVITY DIARY

A. Education material regarding IHD

How can I make my lifestyle healthier? (Page 10)

B. Education material regarding the physical activity programme

How do I know I am exercising at a moderate intensity level? (Page 17)

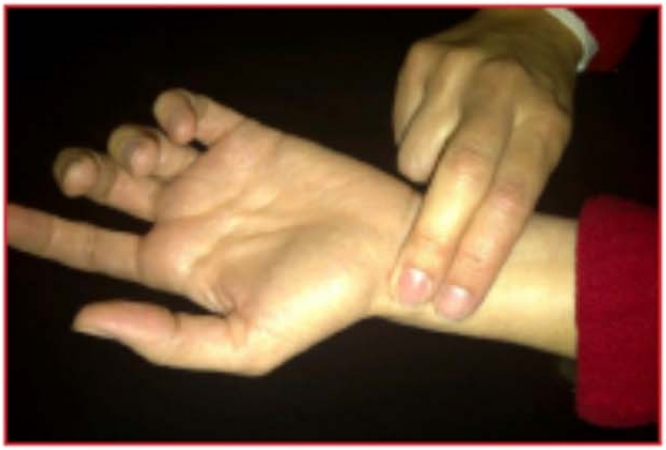
3. How do I know I am exercising at a moderate intensity level?

You can monitor your ***pulse rate/heart rate, your breathing and physical effort/difficulty experienced*** to see if you are exercising at a moderate intensity level.

Firstly, it is important to take your ***pulse rate/ heart rate*** before walking and again afterwards to see if you reached your goal during your individualised walking session.

When taking your pulse rate/heart rate:

- Feel for your pulse at your wrist on the thumbs side as shown in the picture.
- Count the beats for one minute to know what your pulse rate/ heart rate is in one minute.



You were exercising at the right level during your walking session if your pulse rate/heart rate fell within the following range in one minute:

Your individualised suggested pulse rate/heart rate range during walking is:

How do I know I am exercising at a moderate intensity level? (Page 18)

Secondly, when you are walking you can check if your **breathing** is increasing enough. You should still be able to talk a bit when walking but should find singing difficult.

Thirdly, you can evaluate if you are walking at a **moderate/medium physical effort level** (not too slow and not too fast) according to how your body feels.

At a moderate/medium effort you should be feeling:

- ***Warm and maybe slightly sweaty***
- ***Should notice an increase in your breath and pulse rate/ heart rate.***

A physical effort scale that you can use is the Modified Borg Scale. Your physiotherapist will show you an example of this scale during your physiotherapy sessions.

C. Warm-up and cool-down activities

Shoulder and trunk exercise, ankle exercise, calf stretch (Page 22)

SHOULDER AND TRUNK EXERCISE

- Stand upright.
- Clasp hands together.
- Stretch straight arms up towards the sky.
- Keep body still.
- Hold stretch 10 seconds.
- Relax arms back down.
- Repeat exercise another 2 times.

ANKLE EXERCISE

- Stand and gently hold onto a wall/chair for balance.
- Move foot up and down 5 to 10 times.
- Move foot around in a big circle 5 to 10 times.
- Your ankle and foot should feel nice and warm.

CALF STRETCH

- Stand upright with one leg in front of the other one step length apart.
- Lean forward on the front leg.
- Keep the heal of your back leg on the floor with your knee straight.
- Bend your front knee until you feel a stretch in your back leg.
- Hold the stretch for 30 seconds.
- Repeat with your other leg.

APPENDIX 32

DEMOGRAPHIC QUESTIONNAIRE (2)

Participant Code: ……..…… **Date:** ……

Section A

1. Employment status:
   - □ Employed
   - □ Self employed
   - □ Unemployed
   - □ Retired
   - □ Other: Specify……..……

2. Do you receive a governmental grant? □ Yes □ No

3. If you do receive a grant, what grant do you received?

   ……

4. Gross monthly income
   - □ R0 – R500
   - □ R501 – R1000
   - □ R1001 - R2000
   - □ R2001 - R5000
   - □ R5001 – R10 000
   - □ More than R10 000

5. Source of income: ……...

6. Marital status:
   - □ Single
   - □ Married
   - □ Divorced
   - □ Separated
   - □ Cohabitating
   - □ Widower/widow
   - □ Other: Specify……..……

Section B

1. Housing environment (*Do you live in the following dwelling?)*

   □ “Share a space”

   □ Informal settlement: Shack

   □ RDP house

   □ Hostel

   □ Flat

   □ Town house

   □ Residential house

   □ Other: Specify……..……

2. What means of transport do you use on a daily basis?

   □ Walking

   □ Bus

   □ Taxi

   □ Train

   □ Bicycle

   □ Motor vehicle

   □ Other: Specify……..……

APPENDIX 33

6MWT EVALUATION FORM

Participant Code: ……..…… **Date:** ……

Gender: Male □ Female □ Age:……

Height:……. Weight:…… Blood pressure:……

Parameters	Baseline Ax	End of test Ax
Time		
Heart rate	bpm	bpm
Respiratory rate	bpm	bpm
Oxygen saturation (SpO_2)	%	%
Level of dyspnea	(Borg scale)	(Borg scale)
Level of fatigue	(Borg scale)	(Borg scale)
Pedometer step count	steps	steps

1) Stopped or paused before 6 minutes? No □ Yes □ reason:…….……

2) Other symptoms at end of test: No □ Yes □: dizziness □ pain □

Lap counter: One lap = 30m x 2

3) Number of laps:……(x 60m) + final partial lap:……meters. = ……..

4) Total distance walked in 6 minutes:……meters

5) Predicted distance:…….meters Percentage predicted:……..%

APPENDIX 34

STANDARDISED INSTRUCTION DURING 6MWT

Instructions during the six minute walk test

1. "The object of this test is to walk as far as possible for 6 minutes. "

2. "Six minutes is a long time to walk so you will probably get breathless and tired. You are permitted to slow down, stop and rest as needed but start walking again as soon as able."

3. "You will walk back and forth in this hallway around the cones."

4. "Remember the aim is to walk as far as possible for 6 minutes, but don't run or jog."

5. "Start now, or whenever you are ready."

6. *Instructions during the test:*

    - After 1 minute: "You are doing well. You have 5 minutes to go"

    - After 2 minutes: "Keep up the good work, you have 4 minutes to go"

    - After 3 minutes: "You are doing well. You are halfway done"

    - After 4 minutes: "Keep up the good work. You have only 2 minute left"

    - After 5 minutes: "You are doing well. You have only 1 minute to go"

    - "In a moment I'm going to tell you to stop. When I do, just stop right where you are and I will come to you"

    - "Stop!"

7. After assessing parameters ask the patient **"What if anything kept you from walking farther?"**

APPENDIX 35

BORG SCALE

Number	Description
0	Nothing at all
0.5	Very, very slight (just noticeable)
1	Very slight (very light)
2	Slight (light)
3	Moderate
4	Somewhat severe (somewhat heavy)
5	Severe (heavy)
6	
7	Very severe (very heavy)
8	
9	
10	Very, very severe (very, very heavy) [maximal]

Ask these two questions before the six-minute walk test to the study participant:

1) "Please grade your shortness of breath using this scale"

2) "Please grade your level of fatigue/tiredness using this scale"

At completion of the exercise test, remind the participant of the breathing number that they chose before the exercise. Ask the "Please grade your shortness of breath using this scale" again.

Secondly, remind the participant of their fatigue/tiredness number that they chose before the exercise test. Then ask them "Please grade your level of fatigue/tiredness using this scale" again.

APPENDIX 36

PHASE 2 EVALUATION FORM

Participant Code: …… **Date:** ……

MEASUREMENTS	
Vital Signs: Heart rate: *HR 1:* *HR 1:* *Average HR:* Blood pressure: *Right SBP:* *Right DBP:* *Left SBP:* *Left DBP:* *Average SBP:* *Average DBP:* Respiratory rate:	Anthropometric measure: Height: Weight: Waist circumference: Hip circumference: *Placement during hip circumference*
Waist: Hip ratio	Body Mass Index: (*kg/m²)*
Pedometer results Steps per day: Steps per seven days:	_____ _____
LABORATORY RESULTS	
Hs-CRP ▪ *Date:* ▪ *Results:*	Glucose level ▪ *Date:* ▪ *Results:*
Lipid Profile ▪ *Date:* ▪ *Results:* *Total cholesterol:* *HDL:*	Lipid Profile (cont) ▪ *LDL:* ▪ *Triglycerides:*
Existing data from participants file	
Liver Function Data *(Participants clinical captured data)* ▪ Date of latest full LFD data ▪ Date of latest AST/ALT data	 _____ _____
Latest full LFD results AST: ALT: GGT:	Latest AST/ALT results AST: ALT:
Viral load ▪ Date of latest results. _____ ▪ Results: _____	CD4 count ▪ Date of latest results. _____ ▪ Results: _____

APPENDIX 37

FRAMINGHAM IHD RISK PREDICTION EQUATION TABLES

Framingham tables

Men	
Age (years)	Points
20–34	-9
35–39	-4
40–44	0
45–49	3
50–54	6
55–59	8
60–64	10
65–69	11
70–74	12
75–79	13

	Age (years)				
Total cholesterol (mmol/L)	20–39	40–49	50–59	60–69	70–79
< 4	0	0	0	0	0
4.1–5	4	3	2	1	0
5.1–6.2	7	5	3	1	0
6.21–7.2	9	6	4	2	1
≥ 7.2	11	8	5	3	1

	Age (years)				
	20–39	40–49	50–59	60–69	70–79
Non-smoker	0	0	0	0	0
Smoker	8	5	3	1	1

HDL (mmol/L)	Points
≥ 1.6	-1
1.30–1.59	0
1.00–1.29	1
< 1	2

Systolic BP (mmHg)	If untreated	If treated
< 120	0	0
120–129	0	1
130–139	1	2
140–159	1	2
≥ 160	2	3

Points total	10-year risk %
< 0	< 1
0	1
1	1
2	1
3	1
4	1
5	2
6	2
7	3
8	4
9	5
10	6
11	8
12	10
13	12
14	16
15	20
16	25
≥ 17	≥ 30

Women	
Age (years)	Points
20–34	-7
35–39	-3
40–44	0
45–49	3
50–54	6
55–59	8
60–64	10
65–69	12
70–74	14
75–79	16

	Age (years)				
Total cholesterol (mmol/L)	20–39	40–49	50–59	60–69	70–79
< 4	0	0	0	0	0
4.1–5	4	3	2	1	1
5.1–6.2	8	6	4	2	1
6.21–7.2	11	8	5	3	2
≥ 7.2	13	10	7	4	2

	20–39	40–49	50–59	60–69	70–79
Non-smoker	0	0	0	0	0
Smoker	9	7	4	2	1

HDL (mmol/L)	Points
≥ 1.6	-1
1.30–1.59	0
1.00–1.29	1
< 1	2

Systolic BP (mmHg)	If untreated	If treated
< 120	0	0
120–129	1	3
130–139	2	4
140–159	3	5
≥ 160	4	6

Points total	10-year risk %
< 9	< 1
9	1
10	1
11	1
12	1
13	2
14	2
15	3
16	4
17	5
18	6
19	8
20	11
21	14
22	17
23	22
24	27
> 25	≥ 30

The 10-year risk for coronary disease is calculated by adding the points for age, total cholesterol, smoking status, HDLC and blood pressure. The risk can then be read from the points table. The Framingham calculation should not be used in patients with severe monogenic hyperlipidaemia (e.g. familial hypercholesterolaemia), diabetic patients and patients with clinically overt atherosclerotic cardiovascular disease (secondary prevention).

(*Source: Blom, 2011*)

APPENDIX 38

FACE-TO-FACE SESSION WITH PHYSIOTHERAPIST CONTACT SESSION SHEET

FACE-TO-FACE SESSION WITH PHYSIOTHERAPIST

Visit date: .....

During the session with my physiotherapist my physical evaluation confirmed the following:

Body measurements

Weight	
Height	
Body mass index (BMI)	
Waist circumference	
Hip circumference	
Waist: Hip ratio	
Blood pressure	
Pulse rate	

During a discussion with my physiotherapist the following were seen as barriers during the first month:

During the discussion with my physiotherapists the following strategies to achieve my step goals were made:

1.
2.
3.
4.
5.

APPENDIX 39

WEEKLY PHYSICAL ACTIVITY TRACKING SHEET

WEEKLY PHYSICAL ACTIVITY TRACKING SHEETS

My daily pedometer goal for this week:

My pulse rate/heart rate aim is the following:

Daily pedometer findings:

DAY	DATE	PEDOMETER FINDINGS
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Did I reach my daily pedometer goal for this week?

Yes	No

What are possible reasons why I did not reach my daily step count goal?

How did I feel this week?

APPENDIX 40

POST INTERVENTION QUESTIONNAIRE

Participant's Code: …….…….. Date: ……...

(Answer each question below and tick the appropriate box when applicable).

1) Did you receive a pedometer and physical activity diary at the start of the exercise programme ?

   ○ Yes
   ○ No

2) Did you experience any problems with the pedometer during the course of the exercise programme?

   ○ Yes
   ○ No

3) If you did experience problems with the pedometer, what were the problems?
   ……
   ……
   ……
   ……..

4) Did you use/ wear the pedometer during the period of the exercise programme when you had follow-up sessions with the researcher (*baseline to six months*)?

   ○ Yes
   ○ No

5) Did you use/ wear the pedometer during the period of the exercise programme when you did not have follow-up sessions with the researcher (*six to twelve month period*)?

   ○ Yes
   ○ No

6) If you used the pedometer during the time when you did not have follow-up sessions with the researcher (*six to twelve month period*), how often did you wear the pedometer?

- ○ 1-3 times per week
- ○ 4 times per week
- ○ 5 times per week
- ○ I wore the pedometer every day
- ○ I did not use the pedometer frequently during this period
- ○ I could not use the pedometer during this period due to equipment problems e.g. pedometer broken
- ○ I did not use the pedometer during this period

7) Do you feel wearing the pedometer motivated you to increase your physical activity level?

- ○ Yes
- ○ No

8) Would you advise other people to use a pedometer to help them if they wanted to increase their physical activity level?

- ○ Yes
- ○ No

9) Did you find it beneficial to have the monthly contact sessions with the researcher (physiotherapist) during the baseline to six month period during the exercise programme?

- ○ Yes
- ○ No

10) Did you find it easy to continue with your exercise programme during the six to twelve month period when you did not have monthly contact sessions with the researcher (physiotherapist)?

- ○ Yes
- ○ No

11) Did you find the information in the physical activity diary educational?

- ○ Yes
- ○ No

12) Did you learn information during the monthly contact sessions with the researcher (physiotherapist) that would motivate you to exercise?

- ○ Yes
- ○ No

13) What information did you learn during the monthly education sessions that you found most helpful?

……
……
……
……..

14) If you used the pedometer during the time when you did not have follow-up sessions with the researcher (*six to twelve month period*), did you document your pedometer step count findings in your physical activity diary?

- ○ Yes
- ○ No

15) If you did not document your pedometer step count findings in your physical activity diary during the six to twelve month period, what are possible reasons for not documenting your findings?

……
……
……
……..

16) Did you sign the “Commitment to Myself” form in the front of your physical activity diary?

- ○ Yes
- ○ No

17) If you did not sign the “Commitment to Myself” form, what are possible reasons why you did not?

……
……
……
……..

18) Did you find it easy to palpate/feel for your pulse and count your heart rate/pulse rate?

- ○ Yes
- ○ No

19) Did you monitor your heart rate/pulse rate when you exercised?

- ○ Yes
- ○ No

20) Did you monitor your effort during exercise by evaluating your breathing and/or ability to speak to others when you were exercising?

- ○ Yes
- ○ No

21) Did you regularly to do the warm-up and cool-down exercises as was taught during the exercise programme?

- ○ Yes
- ○ No

22) How often did you do the warm-up and cool-down exercises?

- ○ Daily
- ○ Weekly
- ○ Monthly
- ○ I did not do the warm-up and cool-down exercises?

23) Did you enjoy participating in the education and exercise programme that the researcher (physiotherapist) did with you?

- ○ Yes
- ○ No

24) What did you enjoy the most during the education and exercise programme that the researcher (physiotherapist) did with you?

……
……
……
……..

25) Would you recommend the education and exercise programme to other individuals?

- ○ Yes
- ○ No

Thank you for participating in the programme and completing this questionnaire!

APPENDIX 41

RANDOMISATION LIST OF STUDY 4

1	0.020379	Group 2	Intervnetion
2	0.032549	Group 2	Intervnetion
3	0.034015	Group 1	Control
4	0.034118	Group 1	Control
5	0.037421	Group 2	Intervnetion
6	0.060847	Group 2	Intervnetion
7	0.089119	Group 2	Intervnetion
8	0.09987	Group 2	Intervnetion
9	0.112503	Group 2	Intervnetion
10	0.112607	Group 1	Control
11	0.115493	Group 1	Control
12	0.140375	Group 1	Control
13	0.146199	Group 1	Control
14	0.157119	Group 2	Intervnetion
15	0.18751	Group 1	Control
16	0.187557	Group 2	Intervnetion
17	0.232566	Group 1	Control
18	0.237334	Group 2	Intervnetion
19	0.240942	Group 1	Control
20	0.244056	Group 1	Control
21	0.24861	Group 1	Control
22	0.249924	Group 1	Control
23	0.252062	Group 1	Control
24	0.278148	Group 1	Control
25	0.286353	Group 2	Intervnetion
26	0.294287	Group 1	Control
27	0.299946	Group 2	Intervnetion
28	0.310136	Group 1	Control
29	0.319309	Group 2	Intervnetion
30	0.328719	Group 2	Intervnetion
31	0.345151	Group 2	Intervnetion
32	0.348006	Group 2	Intervnetion
33	0.353849	Group 1	Control
34	0.3566	Group 1	Control
35	0.38209	Group 2	Intervnetion
36	0.386862	Group 2	Intervnetion
37	0.391305	Group 2	Intervnetion
38	0.391318	Group 1	Control
39	0.433902	Group 2	Intervnetion
40	0.442316	Group 2	Intervnetion
41	0.44565	Group 1	Control
42	0.47503	Group 2	Intervnetion
43	0.484213	Group 2	Intervnetion
44	0.497974	Group 1	Control
45	0.520024	Group 1	Control
46	0.534859	Group 1	Control
47	0.543477	Group 1	Control
48	0.545852	Group 1	Control
49	0.568512	Group 1	Control
50	0.569709	Group 2	Intervnetion
51	0.582442	Group 1	Control
52	0.604064	Group 2	Intervnetion
53	0.60638	Group 2	Intervnetion
54	0.618408	Group 2	Intervnetion
55	0.639161	Group 2	Intervnetion
56	0.675897	Group 1	Control
57	0.681607	Group 2	Intervnetion
58	0.694567	Group 2	Intervnetion
59	0.695905	Group 1	Control
60	0.711969	Group 2	Intervnetion
61	0.712943	Group 2	Intervnetion
62	0.717727	Group 2	Intervnetion
63	0.717767	Group 2	Intervnetion
64	0.72003	Group 2	Intervnetion
65	0.730091	Group 1	Control
66	0.738497	Group 1	Control
67	0.788189	Group 1	Control
68	0.790224	Group 1	Control
69	0.795338	Group 1	Control
70	0.798117	Group 1	Control
71	0.815533	Group 1	Control
72	0.831463	Group 2	Intervnetion
73	0.837373	Group 2	Intervnetion
74	0.88126	Group 2	Intervnetion
75	0.899625	Group 1	Control
76	0.909336	Group 2	Intervnetion
77	0.916315	Group 1	Control
78	0.927089	Group 1	Control
79	0.931181	Group 1	Control
80	0.944688	Group 2	Intervnetion
81	0.952461	Group 1	Control
82	0.962194	Group 1	Control
83	0.963577	Group 2	Intervnetion
84	0.985334	Group 2	Intervnetion

APPENDIX 42

PILOT STUDY 4

Procedure

An appointment was scheduled for each participant with the research assistant at the physiotherapy room in Themba Lethu clinic. The research assistant followed the same assessment procedure that was followed during the first session of pilot study 2 with the small adjustments concerning cues given during the accuracy test as explained at study 1 in chapter 4. The second adjustment included performing the 6MWT following the pedometer accuracy test as described below.

Procedure for 6MWT

A 30 meter distance was demarcated with two orange cones in a hospital corridor close to the clinic on the ground floor. Participants walked +/- 200 meters to this corridor following the pedometer accuracy test. The participant sat on a stool for a minimum of five minutes at one end of the corridor at the start of the 6MWT to rest. The research assistant explained the parameters that would be assessed prior and after the 6MWT to participants at this time.

a) Evaluation of pulse rate, oxygen saturation and respiratory rate: 6MWT

Pulse rate and oxygen saturation were measured with the finger probe pulse oximeter that was placed on the participant's right index finger while resting his/her hand on his/her thigh. After these two measurements the research assistant counted the participant's respiratory rate for thirty seconds while the pulse oximeter was still positioned on the participant's finger to ensure participants were unaware of this procedure being done.

b) Evaluation of perceived breathlessness and fatigue: 6MWT

The participant was then asked his or her level of breathlessness and fatigue according to the Borg scale as suggested by the American Thoracic Society Guideline (ATS) (2002). All evaluation findings were documented on the 6MWT evaluation sheet.

c) Instructions given to study participants: 6MWT

The participant was instructed to walk as far as possible for six minutes between two cones. They were informed that they could stop at any time if they felt unwell during the six minutes and experienced any symptoms such as severe shortness of breath, fatigue or pain. A second stool was placed at the other end of the corridor near the second cone for in case the research assistant needed to provide a stool for a patient to sit on if he/she felt unwell. The researcher was close by to assist the research assistant in case of an emergency. The participant stood at the first cone where their pedometer was recalibrated to zero at the start of the 6MWT. The test was done according to standardised prompts as per the ATS guidelines. At completion of the test, if participants did not complete a full lap the particular distance that needed to be added was measured with the measuring wheel by the researcher while the research assistant re-evaluated the patient. The research assistant read the pedometer counted steps off the pedometer and documented this finding

on the 6MWT evaluation sheet. The participants rested for a minimum period of thirty minutes and the 6MWT procedure was repeated.

Statistical analysis

Data was captured on Microsoft Excel 2010 spread sheets and imported into IBM SPSS 20 for data analysis by the researcher. Due to the small sample size of pilot study 4, the intra-rater reliability evaluation of the research assistant when performing body measurements, pedometer accuracy test and the 6MWT were assessed using Spearman's rho correlation coefficient. Baseline findings of pilot study 4 participants' body measurements, pedometer accuracy test and 6MWT are reflected as median (Interquartile range). A student's t-test was performed to determine if a significant difference was noted in distanced walked in 6MWT trail one and two. A test was statistical significant if $p \leq 0.05$.

Results

Pilot study 4 consisted of seven women (87.5%) and one male (12.5%) participant with a median age of 32 (29–37.25) years. The median daily pedometer step count of the sample was 5 256.86 (3 434.04–6 833.43) steps per day indicating a "light active" pedometer physical activity category. The pedometer median step count recorded during the pedometer accuracy test was 15.5 (13.25–16) steps and actual counted steps noted to be 13.5 (12.25–15) steps. The Spearman's rho correlation between actual counted steps and pedometer counted steps during the pedometer accuracy test was r=0.66 (p=0.07). The correlation fell within the "moderate to good relationship" category of Portney and Watkins (2009) but the finding was not significant. Table 42.1 reflects the body measurement of pilot study 4 participants.

Table 42.1: Results of the Body Measurements of Pilot Study 4 Participants (n = 8)

Variable	n	Median	Interquartile range	Normal range
Resting heart rate (bpm)	8	**82.75**	75.5 - 95.50	Less than 80 (Palatini, 2007)
Systolic blood pressure (mmHg)	8	115.13	110.31 - 119.56	Less than 120 (Collins and Dias, 2009)
Diastolic blood pressure (mmHg)	8	79.63	72.31 - 82.50	Less than 80 (Collins and Dias, 2009)
Weight (kg)	8	71.25	59.78 – 79.90	
Height (cm)	8	166.25	160.69 – 168.06	
BMI (kg/m^2)	8	24.75	22.05 – 28.90	18.5 – 24.9 (WHO, 2004)
Waist circumference (cm) • Men • Women	8 1 7	79.88 81.50 79.00	73.44 – 84.13 81.50 – 81.50 73.25 – 85	 Less than 102 Less than 88 (ACSM, 2010)
Hip circumference (cm)	8	108.50	96.56 – 110.38	
Waist: hip ratio • Men • Women	8 1 7	0.77 0.85 0.76	0.73 – 0.82 0.85 – 0.85 0.72 – 0.77	 Less than 0.95 Less than 0.86 (ACSM, 2010)

♦ bpm (beats per minute), mmHg (millimetres mercury), kg (kilograms), cm (centimetres), kg/m^2 (kilograms per meters squared).

Resting heart rate was slightly above the suggested normal of less than 80 bpm. Table 42.2 depicts the 6MWT findings of pilot study 4 participants.

Table 42.2: Results of 6MWT of Pilot Study 4 participants (n = 8)

Variable	n	Trial one: Median (Interquartile range)	Trial two: Median (Interquartile range)
6MWT distance (m)	8	539.30 (490.03 – 572.80)	527.20 (489.48 – 588.40)
6MWT Pedometer step count	8	756.00 (703.75 – 797.50)	749.50 (706.25 – 788.75)
6MWT predicted distance (m)	8	704.40 (688.73 – 707.40)	704.40 (688.73 – 707.40)
6MWT % of predicted distance	8	**77.00 (70.75 – 81.75)**	**75.26 (71.09 – 82.75)**
6MWD work (kg.m)	8	38 972.60 (31 734.49 – 43 102.30)	39 216.15 (31 134.88 – 43 759.48)
6MWT HR before (bpm)	8	88.00 (78.00 – 91.25)	86.50 (79.25 – 108.00)
6MWT HR after (bpm)	8	111.00 (94.75 – 121.00)	119.50 (97.75 – 132.00)
Age predicted maximum HR (bpm)	8	184.60 (180.93 – 186.70)	184.60 (180.93 – 186.70)
% of age predicted maximum HR achieved	8	59.69 (52.23 – 65.88)	64.13 (53.64 – 72.19)
6MWT RR before (bpm)	8	16.00 (14.50 – 17.50)	16.00 (14.00 – 18.00)
6MWT RR after (bpm)	8	20.00 (18.50 – 27.00)	27.00 (20.50 – 28.00)
6MWT SpO_2 before (%)	8	98.00 (97.00 – 99.00)	96.00 (95.00 – 98.00)
6MWT SpO_2 after (%)	8	97.00 (95.25 – 97.75)	97.00 (96.25 – 98.50)
6MWT SOB before	8	0.00 (0.00 – 0.38)	0.00 (0.00 – 0.00)
6MWT SOB after	8	0.25 (0.00 – 1.75)	0.50 (0.00 – 1.63)
6MWT Fatigue before	8	0.00 (0.00 – 0.00)	0.00 (0.00 – 0.38)
6MWT Fatigue after	8	0.50 (0.00 – 1.75)	0.50 (0.00 – 1.00)

♦ 6MWT (six minute walk test), m (meters). % (percentage), HR (heart rate); bpm (beats per minute), RR (respiratory rate); bpm (breaths per minute), SpO_2 (percutaneous oxygen saturation), SOB (shortness of breath), kg.m (kilograms time distance walked in meters).

No participants had difficulty performing the 6MWT or experienced symptoms such as dizziness or pain during the test. In both 6MWT trials, participants walked less than 82% of their predicted 6MWT distance indicating that their distance walked was abnormal (Troosters, Gosselink and Decramer, 1999). Participants walked a shorter distance in their second trial and therefore the less predicted percentage walked and lower pedometer step count recorded. Even though the distance walked in the second trail was less than the first the difference was not statistically significant (p=0.88). During the second trial participants exerted more cardiovascular effort as demonstrated by the higher percentage of predicted maximum heart rate achieved and 6MWD work. Participants' perceived fatigue only changed from a "nothing at all" to a "very, very slight (just noticeable)" level from beginning to end of both walking trials. Minimal fluctuation was noted in oxygen saturation. Table 42.3 is a representation of the intra-rater reliability findings of the research assistant when performing body measurements during pilot study 4.

Table 42.3: Results of the Intra-Rater Reliability of Research Assistant Four when Performing Body Measurement During Pilot Study 4 (n = 8)

Variable	n	r - value	p - value
Heart rate one	8	0.79	0.02
Heart rate one	8	1.00	<0.00
Systolic blood pressure one	8	0.70	0.05
Systolic blood pressure two	8	0.90	<0.00
Diastolic blood pressure one	8	0.61	0.11
Diastolic blood pressure two	8	0.93	<0.00
Height	8	0.93	<0.00
Weight	8	1.00	<0.00
Waist circumference	8	0.97	<0.00
Hip circumference	8	0.97	<0.00

A “good to excellent relationship” (Portney and Watkins, 2009) with significant p - values were noted in all variables except systolic blood pressure and diastolic blood pressure one. The relationship in these two variables was “moderate to good” (Portney and Watkins, 2009) but not significant. Table 42.4 is a representation of the intra-rater reliability of the research assistant when performing the 6MWT with participants.

Table 42.4: Results of the intra-rater reliability of research assistant four when performing the 6MWT (n = 8)

Variable	n	r - value	p - value
6MWT distance	8	0.95	<0.00

♦ 6MWT (six minute walk test)

Even though the distance walked during the second trial of the 6MWT was less than the first, a “good to excellent relationship” (Portney and Watkins, 2009) existed and was also significant (p<0.00).

Conclusion

The primary aim of pilot study 4 was to evaluate the research assistant’s intra-rater reliability when performing assessments of pilot study 4 participants. The intra-rater reliability of the research assistant when performing the pedometer accuracy tests was “moderate to good”. This finding was similar to the researcher’s results in pilot study 2 when conducting the pedometer accuracy test in individuals living with HIV. Due to the p – value in pilot study 4 not being significant the finding could have been due to chance. With a larger sample size, the p–value might be significant as demonstrated in pilot study 2. Even so, an adequate relationship was found between actual counted steps and pedometer steps. This finding indicated that the pedometers used were reliable and explanations given by the research assistant good.

The intra-rater reliability of the research assistant when evaluating participants’ body measurements were “good to excellent”. This finding was again similar to the researcher’s intra-rater reliability assessment when evaluating body measurements in individuals living with HIV during pilot study 2. It therefore indicated that she followed the assessment procedure effectively

and the equipment used was giving reproducible results. An additional objective of pilot study 4 was to evaluate participants' functional exercise capacity with the 6MWT and tolerance of the test.

The 6MWT was tolerated by all participants and no adverse side effects occurred. It became apparent to the research assistant and the researcher that participants viewed the 6MWT as a bout of exercise as interpreted from their informal feedback given following performing the test. Even though participants achieved a lower than normal median value of their predicted 6MWT distance, they all walked at a comfortable fast pace and seemed focused and determined to walk far. The lower distance walked however did indicate that their functional exercise tolerance was reduced. Their median pedometer physical activity level also indicated that the sample's activity level was "light active" which could explain the reduced exercise tolerance.

More noticeable during the 6MWT was the cardiorespiratory changes that occurred compared to perceived fatigue and SOB experienced by participants. This finding was of clinical significance for the larger study 4. It was deemed more important to teach participants' how to monitor their pulse rate and breathing when performing a walking programme if included in the intervention. As these parameters might fluctuate more during a focussed walk compared to their subjective parameters. The pilot study also highlighted that participants' physical effort during the 6MWT fluctuated 59.69% to 64.13% of age predicted maximum heart rate. The American College of Sports Medicine state that 64-76% of age predicted maximal heart rate is equal to a moderate intensity level (2010). Participants therefore achieved a borderline moderate intensity level during the 6MWT. The aim of the intervention was to encourage a moderate intensity walking programme in intervention participants. Due to them achieving a moderate intensity walking level during the 6MWT, the researcher used the 6MWT as an example to explain to intervention participants the brisk walking speed at which they should perform a focused walk. An additional beneficial finding of pilot study 4 was that no significant difference in distance walked occurred between the first and second trail.

The median 6MWT distance walked during the second trial was less than the first. Having the participants do a second 6MWT did therefore not result in a training effect causing them to walk further in the second trial during pilot study four. This finding was significant considering a challenge that was encountered earlier on in the research project. During study 1 it was identified that participants had difficulty attending research and general clinic appointments due to their work obligations. This challenge was also encountered when doing the 6MWT during pilot study 4 as two individuals declined participation in a second 6MWT due to not willing to wait 30 minutes before repeating the test because of work obligations. Few (n=5) of the remaining participants that did consent to wait 30 minutes to repeat the test were keen to finish their assessments so they could go to work. The remaining three were unemployed and did not have this concern. Due to the 6MWT finding of pilot study 4 and challenge regarding participants' ability to attend appointments as noted in study 1, only one 6MWT trial were done during the remaining assessments of study 4.

One additional challenge that was identified during pilot study 4 was the specific corridor in which the 6MWT was done. The corridor was chosen because it was long enough, close to Themba Lethu clinic, on the ground floor and seemed quiet. During the pilot study it was however noted that the corridor was very cold as the central heating in the corridor did not work and a cold draft permeated through the passage. This was of significance as pilot study 4 was done during the winter season. In addition it also became apparent that the corridor was not as quiet as initially assessed. Hospital traffic frequently passed through this particular corridor that needed to be redirected by the researcher to not disturb the research assistant and study participants. The hospital traffic also tended to stop, wanted to know why the participants were "exercising" and

wished to participate and also “exercise”. Due to these reasons, the remainder of the 6MWT trials of baseline study 4 evaluations were done in a different corridor on the first floor next to a second entrance of Themba Lethu clinic. This corridor was much quieter, a bit closer to the clinic and the central heading in the passage worked in sporadic spots so it was warmer.

APPENDIX 43

ASSESSMENT PROCEDURE OF STUDY 4

The research assistant requested that the participant remove any bulky clothing and position this and any bags on stool in the room. The participant sat in a chair next to the assessment table and the research assistant positioned a pillow behind their back to ensure an upright posture before sitting down on the chair. At the baseline assessment the demographic questionnaire two was firstly completed and then the PSS-10. This process took +/- 15 minutes. At the six and 12 month assessments only the PSS-10 was done at the start of the assessments.

Respiratory rate assessment

The research assistant then asked the participants to expose their arms and/or remove any tight fitting clothing at their arms that could influence their blood circulation. They were instructed to rest their arms on the desk in front of them while the research assistant firstly positioned the sphygmomanometer cuff on their left upper arm +/- 2-3 cm above the elbow joint line. The participant sat quietly on a chair for five minutes while the research assistant started by evaluating their respiratory rate. The participants were not informed that the research assistant was assessing their respiratory rate in an attempt to prevent them from altering their respiratory rate. The research assistant observed the participants' "chest rise" as indicative of respiratory rate for 30 seconds. The value was multiplied by two to equal a value of respiratory rate per minute. Two observations were documented on the phase 2 evaluation form and during statistical analysis the mean of these two observations were analysed.

Heart rate and blood pressure assessment

Resting heart rate and blood pressure were then evaluated with the Microlife BP A100 automated blood pressure sphygmomanometer. Two measurements were taken in the left arm and then subsequently in the right arm. Between each measurement the participant's reading was displayed on the monitor of the device for one minute. After a minute the reading disappeared and the research assistant could do a next measurement. These four measurements were documented on the phase 2 evaluation form. During statistical analysis the mean of the four measurements were analysed.

Weight assessment

The participants were then instructed to remove their shoes and any articles out of their clothing pockets e.g. wallet or cellphones. The participants were weighed on the portable scale twice. Prior to each measurement the device was calibrated as per the manufacturer's instructions. Weight was measured to the nearest 0.1kg. Both these measurements were documented on the phase 2 evaluation form. During statistical analysis the mean of the two measurements were analysed.

Height assessment

The participants were then instructed to stand upright on the Micro Health stadiometer device facing the research assistant with their head in a neutral position to enable the research assistant to measure their height with the stadiometer attached. The research assistant took two height measurements that she documented on the phase 2 evaluation form. Height was measured to the nearest 0.1cm. During statistical analysis the mean of the two measurements were analysed.

Waist and hip circumference

The participants then stepped down of the Micro Health scale to enable the research assistant to evaluate their waist and hip circumference. Waist circumference was measured with a non-stretch tape measure at the narrowest circumference halfway between the lowest ribs and iliac crests (a horizontal measure was taken at the narrowest part of the torso: above the umbilicus but below the xiphoid process) (ACSM, 2010). The participants were encouraged to exhale gently at time of measurement. Participants were standing with their arms at their side's feet together and their abdomen relaxed (ACSM, 2010). Two measurements were taken and documented on the phase 2 evaluation form. During statistical analysis the mean of the two measurements were analysed. Participants' hip circumference was subsequently measured with the non-stretch tape measure at the broadest circumference of the participants' buttocks (ACSM, 2010). Participants stood upright with their feet together during this measurement. Two measurements were taken and documented on the phase 2 evaluation form. During statistical analysis the mean of the two measurements were analysed.

Pedometer and physical activity log sheet

At the baseline assessment the research assistant gave each participant a pedometer to position at the right side of their body at their hip to enable the researcher to measure their physical activity level. The pedometer and physical activity log sheet were again explained to study 4 participants. Factors related to the pedometer that was covered during this discussion were: how to open and close the pedometer, how to reset the pedometer, when and where to wear the waist worn pedometer. Participants were requested to continue with their daily life as normal during the seven days when they wore the pedometer. They were asked to wear the pedometer from the time they got up in the morning until they went to bed at night for seven consecutive days. They were instructed not to wear the pedometer when bathing, showering, swimming or sleeping. Prior to positioning the pedometer each morning, they had to reset the pedometer to zero. They were asked to document the step count recorded by the pedometer on the pedometer log sheet in the evening when the removed the device. The research assistant and participant then stepped outside the room to test the pedometer with the accuracy test and then do the SMWT after.

Pedometer accuracy test

Accuracy was determined by demarcating a 10 meter distance in a corridor outside the physiotherapy room. Pedometer placement in each participant was standardised by positioning the pedometer anterior to the right hip in approximately mid-thigh position. This position was suggested by the manufacturers (Yamax, 2011). The participants were instructed to walk at a normal fast pace as if they were trying to catch a taxi over the 10 meter distance, starting with the right leg. The researcher assistant counted the actual steps taken by the participant and was positioned at a distance behind the participant to not influence the walking speed. This procedure

was done twice. The counted steps were evaluated against the pedometer reading and documented on a pedometer accuracy sheet.

Procedure for 6MWT

A 30 meter distance was demarcated with two orange cones in the same corridor. The participant sat on a stool for a minimum of five minutes after the pedometer accuracy test at the starting point of the 6MWT to rest. Research assistant four explained the parameters that would be assessed prior and after the 6MWT to participants at this time. Pulse rate and oxygen saturation were measured with the finger probe pulse oximeter that was placed on the participant's right index finger while resting his/her hand on his/her thigh. After these two measurements the research assistant counted the participant's respiratory rate for thirty seconds while the pulse oximeter was still positioned on the participant's finger to ensure participants were unaware of this procedure being done. The participant was asked his or her level of breathlessness and fatigue according to the Borg scale. All evaluation findings were documented on the 6MWT evaluation sheet. The participant was instructed to walk as far as possible for six minutes between the two cones. They were informed that they could stop at any time if they felt unwell during the six minutes and experienced any symptoms such as severe shortness of breath, fatigue or pain. A second stool was placed at the other end of the corridor near the second cone for in case the research assistant needed to provide a stool for a patient to sit on if he/she felt unwell. The researcher was close by to assist the research assistant in case of an emergency. The participant stood at the first cone where their pedometer was recalibrated to zero at the start of the 6MWT. The test was done according to standardised prompts as per the ATS guidelines. At completion of the test, if participants did not complete a full lap the particular distance that needed to be added was measured with the measuring wheel by the researcher while the research assistant re-evaluated the patient. The research assistant read the pedometer counted steps off the pedometer and documented this finding on the 6MWT evaluation sheet.

Assessment calculations

- Individuals' predictive 6MWT distance was calculated with Gibbons (2001) prediction equation: $868.8 - (\text{age}_{\text{years}} \times 2.99) - (\text{sex}_{\text{men = 0; women = 1}} \times 74.7)$.
- Percentage walked of predicted 6MWT distance was calculated as follows: Distance walked/ predicted distance x 100
- The participants' BMI was calculated with the following equation: BMI= weight (kg)/ height (m) ^{2} (ACSM, 2010)
- The participants' waist and hip circumference were converted from centimeters to meters and waist: hip ratio was calculated with the following equation: waist: hip ratio = waist/hip circumference.

APPENDIX 44

LABORATORY TESTS INFORMATION SHEET FOR PHASE TWO

Dear Participant,

As part of phase two of this physiotherapy research study, the laboratory nursing sister will need to collect blood samples from you. These blood samples will be collected from your arm. It might be a little bit uncomfortable but it is similar to the blood tests done at the clinic.

The blood test will enable me to evaluate your glucose, cholesterol and inflammatory hs-CRP levels in your blood. This procedure will be done at the beginning of phase two of the research study but also in six months' time and at the end of 12 months when the study is completed. We will therefore be able to see how your blood chemistry changed over this period.

To ensure that the procedure is successful I would appreciate it if you could do the following before your appointment at Helen Joseph Hospital for the blood test:

- Ensure that you had a good night's rest the night before. Try to sleep six to nine hours.

- Don't do any exercise or take any alcohol beverages in the 24 hours (one day) before your appointment.

- The blood sample to be taken should be a "fasting" blood sample. This means that you should not eat anything following your dinner the previous night. No breakfast is therefore allowed on the morning of the blood test. After the blood test you can eat again. You can drink water in the "fasting" period but no milk, tea, coffee, juice or cold drinks should be taken in this period.

It is very important that you continue with your antiretroviral medication as prescribed by your medical doctor at Themba Lethu clinic.

Thank you for adhering to these "do's and don'ts" of the blood test.

The Researcher,
Ronel Roos

APPENDIX 45

CONTRACT LABORATORY SERVICES REQUISITION FORM

Ronel Roos PHD Evaluation Study P1092
Clinical Requisition Form

CONTRACT LAB SERVICES

CP NUMBER

PARTICIPANT DEMOGRAPHICS

CLS Project Location P1092 (for CLS use only)

Participant ID | I | D | | | | (Enter on Loc.field on Disa) | Initials | | | |

Date of Birth | d | d | m | m | m | y | y | y | y | Gender | M | F |

VISIT SECTION

24 hour Clock	Day	Month	Year
:			
Time of Blood Collection	Sampling Date		

Blood collected by :

VISIT *(Please tick)*

BASELINE	
FOLLOW-UP 6 MONTHS	
FOLLOW-UP 12 MONTHS	

(Please tick)

FASTING STATUS	Y	N

Name: _____

SAMPLE COLLECTION / TEST REQUEST

No	Type of Tube	Specimen Type	Specimen Code	Test	SITE USE REQUESTED	CLS USE DISA CODE	CLS USE CLS RECEIVED
1	5ml SST	Blood	B	Lipogram		LIPO	
				C-Reactive Protein *(Ultrasensitive)*		CRPUS	
1	4ml Glucose	Blood	B	Glucose *(Fasting)*		GLUCF	
				Glucose *(Non- Fasting)*		GLUCR	

5ML SST		4ML GLUCOSE		OTHER	

ADDITIONAL INFORMATION

SPECIAL INSTRUCTIONS

SITE CONTACT INFORMATION:

P.INVESTIGATOR Ronel Roos
ADDRESS: Themba Lethu Clinic
Helen Joseph Hospital
Perth Road
Westdene

Site coordinator : Ronel Roos
Tel: (011) 717-3723
Cell: 076 097 3458
Fax: 086 5703644
E-mail: ronel.roos@wits.ac.za

Received By		Entered By		Separated By		Checked By		

APPENDIX 46

PHLEBOTOMY SET-UP STATION

Figure 46.1: Blood Sampling Testing Kit

Figure 46.2: Phlebotomy Set-Up Station

APPENDIX 47

INTERVENTION PROGRAMME OF STUDY 4

Introduction

The intervention programme was initiated with study 4 participants allocated to the intervention group at their second baseline assessment session. At this time the aim of the specific home-based education and walking programme was explained. The aim of the intervention was to assist study participants in increasing their physical activity level (total pedometer step count per day) as a means of addressing their risk factors for IHD. To improve individuals understanding on why they should be more active certain educational topics were covered during the contact sessions. These topics were informed by results found in study 1 and 2. A strong emphasis was placed on self-monitoring during this programme as a means of making participants aware of how their body reacted when they were active at a moderate intensity level. An important aim was ultimately to encourage self-management through empowerment by education and monthly guidance. To achieve this aim the programme consisted of the following facets:

- Each participant received a Yamax SW200 pedometer to allow for self-monitoring of daily step count at home.
- Each participant received an education physical activity diary to be used during the course of the programme as an educational and self-monitoring tool.
- Participants were encouraged to attend the five monthly face-to-face contact sessions with the researcher at Themba Lethu clinic during the baseline to six month period. The role of these sessions was to create a supportive environment where participants' adherence to the programme could be monitored and barriers and facilitators could be highlighted. Pedometer walking goals would be set and strategies suggested improving adherence to walking.
- Participants were sent five cellphone SMS texts messages (one per month) as a reminder to encourage increased walking behavior during the baseline to six month period.

The home-based education and walking programme focused on two main areas: education of individuals and encouraging increased physical activity in the form of a home-based walking programme.

Education Component

The Five A's organisational construct for clinical counseling was followed during the contact sessions to assist with providing a motivational atmosphere to enhance physical activity levels of participants (Jamison, 2010; Whitlock et al., 2002). The Five A's consist of the following: Assess (e.g. screen risk factors), advise (e.g. advice on how these risk factors can be modified), agree (e.g. participant and physiotherapist liaise on what needs to be altered), assist (e.g. implementation of strategies) and arrange (e.g. monitor progress and arrange follow-up sessions). The educational topics that were discussed during the contact sessions are presented below. During these sessions their education physical activity diary was used as reference guide for explanations.

<u>Second baseline assessment session</u>

Participants were given their Yamax SW200 pedometer that they used during their physical activity level assessment at baseline for use during the programme. They were informed that the

pedometer would be the tool that they could use to self-monitor their daily step count to ensure that they reached the specific daily pedometer step count goal.

Each participant received an education physical activity diary and was orientated regarding the specific sections in the diary that would be covered during the course of the programme. Their baseline assessment findings were documented in their dairy and explained. The risk factors that could be improved during the course of the programme were highlighted at this stage. Each participant's daily step count goal for the next month was then calculated using their baseline value as reference point and subsequently documented on the "weekly physical activity tracking sheets". Kindly refer to the pedometer step count goal table at the end of the appendix for how step counts were calculated throughout the programme.

Their step count goal was explained using the pedometer step count achieved during the 6MWT to give the participants an idea of how long they should walk e.g. a participant might have clocked 700 pedometer steps in six minutes. During the first month they were encouraged to monitor their intensity of walking according to their perceived level of breathlessness and how fast they were breathing. It was emphasized that they should walk at a brisk pace to ensure a moderate intensity level (Murtagh, Boreham and Murphy, 2002). A brisk pace was defined as a faster than normal pace that would leave the participants' slightly breathless but still able to talk (Tully et al., 2005). The researcher referred back to the Borg scale that was used during the 6MWT to explain the levels of breathlessness. The following example was used: if they were walking with a friend and were able to talk in short phrases because of feeling moderately breathless they would be exercising at a moderate intensity level. If they were walking and able to have a long conversation without feeling breathless they were walking at too low an intensity level. Lastly, if they were walking and unable to talk at all due to feeling severely breathless they were exercising at too high a level.

At this session the warm-up and cool down ankle exercise presented in their education physical activity diary was demonstrated and taught to participants. Their first monthly appointment were scheduled and documented in their education physical activity diary.

<u>Face-to-face contact session one</u>

A discussion regarding how participants managed with the walking programme in the preceding month was held and specific questions related to their health raised. If they achieved their daily pedometer step count goals they were asked to explain what enabled them to do this. If they could not achieve their aims they were requested to elaborate on the possible barriers that they had encountered. These barriers were discussed and possible solutions for these challenges suggested to be implemented in the next month.

Body measurements of participants were done e.g. blood pressure, weight, waist circumference and documented on the "face-to-face interview with physiotherapist" sheet of the researcher and participant's education physical activity diary. These evaluations were done to monitor participants' physical status. Their notations on the "weekly physical activity tracking sheets" in their education physical activity diary were reviewed and discussed.

An educational discussion was held concerning the benefits of being physically active and methods to increase once daily pedometer step count. Secondly, the intensity (moderate intensity level) was again explained according to breathlessness level as well as heart rate ranges. A moderate

intensity physical activity level is classified as a range of three to six metabolic equivalent units. This metabolic equivalent range is equal to 40-59 oxygen uptake reserve percentage which is said to be equal to 64-76 maximal heart rate percentage (ACSM, 2010). An exercise intensity level of 40-60% of oxygen uptake researve is suggested as a save exercise intensity level in individuals living with HIV to avoid possible immune suppression from occurring with more intense exercise (ACSM, 2010). The participants were asked if they knew how to palpate their pulse rate. None of them knew how to perform this assessment technique. The researcher then taught them how to measure their radial pulse rate.

Their age predicted maximum heart rate was calculated with the following equation: 207 – (0.7 x age) (ACSM, 2010; Gellish et al., 2007). Their individualised 60 to 75% of age predicted maximum heart rate range was calculated and documented on their "weekly physical activity tracking sheets" for the next month. The slightly lower start range (60%) was chosen due to the participants in this study presented with already low CD_4 values when compared to an international home-based exercise study population group (Dolan et al., 2006). The aim was also to start at a lower level and slowly progress in an attempt to ensure adherence to exercise prescription.

Individuals were asked to assess their pulse rate prior to a focused walk and again at completion to see if they were able to increase their heart rate to the specific intensity level. Additional warm-up and cool-down exercises were taught as the walking programme had now progressed and would require walking for a longer period of time to achieve the required step count goal. The additional exercises were a calve stretch, anterior thigh stretch and posterior thigh stretch as explained in their educational physical activity diary. Their daily pedometer step count goals were progressed to the next level if they achieved their previous month's goals. If they did not achieve their specific goals the daily step count goals were not adjusted. The daily pedometer step count goals were documented on the "weekly physical activity tracking sheets" for the next month. Their next month's appointment was scheduled.

Face-to-face contact session two

The above format for the second physiotherapy appointment was again followed. At this session the participants were specifically asked if participants were coping with evaluating their pulse rate. The majority of them reported that they palpated their pulse to review if a change in speed occurred but did not necessarily count the number of beats. This was due to difficulty palpating the pulse point and often having difficulty counting. The educational session consisted of a discussion regarding what is IHD and how can being physically active influence IHD. Their daily step count goal was progressed if they achieved their goals and maintained the same if not. The warm-up and cool down activities that were added at this session were a range of motion neck exercise and range of motion trunk exercise. Their next month's appointment was scheduled.

Face-to-face contact session three

The above format for the third physiotherapy appointment was again followed. The educational session consisted of a discussion regarding the risk factors of IHD and how being physically active could potentially influence these risk factors of IHD. They were informed about the normal value ranges of the risk factors measured and how their findings related to the normal. Their daily step count was progressed if they achieved their goals and maintained the same if not. Participants were encouraged to when they do a focussed walk to walk with "attitude". This entailed a good upright posture with a more focussed hip propelling action to increase contraction of muscles

around the trunk and pelvis area. This walking pattern also encouraged a longer stride length. The walking pattern was explained, demonstrated and participant's attempt reviewed. The warm-up and cool down exercises incorporated at this session included two range of motion exercises of the shoulder joints. Their next month's appointment was scheduled.

Face-to-face contact session four

The above format for the fourth physiotherapy appointment was again followed. At this stage of the programme it was summer in South Africa. A number of participants reported it was more difficult to follow the programme due to difficulty walking outside in the heat. Strategies to overcome this was suggested e.g. walking early in the morning or late in the afternoon when it was not as warm, ensuring good hydration before/during and after a focused walk, walking in an air conditioned shopping center or increasing physical activity indoors while doing housework. Their daily step count was progressed if they achieved their goals and maintained the same if not. The warm-up and cool down exercises were reviewed. Their next month's appointment was scheduled and documented in their educational physical activity diary.

Face-to-face contact session five

The above format for the fifth physiotherapy appointment was again followed. The majority of participants were now doing the activity programme five times a week. They were motivated to keep up the good work for the remainder of the programme. At this stage the six month assessment procedure was again reviewed with them and an appointment scheduled.

Exercise Component

The ACSM and American Heart Association (AHA) recommend the following guidelines for physical activity: ≥ 30 minutes of moderate intensity five times per week or ≥ 20 minutes of vigorous activity on three days per week (Haskell et al., 2007). Marshall et al. (2009) translated these recommendations into pedometer based step goals. The researchers reported that 3 000 pedometer steps walking at a moderate intensity level would equal to 30 minutes of walking time.

The current study's walking programme was created to incrementally progress to ultimately reach the ACSM and American Heart Association recommendations while monitoring how participants reacted to the changed activity level. The walking programme is presented below in the table. If participants achieved their pedometer step count goals their step count was progressed bi-weekly as set out in the table. If they did not achieve their specific step count goals, they were motivated to try and implement the suggested strategies to reach their goal and their goal was not altered until this was achieved.

If participants developed an illness e.g. flu or cold during the course of the programme they were instructed to stop exercising and to only resume their programme when their physical ailment had passed. When restarting their walking programme they were initiated at a lower level than prior to their illness. The timeframes to achieve a goal could therefore not be standardised between individuals.

The exercise programme also included the specific warm-up and cool-down exercises that were systematically included as they progressed through the programme.

The following general advice was given to participants regarding the walking programme:

- Wear comfortable shoes and clothing when walking.
- They should try and incorporate the warm-up and cool-down exercises before and after the walking programme.
- When they walked in the summer they should wear light weight clothing.
- When they walked outside in the winter they had to remember to dress warmly.
- If it was very hot or cold outside, they could have rather walked in a shopping center where the temperature was controlled.
- If they were worried about traffic when walking, they could walk around a soccer or sports field or park in their neighbourhood.
- When they walked they should try to take big steps and swing their arms.
- Drinking water regularly was important during and after their walking programme.
- If they could walk with friends in a group it was better for safety as well as companionship.
- They had to be safe when walking outdoors.

Table 47.1: Six-Month Pedometer Based Home-Based Walking Programme

Timeframe	Pedometer step count goal
Week 1	To walk an extra 1000 steps (from baseline value) on at least 3 days of week.
Week 2	To walk an extra 1000 steps (from baseline value) on at least 3 days of week.
Week 3	To walk an extra 1500 steps (from baseline value) on at least 3 days of week.
Week 4	To walk an extra 1500 steps (from baseline value) on at least 3 days of week.
Week 5	To walk an extra 2000 steps (from baseline value) on at least 3 days of week.
Week 6	To walk an extra 2000 steps (from baseline value) on at least 3 days of week.
Week 7	To walk an extra 2500 steps (from baseline value) on at least 3 days of week.
Week 8	To walk an extra 2500 steps (from baseline value) on at least 3 days of week.
Week 9	To walk an extra 3000 steps (from baseline value) on at least 3 days of week.
Week 10	To walk an extra 3000 steps (from baseline value) on at least 3 days of week.
Week 11-14	To walk an extra 3000 steps (from baseline value) on at least 4 days of the week.
Week 15-24	To walk an extra 3000 steps (from baseline value) on at least 5 days of week.

APPENDIX 48

SMS PROMPTS OF THE INTERVENTION PROGRAMME OF STUDY 4

1. Good morning, I hope you are enjoying the lovely weather! Remember your walking and step count goals, Ronel.

2. Good afternoon, hope you are all well! Enjoy your walking, Ronel.

3. Good afternoon, you are all doing really well with your walking. Remember to drink enough fluids now that it is warmer, when you are walking, Ronel.

4. Good afternoon, remember to do your walking, Ronel.

5. Good afternoon, remember exercise (walking) is “medicine” and should be done regularly so maintain your step count goals! Have a lovely festive season and blessed 2013, Ronel.

APPENDIX 49

GOODNESS TO FIT TESTING

Figure 49.1 presents information pertaining to pedometer physical activity level data without restrictions applied during the goodness to fit testing in the GEE model prior to multiple variate logistic regression analysis.

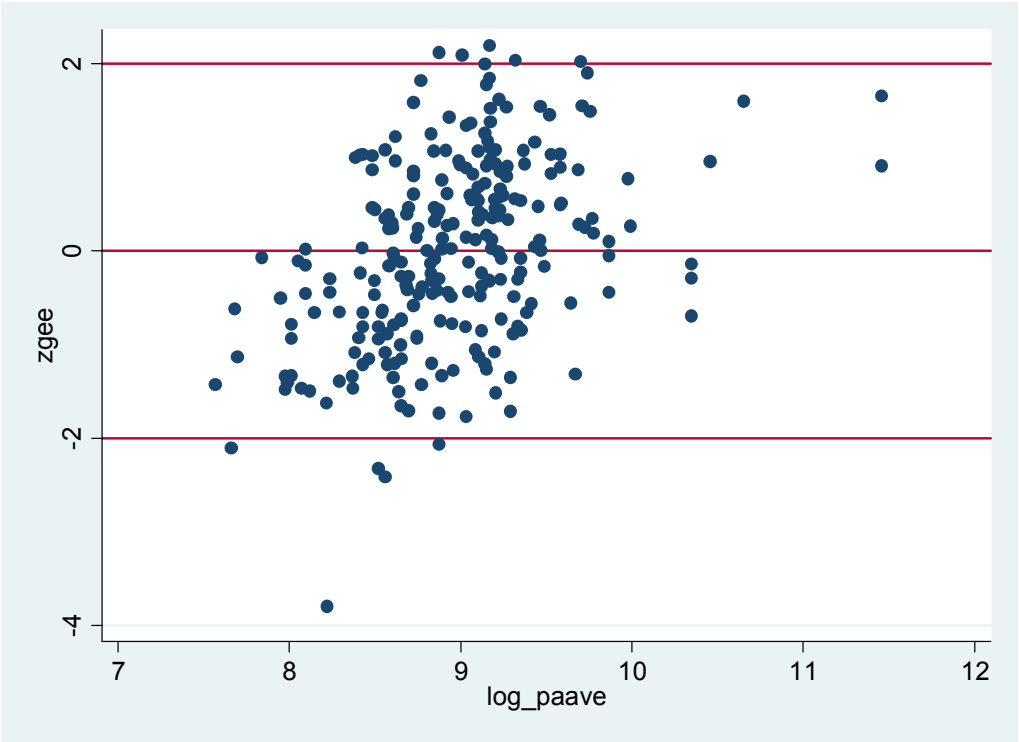


Figure 49.1: Pedometer Physical Activity Level Prior to Restrictions Applied in GEE Model

Applying the restriction more than -3 reduced the outlier effect of the residuals as noted by the y axis (Zgee) and the restriction less than 11 lessened the outlier effect of the leverage as noted on the x axis (log_paaave).

Figure 49.2 provides information pertaining to the goodness to fit testing in the MEM model when restrictions were not yet applied and Figure 51.3 presents the scatter plot with restrictions (> -2 and < +2) applied.

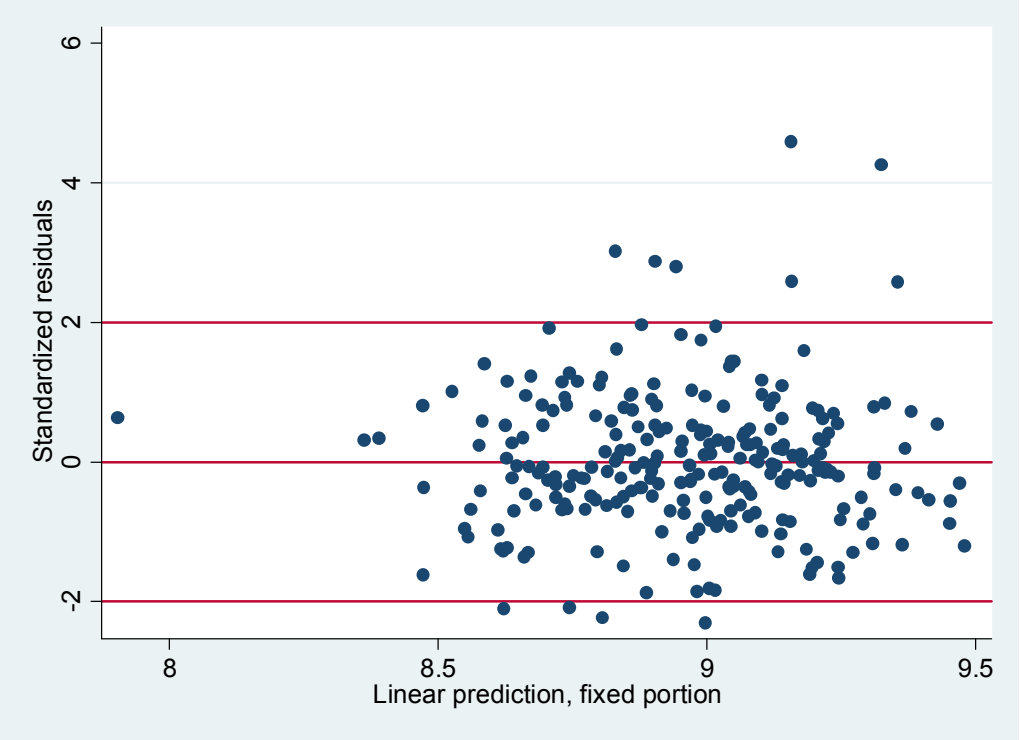


Figure 49.2: Pedometer Physical Activity Level Prior to Restrictions Applied in MEM Model

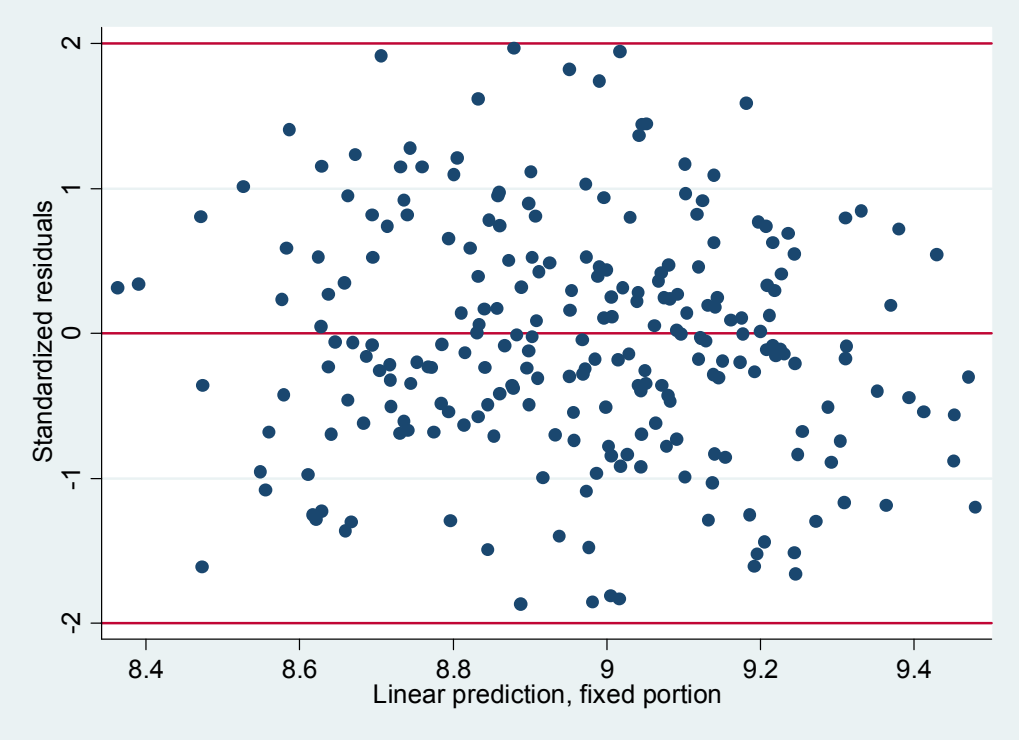


Figure 49.3: Pedometer Physical Activity with Restrictions (> -2 and < +2) in MEM Model

APPENDIX 50

INTERVENTION PARTICIPANTS' FEEDBACK POST PHYSICAL ACTIVITY MODIFICATION

Table 50.1: Participants' Feedback Regarding Helpful Monthly Session Information

ID	Helpful Information Obtained at Monthly Sessions
1	Be active and try and do exercise.
5	The information about exercise and the contact sessions to motivate patient. Participant started walking then running and cycling.
6	How exercise can help lose weight and how exercise can improve heart health.
8	Exercises helped to feel healthier.
9	Exercise helps to improve the pumping of the heart and can improve heart health.
14	How to monitor that you are exercising enough. How to check your pulse.
16	The warm up and cool down exercises as it was not difficult to do.
27	The importance of doing exercise to lessen stress and maintain joint mobility.
29	Information on intensity of exercise motivated her to walk fast and increase her exercise level.
30	Motivation received in contact session and exercises done in session.
32	The importance of exercising regularly for your health.
35	How to use the pedometer to increase your walking. To do the warm-up and cool- down exercises before doing the programme to lessen stiffness.
36	Exercise is important in her life and should not only depend on medication.
39	Exercise is important and can use walking to increase exercise level.
42	Exercise can lessen cholesterol level and increase fitness. Exercise helps control lifestyle diseases.
50	How exercise is important for your heart.
52	Using the pedometer to exercise.
55	How exercise is helpful for health.
57	Healthy eating, not to stress too much, exercise to help your heart.
58	Exercise makes you stronger. It helps to make your legs stronger and help with the blood flow. If you live well, not smoking and drinking it helps to protect your heart.
61	Warm-up and cool-down exercises. Exercise is important for health.
62	Warm-up and cool-down exercises very helpful to prepare to exercise. Learning how exercise can helps to reduce heart problems. The risk factors of heart disease.
63	Exercises are important to improve your health and it made her feel good.
64	Exercise can influence viral load and exercise is important for health.
72	Exercise is very healthy and can protect you from other types of diseases e.g. heart problems. How exercise can affect cholesterol and how exercise can protect against stroke and heart problems by lessening cholesterol.
73	It is good and healthy to do exercise.
80	Exercise helps for circulation, smoking and how it relates to circulatory problems.
83	Exercise is important to improve one's health. How to do cool- down and warm-up exercises.
84	The function of the heart and influences of doing exercise. Effects of smoking.

Table 50.2: Participants' Feedback Regarding what they Enjoyed most about the Education and Home-Based Walking Programme

ID	Participants' Feedback
1	Exercises; warm-up and cool-down. Having a pedometer and a booklet to record findings. Monthly sessions with education.
5	Having to do exercise increased her friends. She met people when she exercised and known friends exercised with patient. This gave patient support.
6	The exercises and walking programme. Being able to walk with family.
8	Everything: walking and face to face sessions
9	The walking encouraged her to exercise and get out of the house. Before she was just at home the whole time.
14	Exercises made her feel well physically.
16	The exercises especially the warm up and cool down exercises.
27	Receiving a SMS to remind regarding exercise as this indicated that someone cared about you. Having a pedometer and the walking programme.
29	Exercises and walking with the pedometer.
30	Enjoyed everything
32	The exercising especially learning the warm-up and cool-down exercises. Now able to walk far.
35	Having a pedometer and being able to monitor the steps that you take per day and to try and walk more to increase steps.
36	Stretches improved mobility in legs
39	Walking programme and warm-up and cool-down exercise. The programme reminded her that exercise is important.
42	The walking programme.
50	Walking programme as she lost weight.
52	The exercises.
55	Exercise and monthly sessions were helpful and enjoyable.
57	Contact session for motivation, receiving SMS for motivation, physiotherapist was friendly.
58	It helped to keep her focused on the importance of exercising even though she had a lot of problems in her family and being unemployed. It helped her to decrease her stress level by walking and using the pedometer.
61	Knowledge that he gained during the programme. Knowledge about exercise, weight, warm-up and cool-down exercise.
62	Having the pedometer to self-monitor activity level and see if she was improving or not doing so well. Also motivated her to keep up with her volleyball.
63	Her tiredness is less since doing exercise and she did not get flu during this period. Her body is feeling better. She enjoyed the warm-up and cool-down exercises and walking with the pedometer. With the pedometer she was able to see her steps and adjust her walking.
64	Having a pedometer and activity booklet.
72	Exercise is important to live a healthy lifestyle. Enjoyed the exercises and found it helpful to lessen her stress levels.
73	Walking programme
80	Motivation received to exercise, and information on effect of exercise on blood pressure.
83	The exercises; warm-up and cool-down and walking with pedometer.
84	Exercises and motivation received.

APPENDIX 51

ABSTRACTS OF JOURNAL ARTICLES SUBMITTED FOR PUBLICATION

Authors: Roos R, Myezwa H, Van Aswegen H, Musenge E

Title: Physical activity and risk factor screening for ischaemic heart disease in South African individuals living with HIV.

Abstract:

Individuals living with HIV are at risk of developing chronic lifestyle diseases such as ischaemic heart disease (IHD). Physical inactivity is a well known modifiable risk factor for IHD. Currently, the level of ambulation physical activity in individuals living with HIV in a South African context is not known. The aim of this study was to assess the physical activity levels and other risk factors for IHD in individuals living with HIV on antiretroviral therapy. An observational study was conducted from October 2010 to June 2012 at a large outpatient clinic in Johannesburg, South Africa. Two hundred and five individuals who were on antiretroviral therapy for 6-12 months were screened. Physical activity was measured with the Yamax SW200 pedometer over a seven day period. Physical activity of the sample was reduced at 7 673.2 (±4 017.7) steps per day with women walking less than men [6 993.3 (±3 462.6) and 10 076.3 (±4885.6) respectively]. Body mass index was increased to 25.6 (±1.4) kg/m^2 with women noted to be overweight [26.6 (±5.5) kg/m^2]. Independent predictors of being overweight were systolic blood pressure, waist and hip circumference, CD_4 count and daily fruit and vegetable intake. Smoking was less common in the study population with 16.1% of the sample being current smokers and former smokers at 25.9%. Individuals' mean perceived stress levels were 19.2 (±7.8) on the Cohen's Perceived Stress Scale. The physical activity level of individuals living with HIV requires modification to assist with reducing risk factors of IHD.

Keywords: physical activity level, HIV, ischemic heart disease

Authors: Roos R, Myezwa H, Van Aswegen H

Title: Physical activity levels and activity preferences of a cohort of South African individuals living with HIV.

Abstract:

Physical inactivity is a risk factor for many lifestyle diseases. It is still poorly understood in individuals living with HIV. The aims of this study were to evaluate the physical activity levels of individuals living with HIV on antiretroviral therapy (ARV) and to assess their physical activity preferences. An observation study was done from October 2010 to June 2012 at a large urban HIV clinic in Johannesburg where 205 individuals were consecutively sampled. Physical activity was assessed with the Yamax SW200 pedometer over a seven day period. The mean age of the sample was 38 (±9.5) years, CD_4 count 285.1 (±157.9) and time on ARV 8.7 (±2.3) months. Physical activity of the sample was reduced at 7 673.2 (± 4 017.7) steps per day with women walking less than men [6 993.3 (±3 462.6) and 10 076.3 (±4 885.6) respectively]. Eight individuals (3.9%) did formal sporting activities and a hundred and twenty three individuals (60%) did some form of exercise. Walking (45.5%, n=56) and running (26.8%, n=33) were most frequently reported. Physical inactivity was present in the majority of the sample and interventions including activity preferences of individuals could be strategies to address this health concern.

Keywords: Physical activity, pedometer, activity preferences, HIV

Authors: Roos R, Myezwa H, Van Aswegen H, Musenge E

Title: Effects of an education and home-based pedometer walking programme on ischemic heart disease risk factors in people infected with the human immunodefiency virus: a randomised trial.

Abstract:

People infected with the human immunodeficiency virus (HIV) are at an increased risk of developing ischemic heart disease (IHD); however the effects of an education and home-based pedometer walking programme on risk factors of IHD are not known. We conducted a 12 month randomised study of an education and home-based pedometer walking programme in 84 HIV-infected individuals with risk factors of IHD. Pedometer step count of the control and intervention group improved significantly (p=0.03 respectively) at six months but was not significant at 12 months (p=0.33 and p=0.21). Significant between-group effects were observed in six-minute walk test distance (p=0.01), waist: hip ratio (p<0.00), glucose (p<0.00) and high density lipoprotein (p=0.01) over the 12 month period. The programme did not result in change in high sensitivity C-reactive protein as it was associated with perceived stress (r=0.23; p=0.03), weight (r=0.28; p=0.01), body mass index (r=0.35; p<0.00), waist (r=0.28; p=0.01) and hip circumferences (r=0.28; p=0.01). Multivariate generalised estimation equation analysis demonstrated an inverse association between interaction and perceived stress (*log B* = -0.01; 95% CI: -0.02, -0.01; p <0.00) and body mass index (*log B* = -0.02: 95% CI: -0.03, -0.002; p = 0.02) at group level. An education and home-based pedometer walking programme improves physical activity levels and beneficial changes in other IHD risk factors were noted.

Keywords: HIV, pedometer walking programme, heart disease

Authors: Roos R, Myezwa H, Van Aswegen H

Title: “Not easy at all but I am trying”: Barriers and facilitators to physical activity in a South African cohort of PLWHA participating in a home-based pedometer walking programme.

Abstract:

The promotion of physical activity is encouraged in people living with HIV (PLWHA) as a means of promoting wellness and health. Adherence to programmes that promote exercise are often reduced and a home-based programme are suggested to improve adherence. This study investigated the personal and environmental factors that cause barriers and facilitators of physical activity in a home-based pedometer walking programme as a means of highlighting adherence challenges. An observational study nested in a randomised controlled trial was conducted in a cohort of South African PLWHA on antiretroviral therapy over a six month period. Descriptive analysis and qualitative content analysis of 42 participants that underwent physical activity modification assisted with data review. The mean age of the sample was 38.7 (±8.9) years, consisted mostly of women (n=35; 83.3%) who were employed (n=19; 45.2%) but earning very little (less than R500 per month) and often single or widowed (n=23; 54.8%). Barriers to physical activity identified included physical complaints e.g. low energy levels and psychological complaints e.g. stress levels, family responsibility e.g. being primary care givers, the physical environment e.g. adverse weather conditions, social environment e.g. domestic abuse and crime and workplace e.g. being in a sedentary job. Facilitators of physical activity included support and encouragement from friends and family, religious practices during worship and community environment e.g. having access to parks and sport fields. The study is of benefit as it highlights personal and environmental factors that need to be considered when developing or implementing a home-based walking programme in PLWHA.

Keywords: physical activity, adherence, HIV

Authors: Roos R, Myezwa H, Van Aswegen H

Title: 'If you have a problem with your heart, you have a problem with your life': Self-perception and behaviour in relation to the risk of ischaemic heart disease in people living with HIV.

Abstract:

Ischaemic heart disease (IHD) is a global health problem and specifically relevant in the African context as the presence of risk factors for IHD is increasing due to the high prevalence of the human immunodeficiency virus (HIV). People living with HIV are at an increased risk for IHD due to increased longevity, treatment specific causes and viral effects. This study determined the self-perception and behaviour in relation to the risk for IHD in a cohort of South African PLWHA. A qualitative study design using semi-structured interviews with a card sort technique was used to gather data from thirty individuals at an HIV clinic in Johannesburg, South Africa. Descriptive analysis and an inductive approach with conventional content analysis were done to generate the findings. The median age of the cohort was 36.5 (31.8 – 45.0) years and consisted mostly of women (n = 25; 83.3%) who were employed (n = 17; 56.7%) and supporting dependents (n = 26; 86.7%). The majority of participants (n = 15; 50%) did not perceive themselves at risk of IHD due to reporting having adequate coping behaviour, living a healthy lifestyle and being healthy since initiating highly active antiretroviral therapy. Twelve (40%) participants did however because they experienced physical symptoms and had poor behaviour consisting of a poor diet, elevated stress levels and lack of exercise. Three (10%) participants were unsure of their risk for IHD. Knowledge and understanding related to IHD, insight into their own risk for IHD and health character in an HIV context were identified as three prominent themes, emerging from the data. This study highlights that participants did not perceive themselves to be at risk of IHD due to their HIV status or antiretroviral management. Education strategies are required in people living with HIV to inform their personal risk perception for IHD which may in turn influence behaviour changes and prevention of IHD.

Keywords: ischaemic heart disease; HIV; risk perception.