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Dissertation

**The Effect of a 18-Week Supervised Exercise Program on
Changes in Weight and Health Status in Overweight Individuals:
The Healthy Weight Beginner and Intermediate Program**

**Submitted in partial fulfilment of the Master of Philosophy with endorsement in
Biokinetics Degree in the Division of Exercise Science and Sport Medicine,
Department of Human Biology, Faculty of Health Science at the University of
Cape Town.**

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DEDICATIONS

This dissertation is dedicated to my parents, who have helped me through every step of my education; inspired me to acknowledge and pursue my passion in Exercise Science and Sport Medicine research.

ACKNOWLEDGEMENTS

ABSTRACT

Background: According to the South African National Health and Nutrition Examination Survey, approximately 69% of South African women and 29% of men are considered overweight/obese. In South Africa, overweight and obesity rates are on the rise and have reached epidemic proportions. Several conventional weight loss strategies have been employed and have been unsuccessful in addressing this issue. It is for this reason that this study strives to uncover if any improvement in weight and fitness status are associated with an improvement in health status.

Methods: One of our main aims were to determine the success in weight loss and reduction in health risk factors in members who have completed 18-weeks of the Healthy weight programme. Therefore, this study is a retrospective, observational study of adults with a mean body mass index (BMI) of 32.63 ± 7.39 who completed an 18-week supervised exercise program. An online health questionnaire was completed followed by pre- intervention assessments which included: Anthropometric measures (height, weight, waist circumference, body fat percentage) followed by blood pressure, finger-prick random glucose and cholesterol measurements. A 12-min motion test to assess functional capacity were completed. All anthropometric, resting health measures and fitness tests were repeated at 12-weeks (post-beginner programme) and 18 weeks (post-intervention) after the start of the intervention. The intervention included 2 weekly classes with an optional gym class. The type of exercise intervention that was included in this study largely focused resistance training and cardiorespiratory fitness which targeted multiple large muscle groups. Each exercise session included 80 to 90 % exercise intensity as well as lumbopelvic core exercises. The data set was analysed as an intention to treat (ITT) protocol as some of the testing time points were missing.

Results: Out of a possible 50 participants, 34 met the inclusion criteria of at least all 3 health measures taken on the 3 different occasions (baseline, post-beginner, post-intervention). The 34 participants had a mean age of 47.26 ± 10.44 ranging between 24 years and 76 years old. 65 % of the participants were female. Anthropometric results showed significant changes in weight and waist circumference at 12- and at 18-weeks compared to baseline measures ($p < 0.005$). Additionally, body fat % significantly reduced at 12-weeks but increased slightly at 18 weeks diminishing the significant reduction compared to the baseline measure. In terms of fitness, participants succeeded in improving their average distance to complete a 12-min motion test by 14.5% ($p < 0.001$) at 12-weeks and 20% ($p < 0.001$) at 18-weeks compared to starting measures, respectively. After adjusting for multiple comparisons during post-hoc analysis, none of the health status outcomes (blood pressure, random glucose, random cholesterol) showed a significant improvement at any of the time points. In terms of associations, a change in body fat % could significantly explain some of the variance in the change (from baseline to 18-weeks) in cholesterol; and a change in weight could significantly explain some of the variance in the change in glucose over the same intervention time.

Conclusion: The results of this study revealed the 18-week supervised exercise intervention led to a modest reduction (approximately 5%) in weight and a substantial improvement in fitness. However, no changes in health status were observed, suggesting that greater improvements in weight and fitness may be required to have a profound influence on health status.

Keywords: aerobic exercise, blood pressure, random glucose, random cholesterol, blood pressure, waist circumference, weight loss

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1 CHAPTER ONE

PURPOSE OF THE STUDY

This study seeks to determine the success of a long-standing commercially available healthy lifestyle intervention, relative to adherence to the program and possible changes in health status and fitness. The Healthy Weight Program (HWP) offered by the Sports Science Institute of South Africa was an evidence-based scientific lifestyle intervention which aimed to promote healthy lifestyle changes, with specific focus on weight loss. It was rendered as a two-part program: the Healthy Weight Beginner and Healthy Weight Intermediate. The HWP was characterized by weekly group exercise classes, dietary consultations and psychological assessments. The commercially available HWP has extensive data since its electronic database conception in 2011.

The objective of the study was to determine if members who completed both the beginner and intermediate healthy weight programme, experienced weight loss and reduction in certain health markers. Additionally, the study assessed if the degree of weight loss was associated with the reduction in health risk markers. This study was a retrospective observational study and data was drawn from a registered research database. Ethics for accessing the data base was sort from the Human Research Ethics Committee (Faculty of Health Sciences, University of Cape Town, R025/2015). The research database consisted of all pre-and post-program assessment data of risk factors, anthropometry and health and fitness markers of members from the beginner and the intermediate HWP.

BACKGROUND

A healthy body weight is vital in obtaining and maintaining optimal health. However, it has been cited as a key factor in promoting longevity (Goedecke and Micklesfield, 2014), this can be attributed to the association between excessive body weight and numerous diseases, especially cardiovascular (CDV) disease. Weight gain usually occurs if the energy balance of an individual is skewed, thus, greater energy consumption while energy expenditure remains low (Swift *et al.*, 2014). Weight loss among overweight and obese individuals has been associated with improved prevalence of metabolic syndrome, insulin resistance, type 2 diabetes, dyslipidaemia (Swift *et al.*, 2014). Moreover, a 5% decrease in weight has shown to be effective in

reducing CDV and type 2 diabetes risk factors (Cromwell *et al.*, 2016), and thus finding effective treatment methods to promote weight loss is vital. High physical activity levels have been advocated to form part of any treatment plan for obese individuals (Swift *et al.*, 2014).

EPIDEMIOLOGY OF OBESITY

Prevalence of Obesity

Without doubt, obesity is a growing global concern. Obesity has been cited as one of the leading causes of preventable death, and has been argued to be a significant factor in reducing overall quality of life and life expectancy (World Health Organization, 2021b). Obesity puts people at higher risk for diabetes, heart disease, and even certain types of cancer. Additional health risks from diabetes include osteoarthritis, sleep apnea, kidney disease, strokes, and high blood pressure. Despited obesity being preventable, globally obesity has nearly tripled since 1975 (World Health Organization, 2021b). In 2016, more than 1.9 billion adults, 18 years and older, were overweight and of these over 650 million were obese (World Obesity, 2019).

By 2030, it is expected that more than 2.16 billion people globally will be overweight and 1.12 billion obese (Swinburn *et al.*, 2011). In the previous decades obesity used to a big public health concern for developed countries. For instance in the United States of America, the general prevalence of obesity has not decreased over the last 10 years, with about 66.3 % adults reported to be overweight or obese (Mehta *et al.*, 2016). However, several studies in literature have reported a complex coexistence of undernutrition and overnutrition in Africa (Cusick and Kuch, 2012; Shimpton and Rokx, 2012; Kimani-Murage *et al.*, 2015; Mehta *et al.*, 2016; Sanders *et al.*, 2017; Menon and Peñalvo, 2019; Modjadji and Madiba, 2019). The prevalence of overweight is now a growing concern in Africa, looking at the 5 African countries with the highest prevalence of overweight as of 2016; Seychelles (64%), Mauritius (44.8%), Cameroon (43.9%), Botswana (41.6%), and South Africa (41%) (Agyemang *et al.*, 2016), it can be deduced that the prevalances of overweight is alarming.

South Africa's overweight and obesity rates have been argued to be on the rise, as 2011 statistics showed that, 56% of black African females were either overweight or

obese compared to 29% of males (Shisana *et al.*, 2014). As of 2020, in the Western Cape, 62.2% females and 25.1% males were reported to be overweight or obese (Western Cape Government, 2020). A study done in South Africa on trend associations between the country's economic growth with adult obesity prevalence uncovered that females presented higher levels of obesity relative to males (Pisa and Pisa, 2017). Also, in the same study it was evident that for both genders in urban settings presented higher obesity level than rural settlements. Furthermore, Blacks, Coloureds and Asians/Indians females had higher obesity levels as compared to males for all time points, with exception to Whites (Pisa and Pisa, 2017).

Due to the rapid rise in the prevalence of obesity, there has been an increased effort to develop ways to prevent weight gain. Therefore, this presents a critical need to identify effective treatment approaches for the fast-growing South African population who are currently overweight (body mass index (BMI) >25) or obese (BMI >30).

Measures of Obesity

Obesity is defined as excess adiposity which can be located subcutaneously or centrally around the abdomen (Rayner *et al.*, 2010). It is commonly quantified by body mass index (BMI) (McCafferty, Hill and Gunn, 2020). BMI is not a direct measure of adiposity but is a robust measurement to differentiate between healthy weight and overweight individuals in the general population. BMI is a relatively simple and low-cost indirect measure for assessing obesity and has well established cut-offs to define obesity (Adab, Pallan and Whincup, 2018). Furthermore, when evaluating specificity of BMI compared to direct measures, it has a specificity of 0.90, but low sensitivity of 0.50 for assessing obesity (Adab, Pallan and Whincup, 2018).

An upward trend demonstrated an increase in BMI with age in both sexes, while it later decreased in females in the group 65 years of age and older. The groups 45–54 years of age, 55–64 years of age and 65 years of age and older had significantly higher mean BMI (31.7 kg/m2, 31.3 kg/m2, 30.0 kg/m2 for females, respectively and 26.0 kg/m2, 25.2 kg/m2, 25.6 kg/m2 for males, respectively), when compared with the groups 15–17 years of age and 18–24 years of age (23 kg/m2 and 26.2 kg/m2 for females and 20.4 kg/m2 and 21.3 kg/m2 for males, respectively) (McHiza *et al.*, 2019).

Other methods such as magnetic resonance, thus imaging of total adipose tissue and dual-energy X-ray absorptiometry are commonly employed (McCafferty, Hill and Gunn, 2020). However, these methods provide accurate fat distribution and indicate obesity, but they are often cumbersome, expensive and not standardised methods for classifying or defining high risk (Adab, Pallan and Whincup, 2018). Nevertheless, measures of central obesity known to be good and inexpensive predictors for visceral adiposity, cardiometabolic disease, and mortality are: waist circumference, waist: hip ratio and waist: height ratio. Measures of central obesity will be discussed in sections to follow.

IMPACT ON HEALTH AND ASSOCIATED CARDIOVASCULAR DISEASE (CVD) RISK FACTORS

Obesity can have significant implications for an individual's health. Obesity has since been identified as a risk factor for arthritis, asthma, gallbladder disease, osteoarthritis, chronic back pain, hypertension and cardiovascular (CV) disease, adult-onset diabetes, and various types of cancer (Medvedyuk, Ali and Raphael, 2018). Adverse psychosocial risk factors as low self-esteem, disordered eating patterns, social stigma, weight discrimination, anxiety and depression have been argued to be driven by obesity (Swift *et al.*, 2018).

Furthermore, CV diseases have been cited as the leading cause of death globally (World Health Organization, 2021a). Obesity has often adverse effects on cardiovascular structure and function with most notable effects represented by increased total blood volume, cardiac output, and cardiac workload (Ibarra, 2009). Some CV disease risk factors include blood pressure, low density lipoproteins and total cholesterol levels (McCafferty, Hill and Gunn, 2020). Obese individuals are more likely to have high blood pressure as weight gain tends to increase arterial pressure (Hall *et al.*, 2015). As arterial pressure rises, overweight and obese individuals develop left ventricular chamber dilation which may warrant unfavourable medical complications (Ibarra, 2009).

The distribution of body fat is more closely associated with insulin resistance and type 2 diabetes (Goedecke and Micklesfield, 2014). The link to type 2 diabetes and the high global prevalence of obesity is mostly compounded by low levels of physical activity

(Hruby and Hu, 2015). The following sections will expand on how risk factors such as waist circumference, blood pressure, dyslipidaemia, insulin resistance and sedentary lifestyle that are associated with obesity.

OBESITY RISK FACTORS CAUSING CO-MORBIDITIES

Waist circumference

Waist circumference is a measurement of the distance around the abdomen and is often used as an indicator of adipose tissue distribution (Tuttle, Montoye and Kaminsky, 2016). They are different anthropometric measures for abdominal obesity such as waist circumference (Ahmad *et al.*, 2016). Abdominal adiposity for male and female genders have been defined as 88cm or more for women and 102 cm or more in men according to the World Health Organisation cut-points (World Health Organisation (WHO), 2008). These measurements require standardization from a trained technician although they are relatively quick and inexpensive to perform (Tuttle, Montoye and Kaminsky, 2016).

A study in China assessed the association between perceived stress and adiposity among Chinese adults (Tan and Leung, 2021). In the Chinese study waist circumference was measured by trained staff at a horizontal position of the lower margin of the rib arch and midline of the iliac crest (Tan and Leung, 2021), and abdominal obesity was defined as >102cm for males and >88cm for females. Using the WHO cut-points for waist circumference (World Health Organisation (WHO), 2008), the study reported that 25.5% of the adults had moderate abdominal obesity and 19.2% had abdominal obesity (Tan and Leung, 2021).

A South African study revealed that abdominal obesity was highest in white urban and non-urban African women (Puoane *et al.*, 2002). The study showed that obesity in women started at a young age where 10% of women were obese at the ages, 15 to 24 years (Puoane *et al.*, 2002). When comparing abdominal obesity data from Ghana, Mali, and Tanzania with those from South Africa, the study showed the other countries to have much lower abdominal obesity rates than South Africa (Puoane *et al.*, 2002).

From the latter arguments it can be deduced that waist circumference is a risk factor for chronic diseases (Darsini *et al.*, 2020). The highest prevalence of an increased

waist circumference (equal to or more thab 102cm in males and 88cm in females) was seen in males 45-54 years of age (22.1%) and females 55-64 years of age (70%) (Shisana *et al.*, 2014). Furthermore, partcipants living in urban formal settlements had the highest mean waist circumference and the waist circumference in both males and females increased (Shisana *et al.*, 2014).

Excess body weight is known to increase total blood volume and cardiac output thus increasing metabolic demand (Poirier *et al.*, 2006). The continuous increase in cardiac output is driven by increased stroke volume. This phenomenon is largely affected by high left ventricular filling pressure and volume. A cascade of unfavourable cardiovascular effects such as sleep apnea, intrinsic pulmonary disease or recurrent pulmonary thromboembolism usually occur (Poirier *et al.*, 2006). Laxity of anterior abdominal muscles, posture of the individual and phases of respiration may influence waist circumference (Misra, Wasir and Vikram, 2005).

Furthermore, high body fat and truncal adiposity may affect insulin sensitivity (Patel and Abate, 2013). Therefore, insulin resistance syndrome, type 2 diabetes mellitus and cardiovascular risk factors are commonly associated with large waist circumference (Poirier *et al.*, 2006). Visceral adipose tissue (VAT) is a stronger determinant of insulin resistance and type 2 diabetes than abdominal subcutaneous adipose tissue (SAT) (Goedecke and Micklesfield, 2014). VAT is more lipolytic, has enzymes that reactivate inactive cortisone to active cortisol, lower adiponectin levels and a higher inflammatory profile (Freedland, 2004). On the other hand, SAT deposition has shown to be 'protective' against insulin resistance and type 2 diabetes (Longo *et al.*, 2019). Therefore, the factors presented by VAT are correlated to insulin resistance and obesity-related metabolic disease (Goedecke and Micklesfield, 2014). While SAT and VAT, provide meaningful information it is often an time consuming process and costly procedure to undertake.

The above highights the pathophysiology related to an increase in waist circumference. Therefore, proper management of waist circumference is necessary to prevent clinical complications and improve an individual's quality of life.

Blood pressure

Blood pressure (BP) is defined as the force of blood against the walls of the arteries and veins created by the heart as it pumps bood to every part of the body (Molnar and Gair, 2019). BP is expressed in millimeters of Mercury, mmHg (American College Medicine of Sports, 2013). Systolic BP is the maximum pressure in the arteries when the ventricles contract during a heartbeat and an important indicator of cardiovascular function during exercise. Diastolic BP is an indirect indicator of peripheral resistsnce as it represents the minimum pressure in the arteries when the ventricles relax. Hypertension is defined as sustained elevation of brachial blood pressure (Cromwell *et al.*, 2016).

Hypertension is a major risk factor for chronic diseases. Some chronic diseases that have a strong association with obesity are: coronary artery disease, hypertension, diabetes, hyperlipemia and certain cancers (American College Medicine of Sports, 2013). As of 2018, sub-Saharan African reported the highest prevalence of 30%, with 54.1% mean prevalence reported in Soweto, South Africa (Mohamed *et al.*, 2018). If the current trend in prevalence of hypertension remains unchanged, it is projected that by 2025 the number of people with hypertension in sub-Saharan Africa will fluctuate to 68% (Mohamed *et al.*, 2018).

Consequently, obesity increases cardiac output and results in the development of increased arterial pressure and total peripheral resistance. In addition, increased vascular resistance is caused by increased venous return (Susic and Varagic, 2017). Obesity and obesity-related hypertension is an impairment in arterial baroreceptor control of sympathetic nerve activity (Seravalle *et al.*, 2017). An increase in arterial blood pressure is as a result of the activation of the sympathetic nervous system (Seravalle *et al.*, 2017). Therefore, proper management of high blood pressure is necessary to prevent it's complications and improve an individual's quality of life. Despite a growing body of evidence, there are still gaps in literature regarding the mechanism of obesity or weight gain causing hypertension (Susic and Varagic, 2017).

Cholesterol

Total cholesterol (TC) levels, triglyceride levels, and low-density lipoprotein cholesterol (LDL-C) levels have been linked to coronary heart disease (Rosinger *et al.*, 2017).

Dyslipidemia is defined as elevated total or low-density lipoprotein (LDL) cholesterol levels or low levels of high-density lipoprotein (HDL) cholesterol (Healthline, 2017). High total cholesterol was described by the American College of Sport Medicine as >5.2 mmol/L (Mohamed *et al.*, 2018). Dyslipidemia is an important risk factor for coronary heart disease and stroke (Susic and Varagic, 2017). Dyslipidaemia phenotype has been commonly associated with obesity (Repas, 2011).

As all components of obesity-associated dyslipidaemia have been linked with increased cardiovascular risk and low high-density lipoproteins have emerged as one of the most potent risk factors (Repas, 2011). Obesity has been reported to increase the risk for diabetes and dyslipidaemia in all age groups (Repas, 2011). Obesity also increases per person medical costs and the magnitude of increase is greater with older ages. However, it remains unclear whether or not obesity is the root cause of dyslipidaemia as some individuals may be diagnosed with dyslipidaemia and are not overweight or obese.

Some scientists have rationed that due to an increase in circulating free fatty acids, orgininating in adipocytes, and enhanced hepatic synthesis it might be a causative factor to obesity (Ntusi, 2018). Similarly, in a case of insulin resistance there is less lipolysis and higher levels of free fatty acids. Because of the free fatty acids influx to the liver, fat accumulation occurs within the liver and thus resulting in increased circulating triglycerides (Ntusi, 2018). Long-term increase in blood lipids can easily cause cholesterol to invade walls of blood vessels, deposit and accumulate, and promote the proliferation of smooth muscle cells and fibroblasts in the arterial intima leading to coronary heart disease, atherosclerosis and other cardiovascular and cerebrovascular diseases (Cao, Zhu and Liu, 2021).

Therefore, to mitigate the effects of dyslipidemia, aerobic exercise has been shown to improve prognosis of CVD. Exercise improves serum lipids in individuals with hyperlipidemia by lowering serum triglyceride levels, total cholesterol and LDL-cholesterol, while increasing HDL- cholesterol levels. Lipoprotein lipase is critical in the formation of HDL, and is increased with aerobic exercise (Cao, Zhu and Liu, 2021). Aerobic exercise is defined as any form of physical activity that produces an increased heart rate and respiratory volume to meet oxygen requirements of the activated muscle (Wang and Xu, 2017). Aerobic exercise presents fewer side effects as

compared to medications (Netz, 2017). It is recommended that regular exercise training for 3 or more times a week for 30-45 mins reaps benefits (American College Medicine of Sports, 2013). In a prospective cohort study of exercise and lipid metabolism, individuals were grouped by evaluating peak metabolic equivalents (MET) during exercise endurance tests (Wang and Xu, 2017). After 10 years, individuals who took statins treatment had mortality risk decreased while their fitness increased (>9 MET). Therefore, the study concluded that the mortality risk was significantly reduced when combined with statin therapy and aerobic exercise (Wang and Xu, 2017). However, more understanding is needed regarding the aerobic exercise intensity specifications to induce change on total cholesterol, LDL, HDL-concentrations and triglycerides.

Insulin resistance/ Type 2 Diabetes

Type 2 diabetes is a chronic disease traditionally viewed as adult-onset disease (Franssen *et al.*, 2011). Diabetes mellitus (DM) is a chronic condition which results in the inability of the pancreas to produce enough insulin or failure of the body to effectively use insulin it produces (Ampofo and Boateng, 2020). This results in increased blood glucose over time and causes health complications such as hypertension, kidney failure, stroke. Globally, diabetes prevalence has been defined as having a fasting blood glucose equal to or higher than 7.0 mmol/L (Ampofo and Boateng, 2020). Overweight and obesity have become the strongest risk factors for type 2 diabetes and insulin resistance. On the otherhand, insulin resistance's symptoms present as a waistline of >102 cm in men and >88cm in women; blood pressure readings of 130/80 or higher; fasting glucose of >5.2mmol/l; fasting triglyceride of 8.3 mmol/l (WebMD, 2021).

The high prevalence of type 2 diabetes has been argued to be most likely to be associated with proinflammatory cytokines (tumor necrosis factor and interleukin-6), fatty acid metabolism, mitochondrial dysfunction, and endoplasmic reticulum stress (Eckel *et al.*, 2011). Eckel *et al.*, (2011) uncovered the link between beta cells dysfunction and type 2 diabetes to be caused by genetics. An additional study in literature, revealed that lifestyle behaviours associated with obesity and type 2 diabetes are established in childhood hence difficult to modify in adulthood (Arenaza *et al.*, 2017). Some lifestyle behaviours such as a high consumption of sugar-

sweetened beverages, energy dense diets, reduced consumption of fibre, fruits and vegetables and meal skipping have been found to have a cumulative effect towards risk of type 2 diabetes (Arenaza *et al.*, 2017).

The association between type 2 diabetes and obesity is complex and has not been fully elucidated (McCafferty, Hill and Gunn, 2020). However, obesity has been shown to be associated with hormonal and inflammatory mechanisms. This association has been illustrated by the interaction of two hormones: Tumour necrosis factor alpha and Adiponectin (McCafferty, Hill and Gunn, 2020). The Tumour necrosis factor alpha is an inflammatory mediator and is increased in obese individuals as it triggers a reduction in insulin sensitivity thereby preventing glucose uptake. On the other hand, adiponectin is an insulin sensitizer secreted by adipocytes. Adiponectin levels are reduced in obese individuals and type 2 diabetes patients due to decreased hepatic expression of adiponectin receptors (McCafferty, Hill and Gunn, 2020).

In mitigating random glucose coming from the bloodstream into skeletal muscle, intensity and duration of exercise are key determinants of muscle glucose uptake (Sylow *et al.*, 2017). Sylow *et al.*, (2017) argued that exercise can improve hyperglycaemia by: a) stimulation of insulin-independent signalling pathways which increases glucose uptake in muscle; b) improved insulin-stimulated glucose uptake occurs in the hours following an acute bout of exercise; c) insulin sensitivity and responsiveness become elevated in the exrcise-trained state. However, more understanding is needed regarding the mechanism underlying exercise-stimulated glucose uptake to treat insulin-resistant states , such as type 2 diabetes.

Interventions done to address obesity

A growing number of morbidities are linked with obesity. Lifestyle interventions have been shown to improve cardiorespiratory fitness and CV risk factors. In this section, three main elements that address obesity will be discussed, including: (1) increasing physical activity , (2) modifying unhealthy behaviours and (3) dietary interventions..

Physical Activity

Physical Activity (PA) is defined as any bodily movement produced by skeletal muscles that results in energy expenditure (Piggin, 2020). PA intervention is strongly

recommended by experts for medical management of obesity (Ibarra, 2009). Consequently, exercise is defined an activity that is specifically geared towards a purpose of improving CV fitness, strength, flexibility or balance and agility (Dasso, 2019). Exercise is a subcategory of physical activity that is planned, structured, repetitive and purposefully focused on improvement or maintenance of one or more components of physicl fitness (Dasso, 2019). For the purpose of this study, the words exercise and physical activity will be used interchangeably.

Thus, the health-related beneficial effects of physical activity occur in a dose-response manner. For example, 15-100 minutes of physical activity per day reduces risks of all-cause mortality related to cardiovascular diseases by about 4% (Garber, 2019). 150 minutes of PA through participating in >30 minutes of moderate to vigorous PA on most days of the week has been recommended in literature (Madjd A, 2016). At present, experts advise adults to undertake moderate to vigorous PA for >150 minutes per week, in sessions of >10 minutes. Current practice guidelines include recommendations that PA be undertaken for 30 minutes per day for most days of the week, increasing, when appropriate to 60 minutes per day (Madjd *et al.*, 2016).

Physical activity results in more healthful body composition, enhanced bone health, better cognitive function and alteration in the number of biomarkers associated with depression (Garber, 2019). Thus, engaging in regular aerobic or muscle strengthening exercise is known to be associated with an increase in glucose uptake into insulin sensitive tissue, improved glucose tolerance and decreased risk for insulin resistance and type 2 diabetes (Goedecke and Micklesfield, 2014). Goedecke and Micklesfield, (2014) have argued that moderate intensity longer exercises induce improvements in insulin activity. Thus, there are notable improvements in cardiorespiratory fitness that occur among individuals who engage in aerobic exercises. Aerobic exercises have been cited to improve blood pressure, total body fat/visceral abdominal fat, glucose intolerance, insulin resistance and dyslipidaemia (elevated triglycerides, low density lipoprotein cholesterol, low high-density lipoproteins) (Garber, 2019).

Modifying unhealthy behaviours

There are five main elements that address modifying unhealthy behaviors which will be discussed: a) medical nutrition therapy in obesity management, b) physical activity

in obesity management, c) pharmacology in obesity management; d) bariatric surgery: surgery options and outcomes; e) emerging technologies and virtual medicine in obesity management

Medical nutrition therapy in obesity management

Wharton *et al.*, (2020) proposed that all nutrition recommendations for adults of all body sizes be personalized to meet individual values, preferences and treatment goals. The clinical practice guidelines recommended that adults living with obesity should receive individualized medical nutrition therapy provided by a registered dietician to improve weight outcomes (body weight, BMI), waist circumference, glycemic control, established lipid and blood pressure targets (Wharton *et al.*, 2020). Furthermore, adults living with obesity and impaired glucose tolerance were encouraged to consider intensive behavioral interventions that target 5-7% weight loss (Wharton *et al.*, 2020). The latter suggestions would be aimed at improving glycemic control, blood pressure and blood lipid targets, and reduce the incidence of type 2 diabetes, microvascular complications (retinopathy, nephropathy, neuropathy) and cardiovascular.

Physical activity in obesity management

The clinical practice guidelines showed that increasing exercise intensity, including high-intensity interval training may promote weight maintenance or modest increases in muscle mass/ fat-free mass and morbility (Wharton *et al.*, 2020). Thus, regular physical activity, with and without weight loss, can improve many cardiometabolic risk factor in adults who are overweight or obese, including hyperglycemia and insulin sensitivity, high blood pressure and dyslipidemia (Ryan and Yockey, 2017). Consequently, aerobic physical activity (30-60 minutes of moderate to vigorus intensity most days of the week) can be considered for adults who want to: (1) achieve small amounts of body weight and fat loss, (2) achieve reduction in abdominal visceral fat and ectopic fat (such as liver and heart fat), (3) favour weight maintenance after weight loss, (4) increase cardiorespiratory fitness and mobility.

Dietary interventions: Obesity treatment

There are numerous treatment interventions that used exercise and diet intervention in reducing weight and health markers. For starters, the treatment of choice for severe obesity (BMI>35kg/m²) is bariatric surgery, which aims to restrict the amount of food the stomach can hold through a different procedure (Forcano *et al.*, 2018). Although majority of patients achieve a successful degree of weight loss after surgery(>50% excess weight loss), there is a significant proportion (20-40%) who fail to achieve this goal or regain weight a few years after intervention (Forcano *et al.*, 2018).

In a randomised control trial (RCT), Baetge *et al.*, (2017) compared a commercial program providing an exercise component (Curves Complete 90-day Challenge (CC; Curves International Inc.)) versus several programs advocating physical activity such as Weight Watchers Points Plus (WW; Weight Watchers International Inc.), Jenny Craig At Home (JC; Jenny Craig Inc., Carlsbad, Calif., USA) and Nutrisystem Advance Select (NS; Nutrisystem Inc.) on MetS and weight loss. The secondary outcomes of the RCT included changes in (i) body anthropometry, (ii) respective component indices of MetS, and (iii) cardiorespiratory fitness. In this study, the researchers hypothesized that the combination of aerobic training, strength training, and diet would prove more advantageous for reducing MetS than commercial diets, thus solely advocating PA.

Fasting blood profiles were obtained to measure cholesterol, triglycerides, HDL-C, low-density lipoprotein cholesterol (LDL-C), glucose, liver enzymes, whole-blood analysis, insulin, and leptin. Exercise training sessions for the CC participants consisted of 4 supervised circuit-training sessions per week for 12 weeks. Each training session lasted 30 minutes and was monitored by a trained fitness instructor. Three of the workouts consisted of 13 bi-directional resistance-training machines interspersed by 30 seconds of floor-based callisthenic exercises. Aerobic intervals consisted of callisthenic exercises performed at 60%–80% of maximal heart rate (Baetge *et al.*, 2017). During each session, the exercise circuit was completed twice.

Following baseline testing, all participants were assessed again at 4, 8, and 12 weeks (i.e., follow-up). Their results revealed the CC group demonstrated other benefits related to their intervention, such as the maintenance of HDL-C (p<0.001), an improvement in absolute fitness, and a decrease in daily sitting time (-339 min; 95% CI, -574,82). Although the other diet groups improved their relative fitness, this finding

can be attributed directly to weight loss, whereas an improvement in absolute fitness reflects an improvement in cardiorespiratory capacity (Baetge *et al.*, 2017). From this study, it is evident that a high frequency of exercise as well as the type of exercise employed (aerobic and resistance training) often plays a pivot role yielding health benefits such as increased HDL-C, improved fitness and cardiorespiratory markers.

Additionally, Cramer *et al.*, (2016) investigated the effect of yoga on waist circumference and other anthropometric variables. In this randomised control trial waist circumference was the primary outcome, while secondary (exploratory) outcomes included the waist/hip ratio, body weight, BMI, body fat percentage, body muscle mass percentage, blood pressure, health-related quality of life, self-esteem, subjective stress, body awareness, and body responsiveness, and the safety of the intervention. The yoga intervention consisted of an initial full day workshop, followed by 2 weekly 90-minute classes of hatha yoga over a 12-week period. Hatha yoga was defined as a preparatory process of Yoga (Cramer *et al.*, 2016). The word 'Ha' means sun, 'tha' means moon. Hatha means the Yoga to bring balance between the sun and moon in you (Cramer *et al.*, 2016). The yoga classes were based on integral yoga as developed by Swami Sivananda (Cramer *et al.*, 2016).

The RCT results showed that Yoga reduced the waist-hip ratio (p=0.034), body weight (p=0.003), BMI (p=0.008), and percentage of body fat (p=0.007) and increased the percentage of body muscle (p=0.010). Furthermore, there were improvements in mental (p=0.009) and physical (p=0.018) quality of life and self esteem and notable reduction in subjective stress through administered health surveys (p<0.05) (Cramer *et al.*, 2016). From this study, it is evident that >150 minutes of PA showed good results, especially coupled with yoga which helped modify unhealthy behaviours such as acute/chronic stress and enhance positive seld esteem .

Lastly, Clamp *et al.*, (2020) investigated fat oxidation promoting gynoid fat mobilization in response to a 12-week exercise intervention in sedentary, obese black South African women. The study entailed a pre and post-intervention testing which included peak oxygen consumption, resting and steady state energy expenditure, respiratory exchange and body composition (via dual-energy X-ray absorptiometry). It also entailed 12 weeks of moderate to vigorous intensity (>75% peak heart rate) aerobic and resistance exercise training progressing from 40-60 minutes per session, 4 days

per week and supervised by a trained biokineticist (human movement specialist). Participants wore hear rate monitors during exercise session to maintain target heart rate zone. Aerobic exercise (75-80% heart rate peak) included dance, boxing related exercise, running, skipping, stepping (Clamp *et al.*, 2020). Resistance exercise (60-70% heart rate peak) included press-ups, shoulder press, bicep curls, squats and lunges using body weight, resistance bands and free weights.

It is worth noting that the main finding of the study was that 12 weeks of combined aerobic and resistance exercise training among black SA obese, women resulted in an unanticipated relative reduction in gynoid fat mass. The exercise stimulus resulted in increased cardiorespiratory fitness (CRF) from very low base and improvements in energy expenditure and fat oxidation during steady state exercise ($p<0.001$), compared with no change in non-exercising controls ($p>0.05$). The moderate to high intensity combined aerobic and resistance exercise training intervention stimulated improvements in CRF and whole-body fat oxidation (Clamp *et al.*, 2020).

Importance of interventions

Obesity is a complex and heterogeneous chronic disease that does not present in the same way in all patients and it requires individualized treatment (De Lorenzo *et al.*, 2019). To outline the importance of interventions, scientists suggest that clinicians should promote a holistic approach to health with a focus on health behaviours in obese patientsand address the root cause of weight gain with care to avoid stigmatizing. Interventions allow adults living with obesity to receive individualised care plans that address their root causes of obesity and provide support for behavioural change and adjunctive therapies, which may include psychological, pharmacologic and surgical interventions. Furthermore, interventions allow health care providers to engage individuals about realistic expectations, person-centred treatments, sustainable goals for bahviour change and health outcomes and allow health care provider and individual to agree on a personalized action plan that addresses drivers of weight gain.

The interventions reported on have shown significant improvement in health and fitness markers. The next section will provide an overview of the inconclusive findings in the literature and provide a rationale and benefits of current investigation.

Problem statement

Obesity is a complex chronic disease in which abnormal or excess body fat (adiposity) impairs health, increases the risk of long-term medical complications and reduces lifespan (Wharton *et al.*, 2020). In an attempt to treat/cure obesity, one of the treatment interventions are commercial weight loss programmes. These programmes offer a structured diet- or diet-and-exercise prescribed plan to achieve weight loss.

Multiple adult weight management guidelines recommend that individuals with obesity participate in a comprehensive lifestyle program for first-line treatment as sustained, modest weight reductions improve cardiometabolic outcomes (Laudenslager *et al.*, 2021). For programs to be in accordance with these guidelines, there is need to encourage a reduced calorie diet and increased physical activity combined with behavioral strategies such as self-monitoring. The recommended program intensity varies between guidelines ranging from moderate (12 sessions over 12 months) to high intensity (≥ 14 sessions over 6 months) to illicit success in the reduction of weight and the improvement of health markers such as LDL cholesterol, prevalence of metabolic syndrome and blood pressure (Laudenslager *et al.*, 2021).

This warrants the use of commercial weight loss programmes as an intervention to be followed by individuals either at high risk or diagnosed with obesity-related cardiovascular or metabolic diseases. The reviewed literature suggested that disease-diagnosed weight loss programmes exclusively for patients with positive diagnosis, are not sustainable in the long-term, due to the small scale and limited places of offering of these programmes; whereas commercial weight loss programmes reaches the masses and even reach individuals unaware of their risk for obesity-related diseases (Cramer *et al.*, 2016; Baetge *et al.*, 2017; Ryan and Yockey, 2017; Forcano *et al.*, 2018; De Lorenzo *et al.*, 2019; Clamp *et al.*, 2020; Laudenslager *et al.*, 2021).

Commercial weight loss programmes may present limitations. First, these programs are continually evolving and may not be the same version currently available to patients. Given the proprietary nature of these programs, it can be difficult for clinicians to determine whether "new" versions of a program reflect the substantial differences from the evaluated version that demonstrated efficacy. In a research setting, participants may represent an activated sample, and many trials offer incentives to participants through waiver of program fees or other methods. Program fees, and

particularly the costs of meal replacements, can be financially prohibitive to many patients.

Furthermore, scientific literature is still inconclusive as to content and structure of commercial weight loss programmes that are the most beneficial for weight loss and improvement of health. The majority of scientific literature still experience many methodological shortcomings (adherence numbers, long term follow-up, additional counselling sessions) to enable scientists to conclude the best adherence and success in improving markers of health and reduce disease risk. This warrants further investigation to come to a conclusion. With regards to the Healthy Weight Programme, no in-depth scientific evaluations have been done nor its success in terms of weight loss and change in health status. Apart from the lack of knowledge to the success of this specific programme, to the researchers knowledge, the investigation into the success of commercial weight loss programmes in South Africa have not been documented yet. Therefore, the current study will analyse data from the Healthy Weight Research database (R025/2015) to investigate the success of the Healthy Weight Program as a health intervention.

2 CHAPTER TWO

Introduction

Since the 1980s, obesity has more than doubled globally and is often considered a major health hazard and epidemic (McCafferty, Hill and Gunn, 2020). Despite improvements in understanding the pathophysiology, its prevalence continues to rise. The clinical significance of the possible results of the study are three-fold: Firstly, the results of the study will be used to report back to the Institute on the effectiveness of the HWI programme, give input regarding factors that were beneficial compared to those factors not so successful within the programme. This will enable researchers to make suggestions on components to include in the Healthy Weight Beginner (HWB) and Healthy Weight Intermediate (HWI) Program to make it possibly more successful in terms of improvements in weight status, health, and fitness. Secondly, the results will enable the researchers and stakeholders to disseminate the information on the effectiveness of the programme, especially on the possible reductions in risks for cardiovascular and metabolic diseases, to health care providers and specialists. Lastly, the evidence will enable doctors to refer patients to the program as part a comprehensive treatment plan. sponsorship or incentive plans for their members completing the HWI Programme.

Aims

This study had two aims in the incorporation a comprehensive evaluation of the HWI program offered as a commercial lifestyle intervention program by the Sport Science Institute of South Africa:

Aim 1

To determine the success in weight loss and reduction in health risk factors in members who have completed 18-weeks of the Healthy weight program (Beginner and Intermediate program combined).

Aim 2

To determine if the change in weight (measured in kilograms) correlates with a reduction in risk factors for metabolic disease i.e. blood pressure, cholesterol, glucose, and waist circumference.

RESEARCH QUESTIONS

a) Does the participation in Healthy Weight program (Beginner and Intermediate programmes) elicit a reduction in weight and an improvement in health status at each time point?

b) Are there any associations between weight change and blood pressure change; weight change and cholesterol change; weight change and glucose change; weight change and waist circumference change for members taking part in the Healthy Weight Beginner and Intermediate program combined?

c) What percentage of participants continued with the Healthy Weight Intermediate program versus the Healthy weight Beginner Programme?

3 CHAPTER THREE

Methodology

Study design

This study is a retrospective, observational study of adults with a mean body mass index (BMI) of 32.63 ± 7.39 who completed an 18-week supervised exercise programThe old HWP started in January 2008 and concluded in July 2018. The new 12-week HWP commenced in August 2018 and was concluded in 2020. However, the commercially available program had an extensive electronic database from 2011. Since 2011, members of the HWP gave consent for the data to be used for research purposes (refer to Appendix B). However, there are not many commercial weight loss programs concentrating or prescribing exercise component ony, thus further investigation is needed to explore if it is good enough for weight loss, health changes and change in fitness.

The Beginner HWP had 2 testing procedures time points: the pre- and post-intervention testing procedures and all exercise sessions were conducted in the Fitness Centre of the Sport Science Institute of South Africa (SSISA), Cape Town, South Africa. Potential individuals interested in participating had to complete a health, medical history, and pre-participation questionnaire prior to admission into the program (refer to Appendix C). This questionnaire had to be completed with the assistance of a sales consultant. Once the individual is classified as eligible for the programme, they received a link to complete further fitness and eating behaviour questionnaires on an online platform.

Once the online questionnaire was completed, the program manager or qualified Biokineticist scheduled contact time with the member to complete the pre- intervention assessments. The pre- intervention assessments included: Anthropometric measures (height, weight, hip, and mid-thigh girth) followed by blood pressure measurements. Body fat analysis, flexibility testing, modified sit-ups and a 12-min motion test to assess functional capacity were completed (refer to Appendix D). Once the screening process was complete, prospective participants would confirm the times and days that they would attend the weekly exercise sessions. After completion of the pre-intervention assessment, post-intervention assessments (same as the pre-intervention assessments) were completed within 2 weeks.

Consequently, potential individuals interested in participating in the Intermediate program had to advise on availability so Biokineticist could schedule contact time with the member

to complete the pre- intervention assessments. The Intermediate HWP entailed 12 weeks in duration and offered two exercise sessions per week (24 sessions in total). The intermediate program consisted of the same structure and layout compared to the beginner program in group-based format. The major differences between the intermediate and beginner program was the complexity and intensity of exercises. It also followed a 3 time point testing procedure: the pre-; mid and post-intervention testing procedures and all exercise sessions were conducted in the Fitness Centre of the Sport Science Institute of South Africa (SSISA), Cape Town, South Africa. The mid-intervention testing procedure was conducted at the halfway mark of the program. Once the screening process was complete, prospective participants would confirm the times and days that they would attend the weekly exercise sessions.

Lastly, participants had to have completed the beginner program to take part in the intermediate program within 6 months of completion of the beginner programme. If a participant wanted to enrol in the intermediate program beyond 1 year of completion of the beginner programme, they would have to repeat the beginner program first in order to advance to the intermediate programme.

Recruitment and enrolment

The Program was offered in a recurrent manner 6-7 times per year by SSISA. Advertisements and specific dates of the upcoming program were advertised on the SSISA website and Facebook page. Prospective participants contacted the sales department where they received more information on the program and schedule a consultation time with a sales representative. Once the enrolment was concluded, the prospective participant would advise on their availability for the pre-intervention assessment to take place. Upon consultation with the Biokineticist, the participant was screened for eligibility to enrol in the programme. Once the partcipant was cleared for exercise, the individual would be enlisted to an exercise class (morning, mid-morning or evening intake). Participants were offered a gym membership contract to aid their exercise output in conjunction with the group exercise sessions. The contract also included the consent form to use all questionnaire data, anthropometric, health markers and fitness data collected during the program for research purposes.

Study population

The HWI Program was a lifestyle commercial intervention program available to the public and inclusive of all genders between the ages of 18-70 years old, mean 47.26 (10.44). Fifty participants who completed the Healthy weight beginner program (first 12 weeks) enrolled in the Intermediate program (12-18 weeks). However, only participants who completed at least 3 of the 4 important health measures – blood pressure, waist circumference, cholesterol and/glucose at all three time points (baseline, 12 weeks and 18 weeks) were included in the study for data analysis. After the implementation of this criteria 34 participants remained. Due to the cyclic nature of the intake, 18 (52.9%) participants enrolled in January 2019, 1 (2.9%) participant in February 2019, 2 (5.9%) participants in April 2019 and 13 participants (38.2%) in July 2019 bringing the total to 34 participants in the 18 week program . The gender enrolment for the HWI program for women was n= 22 (64.7%), men n= 12 (35.3%).

If the prospective member had a diagnosed cardiovascular or metabolic disease, they were required to obtain medical clearance from a consulting doctor/physician for taking part in the Healthy Weight programme. Inclusion criteria included men or women between the ages 18 and 70 years, apparently healthy or known medical condition cleared by doctor/specialist to exercise, no major orthopaedic condition that will prevent prospective member to complete most of the prescribed exercises. Exclusion criteria include pregnant or lactating women, individuals with an extreme BMI > 45 kg/m^2, and individuals with mental and/or physical disability who are unable to exercise in group-based format.

Data collection procedures

Health and Medical questionnaire

Health and medical questionnaire determined the participants risk profiles for cardiovascular and metabolic diseases, family medical history, weight loss history, general socio-economic status and eating behaviour as well as stress/tension states.

Anthropometry

Anthropometric measures included height (cm), weight (kg with shoes off and one layer of clothing), waist circumference (cm) and body fat (kg). Weight was measured on platform scale (Pentronic A12E, Peninsula Scales, Cape Town, South Africa). Height was measured

using a portable stadiometer (SECA, Hamburg, Germany). Circumferences was measured using an anthropometric measuring tape (CESCORF, Brazil). Circumference measures was repeated and the average value of the two was used as the final measurement. This is where abdominal obesity was defined as >102cm for males and >88cm for females (Tan and Leung, 2021). If the two measures differed more than 1% from each other a third measurement was recorded and the median of the three measures was used as the final measurement.

Body fat percentage

Body composition was assessed via Bioelectrical impedence analysis (Tanita© Corporation of America inc, Illinois, USA). Participants were required to stand barefoot dressed in minimal clothing on the Tanita scale. Instructions were given to the participants prior to the Tanita scale measurement to ensure reliable results. Prediction equations were provided by the manufacturer. The prediction equation for men was derived against body density (BD) as follows: $BD = 1.1006962 - 0.107903 \times weight \times Impedance/height^2 + 0.00017 \times Impedance$. Body fat percentage was calculated using the equation, $\% fat = (4.57/BD - 4.142)$ (Brozek J, 1963). For women the prediction equation was estimated as fat-free mass firstly: $FFM (kg) = 13.96674 + 0.348613 \times height^2/Impedance + 0.168998 \times weight$. Body fat percentage is calculated as $(Weight - FFM)/Weight \times 100$ (Brozek J, 1963). Participants were asked not to eat or drink anything for 4 hours prior the test, not do any moderate-high exercise 12 hours prior to the test, and not to consume caffeine or alcohol within 12 hours prior to the test.

Health markers

Blood pressure was taken once, from the left arm using a large blood pressure cuff (32 to 43 cm; Welch Allyn©, FlexiPort, New York, Sphygmomanometer) and a stethoscope. This is where blood pressure was defined as systolic blood pressure (SBP) > 140 mmHg or diastolic blood pressure (DBP) > 90 mmHg or taking antihypertensive medication (Mohamed *et al.*, 2018). To administer the cholesterol and glucose tests, the flexible hand-held Accutrend Plus© (Roche Diagnostics, GmbH Germany) meter was used. Tests were administrated on the right-hand index finger via a finger prick and capillary blood was pipetted to the Accutrend glucose and cholesterol Test strips to measure once-off random levels of glucose and cholesterol. The finger prick onto the right-hand index finger was administered by the 1-Click line© of pressure-activated clinical/safety lancets. The measurement of glucose and cholesterol using the Accutrend Plus was validated and tested

for reliability (Coqueiro *et al.*, 2014). This is where cholesterol was defined as >5.2mmol/l and glucose >6.0 mmol/l (Mohamed *et al.*, 2018).

Fitness Markers

The Cooper twelve-minute walk test was designed to measure submaximal aerobic endurance in individuals who are not well-trained and are unable to complete a maximum aerobic capacity test. The test is easy to administer in settings where groups of people are assessed simultaneously. Participants were required to walk or run for a total of 12 minutes around an indoor track (140m in distance) with the goal to cover as much distance (m) as possible. The total distance covered was used to rate the participants fitness level or estimated VO_{2max} using the following equation: VO_{2max} = (22.35 x kilometers covered) – 11.29. The protocol and validation of this method was described by Cooper

The Healthy Weight Programme- The intervention

The Healthy Weight Beginner Program

Exercises were provided in group-based format with participants having a choice on the time of day that they would like to take part in the programme, early morning (6:30am), mid-morning (10:00am) or evening classes (6:00pm). Participants needed to commit to attending three sessions per week which accumulated to a total of 36 sessions during the new 12-week programme. All exercise sessions had a warm-up, strength and aerobic training and cool-down phase and were performed collectively as a group. The aerobic training phase consisted of 2 to 3 circuits (cluster of different exercises). Each circuit comprised of 3 to 4 different stations. During this phase participants were often divided into groups of two, one group per station, and move from station to station until all exercises were completed within the circuit.

For example, Station 1 – pelvic bridge, station 2 – bench tricep dips, station 3 – modified mountain climbers. Each circuit of the strength and aerobic training phase was structured to include lower and upper body exercises. The intensity of exercises were instructed to be at 65 to 80% of maximal effort. Participants suffering from high blood pressure were required to get their blood pressure monitored before and after each exercise session. The warm-up phase consisted of 5 minutes on a stationary bike and 3 minutes on a different cardio-machine (at 50% of maximal effort) and 2 minutes of light upper body and lower body stretches. The cool-down phase consisted of 3 minutes of cardio-machine of choice (at 35%

of maximal effort) and a series of upper and lower body stretches. All exercises were instructed and supervised by two intern biokineticists. The two instructors allocated to the sub-group of participants remained unchanged throughout the duration of the programme. Prior to the mid-week exercise session, participants are required to complete their weekly weigh-in with one of the instructors.

The Healthy Weight Intermediate Program

The intermediate program was offered in a cyclic manner of 12 weeks in duration which offered two exercise sessions per week (24 sessions in total). The intermediate program consisted of the same structure and layout compared to the beginner program in group-based format. The major differences between the intermediate and beginner program was the complexity and intensity of exercises. Combination exercises working multiple muscle groups simultaneously were included in each strength and endurance circuit. Each session included approximately ten minutes of core stability/abdominal exercises and the intensity of the strength and endurance bouts at each station were at 80 to 90% of maximal effort. Participants had to have completed the beginner program to take part in the intermediate program within 18 weeks of completion of the beginner programme. If a participant had an interest in enrolling in the intermediate program beyond 1 year of completion of the beginner programme, they would repeat the beginner program first in order to advance to the intermediate programme.

Statistical analysis

Mean and standard deviation were reported for continuous variables and count/percentages are reported for categorical variables. The data set was analyzed by intention to treat (ITT) protocol as some of the testing time points were missing. The ITT analyses used multiple imputation to replace missing values. For ITT analyses, the primary composite outcome included 24 variables measured at 3 time points each, i.e. weight, body fat, systolic blood pressure, diastolic blood pressure, cholesterol, glucose, waist circumference and Cooper 12 min distance test. Among the 24 variables, 58.33% of the 24 variables had complete data. Of the 34 participants, 47.06% had complete data for all variables at all time points. Lastly, 4.16% of the total number of values (34 participants x 3 time points x 24 variables) had missing data. However, the mid-intermediate time point of the cooper 12 min test had 50% of the data missing. Repeated measures ANOVA (with

within subjects effect) was performed to determine significant changes in physical characteristics, fitness and health markers over time (baseline, 12 weeks, 18 weeks). Pairwise comparisons were performed (IBM SPSS Statistics, 2012) with a Bonferroni correction for multiple comparisons. A multiple regression was run to determine the magnitude of influence that dependent variables - age, delta weight, delta body fat, delta waist circumference and delta Cooper 12 minute test – could have on each dependent variable (blood pressure, cholesterol, glucose), separately. Due to the retrospective design of the data collected *a priori* sample size determination was not possible. The *Post hoc* achieved power given the alpha level of 0.05, N = 34 and effect size calculated from the direct partial η^2 ranged from 0.85 to 0.97. Multiple regression was repeated after removing the non significant independent factors that did not significantly contributed to the variance in the change in the applicable health marker. Where applicable, a linear regression was performed where a single independent variable were involved in the regression analysis. Statistical analyses were performed with IBM SPSS software (IBM, 2012) and the level of significance for all other statistical tests, except for multiple time comparisons (changes over time), was set at $P < 0.05$.

4 CHAPTER FOUR

Results

Descriptive statistics

There were 34 participants in the 18 week program, 22 women (65%) and 12 men (35%). The mean age score across both genders was (47.26 ± 10.44) ranging between 24 years and 73 years old. Physical characteristics of the participants are described in Table 1. Baseline characteristics depicting disease prevalence of participants in the 18-week program are summarized in Table 2. A high percentage of participants suffered from orthopaedic injuries or conditions (approx. 80%); more than 60% were on one or more chronic medications; more than 50% were diagnosed with a cardiovascular disease (CVD); and 12% of the participants suffered from diabetes.

Physical characteristics

Table 1: Physical characteristics of participants over the 18-week program.

	Mean		SD	Min	Max
Weight (kg)	102.2	±	24.8	50.8	153.5
Body fat (%)	40.3	±	7.8	22	54.4
Waist circumference (cm)	102.2	±	16.5	81.3	150.2
Cooper 12 min (distance in meters)	1310.4	±	295.7	700	1820

The Cooper 12 minute run is a maximal running test of aerobic fitness, in which participants try and cover as much distance as they can in 12 minutes

Conditions and classifications

Table 2: Baseline disease prevalence of HWI individuals over the 18-week program

	Count	%
Conditions:		
CVD	18	52.9
Diabetes	4	11.8
Orthopaedic injury	27	79.4
Medication use	21	61.8
Classifications:		
Obese (according to BMI)	25	73.5
Adequate weight loss	16	47.1
Adequate improvement in fitness	26	76.5

Adequate weight loss : number of participants who achieved ≥ 5% weight loss over 18 weeks
Adequate improvement in fitness: number of participants who achieved ≥ 12.5% improvement in fitness over 18 weeks

Health markers

Baseline characteristics depicting health markers of participants in the 18-week program are summarized in Table 3.

Table 3: Health markers of HWI individuals over the 18-week program

	Mean	SD	Min	Max
Systolic blood pressure (mmHg)	127.3	± 2.2	100	158
Diastolic blood pressure (mmHg)	77.7	± 1.4	60	90
		± 0.1		7.7
Cholesterol (mmol/l)	5.8		3.8	
Glucose (mmol/l)	4.9	± 0.2	2.6	8.1

Changes over time

Participants achieved significant improvements in weight status where a 4.49kg difference was seen between 12 weeks and baseline and 5.15kg between 18 weeks and baseline. A statistically significant improvement was in bodyfat where 2.43kg was seen between 12 weeks and baseline and 1.94kg seen between 18 weeks and baseline. When observing Cooper distance test, there was a significant improvements between 12 weeks and 18 weeks of the program with 71.22 m distance improvement.

Weight

	Mean		SD
Baseline (0 weeks)	99.88	±	54.81
Post Beginner (12 weeks)	92.39	±	22.90
Mid Intermediate (18 weeks)	94.72	±	23.37

Figure 1: Changes in weight form baseline(0 weeks) to 12 weeks and 18 weeks

A one-way repeated measures ANOVA was conducted to determine whether there were statistically significant differences in weight over the course of 18 weeks exercise intervention. There were no outliers, and the data was normally distributed, as assessed by boxplot and Shapiro-Wilk test ($p > 0.05$), respectively. The assumption of sphericity was violated, as assessed by Mauchly's test of sphericity, $\chi^2(5) = 10.75$, $p < 0.001$. Therefore, a Greenhouse-Geisser correction was applied ($\varepsilon = 0.364$). The exercise intervention elicited statistical significant changes in weight over time, $F(1.556, 51.343) = 59.83$, $p < 0.001$, partial $\eta^2 = 0.645$, with weight decreasing significantly from 100.0 ± 24.8 kg pre-intervention to 95.4 ± 22.9 kg at 12 weeks (p<0.001), to 94.7 ± 23.4 kg at 18 weeks (p<0.001)

Bodyfat

	Mean		SD
Baseline (0 weeks)	40.39	±	7.88
Post Beginner (12 weeks)	37.96	±	7.98
Mid Intermediate (18 weeks)	38.44	±	7.75

Figure 2: Changes in bodyfat from baseline (0 weeks) to 12 weeks and 18 weeks.

A one-way repeated measures ANOVA was conducted to determine whether there were statistically significant differences in bodyfat over the course of 18 weeks exercise intervention. There were no outliers, and the data was normally distributed, as assessed by boxplot and Shapiro-Wilk test ($p > 0.05$), respectively. The assumption of sphericity was violated, as assessed by Mauchly's test of sphericity, $\chi^2(5) = 25.16$, $p < 0.001$. Therefore, a Greenhouse-Geisser correction was applied ($\varepsilon = 0.663$). The exercise intervention elicited statistical significant reductions in bodyfat over time, $F(1.295, 42.730) = 4.750$(p < 0.001), partial $\eta^2 = 0.126$, with body fat changing on average from 40.4 ± 7.9 % pre-intervention (p<0.001) to 38.0 ± 8% at 12 weeks, but no significant changes from pre-intervention to 18 weeks (38.5 ± 7.8 , p = 0.221).

Waist circumference

	Mean		SD
Baseline (0 weeks)	102.26	±	16.55
Post Beginner (12 weeks)	102.26	±	16.55
Mid Intermediate (18 weeks)	100.95	±	17.83

Figure 3: Changes in waist circumference from baseline (0 weeks) to 12 weeks and 18 weeks

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A Friedman test was run to determine if there were differences in waist circumference throughout the 18 weeks. Waist circumference was statistically significantly different at the different time points during the exercise intervention, $\chi^2(2) = 48.933$, $p < 0.0005$. Post hoc analysis revealed statistically significant differences in waist circumference from pre-intervention to 12-weeks (on average 6% reduction $p < 0.001$) and from pre-intervention to 18 weeks (on average 5% reduction, $p < 0.001$).

Cooper 12 minutes test
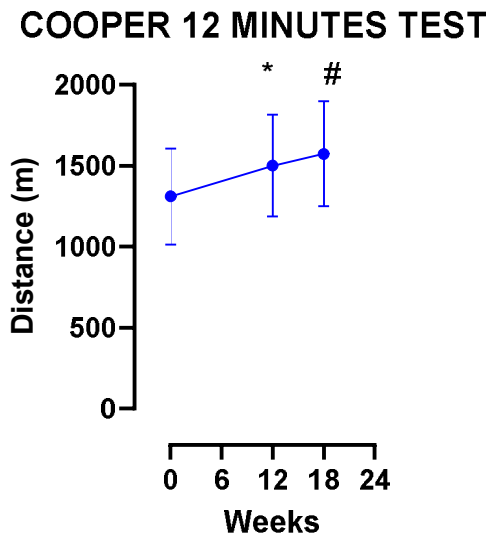
Figure 4: Changes in Cooper 12 minutes test from baseline (0 weeks) to 12 weeks and 18 weeks

 * significant change from baseline to 12 weeks; # significant change from baseline to 18 weeks.

A one-way repeated measures ANOVA was conducted to determine whether there were statistically significant differences in Cooper 12 minute test over the course of 18 weeks exercise intervention. There were no outliers, and the data was normally distributed, as

assessed by boxplot and Shapiro-Wilk test (p > 0.05), respectively. The assumption of sphericity was violated, as assessed by Mauchly's test of sphericity, $\chi^2(5) = 0.830$, p < 0.001. Therefore, a Greenhouse-Geisser correction was applied ($\varepsilon = 1.000$). The exercise intervention elicited statistically significant changes in Cooper distance test over time, $F(2,66) = 39.862$, p < 0.001, partial $\eta^2 = 0.547$ with distance increasing from pre-intervention (p<0.001) of 1310m ± 296 to 1501m ± 313.41 at 12 weeks and 1573m ± 325 between pre-intervention to post-intervention p< 0.001.

Health Markers

Systolic blood pressure had no significant changes from baseline to 12 weeks and from baseline to 18 weeks. Participants exhibited small but no significant changes when cholesterol levels declined by 0.29 mmol/l from baseline to 12 weeks and by 0.20 mmol/l from baseline to 18 weeks. Glucose health marker presented an interesting result for participants baseline and 12 weeks with an increase in glucose 0.31mmol/l and 0.54 mmol/l between baseline and 18 weeks thereby representing no significant changes.

Blood pressure

Figure 5: Changes in blood pressure from baseline (0 weeks) to 12 weeks and 18 weeks

A one-way repeated measures ANOVA was conducted to determine whether there were statistically significant differences in systolic blood pressure over the course of 18 weeks exercise intervention. There were no outliers, and the data was normally distributed, as assessed by boxplot and Shapiro-Wilk test (*p* > 0.05), respectively. The assumption of sphericity was violated, as assessed by Mauchly's test of sphericity, $\chi^2(5) = 0.031$, *p* <

0.001. Therefore, a Greenhouse-Geisser correction was applied ($\varepsilon = 1.000$). The exercise intervention elicited statistically significant changes in systolic blood pressure over time, $F_{(2,66)} = 3.875$, $p = 0.026$, partial $\eta^2 = 0.105$ over time. However, due to the Bonferroni correction applied to multiple post-hoc analysis, there was no significant reductions from pre- to post intervention. Blood pressure decreased from 127.4 ± 13.1.30 mmHg pre-intervention to 121.5 ± 12.3 mmHg (p = 0.053) at 12 weeks, to 122.1 ± 9.2 mmHg (p = 0.078) at 18 weeks.

A Friedman test was run to determine if there were differences in diastolic blood pressure throughout the 18 weeks. Diastolic blood pressure was no statistically significantly difference at the different time points during the exercise intervention, $\chi^2(2) = 3.184$, $p = 0.204$. Post hoc analysis revealed no statistically significant differences in diastolic blood pressure from pre- (*Mdn* = 80.00) to post-intervention (*Mdn* = 78.00) (*p* > 0.05) and 12 weeks (*Mdn* = 78.00) (*p* > 0.05).

Cholesterol
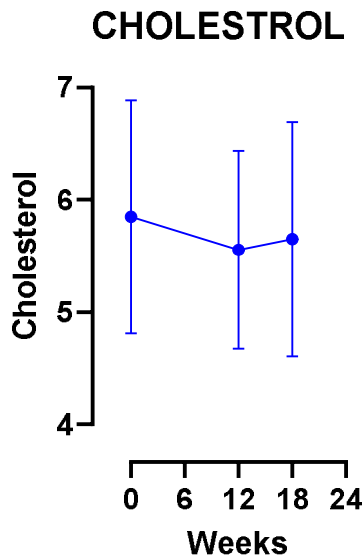
Figure 6: Changes in cholesterol from baseline (0 weeks) to 12 weeks and 18 weeks
A one-way repeated measures ANOVA was conducted to determine whether there were statistically significant differences in cholesterol over the course of 18 weeks exercise intervention. There were no outliers, and the data was normally distributed, as assessed by boxplot and Shapiro-Wilk test (p > .05), respectively. The assumption of sphericity was violated, as assessed by Mauchly's test of sphericity, $\chi^2(5) = 0.793$, p < 0.001. Therefore, a Greenhouse-Geisser correction was applied ($\varepsilon = 0.867$). The exercise intervention elicite

statistically no significant changes in cholesterol over time, F(1.657, 54.689) = 1.878, p = 0.169, partial η^2 = 0.054, with cholesterol showing a non-signficant reduction from 5.85 ± 1.04 mmol/l pre-intervention, to 5.56 ± 0.88 mmol/l at 12 weeks (p= 0.051) , but increased to 5.65 ± 1.05 mmol/l at 18 weeks (MI) (p = 0.813).

Glucose

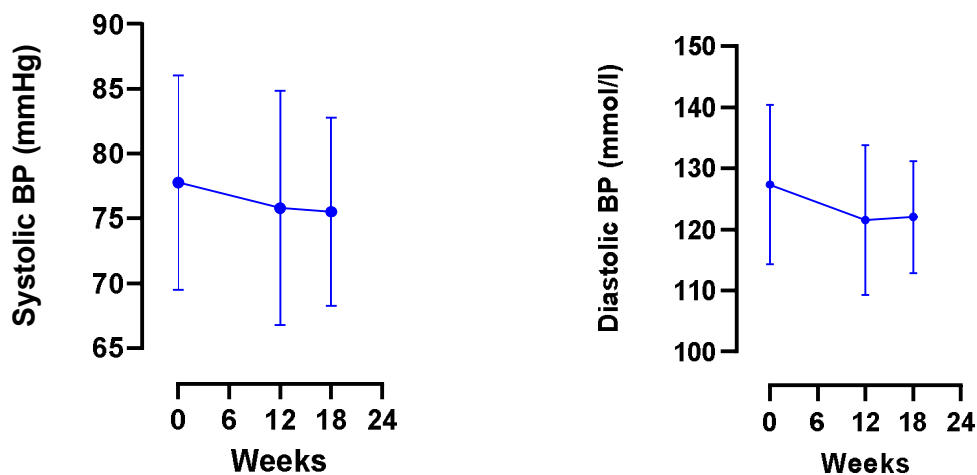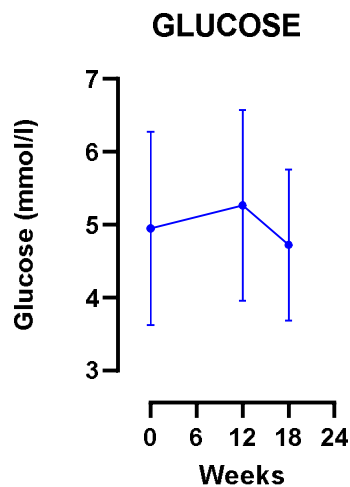**Figure 7: Changes in glucose from baseline (0 weeks) to 12 weeks and 18 weeks**
A one-way repeated measures ANOVA was conducted to determine whether there were statistically significant differences in glucose over the course of 18 weeks exercise intervention. There were no outliers, and the data was normally distributed, as assessed by boxplot and Shapiro-Wilk test (p > 0.05), respectively. The assumption of sphericity was violated, as assessed by Mauchly's test of sphericity, $\chi^2(5)$ = 0.698, p < 0.001. Therefore, a Greenhouse-Geisser correction was applied (ε = 0.798). The exercise intervention elicited no statistically significant changes in glucose over time, F(1.536, 50.703) = 0.698, p = 0.105, partial η^2 = 0.070, with glucose increasing from 4.95 ± 1.33 mmol/l pre-intervention to 5.26 ± 1.31 mmol/l at 12 weeks (p = 0.899), to 4.72 ± 1.04 mmol/l at 18 weeks (p > 0.05).

Associations with changes in health markers

Table 4: Multiple regression results for change a)systolic blood pressure and b)iastolic blood pressure with anthropometric and fitness measures as independent variables.

a)Systolic blood pressure

	B	95% CI for B		SE B	B	P value	R²	ΔR²
		LL	UL					
Model: Delta diastolic blood pressure							0.06	0.10
Constant	-2.30	-24.91	20.30	11.03		0.83		
Age	-0.09	-0.51	0.33	0.20	-0.08	0.66		
Delta Weight	-0.2	-1.42	0.91	0.57	-0.08	0.66		
Delta Bodyfat	0.45	-0.39	1.30	0.41	0.26	0.28		
Delta waist	-0.18	-0.89	0.52	0.34	-0.11	0.59		
Delta Cooper	0.01	-0.20	0.40	0.15	0.16	0.50		

b)Diastolic blood pressure

	B	95% CI for B		SE B	B	P value	R²	ΔR²
		LL	UL					
Model : Delta systolic blood pressure							0.12	- 0.02
Constant	-6.14	-33.37	21.07	13.29		0.64		
Age	-0.54	-0.56	0.45	0.24	-0.42	0.83		
Weight	-110	-1.51	1.29	0.68	-0.02	0.87		
Body fat	0.96	-0.05	1.99	0.49	0.44	0.06		
Waist circumference	0.01	-0.84	0.87	0.41	0.009	0.96		
Cooper 12 minute test	0.01	-0.01	0.05	0.01	0.24	0.30		

A multiple regression was run to predict delta systolic blood pressure and diastolic blood pressure from age, weight, body fat, waist circumference and Cooper 12 minute test. Regression coefficients and standard errors can be found in Table 4.

Table 5: Multiple regression results for change in cholesterol with anthropometric and fitness measures as independent variables.

	B	95% CI for B		SE B	B	P value	R²	ΔR²
		LL	UL					
Model: Delta Cholesterol							0.24	0.32
Constant	-1.16	-2.89	0.57	0.84		0.18		
Age	0.01	-0.01	0.49	0.01	0.30	0.30		
Delta Weight	-0.10	-0.19	-0.01	0.44	0.02	0.02		
Delta Bodyfat	0.07	0.012	0.14	0.03	0.02	0.02		
Delta waist	0.007	-0.47	0.06	0.02	0.78	0.78		
Delta Cooper	-0.001	-0.003	0.002	0.001	0.57	0.57		

Table 6: Multiple regression results for change in cholesterol with weight and bodyfat as independent variables.

	B	95% CI for B		SE B	B	P value	R²	ΔR²
		LL	UL					
Model: Delta Cholesterol							0.28	0.26
Constant	-0.24	-0.35	0.32	0.16		0.88		
Delta Bodyfat	0.09	0.04	0.14	0.03	0.53	0.001		

A multiple regression (Table 5) was run to predict delta cholesterol from age, weight, body fat, waist circumference and Cooper 12 minute test. Regression analysis was repeated after removing the non significant factors that did not significantly contribute to the variance in delta cholesterol. A change in weight and change in body fat significantly contributed to the change in cholesterol, however, body fat and weight can be seen as the same genre of measure – a change in body composition. To lower the risk of multiple collinearity, separately linear regressions were performed to determine the association of change in weight vs change in cholesterol; and change in body fat vs change in cholesterol, respectively. The linear regression of delta weight as independent variable and delta cholesterol as dependent variable resulted in a non-significant model [F (1, 33) = 1.917, P = 0.176). However, the linear regression of delta body fat as independent variable and delta cholesterol as dependent variable resulted in a significant regression model [F (1, 33) = 12.714, P < 0.001). Regression coefficients and standard errors for the latter model are depicted in Table 6.

Table 7: Multiple regression results for change in glucose with anthropometric and fitness measures as independent variables.

	B	95% CI for B		SE B	B	P value	R²	ΔR²
		LL	UL					
Model: Delta Glucose							0.29	0.17
Constant	1.09	-1.48	3.67	1.25		0.39		
Age	-0.02	-0.06	0.02	0.02	-0.14	0.40		
Delta Weight	0.18	0.05	0.31	0.06	0.45	0.00		
Delta Body fat	-0.36	-0.13	0.06	0.04	-0.15	0.45		
DeltaWaist circumference	0.003	-0.05	0.10	0.04	0.12	0.53		
Delta Cooper	0.003	-0.00	0.00	0.00	0.31	0.14		

A multiple regression was run to predict delta glucose from age, weight, body fat, waist circumference and Cooper 12 minute test. Regression analysis was repeated after removing the non significant factors that did not sign contributed to the variance in delta gluocose. It was repeated again with only weight, resulting in a significant regression model of $F_{(1, 33)} = 4.796$, P = 0.036. Regression coefficients and standard errors can be found in Table 7 and 8.

Table 8: Multiple regression results for change in glucose with weight as independent variable

	B	95% CI for B		SE B	B	P value	R²	ΔR²
		LL	UL					
Model: Delta Glucose and Weight							0.13	0.10
Constant	0.51	-1.48	3.67	0.40		0.21		
Delta Weight	0.14	0.05	0.31	0.06	0.36	0.03		

5 CHAPTER FIVE

Discussion

The primary aim of this study was to determine the success in weight loss and reduction in health risk factors in members who have completed 18-weeks of the Healthy Weight Program (Beginner and Intermediate program combined). Interesting, the results showed that there was a significant change in weight, body fat, waist circumference and Cooper 12 minutes distance test. The following sections will discuss the how these changes had an impact on physical characteristics and health markers.

Anthropometry/Physical characteristics

When examining if participation in HWP (Beginner and Intermediate programmes) elicit a reduction in weight at each time point, we found the exercise intervention elicited statisticaly significant changes in weight over time. Compared to baseline, individuals had a weight loss of 4.6kg ($p < 0.001$) on average after 12 weeks and 5.3 kg ($p < 0.001$) after 18 weeks. However, other studies have found exercise interventions to elicit greater significant changes in weightloss over time. Dieli-Conwright *et al.*, (2018) conducted randomised control trial on breast cancer surviors (n= 100), who were randomly assigned to exercise (n= 50) or usual care (n= 50). The findings revealed that lean mass increased significantly in the exercise group compared with baseline (p≤ 0.001) and the usual care group (p≤ 0.001).

Dieli-Conwright *et al.*, (2018) argued that the exercise induced effects may have been due to the nature of the study, as it was a controlled clinical setting. As in this RCT participants were given flexible exercise sessions times, one-on-one supervision and provision of parking permits or bus passes to overcome transportation barriers which ultimately led to high adherence to the program. However, this was not the case with this study as it was not conducted in a controlled clinical setting, hence, the difference.

Even though this study findings showed small yet significant changes, it is consistent with what has been observed in literature. Petridou, Siopi and Mougios, (2019) argued that consistent exercise with the minimum levels of physical activity recommendations (approximately 150 mins of moderate-intensity intensity per week) without dietary restriction may induce modest weight loss (about 2-3kg), however, it is inadequate for clinical

significant weight loss (≥5%). Additionally, Donnelly *et al.*, (2009) suggested that close attention should be given to exercise volume, arguing that individuals should complete approximately 225 to 420 minutes of exercise per week to elicit weight loss and long term weight management. However, the current study had an exercise volume of 60 to 120 minutes of exercise per week which does concurr with Donnelly *et al.*, (2009) requirements to elicit weight loss and long term weight management.

The exercise intervention elicited statistical significant reductions in bodyfat over time, with body fat changing on average from 40.4 ± 7.9 % pre-intervention (p<0.001) to 38.0 ± 8% at 12 weeks, but no significant changes from pre-intervention to 18 weeks (38.5 ± 7.8 , p = 0.221). Comparing with existing literature, Valsdottir *et al.*, (2021) explored the effect of a 10-week intervention on body composition by using a low-carbohydrate-high-fat diet, with or without interval exercise. Participants were n= 57 overweight and obese women age 40 ± 3.5 years, body mass index 31.1 ± 2.6 kg.m². In the Valsdottir *et al.*, (2021) study an equal deficit of 700 kcal·day−1 was prescribed, restricting diet only, or moderately restricting diet and adding exercise, thus, producing four groups; normal diet (NORM); low-carbohydratehigh-fat diet (LCHF); normal diet and exercise (NORM-EX); and low-carbohydrate-high-fat diet and exercise (LCHF-EX). Post-intervention % fat was lower in NORM-EX than NORM (40.0 ± 4.2 vs. 43.5 ± 3.5%, p = 0.024). When comparing Valsdottir's study, our findings revealed a very minimal change in bodyfat. Valsdottir *et al.*, (2021) incorporated a low carbohydrate high fat diet and exercise while this study focused on exercise without a dietary component. This suggests that if the dietary component was incorporated, the body fat percentage could have yielded a greater reduction in bodyfat.

Furthermore, Heydari, Freund and Boutcher, (2012) determined the effect of a 12-week high intensity intermittent exercise (HIIE) intervention on total nody, abdominal, trunk, visceral fat mass and fat free mass of young overweight males. Participants (n= 46) were inactive overweight men that were randomly assigned to exercise (n= 25) or control (n= 21) group with a BMI (28.4 ± 0.5 and 29 ± 0.9 kgm²). They received HIIE three times per week, 20 minutes per session. While the study design differed from the current one, the findings revealed 17% reduction (p< 0.01) in body fat. The HIIE training was based on 8 seconds sprint and 12 seconds recovery continuously throughout each 20-30 min session. As participants adapted to producing heart rate peak between 80-90%, workload was increased. It is worth noting that the authors found that HIIT programs with shorter activity to rest interval of 8-12 seconds in young men led to significant changes in body fat. The current study employed some HIIT session, however, more sessions would have facilitated

better results in reducing body fat and improving body composition. Additionally, in the current study 65% of the population were women suggesting that bodyfat might respond differently in females than in males.

Waist circumference revealed statistically significant differences in waist circumference from pre-intervention to 12-weeks (on average 6% reduction p < 0.001) and from pre-intervention to 18 weeks (on average 5% reduction, p < 0.001). Rothberg *et al.*, (2017) investigated the impact of weight loss on waist circumference and components of the metabolic syndrome. The study had 430 obese participants that enrolled in a 2 year intensive, behavioral, weight management program. Participants were 49 ± 9 years of age, 56% were women and 85% were white. When comparing the current study's findings with Rothberg *et al.*, (2017), their findings revealed a decrease of 11cms in waist circumference which was associated with greater improvements in; blood lipid profile, blood pressure and blood glucose in the 6 months and 2 year time frames. The aforementioned indicates similar variance observed in the current study.

Furthermore, Rothberg *et al.*, (2017)suggested that a decrease in waist circumference was linked with moderate weight loss (5-10%) thus reducing metabolic syndrome risk. To achieve moderate weight loss, a cumulative exercise dose can be employed and may have profound benefits towards one's health status. Although we did not measure compliance, dietary adherence and social support, the exercise intervention uncovered lower than expected weight loss. These may have been attributed by poor exercise compliance, poor dietary adherence and poor social support or program was not intensive enough.

This agrees with the evidence shown by Lemstra *et al.*, (2016) were exercise adherence was largely affected by social support. Social support contracts often allow ongoing support outside the program thereby increasing adherence to the program (Lemstra *et al.*, 2016). From a public health perspective, exercise interventions should therefore be encouraged; and even though body weight may not change markedly, or match expectations, lean tissue will be increased and body shape altered (King *et al.*, 2009).

Other studies, on exercise interventions have showed that 2.5% or more weight loss could result in glycemic improvement and triglyceride reduction (Jensen, Ryan and Apovian, 2014); 5-15% weight loss would increase high density lipoproteins (Leidy *et al.*, 2007) and 5-10% weight loss would improve knee functionality, speed, walk distance and pain (Messier *et al.*, 2013) ; 5-10% weight loss to prevent knee pain in individuals (White *et al.*, 2015) and lastly 16% weight loss would reduce all-cause mortality (Sjöström *et al.*, 2007).

Based on the evidence above, it remains important for health professionals to promote physical activity/exercise as a contribution to health and possible change in fitness but also as an instrument to improving weight status in the long term.

Fitness marker

The exercise intervention elicited statistically significant changes in Cooper distance test over time, with distance increasing from pre-intervention ($p<0.001$) of 1310 ± 296m to 1501 ± 313.41m at 12 weeks and 1573 ± 325m between pre-intervention to postintervention $p< 0.001$. Grant *et al.*, (2014) investigated the correlation between the health-related fitness of healthy participants via direct methods of VO_{2max} and indirect methods of VO_{2max}. Participants that completed the Cooper 12 minute test (n=150) test revealed an indirect VO_{2max} (p= 0.45; p < 0.001). Although, the current study did not have the same study design and sample size that was as big the current study findings concur with Grant *et al.*, (2014) study findings.

Health markers

Systolic blood pressure had no significant reductions from pre- to post intervention. Blood pressure decreased from 127.4 ± 13.1.30 mmHg pre-intervention to 121.5 ± 12.3 mmHg (p = 0.053) at 12 weeks, to 122.1 ± 9.2 mmHg (p = 0.078) at 18 weeks. Lemes *et al.*, (2016) conducted a systematic review and meta-analysis of randomise controlled trials where they evaluated the effects of resistance training on metabolic syndrome risk factors through comparison with a control group. The included studies had participants n= 341 men and n= 178 women. The intervention ranged from 12 weeks to 9 months and all studies had an incremental workload in intensity or volume. The systematic review revealed that systolic blood pressure significantly reduced by 4.08 mmHg (p< 0.01) following exercise. These findings concur with what was observed in this study as our intervention included some components of resistance training which may explain the observed decrease in systolic blood pressure even though it was not statistically significant.

In another study, (Peters *et al.*, 2006) investigated a short-term isometric exercise protocol on ten hypertensive individuals (n= 8 men, n= 2 women, mean age= 52 + 5 years) to determine its efficacy as a high blood pressure-reading intervention. After six weeks, SBP decreased by 13mmHg (p< 0.05) from mean blood pressure of 146 to 133 mmHg. The study suggested that these changes were associated with exercise/physical activity. It has been reported that a blood pressure is reduced following 8-12 weeks of dynamic exercise.

The mechanism of dynamic exercise facilitates blood pressure-lowering effects such as weight loss, post exercise decrease in stroke volume and cardiac output, total peripheral resistance and decreased tonic sympathetic nerve activity. Thus, these outcomes reinforce the importance of exercise/physical activity in reducing risk factors.

Participants exhibited no significant changes even though cholesterol levels declined by 0.29 mmol/l between baseline and 12 weeks and 0.20 mmol/l between baseline and 18 weeks. Ozbay *et al.*, (2020) investigated the acute and chronic effect of aerobic training performed indoors and outdoors on irisin, adropin and cholesterol levels following an 18-week training period. Exercise sessions were performed 4 days/week for 18 weeks and were 40 minutes. The study reported that aerobic exercise had no significant effect on total cholesterol following the 18 weeks of training (Ozbay *et al.*, 2020). Therefore, the results concurr with the current study's findings as aerobic exercise was incorporated in the intervention although population sample size and study design differed.

In contrast, Wewege *et al.*, (2018) conducted a systematic review and meta-analysis on reducing CVD risk in adults with metabolic syndrome by using aerobic, resistance or combined training over a 12 week period. Intervention frequency was 3 days/ week and intensity of aerobic or resistance exercise was categorised as moderate or moderate to vigorous. 11 included studies examined 588 participants with syndrome X (hypertension, dyslipidemia and impaired glucose tolerance) and not taking medication. Mean age was 51 years, range 38-60. Aerobic-based exercises included jogging, walking, running and cycling and resistance exercises utilised resistance machines such as leg press, chest press, shoulder press and leg extension as well as use of free weights. Their findings revealed a 15% reduction in total cholesterol and other cardiovascular risk factors (Wewege *et al.*, 2018), while this study revealed 4.9% reduction (at 12 weeks) and 3.4% reduction (at 18 weeks) in cholesterol suggesting much smaller reductions than what was reported by Wewege *et al.*, (2018). However, Wewege's study does not mention what the baseline values were at the start of the intervention and this could support why the reduction were far greater than the current study's findings. Finally, our intervention's findings coincide with Wewege's study as we employed aerobic, resistance and combined training in our 18 week intervention.

Zhao *et al.*, (2021) suggest that exercise improves serum lipids by lowering serum triglyceries, total cholesterol and low density lipoproteins (LDL) levels while increasing high density lipoprotein (HDL) levels. The authors argued that lipoproteins lipase is critical in the

formation of HDL and is increased with aerobic exercise (Zhao *et al.*, 2021). Interestingly, in the current study there was a reduction in body fat which improved cholesterol but it was not significant. Therefore, the measurement of body fat is important in lifestyle interventions to improve health status and diagnose adiposity. Lastly, this study did not measure the full lipid profile the evidence supports that aerobic exercise may have had a positive impact on blood lipids of the participants.

Participants exhibited no statistically significant changes in glucose over time as glucose increased from 4.95 ± 1.33 mmol/l pre-intervention to 5.26 ± 1.31 mmol/l at 12 weeks (p = 0.899), to 4.72 ± 1.04 mmol/l at 18 weeks (p > 0.05). In contrast, Wewege *et al.*, (2018) in their systematic review and meta-analysis revealed 9% reduction in blood glucose which is different to the current study's findings as glucose had an increased by 6.2% at 12 weeks.

However, Feito *et al.*, (2019) in their investigated the effects of eight weeks of high intensity functional training on glucose control and body composition among overweight and obese adults. Intervention had 67% female participants, age = 26.8 ± 5.5 years and BMI = 30.5 ± 2.9 kg/m². Participants were randomly placed in two groups :combined aerobic and resistance exercise training program (A-RT) (n= 11) and shorter duration, high-intensity functional training (HIFT) (n=12). Their study findings did not demonstrate significant changes after the eight weeks of training which agrees with the findings of the current study. Feito *et al.*, (2019) acknowledged that the intervention would reported improvements in blood pressure, body composition, fat oxidation, plasma triglycerides and very-low density lipoproteins at 8-12 weeks of training. As that period would have been sufficient in decreasing body fat and preserving lean mass but may not be enough time to significantly improve glucose metabolism after endurance and resistance training programs (Feito *et al.*, 2019). This is seen in the current study where at 12 week of the intervention an upward trend in random glucose measures was observerd, thereeafter a downward trend was observed from 12 to 18 weeks. None of the trends revealed significant changes in glucose.

Associations with changes in health markers

The secondary aim of this study to determine if the change in weight (measured in kilograms) is associated with a reduction in risk factors for metabolic disease i.e. blood pressure, cholesterol, glucose, and waist circumference. We ran multiple regressions on independent variables and found a change in body fat influenced a change in random cholesterol and change in weight influenced a change in random glucose measurement. The following sections will discuss the impact these associations have on this intervention.

Change in cholesterol was influenced by change in body fat

In the current study it is estimated that 26% of the variation in the improvement in cholesterol measures can be explained by the reduction in body fat percentage (p < 0.001). A study investigated the effects of an intensive lifestyle intervention including Mediterranean diet nutritional counselling and high-intensity interval training (HIIT) on body composition, cardiometabolic and exercise parameters were studied in metabolically unhealthy obese (NMHO) and metabolically healthy but obese (MHO) subjects (Dalzill *et al.*, 2014). The study had 55 MHO participants (51 ± 8 years; waist circumference 109 ± 13cm) and 79 NMHO participants (54 ± 9 years; waist circumference 112 ± 13cm) (Dalzill *et al.*, 2014). HIIT would take place 2-3 times per week and body composition, cardiometabolic and exercise parameters were measured at baseline and after 9 months. The study's findings recorded lower cholesterol (p< 0.05) in the MHO group (Dalzill *et al.*, 2014). These findings concurr with the findings of the current study where multiple regression was repeated after removing the non significant factors that did not significantly contribute to the variance in delta cholesterol and a change in bodyfat still influenced a change in cholesterol (p= 0.001). Therefore, the measurement of body fat is important in lifestyle interventions to improve health status and diagnose adiposity. Lastly, this study did not measure the full lipid profile the evidence supports that aerobic exercise may have had a positive impact on blood lipids of the participants in this study.

Bioelectric Impedence Analyis Tanita scale was used for measuring body fat, although not the gold standard (gold standard would be Dual Energy X ray Absorptiometry). it is important to include in commercial programmes, due to the link to improvement in cholesterol. Likewise, the measure of random cholesterol can be influenced by many factors and may not have been sensitive enough to reveal a change in the lipid profile of participants after exercise intervention. Measuring serum lipid would have been more sensitive and accurate, but is it practical and cost effective for a program of this nature and scale

A change in glucose influenced a change in weight

In the current study it is estimated that 10% of the variation in the improvement in random glucose measures can be explained by the reduction in weight (p = 0.036). A study investigated the effect of a supervised exercise program would have on BMI and risk of Type 2 Diabetes in subjects with normal or impaired fasting glucose. Participants were n= 7,233 , 40-79 years old and not diagnosed with diabetes at baseline. All particpants underwent 6 months program of moderate-intensity exercise (300 min/week) without dietary

advise (Chae *et al.*, 2012). During the follow up (mean= 2 years), the overweight/obese subjects exhibited improved fasting glucose (p<0.001) which concurrs with the findings of the current study when multiple regression were repeated after removing the non significant factors that did not sign contributed to the variance in delta glucose. Chae *et al.*, (2012) reported a decrease in bodyweight of 1.5kgs which improved glucose levels (36%) thus reducing the risk of type 2 diabetes. This warrants that a cumulative exercise dose (minimum of 210 minutes/week) can have profound benefits towards one's health status.

Strength and limitations

The current study is strengthened by having exercise programs prescribed and monitored by a qualified health care professional (biokineticist). Whereas previous studies often used self-reports of physical activity, which are less accurate and usually result in bias. The study is a commercial program and give more in-depth understanding of weightloss programs in the real world in terms of effectiveness and adherence, etc compared to strictly clinically trials that often cannot function in a sustainable way as a commercial product. However, the current study is not without limitations. The exercise may have been one of the reasons for the changes found above, however, difficult to exclusing conclude this for lack of control group doing no intervention as comparator group. When analsying the methods of measurement; the pre-intervention screening for glucose and cholesterol could have provided more meaningful data had they been fasting intravenous glucose and cholesterol tests as opposed to finger prick random tests. Additionally, the missing data (prior to multiple imputation) from this study could have introduced random and systemic error that could have lead to not a true representation of the outcomes. Consequently, the study did not consider a nutritional intervention whereby participants get prescribed dietary intervention to aid the 18-weeks of supervised exercise. The study also did not have a control group to compare the exercise group with and observe what the effect of time would have had on the changes in all anthropometric, fitness and health markers. Lastly, the study did not take report on the differences that exist between the different age groups and gender. Despite these limitations, the current study shows that exercise can be one of the reasons for a reduction in the risk of non-communicable diseases in individuals who are overweight or obese, without dietary changes.

Conclusion

The 18-Week supervised exercise program elicited a modest reduction in weight (5%) and substantial improvement in fitness (20%) after 18 weeks of supervised exercise intervention.. There were no changes in individual health status, suggesting no improvement in overall health status, contradictory to the literature suggesting that modest changes in weight and improvemtn in fitness is beneficial to your health. The change in weight and fitness did not substantially explain the change in health, except for change in body fat on change in chol and change in weight on change in glucose, even though the improvements in cholesterol and glucose were not significant. The measure of bodyfat is important for a significant improvement in bodyfat may lead to improved metabolic health, and should be included in the commercial lifestyle programmes where the focus is on improving health. However, more research on this is vital in the field of exercise science and sports medicine such as an inclusion of control group not doing exercise and randomly select subgroup of individuals from commercial weight loss program for analysis. Finally, find ways and means to accurately measure health outcomes, easily conducted, cost effective, and fit within time constraints applicable to commercial programmes at large scales.

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1.1.1 APPENDIX A

UNIVERSITY OF CAPE TOWN

HUMAN RESEARCH
ETHICS COMMITTEE OF HEALTH SCIENCES
Human Research Ethics Committee
0 5 MAR 2021
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30 . 3 . 22
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	8 /3/221

Note: Please note that incomplete submissions will not be reviewed.
Please email this form and supporting documents (if applicable) in a combined pdf-file to
hrec-enquiries@uct.ac.za.
Please clarify your plan for research-related activities during COVID-19 lockdown

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	12 May 2020		
HREC REF Number	278/2019	Current Ethics Approval was granted until	30 May 2020
Protocol title	AN ANALYSIS OF THE SUCCESS OF COMMERCIALLY AVAILABLE LIFSTYLE INTERVENTION PROGRAMME THROUGH REGULAR EXERCISE UNDER SUPERVISION – THE HEALTHY WEIGHT PROGRAMME		
Protocol number (if applicable)	n/a		
Are there any sub-studies linked to this study?		☑ Yes ☐ No	
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.		R025/2015	

25 March 2020   Page 1 of 6   FHS016

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Principal Investigator	Dr Jacolene Kroff
Department / Office Internal Mail Address	Division of Exercise Science and Sports Medicine, Department of Human Biology, 3rd Floor, Sport Science Institute of South Africa, Boundary Road, Newlands

1.1 Does this protocol receive US Federal funding?		☐ Yes	☑ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? Note: Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please send electronic copy for full committee review to hrec-enquiries@uct.ac.za)		☐ Yes	☐ No

If yes in 1.2 please complete section 1.3 below for invoicing purposes

1.3 Annual Approval for full committee review	- R 3450 (inclusive of vat)
For invoicing purposes, please provide:	
Sponsor's name	
Contact person	
Address	
Telephone number	
Email Address	

2. List of documentation for approval

3. Protocol status (tick ✓)

☑	Open to enrolment
☐	Closed to enrolment (tick ✓)
☑	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☑	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

| ☐ | Study is closed → Please submit a Study Closure Form (FHS010) |

4. Enrolment

Number of participants enrolled to date	800
Number of participants enrolled, since last HREC Progress report (continuing review)	81
Additional number of participants still required	120

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	0

6. Cumulative summary of participants

Total number of participants who provided consent	800
Number of participants determined to be ineligible (i.e. after screening)	100
Number of participants currently active on the study	27
Number of participants completed study (without events leading to withdrawal)	533
Number of participants withdrawn at participants' request (i.e. changed their mind)	240
Number of participants withdrawn by PI due to toxicity or adverse events	0
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	0
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	n/a
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	n/a

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Data spreadsheets from 2013 to Aug 2018 have been cleaned and processed to final format for data analysis.

Data spreadsheets from Aug 2018 to End of 2019 have been cleaned and processed to final format for data analysis.

Data is currently being analysed.

A literature review is completed and currently two papers are being drafted, both answering aim 3 of the study, one paper focus on the success of the old programme and one paper focus on the success of the new programme.

8. Protocol violations and exceptions (tick ✓ all that apply)

☑	No prior violations or exceptions have occurred since the original approval
☐	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
☐	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

☐	No prior amendments have been made since the original approval
☐	Prior amendments have been reported since the last review and have already been approved
☑	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).
Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.
n/a

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
☑ Yes	☐ No	☐ Not applicable
If yes, please describe:		

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

58

Interested participants who were screened but were classified as not-eligible to take part in the Healthy Weight Programme due to cardiovascular and/or orthopaedic complications, received referral to either a cardiovascular or orthopaedic specialist for treatment. Participants classified as "high risk" due to cardiovascular risk factors were referred to a medical practice to be assessed and enrol in the high risk cardiac rehabilitation programme.

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?

☐ Yes	☐ No	☑ Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?

☐ Yes	☐ No	☑ Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.

Agency Name		Report attached	☐ Yes	☐ No	☐ Not applicable
		DSMB report attached	☐ Yes	☐ No	☐ Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?

☐ Yes	☑ No

If yes, please explain:

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:

☐	Increased
☐	Decreased
☑	Shown no change

If there has been a change, please explain:

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.

Currently the Healthy Weight Programme is not running at the Sport Science Institute, and the Healthy Weight Programme will only commence again, once the national lockdown rules will change to the appropriate level that will allow this type of activity.

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

13. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	☑ No
If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):	

14. Signature

My signature certifies that the above is complete and correct.			
Signature of PI		Date	27 May 2020

FHS017: Annual Progress Report / Renewal

Record Reviews/Audits/Collection of Biological Specimens/Repositories/Databases/Registries

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30/11/22
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	17/11/21

Note: Please note that incomplete submissions will not be reviewed.
Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.

Please clarify your plan for research-related activities during COVID-19 lockdown

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	8 November 2021		
HREC REF Number	R025/2015	Current Ethics Approval was granted until	31/08/2021
Protocol title	Sport Science Institute of South Africa Wellness Division Database (2008 – ongoing)		
Principal Investigator	Dr Jacolene Kroff		
Department / Office Internal Mail Address	U3-12, 3rd Floor, Sport Science Institute of South Africa, Boundary Road, Newlands, Department of Human Biology, University of Cape Town, 7700		

1.1 Does this protocol receive US Federal funding?	☐ Yes	x No

2. Protocol status (tick ✓)

x	Research-related activities are ongoing
x	Data collection is complete, data analysis only
Please indicate (in the block below) the titles and HREC reference numbers of any projects currently making use of the Database/registry/repository.	
278/2019	

3. Protocol summary

Total number of records or specimens collected, reviewed or stored since the original approval		140
Total number of records or specimens collected, reviewed or stored since last progress report		60
Have any research-related outputs (e.g. publications, abstracts, conference presentations) resulted from this research? If yes, please list and attach with this report.	☐ Yes	x No

4. Signature

Signature of PI		Date	8 November 2021

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS011: Study deviation

HREC office use only (FWA00001637; IRB00001938)			
This serves as acknowledgement of a protocol deviation as described below.			
Chairperson of the HREC signature/ Designee		Date	17/11/24

Note: Please note that incomplete submissions will not be reviewed.
Please email this form and supporting documents (If applicable) In a combined pdf-file to
hrec-enquiries@uct.ac.za.

Please clarify your plan for research-related activities during COVID-19 lockdown

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	9 November 2021
HREC REF Number	R025/2015
Project Title	Sport Science Institute of South Africa Wellness Division Database (2008 – ongoing)
Protocol number (if applicable)	
Principal Investigator	Dr Jacolene Kroff
Department / Office Internal Mail Address	U3-12, 3rd Floor, Sport Science Institute of South Africa, Boundary Road, Newlands, Department of Human Biology, University of Cape Town, 7700

2. Protocol deviation description

Please describe the deviation below, including the reason why the deviation occurred.
Late submission of progress report

3. Follow-up actions

3.1 Please describe any follow-up action(s) taken or planned as a result of this deviation e.g. DSMB reporting, report to sponsor, Informing participants.
Report to HREC that this is a late submission.

3.2 Please describe what action(s) have or will be taken to prevent similar deviations in future.
Automatic calendar reminder to update and complete next progress report.

4. Principal Investigator's acknowledgement of responsibility

HUMAN RESEARCH
ETHICS COMMITTEE

1 5 NOV 2021

HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN
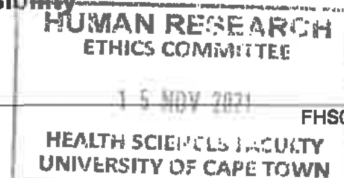
This signature indicates the PI has reviewed the deviation, taken appropriate follow-up action and implemented or plans to implement preventative steps where possible.			
Signature of PI		Date	9 November 2021

HUMAN RESEARCH ETHICS COMMITTEE

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

0 1 AUG 2018

HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

FHS017: Annual Progress Report / Renewal

Record Reviews/Audits/Collection of Biological Specimens/Repositories/Databases/Registries

HREC office use only (FWA00001637; IRB00001938)				
This serves as notification of annual approval, including any documentation described below.				
☒ Approved	Annual progress report	Approved until/next renewal date		30.8.202
☐ Not approved	See attached comments			
Signature Chairperson of the HREC			Date Signed	1/8/2008

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	1 August 2018		
HREC REF Number	R025/2015	Current Ethics Approval was granted until	30 May 2018
Protocol title	Sport Science Institute of South Africa (SSISA) Wellness Division Database 2008-ongoing		
Principal Investigator	Dr Jacolene Kroff		
Department / Office Internal Mail Address	U3-12, 3rd floor, Sport Science Inst of South Africa Building, Division of Exercise Science and Sports Medicine, Department Human Biology, Boundary Road, Newlands		
1.1 Does this protocol receive US Federal funding?		☐ Yes	☒ No

2. Protocol status (tick ✓)

☒	Research-related activities are ongoing
☐	Data collection is complete, data analysis only

Please indicate (in the block below) the titles and HREC reference numbers of any projects currently making use of the Database/registry/repository.

HREC REF: 430/2015

3. Protocol summary

Total number of records or specimens collected, reviewed or stored since the original approval		13439
Total number of records or specimens collected, reviewed or stored since last progress report		
Have any research-related outputs (e.g. publications, abstracts, conference presentations) resulted from this research? If yes, please list and attach with this report.	☐ Yes	☒ No

4. Signature

Signature of PI		Date	1 August 2018

HUMAN RESEARCH ETHICS COMMITTEE

0 1 AUG 2018

HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

FHS017: Annual Progress Report / Renewal

Record Reviews/Audits/Collection of Biological Specimens/Repositories/Databases/Registries

HREC office use only (FWA00001637; IRB00001938)				
This serves as notification of annual approval, including any documentation described below.				
☑ Approved	Annual progress report	Approved until/next renewal date		30.8.2020
☐ Not approved	See attached comments			
Signature Chairperson of the HREC			Date Signed	16/8/2018

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	1 August 2018		
HREC REF Number	R025/2015	Current Ethics Approval was granted until	30 May 2018
Protocol title	Sport Science Institute of South Africa (SSISA) Wellness Division Database 2008-ongoing		
Principal Investigator	Dr Jacolene Kroff		
Department / Office Internal Mail Address	U3-12, 3rd floor, Sport Science Inst of South Africa Building, Division of Exercise Science and Sports Medicine, Department Human Biology, Boundary Road, Newlands		
1.1 Does this protocol receive US Federal funding?		☐ Yes	☒ No

2. Protocol status (tick ✓)

☒	Research-related activities are ongoing
☐	Data collection is complete, data analysis only

Please indicate (in the block below) the titles and HREC reference numbers of any projects currently making use of the Database/registry/repository.

HREC REF: 430/2015

3. Protocol summary

Total number of records or specimens collected, reviewed or stored since the original approval		13439
Total number of records or specimens collected, reviewed or stored since last progress report		
Have any research-related outputs (e.g. publications, abstracts, conference presentations) resulted from this research? If yes, please list and attach with this report.	☐ Yes	☒ No

4. Signature

Signature of PI		Date	1 August 2018

UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences

Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492 • Facsimile [021] 406 6411
Email: Sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/research/humanethics/forms

28 May 2015

HREC/REF: R025/2015

Dr J Kroff
Division of Exercise Science & Sports Medicine
Human Biology
Newlands

Dear Dr Kroff

Project Title: Sport Science Institute of South Africa (SSISA) Wellness Division Database 2008-ongoing

Thank you for registering your database with the Faculty of Health Sciences Human Research Ethics Committee.

The HREC has **approved** the registration of your registry.

The registration of this registry is valid until 30 MAY 2018.

Please provide the HREC with an update if the registry continues beyond this period.
Please Note: All research, including that undertaken for a master's or doctoral degree, using registered databases, registries and repositories, requires submission as a new study. It requires an application form (FHS013) and a protocol which has undergone departmental review. The study will receive its own HREC REF number which will be linked to the main database or repository.

Please clarify in the opening paragraph of the ICF that the data collected may be used for research purposes.

Please provide the HREC with an update if the registry continues beyond this period.

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Hrec/ref:R025/2015

HUMAN RESEARCH ETHICS COMMITTEE

0 1 AUG 2018

HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

FHS017: Annual Progress Report / Renewal

Record Reviews/Audits/Collection of Biological Specimens/Repositories/Databases/Registries

HREC office use only (FWA00001637; IRB00001938)				
This serves as notification of annual approval, including any documentation described below.				
☑ Approved	Annual progress report	Approved until/next renewal date		30.8.2021
☐ Not approved	See attached comments			
Signature Chairperson of the HREC			Date Signed	1/8/2018

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	1 August 2018

HREC REF Number	R025/2015	Current Ethics Approval was granted until	30 May 2018

Protocol title	Sport Science Institute of South Africa (SSISA) Wellness Division Database 2008-ongoing
Principal Investigator	Dr Jacolene Kroff
Department / Office Internal Mail Address	U3-12, 3rd floor, Sport Science Inst of South Africa Building, Division of Exercise Science and Sports Medicine, Department Human Biology, Boundary Road, Newlands

1.1 Does this protocol receive US Federal funding?	☐ Yes	☒ No

2. Protocol status (tick ✓)

☒	Research-related activities are ongoing
☐	Data collection is complete, data analysis only

Please indicate (in the block below) the titles and HREC reference numbers of any projects currently making use of the Database/registry/repository.

HREC REF: 430/2015

3. Protocol summary

Total number of records or specimens collected, reviewed or stored since the original approval		13439
Total number of records or specimens collected, reviewed or stored since last progress report		
Have any research-related outputs (e.g. publications, abstracts, conference presentations) resulted from this research? If yes, please list and attach with this report.	☐ Yes	☒ No

4. Signature

Signature of PI		Date	1 August 2018

UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences

Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 792!
Telephone [021] 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

14 May 2019

HREC REF: 278/2019

Dr J Kroff
Division of Human Biology
3rd Floor
Sports Science Institute
Boundary Road, Newlands

Dear Dr Kroff

PROJECT TITLE: AN ANALYSIS OF THE SUCCESS OF COMMERCIALLY AVAILABLE LIFESTYLE INTERVENTION PROGRAMME THROUGH REGULAR EXERCISE UNDER SUPERVISION - THE HEALTHY WEIGHT PROGRAMME (SUB-STUDY LINKED TO R025/2015) (MPHIL CANDIDATES: MS F SOEKER & MS N ANGOURAS)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

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

Approval is granted for one year until the 30 May 2020.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the students: Ms F Soeker & Ms N Angouras will also be involved in this study.

Please quote the HREC REF in all your correspondence.

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

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

1.1.2 APPENDIX B

Division of Exercise Science and Sports Medicine

Department of Human Biology
Faculty of Health Sciences
University of Cape Town
P.O. Box 115, Newlands 7725, South Africa
Tel: +27 21 650 4561 Fax: +27 21 650 1796
Head of Division: Professor E V Lambert

APPENDIX H: SSISA WELLNESS DIVISION DATABASE

INFORMED CONSENT FORM

I,_____, agree voluntarily that my assessment data will be stored on a database registry managed by Division of Exercise Science and Sports Medicine, University of Cape Town, in conjunction with the Sports Science Institute of South Africa.

I have read the subject information sheets and the procedures and concepts have been explained to me in full:

WHAT IS INVOLVED?

The assessment will take approximately 1hour and involves completion of questionnaires regarding my health history, dietary intake, physical activity and general mental-health status. Body measurements will be taken to determine my body composition, such as height and weight. Other measurements will include blood pressure and finger prick cholesterol and glucose values using a single drop of blood. The fitness test that I will undergo include either a 12 min-walk test or a step test and the number of sit-ups that I can complete in one minute. Depending on the type of fitness programme that I will enrol in, I may have to undergo additional fitness or muscle strength tests to determine my physical fitness level.

ARE THERE ANY RISKS INVOLVED?

I understand that I may experience minimal discomfort during the blood finger prick test which involves pricking of the skin on my finger in order to provide a blood drop for the measurements. I understand that I may experience minimal discomfort, i.e. elevated breathing, elevated heartbeat, sweating, mild tiredness and minimal muscle pains during the 12 min-walk test, step test, muscle strength tests and/or during the one minute sit-up tests. The risks involved in following the exercise programme will be similar to risks involved in undergoing the fitness tests. I will undergo a pre-programme assessment to make sure that you are suitable for the specific programme, which will ensure that minimal risks are involved. Knowing these risks and discomforts and having had the opportunity to pose questions answered to my satisfaction, I hereby consent to participate in this programme/membership. I understand that I may withdraw from this programme at any time without further question. I have been informed that the individual data derived from my participation in these protocols will remain confidential. I understand that the medical staff and the research team have professional medical insurance.

WHAT IS SOMETHING GOES WRONG?

The University of Cape Town (UCT) undertakes that in the event of you suffering any significant deterioration in health or well-being, or from any unexpected sensitivity or toxicity, that is caused by your participation in the study, it will provide immediate medical care. UCT has appropriate insurance cover to provide prompt payment of compensation for any trial-related injury according to the guidelines outlined by the Association of the British Pharmaceutical Industry, ABPI 1991. Broadly-speaking, the ABPI guidelines recommend that the insured company (UCT), without legal commitment, should compensate you without you having to prove that UCT is at fault. An injury is considered trial-related if, and to the extent that, it is caused by study activities. You must notify the study doctor immediately of any

side effects and/or injuries during the trial, whether they are research-related or other related complications.

UCT reserves the right not to provide compensation if, and to the extent that, your injury came about because you chose not to follow the instructions that you were given while you were taking part in the study. Your right in law to claim compensation for injury where you prove negligence is not affected. Copies of these guidelines are available on request.

ARE THERE ANY BENEFITS FOR ME?
I understand that my participation in this research project (SSISA Wellness Division database) has no direct benefits to me during the participation in the SSISA membership programme.

However, I understand that my participation in the research project will advance the medical and scientific knowledge related to lifestyle intervention programmes.

Therefore, information gathered through my participation in this project could advance the future medical care, training advice and performance of lifestyle programme interventions.

ASSURANCES
The study will be performed in accordance with the Declaration of Helsinki, ICH Good Clinical Practice and the laws of South Africa. Appropriately trained personnel will conduct all procedures. In addition I will be given all results as well as a summary of the testing results. Strict confidentiality of results will be maintained. All records will be kept under lock and key and individuals will not be identified by name in any written work arising from this research.

I understand that if I have any additional queries regarding this study, I may contact the chairperson of the Human Ethics Committee of the Faculty of Health Sciences or the investigators involved in the study whose details are below.

I have read (or, where appropriate, have had read to me) and understood the information about this study, and any questions I have asked have been answered to my satisfaction.

Name of Participant: _____

Signature: _____

Date: / __/ _____

Administrator: _____

Signature: _____

Date: / __/ _____

Primary Investigators		
Dr. Jacolene Kroff	**Ms Suzana de Pina**	**Mr B. Walsh**
Jacolene.kroff@uct.ac.za	sdepina@ssisa.com	bwalsh@ssisa.com
021 650 5126	021 659 5681	021 659 5600
Faculty of Healthy Sciences – Human research Ethics Committee **Professor Marc Blockman**		
PH: 021 4066338 Email: hrec-enquiries@uct.ac.za		

HEALTHY WEIGHT PROGRAMME PRE-PARTICIPATION SCREENING

Office use	
Client number	
Month	
Year	
Group time	

Please complete the questions (Part 1 – 7) to the best of your ability, in BLOCK LETTERS. All information will be kept strictly confidential.

Personal details	
Name and surname	
Home telephone	
Work telephone	
Cellphone	
Email address	
Home doctor	

Consent
I, _____ agree to participate in the Discovery Healthy Weight programme. I understand that I do so entirely at my own risk. I accept that I must be examined by my doctor to be cleared for participation in this programme of graded exercise prescription and food energy restriction, prior to entering. I also give permission for results of my participation in the programme to be used confidentially for the purposes of research, and understand that I will not be identified in any way with these results.

Signed	
Witness	
Date	

Office Use	
Biokineticist's summary	Dietician's summary:

1.1.4 APPENDIX D

HEALTHY WEIGHT PROGRAM PRE-PARTICIPATION

SCREENING

Office use		Please complete the questions (Part 1 – 7) to the best of your ability, in BLOCK LETTERS. All information will be kept strictly confidential.
Client number		
Month		
Year		
Group time		

Personal details	
Name and surname	
Home telephone	
Work telephone	
Cellphone	
Email address	
Home doctor	

Consent	
I, _____ agree to participate in the Discovery Healthy Weight programme. I understand that I do so entirely at my own risk. I accept that I must be examined by my doctor to be cleared for participation in this program of graded exercise prescription and food energy restriction, prior to entering. I also give permission for results of my participation in the program to be used confidentially for the purposes of research, and understand that I will not be identified in any way with these results.	
Signed	
Witness	
Date	

Office Use	
Biokineticist's summary	Dietician's summary:

Client goals:

Part 1		
1	Age (years)	
2	Birthdate (yyyy/mm/dd)	
3	Sex (M or F)	
4	Height (cm)	
5	Weight (kg)	

Part 2			
1	Highest adult weight (kg)		
2	Age at highest adult weight (years)		
3	Lowest adult weight (kg)		
4	Age at lowest adult weight (years)		
5	Weight at age 20 (kg)		
6	Weight 3 months ago (kg)		
7	What do you consider your ideal weight to be? (kg)		
8	How would you describe you present body weight? (tick one)	1	Ideal
		2	0 – 5 kg overweight
		3	6 – 10 kg overweight
		4	11 – 15 kg overweight
		5	> 15 kg overweight
		6	Underweight
9	If you weigh between 65 and 100 kg, how many times over the last 2 years have you lost more than 7 – 10 kg and regained it?		
10	If you weigh more than 100 kg, how many times over the last 2 years have you lost more than 10 kg and regained it?		
11	Which of these factors do you believe contribute to your current weight concerns? (tick one or more)	1	Ill health
		2	Lack of exercise
		3	Bad eating habits
		4	Stress
		5	Pregnancy
		6	Emotional problems
		7	Injury
		8	Family history

12	Of these weight loss methods, which are the 3 most recent you've attempted. For each, indicate the length of time you followed the method, the amount of weight lost (kg) and the length of time you maintained your reduced weight. (tick one or more and provide detail where required)	METHOD		Months followed (months)	Weight lost (kg)	How long maintained (months)
		1	Sureslim			
		2	Weighless			
		3	Atkins			
		4	Weight Watchers			
		5	Fit for Life			
		6	Herbalife			
		7	Exercise			
		8	Other (specify)			

	Part 3						
1	Working status (tick one)	1	Employed full time				
		2	Employed part time				
		3	Unemployed				
		4	Housewife				
		5	Retired				
		6	Student				
2	Number of children						
3	Ages of children	n.a	1	2	3	4	5
4	Marital status (tick one)	1	Single				
		2	Married				
		3	Divorced				
		4	Widowed				
		5	Living with a partner				

	Part 4 Risk profile for chronic disease and exercise					
1	Please tick if either you (SELF), your parents (MOTHER; FATHER; BOTH) or no one (NONE) have any of the conditions listed below					
	CONDITION	SELF	MOTHER	FATHER	BOTH	NONE
	1 Obesity	A	B	C	D	E
	2 Diabetes	A	B	C	D	E
	3 High blood pressure	A	B	C	D	E
	4 Heart disease	A	B	C	D	E
	5 High cholesterol	A	B	C	D	E
	6 Cancer	A	B	C	D	E
	7 Other	A	B	C	D	E
2	Do you smoke?	1. Yes	2. No	If yes, how many per day?		
3	Do you drink alcohol?	1. Yes	2. No			

			How many units per day?	
	If yes, what type of alcohol?			
4	Have you ever had a heart attack or been diagnosed with heart disease?	1. Yes	2. No	
5	Are you currently taking medication?	1. Yes	2. No	

If yes, which of the following (tick one or more)	
Medication type	Medication name
1 Anti-inflammatory	
2 Blood pressure	
3 Cholesterol	
4 Diabetes	
5 Anti-depressant	
6 Anti-anxiety	
7 Allergy/asthma	
8 HRT	
9 Thyroid	
10 Other	

6	Do you have a muscle of joint disorder?	1. Yes	2. No
	If yes, does it limit exercise?	1. Yes	2. No
7	Have you any other chronic medical condition?	1. Yes	2. No
	If yes, please specify:		

Part 5
Stress and tension
Please indicate below which best describes the stress you experience in your day-to-day life (tick one).
1 No stress, very relaxed
2 Moderate stress and relaxed personality
3 High stress, but cope well
4 Very high stress and tense personality
5 Very high stress and highly-strung personality

Part 6		
Stress and tension		
On a scale of 1 - 10, with 1 being the very poor/negative rating and 10 being excellent/highest positive rating, please rate the following:		
1	The depth of your commitment towards achieving your goals.	
2	How confident are you about maintaining the healthy changes over time	
3	How would your rate your overall mental or emotional health.	
4	Please rate your current happiness with your relationships/social life	
5	Please rate your current happiness with your work, career and financial situation	
6	Please rate your current happiness with spiritual aspects of your life, if applicable	
7	Do you think there might be any emotional issues that need to be resolved in order to maximize your chances of achieving your goals?	
	Typically, during the week how many hours do you sleep per night on average?	Less than 5 hours	
		Between 5 – 7 hours	
		Between 7 – 8 hours	
		More than 8 hours	
	Typically, during the weekend how many hours do you sleep a night on average?	Less than 5 hours	
		Between 5 – 7 hours	

		Between 7 – 8 hours	
		More than 8 hours	

	Part 7 Eating behaviour and dietary information		
Please tick the answer that best corresponds to your eating behaviour.			
1	Do you eat sensibly I front of others, and splurge when you are alone?	1. True	2. False
2	Do you often feel so hungry that you have to eat something?	1. True	2. False
3	Do you have a pretty good idea of the number of calories in common food?	1. True	2. False
4	Do you frequently skip dessert because you are no longer hungry?	1. True	2. False
5	How often do you start dieting in the morning and by the evening, have given up, promising yourself you'll start tomorrow?	1. True	2. False
6	Do you consciously choose foods that are low in fats and oils?	1. True	2. False

1.1.5 APPENDIX E

HEALTHY WEIGHT PROGRAM DATA CAPTURE SHEET

<table>
<tr><td colspan="4" align="center">HEALTHY WEIGHT PROGRAM DATA
CAPTURE SHEET</td></tr>
<tr><td colspan="4">

Name & Surname_____

Age & Gender_____ _____

Personal Medical History _____
_____

Current Medications_____
_____

Orthopedic Limitations_____
_____
_____

Family History_____

Smoking ☐ Yes ☐ No   Stress Levels _____

How Long _____

Testing Bio_____ _____

Date_____

</td></tr>
<tr><td></td><td colspan="3" align="center">Test number: _____</td></tr>
<tr><td>CARDIOVASCULAR RISK FACTORS</td><td colspan="3"></td></tr>
<tr><td>Resting BP (mmHg)</td><td colspan="3"></td></tr>
<tr><td>Cholesterol: Finger prick (mmol/L)</td><td colspan="3"></td></tr>
<tr><td>Glucose: Finger prick (mmol/L)</td><td colspan="3"></td></tr>
<tr><td>Resting Pulse (bpm)</td><td colspan="3"></td></tr>
<tr><td align="center">BODY COMPOSITION</td><td align="center">1st</td><td align="center">2nd</td><td>Recorded Measure</td></tr>
<tr><td>Neck (cm)</td><td></td><td></td><td></td></tr>
<tr><td>Waist (cm)</td><td></td><td></td><td></td></tr>
<tr><td>Hip (cm)</td><td></td><td></td><td></td></tr>
<tr><td>Thigh (cm)</td><td></td><td></td><td></td></tr>
<tr><td>Bicep (cm)</td><td></td><td></td><td></td></tr>
<tr><td align="center">ABDOMINAL ENDURANCE</td><td colspan="3"></td></tr>
<tr><td>60 sec Crunch Test
(Not to be completed if the Individual has current or previous Lower Back Pain)</td><td colspan="3"></td></tr>
<tr><td align="center">FLEXIBILITY</td><td colspan="3"></td></tr>
<tr><td>Sit-'n-Reach (cm) – SHOES OFF
(Not to be completed if the Individual has current or previous Lower Back Pain)</td><td colspan="3"></td></tr>
<tr><td></td><td colspan="3"></td></tr>
<tr><td align="center">TANITA CODE</td><td colspan="3"></td></tr>
</table>

Height (cm)	
Weight (kg)	
BMI (kg/m^2)	
Body Fat (%)	
Fat Mass (kg)	
Eat or Drink (4 hours) □ Yes □ No	Caffeine or Alcohol (12 hours) □ Yes □ No
Vig. Exercise (12 hours) □ Yes □ No	Pacemaker or Metal Implants □ Yes □ No

1.1.6 APPENDIX F

turnitin

Digital Receipt

This receipt acknowledges that Turnitin received your paper. Below you will find the receipt information regarding your submission.

The first page of your submissions is displayed below.

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File size: 126.39K

Page count: 40

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