The association between anthropometric measures and physical performance in black adults of the North West Province, South Africa

P Mamphwe

27067343

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Supervisor: **Prof. HS Kruger**

Co-supervisor: **Prof. SJ Moss**

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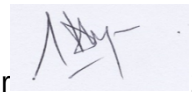
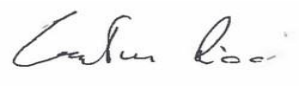
Prof. HS Kruger  26/06/2017 Mrs M Cockeran  26/06/2017

Prof. SJ Moss  26/06/2017 Dr C Ricci  26/06/2017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Call unto me, and I will answer thee, and show thee great and mighty things, which thou knowest not ~ Jeremiah 33 vs. 3 (KJV)

ABSTRACT

South Africa, like many low and upper middle income countries, is undergoing urbanisation with a rapid socio-economic and nutrition transition that may affect the body composition and physical activity patterns of individuals. Obesity has become a major health problem causing an increase in the incidence and prevalence of various non-communicable diseases. Physical activity has been shown to be associated with a lower fat mass and an increase in muscular strength and function and has also been recognised as a key lifestyle factor to prevent and delay muscle loss and obesity during ageing. Maintaining or increasing physical activity levels may decrease the decline of age-associated physical performance. There is a paucity of data on the association between anthropometric measures and the physical performance of black adults in Southern Africa.

The aim of this longitudinal study was to examine the association between anthropometric measures and the physical performance of rural and urban black South African adults in the North West Province, South Africa. Stratified random sampling was used to select participants from four communities to participate in the PURE-SA study in 2005. Follow-up visits were done in 2010 and 2015. Anthropometric measurements, demographic information and information concerning physical activity were collected. Physical performance tests were added in 2015. Participants who were HIV positive, whose data were incomplete and pregnant women were excluded in 2005. Data of 1 428 participants were available. In 2015, 926 individuals returned for a follow up and 774 participants remained after the participants were excluded who were HIV positive.

The combined overweight/obesity prevalence of both men (p=0.02) and women (p<0.001) increased significantly over time. Physical activity decreased gradually in both men and women (p<0.0001). Statistically significant differences in handgrip strength between the tertile groups of calf circumference were found in men (p=0.002) and women (p<0.0001). Calf circumference was positively associated with handgrip strength and walk speed performance even after adjustments were made for potential confounders. This mini-dissertation has shown that the prevalence of being overweight or obese among black South African adults is increasing, particularly in women in the North West Province. Calf circumference may be a useful predictor of physical performance in black men and to a more limited extent in women.

Keywords: Calf circumference, physical performance, handgrip strength, walk speed

OPSOMMING

Soos baie lae en middelinkomste lande, verstedelik Suid-Afrika met 'n gepaardgaande vinnige sosio-ekonomiese en voedingsoorgang wat die liggaamsamestelling en fisieke aktiwiteitspatrone van individue kan beïnvloed. Vetsug het 'n groot gesondheidsprobleem geword wat 'n toename in die invloed en voorkoms van verskeie nie-oordraagbare siektes veroorsaak het. Fisieke aktiwiteit word met ŉ laer vetmassa en verhoogde spierkrag en -funksie geassosieer en word ook erken as 'n sleutelfaktor om spierverlies en vetsug te verhoed met veroudering. Die instandhouding of toename in fisieke aktiwiteit-vlakke kan ouderdomsverwante fisieke prestasie verhoog. Daar is 'n tekort aan data oor die verband tussen antropometriese metings en fisieke prestasie van swart volwassenes in Suidelike Afrika.

Die doel van hierdie longitudinale studie was om die verband tussen antropometriese metings en fisieke prestasie in landelike en stedelike swart Suid-Afrikaanse volwassenes van die Noordwesprovinsie, Suid-Afrika, te ondersoek. Gestratifiseerde ewekansige steekproefneming is gebruik om deelnemers uit vier gemeenskappe te kies om deel te neem aan die PURE-SA studie in 2005. Opvolgbesoeke is in 2010 en 2015 gedoen. Antropometriese metings, demografiese inligting en inligting oor fisieke aktiwiteit is ingesamel. Fisieke prestasietoetse is in 2015 bygevoeg. Nadat deelnemers wat MIV-positief getoets het, diegene met onvolledige data en swanger vroue in 2005 uitgesluit is, was daar 1 428 deelnemers beskikbaar. In 2015 het 926 individue vir ŉ opvolg teruggekeer en 774 deelnemers het deelgeneem nadat deelnemers wat MIV-postief getoets het, uitgesluit is.

Die gesamentlike oorgewig-/vetsug-voorkoms van beide mans (p=0.02) en vroue (p<0.001) neem beduidend toe met tyd terwyl fisieke aktiwiteit stelselmatig afneem in beide mans en vroue (p<0.0001). Statisties beduidende verskille in handgreepsterkte tussen die tertielgroepe van kuitomtrek is by mans (p=0.002) en vroue (p<0.0001) bevind. Kuitomtrek word positief met handgreepsterkte en loopspoedprestasie geassosieer selfs ná ŉ aanpassing vir potensiële botsende veranderlikes. Hierdie skripsie het getoon dat die voorkoms van oorgewig en vetsug onder swart Suid-Afrikaners aan die toeneem is − veral in vroue in die Noordwesprovinsie. Kuitomtrek kan 'n nuttige voorspeller van fisieke prestasie in swart mans wees en tot ŉ mindere mate in vroue.

Sleutelwoorde: Kuitomtrek, fisieke prestasie, handgreepsterkte, loopspoed

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LIST OF ABBREVIATIONS

ANOVA	Analysis of variance
BIA	Bio-electrical impedance analysis
BMI	Body mass index
CC	Calf circumference
CVD	Cardiovascular diseases
DXA	Dual-energy X-ray absorptiometry
HIC	High income countries
HGS	Handgrip strength
HREC	Health Research Ethics Committee
LMIC	Lower and middle income countries
NCDs	Non-communicable diseases
PA	Physical activity
PURE	Prospective Urban and Rural Epidemiology study
THUSA	Transition of Health during Urbanization in South Africa study
SA	South Africa
SO	Sarcopenic obesity
RCT	Randomised controlled trials
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

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CHAPTER 1 INTRODUCTION

1.1 Background and motivation

1.1.1 The situation in South Africa

In 2011, the South African population was estimated at about 54 million people with the black population representing about 80.5% of people in South Africa. The North West Province accounted for 6.7% of the South African population in 2011 (Lehohla, 2014).

Like many low and middle income countries (LMIC), South Africa is undergoing a rapid socio-economic and nutritional transition. This transition deals with the challenges of infectious diseases and child malnutrition, the upsurge in obesity and its accompanying non-communicable diseases (NCDs) that lead to a double burden of diseases. Many black people in South Africa have been subjected to urbanisation that led to a significant increase in lifestyle diseases (van Rooyen *et al.*, 2000; Bourne *et al.*, 2002; Puoane *et al.*, 2002; Kruger *et al.*, 2005). Modifiable risk factors that contribute to the development of NCDs in South Africa, such as obesity and physical inactivity, require more attention (Bourne *et al.*, 2002). Although the high prevalence of NCDs indicates a need to treat these diseases, little progress has been made and the prevalence of NCDs is still reported to be high in the rural and urban areas. Maimela *et al.* (2016) found that the prevalence of risk factors for NCDs, such as smoking, alcohol consumption, low fruit and vegetable consumption, physical inactivity, hypertension, overweight and high waist circumference was alarmingly high in the Limpopo Province in 2016.

Overweight and obesity are major problems in both high income countries (HIC) and LMIC (World Health Organisation, 2002; World Health Organisation, 2013). Information on body composition of population groups or patients is important and a body composition assessment is becoming a standard measurement in many clinical and nutrition-related studies. One of the most striking and clinically significant anatomical changes in aging humans is the loss of skeletal muscle mass (Rosenberg, 1997). Growing evidence links sarcopenia to functional disability, falls and a decreased bone density in older adults. A decrease in physical activity (PA) and obesity have been implicated in the aetiology of sarcopenia. Progressive resistance training has been noted to be the best intervention to slow down sarcopenia (Kamel, 2003).

Deurenberg *et al.* (2002) indicated that different aspects of body composition can be measured. The main aspect of interest in terms of adiposity is, however, body fat

percentage. Valid and reliable techniques, such as air displacement plethysmography, dual-energy X-ray absorptiometry (DXA), bioelectrical impedance and skinfolds, are used for accurate measures of body composition (Deurenberg *et al.*, 2002). The disadvantages of these techniques are that some are expensive, not widely available and not always easily accepted by subjects when measured (Deurenberg *et al.*, 2002). Calf circumference (CC) is a potential anthropometric marker of physical function − it is an inexpensive, simple, non-invasive measurement for clinicians and relevant in the screening of sarcopenia (Landi *et al.*, 2014). However, Tsai *et al.* (2012) indicated that the role of CC in the incidence of falls is unclear although a clinical association between frailty or sarcopenia and anthropometric variables, such as CC, is frequently recognised.

1.2 Problem statement

Few recent studies have assessed changes in the body composition of black adults in LMIC over time (Newman *et al.*, 2003; Hughes *et al.*, 2004; Hopman *et al.*, 2007; Chantler, 2014). Sarcopenia and obesity have been independently associated with a decline in physical performance. Little information is currently available on the relationship among sarcopenia, obesity and physical performance (Moreira *et al.*, 2016b). Body mass index (BMI) is the most widely used and accepted for classifying overweight and obesity among adults in epidemiological studies (Deurenberg *et al.*, 2002). This study, therefore, focused on the association between anthropometric measures and the physical performance of black adult men and women in the North West Province, South Africa.

1.3 Aims and objectives

1.3.1 Aim

The aim of the study was to determine the association between anthropometric measures and the physical performance of black adult men and women in the North West Province, South Africa.

1.3.2 Objectives

In order to address the aim of the study, the following objectives were formulated:

- To determine changes in the anthropometric measures (body mass, BMI and CC) of the study participants from 2005 to 2015.

- To determine the association between anthropometric measures (BMI and CC, respectively) and physical performance tests measured in 2015 with an adjustment for potential confounding variables.

1.4 Significance of the study

The findings of the study will assist researchers and other nutrition professionals in becoming knowledgeable about changes in anthropometric measures over time and its associations with the physical performance of black adults in the North West Province.

Such knowledge will aid in the design and adoption of prevention programmes for lifestyle diseases in order to prevent weight gain observed during ageing when the body fat percentage increases and muscle wasting starts. In determining an association between anthropometric measures and physical performance tests, information will be provided to guide interventions and inform health policies that may help to reduce the changes in body composition with ageing. Data are provided in an article for future studies concerning anthropometric measures and physical performance and will be submitted for publication to the *Public Health Nutrition Journal*.

1.5 Hypothesis

The following hypotheses were formulated:

- The body mass, BMI and CC of the study participants will increase from 2005 to 2015.
- There will be a positive association between CC and the following components of physical performance tests in black adult men and women in 2015: handgrip strength (HGS) and walk speed.
- There will be a negative association between CC and chair stand test time.

1.6 Contribution of team members

This affiliated study formed part of the larger PURE-SA study and it was planned and carried out by a team of researchers. The contribution of each team member is shown in Table 1.1.

Table 1.1 Contribution of team members

Researcher's name and qualification	Contribution to the research
Dr IM Kruger	PURE-SA project leader.

Researcher's name and qualification	Contribution to the research
Prof. HS Kruger	Project supervisor; planned and coordinated the study; performed the statistical analysis; and interpreted the results.
Prof. SJ Moss	Co-supervisor of the project; co-supervisor of the study; performed the statistical analysis; and interpreted the results.
Ms P Mamphwe	MSc student; primary researcher of the project; planned and wrote the literature review; did the 2015 anthropometric data collection; recorded and entered the data; performed the data analysis; interpreted; and wrote the mini-dissertation.
Mrs M Cockeran and Dr C Ricci	Statisticians – interpreted the results.

1.7 Structure of the mini-dissertation

The referencing method used is according to the North-West University's style. This MSc mini-dissertation is presented in the article format and is presented in the following chapters:

- **Chapter 1** includes the background, problem statement and motivation for the study, the aim and objectives and the contribution of the research team members.

- **Chapter 2** contains a review of literature, provides background information concerning the current research study and includes information on anthropometric measures and physical performance.
- **Chapter 3** describes the methods of the study in detail.
- **Chapter 4** focuses on the methodology, results and discussion of anthropometric measures and physical performance of a group of black South African adults in the North West Province (article format). The article will be submitted to the *Public Health Nutrition Journal*.
- **Chapter 5** summarises the study, provides a brief and general discussion and concluding remarks with reference to the set objectives and recommendations for future studies.

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CHAPTER 2 LITERATURE REVIEW ANTHROPOMETRIC MEASURES AND PHYSICAL PERFORMANCE IN ADULT BLACK PEOPLE

2.1 Introduction

Ageing is the primary risk factor for many diseases and chronic conditions. A critical change in relation with human ageing is a progressive decline in skeletal muscle mass a downward spiral that may lead to a decrease in physical strength and performance (Cruz-Jentoft *et al.*, 2010). Physical performance measurements assess the physical function and its association with mortality and disability in older adults (Roshanravan *et al.*, 2013). Physical inactivity contributes to sarcopenia in a vicious cycle, causing elderly people to become weaker and less able to participate in daily activities (Kruger *et al.*, 2016). Sarcopenia is a gradual loss of lean muscle mass, due to physical challenges that take place during ageing and is often associated with a progressive increase in body fat leading to sarcopenic obesity (Hairi *et al.*, 2010; Batsis *et al.*, 2014; Murton, 2015). CC is a potential marker of physical performance while a chair stand test, walk speed and HGS are regarded as predictors of physical performance and a disability (Waters *et al.*, 2010; Studenski *et al.*, 2011; Lee *et al.*, 2016). The South African government has set targets to reduce obesity in the country but clear strategies to achieve these goals are, however, still lacking (Mungal-Singh, 2012). These targets include increasing PA by 10% by 2020 and reducing the percentage of people who are obese and/or overweight by 10% by 2020. This chapter reviews the literature that has been published on obesity, sarcopenia and physical performance.

2.2 Overweight and obesity

2.2.1 Definition

Being overweight or obese can be defined as a condition in which excessive body fat increases with adverse effects on the well-being of individuals (World Health Organization, 2013). Obesity can be described as an imbalance between energy intake and expenditure: excess energy is stored in fat cells, which enlarge or multiply in number (Spiegelman & Flier, 2001). BMI can be calculated by dividing the body mass of persons in kilograms by height in meters squared (kg/m^2). Being overweight can, therefore, be defined as BMI>25 kg/m^2 and being obese as BMI>30 kg/m^2 (World Health Organization, 2013; Cederholm *et al.*, 2016). Table 2.1 illustrates the BMI classification categories.

Table 2.1 The World Health Organisation's international classification of adults being underweight, overweight and obese, according to BMI

Classification	BMI (kg/m^2)	
	Principal cut-off points	**Additional cut-off points**
Underweight	<18.50	<18.50
Severe thinness		<16.00
Moderate thinness		16.00–16.99
Mild thinness		17.00–18.49
Normal (healthy weight)	18.50–24.99	18.50–24.99
Overweight	≥25.00	≥25.00
Pre-obese: lower	25.00–29.99	25.00–27.49
Pre-obese: upper		27.50–29.99
Obese	≥30.00	≥30.00
Obese class I	30.00–34.99	30.00–32.49
		32.50–34.99
Obese class II	35.00–39.99	35.00–37.49
		37.50–39.99
Obese class III	≥40.00	≥40.00

Source: Adapted from the World Health Organization (2013)

BMI is easy to measure and commonly used to measure obesity worldwide as a representative measure of whole body obesity in a population. However, BMI does not consider body composition, such as muscle and fat mass (Lee *et al.*, 2016). The accuracy of BMI to reflect adiposity is often debated in research (Kruger *et al.*, 2015b; Bosaeus & Rothenberg, 2016; Lee *et al.*, 2016). Compared to young adults, older adults may have more fat mass when given the same BMI levels due to muscle atrophy caused by ageing. Kruger *et al.* (2015b) propose that new cut-off points for BMI should be developed for a cardiometabolic risk diagnosis by taking into account age and ethnicity.

2.2.2 Classification and prevalence of obesity

BMI is a simple index of weight-for-height that is commonly used to classify obesity in adults or being underweight or overweight (World Health Organization, 2002). Obesity has become a global epidemic with an estimated 1.3 billion people being overweight or obese at the beginning of this century (World Health Organization, 2013). The World Health Organization (2013) reported that globally 35% of adults aged 20 years and older were overweight and

11% were obese in 2013. Furthermore, the prevalence of obesity in the United States of America is as high as 26.6% in men and 32.2% in women older than 20 years (World Health Organization, 2013). In their analysis, Ng *et al.* (2014) revealed that the prevalence of individuals being overweight or obese rose by 27.5% in adults between the year 1980 and 2013 and the number of overweight and obese individuals increased worldwide from 857 million in 1980 to 2·1 billion in 2013. The proportion of adults with a BMI of 25 kg/m^2 or more has increased worldwide from 28.8% to 36.9% in men and 29.8% to 38.8% in women since 1980 to 2013 (Ng *et al.*, 2014). However, the NCD Risk Factor Collaboration (2016) showed that globally the mean age-standardised BMI has increased from 21.7 kg/m² in 1975 to 24.2 kg/m² in 2014 for men while the age-standardised BMI of women has increased from 22.1 kg/m² in 1975 to 24.4 kg/m² in 2014.

South Africa has the highest overweight and obesity rate in Sub-Saharan Africa (Mungal-Singh, 2012). In 45% and 37% of households where there is a stunted or underweight child, respectively, there is at least one obese adult (Cois & Day, 2015). Puoane *et al.* (2002) indicated that the overall prevalence of overweight individuals (BMI >25 kg/m^2) and obesity (BMI >30 kg/m^2) in South Africa was high in 1998. Furthermore, over 57% of adult South African women and 29% men are classified as either being overweight or obese (Puoane *et al.*, 2002). Shisana *et al.* (2013) maintain that being overweight and obese is increasing exponentially over time in both men and women. Recently, the NCD Risk Factor Collaboration (2016) indicated that the mean age-standardised BMI between 1975–2014 was high in Southern Africa with men just below 25 kg/m^2 and women just below 30 kg/m^2.

In 2012, the prevalence of overweight and obese South African women was significantly higher at 24.8% and 39.2% compared to 20.1% and 10.6% in men (Shisana *et al.*, 2013). An increase of mean BMI from 28.5 kg/m^2 in 2012 to 31.3 kg/m^2 was observed in the same survey in women between the ages of 55 to 64 years in 2012 (Shisana *et al.*, 2013). Moreover, black South African women had a higher prevalence of being obese than white women and Indians in 1998 (Puoane *et al.*, 2002). A higher prevalence of obesity and a decrease in muscle mass are observed during menopause in women and these health issues are separately related to a decline in physical performance (Jensen & Friedmann, 2002). Men on average have a greater muscle mass than women (Van Kan, 2009). In contrast, the body fat of older women is higher, their physical function is poor, they have a lower muscle strength and a higher rate of nonfatal chronic conditions is reported (Tseng *et al.*, 2014). Cruz-Jentoft *et al.* (2010) are of the opinion that the body composition of black individuals differs from white individuals particularly with regard to height, body fat and body fat distribution. Black people have higher bone mineral density and body protein content

resulting in a greater fat-free body density (Wagner & Heyward, 2000). However, excess body weight may serve as a major contributor to ethnic disparities in cardiovascular diseases (CVD), because the prevalence of obesity is higher in black individuals than white individuals − especially in women (Hendley *et al.*, 2011).

2.2.3 Health consequences of being overweight or obese

When individuals are either overweight or obese, morbidity increases. Morbidity, an impaired quality of life and premature death are consequences of the serious medical complications of being overweight or obese (Chan & Woo, 2010). Excess body weight during middle age may, therefore, contribute to the medical complications and increased medical expenditures that occur during old age (Villareal *et al.*, 2005; Chan & Woo, 2010). Moreover, obesity is associated with numerous health problems, including an impaired physical function and quality of life, the development of type 2 diabetes, hypertension, dyslipidaemia, and CVD in the elderly (Villareal *et al.*, 2005).

Chan and Woo (2010) state that type 2 diabetes is more associated with obesity than other risk-related factors of obesity. Although the high prevalence of type 2 diabetes and glucose intolerance has been previously attributed to aging itself, data suggest that the age-related decline in insulin sensitivity can be associated with abdominal obesity and physical inactivity. Older persons who are, therefore, physically active and who do not have an increased abdominal circumference are much less likely to develop type 2 diabetes (Villareal *et al.*, 2005). Low levels of PA are positively associated with a higher BMI and contribute to obesity due to a low energy expenditure and its effect on the balance of energy (Fogelholm & Kukkonen-Harjula, 2000). Hypertension is common in the older population, indicating that obesity and high blood pressure play an important role − even in old age in increasing the risk of hypertension (Cois & Day, 2015). Furthermore, a higher BMI was associated with high blood pressure in the multi-ethnic study done in the United States of America (Burke *et al.*, 2008). Dyslipidaemia, such as low high-density lipoprotein cholesterol (HDL-C) and high serum triacylglycerol concentrations, is associated with abdominal obesity in both young and old adults (Villareal *et al.*, 2005). Obesity increases the risk of CVD in older men, but not necessarily in older women (Villareal *et al.*, 2005). An increased BMI in older men is associated with an increase in new cases of coronary heart disease, fatal and nonfatal myocardial infarction and mortality concerning CVD (Villareal *et al.,* 2005). Being overweight or obese increases the risk of cancers developing in the oesophagus, pancreas, colon, rectum, breasts, endometrium and kidneys (World Cancer Research Fund, 2007). Evidence also shows that abdominal fatness can be the cause of colon cancer and may increase the

risk of breast cancer (postmenopausal) and endometrium (World Cancer Research Fund, 2007; Chan & Woo, 2010).

Kengne *et al.* (2013) highlight that economic costs are consequences of being underweight, overweight or obese in South Africa and policy interventions are required directed at achieving normal BMIs together with improvements in productivity and economic developments. In South Africa, individuals who present with NCDs often do not bear the full costs of ill health associated with their weight problems unless their medical aid plan is cost-adjusted to accommodate their weight status and lifestyle practices (Kengne *et al.*, 2013). Healthcare costs are tolerated by other parties, such as employers, individuals working in the insurance risk field and taxpayers, depending on medical aid plans and other health insurance policies in the country while unemployed individuals living in rural areas suffer more, because they cannot contribute to a medical aid plan or insurance. The cost regarding the premature deaths of parents due to ill health as a consequence of being overweight or obese in South Africa is carried over to the carers of orphans. Moreover, the personal and social burden of these carers who are mostly young siblings and/or the elderly escalates (Kengne *et al.*, 2013).

2.2.4 Changes in being overweight and obese when ageing takes place

The prevalence of being overweight and obese increases with advancing age in men and women and starts to decline again after the age of 60 years is reached (Spark *et al.*, 2015). Ageing is a continual process that involves physiological changes in multiple body systems resulting in a reduced functional capacity (Silva Neto *et al.*, 2012). Normal ageing involves important changes in body composition, including a decrease in muscle mass and an increase in fat mass and is characterised by a diminished capacity in all bodily functions (Visser *et al.*, 2002; Zamboni *et al.*, 2008; Bosaeus & Rothenberg, 2016). Older adults are normally less effective in regulating weight than younger people. Furthermore, older adults are less able to conserve lean mass during weight loss than younger adults (Newman *et al.*, 2005). Weight gain in adults is often associated with an increase in absolute and percentage fat mass.

Older people tend to weigh less than younger adults and old age is also associated with a tendency to lose weight (Mahan & Raymond, 2016). When older people lose weight, they lose lean tissue (mainly skeletal muscle). When excessive weight loss occurs, the loss of lean muscle tissue results in sarcopenia, which is associated with poor health outcomes (Soenen & Chapman, 2013). The physiological anorexia of aging, a possible cause of weight loss, can be described as a decrease in appetite and energy intake that can occur even in

healthy people and is possibly caused by changes in the digestive tract, gastrointestinal hormone concentrations and activity, neurotransmitters and cytokines (Soenen & Chapman, 2013). A greater understanding of a decrease in appetite and energy intake during aging − and the responsible mechanisms—may aid in the search for ways to treat undernutrition and weight loss in older people (Soenen & Chapman, 2013). Old age is often characterised by poor health due to frailty, morbidities, disabilities and age-related alterations to the sense of taste, smell and touch that can lead to a poor appetite, inappropriate food choices and a lower nutrient intake (Mahan & Raymond, 2016).

2.3 Changes in body composition during ageing

Body composition changes during aging with increases in fat mass and visceral fat while lean muscle mass is decreasing (Mahan & Raymond, 2016). An overall increase in adiposity during aging is associated with a more central distribution of fat. The composition of lean tissues also changes with advancing age. Epidemiological surveys suggest that an age-associated decrease in skeletal muscle mass starts after the second decade of life in both men and women and slowly progresses thereafter (Newman *et al.*, 2005). As individuals age, their skeletal muscle mass starts to deteriorate and as a result of deterioration, they begin to look old. Men experience a more rapid muscle loss between the ages of 41 and 60 years whereas women experience a rapid loss after the age of 60 years (Newman *et al.*, 2005). The body weight of women increases from normal weight to overweight and obesity between the ages of 40 and 50 years and remains stable thereafter. Percent body fat of women is also stable until the age of 40 years and increases onwards from an average of 28% to 35% between 40 and 50 years of age (Newman *et al.*, 2005). Related changes in body composition due to ageing are not evident by measuring the BMI (Bosaeus & Rothenberg, 2016). One of the most striking and clinically significant anatomical changes in aging humans is the loss of skeletal muscle mass (Rosenberg, 1997). These changes are represented by two conditions − sarcopenia and sarcopenic obesity – and are discussed in the following section.

2.4 Sarcopenia

2.4.1 Definition of sarcopenia

Cederholm *et al.* (2011) are of the opinion that the term “sarcopenia” was first used by a concerned physician named Rosenberg in the 1980s at a symposium on nutritional status and body composition. Rosenberg used “sarcopenia” in order to increase awareness of age-related muscle loss and its shattering effects on the freedom of the elderly and also to draw

attention to this significant but then understudied problem of ageing (Rosenberg, 1997; Pathy *et al.*, 2006; Cederholm *et al.*, 2011). Sarcopenia is derived from the Greek word "sarx" for flesh and "penia" for loss (Pathy *et al.*, 2006). Furthermore, sarcopenia is a gradual loss of lean muscle mass and is often associated with a progressive increase in body fat leading to sarcopenic obesity (Hairi *et al.*, 2010; Batsis *et al.*, 2014; Murton, 2015). However, Studenski *et al*. (2014) purport that although the term "sarcopenia" has become widely used in literature, definitions vary due to greater insights in the relationships among muscle mass, muscle quality, muscle strength and muscle function. In addition, the current definition of sarcopenia does not only include muscle mass, but also includes elements of muscle strength and function (Studenski *et al*., 2014). Table 2.2 provides an overview of the different cut-off criteria for sarcopenia defined by different expert groups.

Table 2.2 Definitions of sarcopenia with cut-off points

International Academy on Nutrition and Aging (IANA)	Normal walk speed <1.0 m/s. Low muscle mass: ASM/h2 ≤7.23 kg/m2 for men and ≤ 5.67kg/m2 for women*.
European Working Group on Sarcopenia in Older People (EWGSOP)	Normal walk speed ≤ 0.8 m/s. HGS < 30 kg for men or <20 kg for women. Low muscle mass: ASM/h2 <7.23-7.26 kg/m2 for men and <5.45-5.67 kg/m2 for women*.
Asian Working Group (AWG)	Normal walk speed <0.8 m/s. HGS <26 kg for men or <18 kg for women Low muscle: ASM/h2 <7.0 kg/m2 for men and <5.4 kg/m2 for women*.
Foundation for the National Institute of Health Sarcopenia Project (FNIH)	Normal walk speed <0.8 m/s. HGS <26 kg for men or <16 kg for women. Low muscle mass: ASM/BMI <0.789 for men and <0.512 for women*.

*ASM: appendicular lean mass; ASM/h2: appendicular lean mass divided by height squared; BMI: body mass index; * ASM measured by DXA. (Adapted from Cruz- Jentoft et al., 2010)*.

2.4.2 Classification of sarcopenia

Cederholm *et al.* (2016) state that up-to-date diagnostic criteria for sarcopenia have not yet been firmly established. From the time individuals are born to the age of 30 years, muscles grow larger and stronger (Clark & Manini, 2010). Hairi *et al.* (2010) mention that individuals who are physically inactive can lose as much as 3% to 5% of their muscle mass per decade after the age of 30 years. In contrast to the studies of Clark & Manini (2010); and Hairi *et al.*

(2010), another study indicate that muscle mass decline from 20 years of age. In this study by Hairi *et al.* (2010) skeletal muscle mass in the arms and legs declined by 11 % in women and 15% in men between the ages of 20 and 70 years (Roubenoff *et al.*, 1997). Moreira *et al.* (2016b) highlight that the loss of muscle mass begins around 40 years, a decade later than found by Hairi *et al*. (2010), and it is estimated that muscle mass decreases every decade by 8%. After the age of 70, the rate increases to 15% per decade. Although sarcopenia accelerates around the age of 75 years, it may occur in individuals aged 65 years or even younger (Hairi *et al.*, 2010). Older adults may take in less food due to age-related appetite loss (as mentioned before), medical conditions or financial limits (Goodpaster *et al.*, 2006; Deutz *et al.*, 2014). Other reasons for muscle loss include lack of PA, inflammatory diseases, anabolic resistance and hyper metabolic diseases (Fogelholm & Kukkonen-Harjula, 2000; Stephen, 2008).

Older adults may lose muscle mass and strength and eventually experience a physical disability caused by an imbalance between the protein supply and protein needed by the body to synthesise and degenerate (Houston *et al.*, 2008; Koopman, 2011; Silva Neto *et al.*, 2012; Beasley *et al.*, 2013) Adequate protein intake helps limit and treat age-related declines in muscle mass, strength and functional abilities (Koopman, 2011). The musculoskeletal system involving bodily functions, such as muscle contraction and movement, is affected by a loss in lean mass (Goodpaster *et al.*, 2006). A loss in muscle quality (e.g., strength) is often considered to be secondary to a loss in muscle mass. As a result, prevalence estimates for sarcopenia are based on the loss of muscle mass during advancing age. The conceptual stages of sarcopenia are shown in Table 2.3, according to the European Working Group on Sarcopenia in Older People (EWGSOP):

Table 2.3 European Working Group on Sarcopenia in Older People's conceptual stages of sarcopenia (Adapted from Cruz-Jentoft *et al.*, 2010).

Stage	Muscle mass	Muscle strength	Performance
Pre-sarcopenia	↓		
Sarcopenia	↓	↓	Or ↓
Severe sarcopenia	↓	↓	↓

2.4.3 Prevalence of sarcopenia

A study conducted by Baumgartner *et al.* (1998) in New Mexico reported that the prevalence of sarcopenia has increased from 13% to 24% in persons younger than 70 years of age and with 50% in persons older than 80 years of age. Beaudart *et al.* (2014) state that the prevalence of sarcopenia varies from 9.25% to 18% depending on the cut-off points applied. When stratified by gender in the Belgium population, the prevalence of sarcopenia was mainly attributed to women where it ranged from 6.58% to 20.2% and in men from 13.4% to 14.7%. Furthermore, the authors concluded that the prevalence of sarcopenia varies widely depending on the cut-off points applied for women. In addition, Beaudart *et al.* (2014) are of the opinion that the prevalence of sarcopenia in women depends on the applied cut-off criteria proposed by the EWGSOP. In their study in the North West Province, Kruger *et al.* (2015b) found that 8.1% of black women who tested negatively for HIV are sarcopenic while when using the EWGSOP definition (Cruz-Jentoft *et al.*, 2010), the prevalence increased to 12.6%. Van Kan (2009) stated in a review of the definition and consequences of sarcopenia that the prevalence of sarcopenia is between 8% and 40% in individuals over the age of 60 years depending on population characteristics, such as ethnicity, age, setting and diagnostic methodology.

2.4.4 Health consequences of sarcopenia

Muscle loss culminates into an inability to perform certain functions, such as walking, hearing, seeing, remembering, concentrating and self-caring. The ability of elderly individuals to perform self-caring is reduced by aging (Evans, 1997). Sarcopenia is potentially a greater public health concern among women than men (Van Kan, 2009). Men on average have a higher amount of muscle mass but their lifespan is shorter (Van Kan, 2009). Higher body fat, poor physical function, lower muscle strength and higher rates of nonfatal chronic conditions are more often reported among older women than men (Tseng *et al.*, 2014). Murton (2015) indicated that when a significant loss of muscle mass occurs, individuals are at a heighted risk of fall-related fractures and their ability to live an independent life is severely compromised. Waters and Baumgartner (2011) state that the primary functional consequences of sarcopenia are the loss of muscle strength and power that can eventually lead to dysfunctions and an increased risk for falls. Leg muscle weaknesses and a decrease in peak torque and power are associated with impaired walking abilities, such as small steps and a slow walk speed.

Strength is essential to the neuromuscular function that supports mobility. Falls are a serious consequence due to the loss of muscle mass (Morley *et al.*, 2005). Moreover; a loss in

strength below a critical threshold can be associated with an increased risk of falls (Goodpaster *et al.*, 2006; Deutz *et al.*, 2014). Janssen (2006) maintains that older men with sarcopenia have a two-fold greater likelihood of functional impairments and disabilities compared to older men with a normal muscle mass. Older women with sarcopenia are three times more likely compared to non-sarcopenic women to experience functional impairments and disabilities (Janssen, 2006).

A decline in lean body mass and total body water supplemented by an upsurge in body fat are the most relevant changes in body composition leading to a reduction of the basal metabolic rate (Elmadfa & Meyer, 2008). Elderly people are generally less active and their energy needs are lower due to changes in body composition. An age-related reduction in the activities of antioxidant enzymes and an adequate supply of dietary antioxidants are important. Oxidative damage can contribute to processes related with aging and can promote CVD, cognitive disorders, cancer and diabetes mellitus that occur more frequently in older people (Villareal *et al.*, 2005; Elmadfa & Meyer, 2008).

2.4.5 Sarcopenic obesity (SO)

2.4.5.1 Definition of sarcopenic obesity

Baumgartner *et al.* (2004) define SO as a height-adjusted appendicular (arms and legs) skeletal muscle mass of two standard deviations or more below the sex-specific mean for a young adult reference population coupled with a percentage body fat greater than the sex-specific median for older adults. The lack of consensus regarding the definition of this condition means that the true prevalence of SO is unknown (Stephen, 2008). SO has typically been considered in terms of high body fat coupled with low muscle mass rather than in terms of low muscle strength (Tian & Xu, 2016). Roubenoff and Castaneda (2001) purport that age-related body composition change and the increased prevalence of obesity in the elderly produce a combination of excess weight and reduced muscle mass and/or strength. Tian and Xu (2016) are of the opinion that many prospective studies have investigated the relationship between SO and mortality risks. Furthermore, the few published studies define SO by making use of a variety of approaches (Davison *et al.*, 2002; Baumgartner *et al.*, 2004; Zoico *et al.*, 2004).

2.4.5.2 Classification and prevalence of sarcopenic obesity

The prevalence of sarcopenia and SO increases with age. In studies using muscle mass as an indicator of sarcopenia, the prevalence of SO ranged from 4% to 12% (Davison *et al.*, 2002; Baumgartner *et al.*, 2004; Zoico *et al.*, 2004). Based on BMI and HGS measurements

in epidemiological studies, SO can be roughly estimated between 4 and 9% (Stenholm *et al.*, 2008). A Korean study in 2009 wherein adults (n=2221) older than 60 years participated, found the prevalence rate of SO to be 6.1% in men and 7.3% in women (Hwang *et al.*, 2012).

Muscle and fat mass are strongly interconnected from a pathogenetic point of view. An imbalance between obesity and muscle impairment —either defined by low muscle mass or poor muscle strength—is associated with negative health outcomes in older individuals. Recent data suggest that peptides produced by adipose tissue may play an important role in the pathophysiology of SO and more research is, therefore, needed in this new area (Zamboni *et al.*, 2008). Given the age-related changes in body composition, obesity, low muscle mass and low muscle strength may coexist in individuals. However, evidence has shown a causal link between obesity and low strength. Cederholm *et al.* (2016) highlight that there are not yet commonly accepted criteria available for SO beyond the current criteria for sarcopenia and obesity, respectively. Table 2.4 provides details of different SO definitions and prevalence from three different studies in a comparison made by Stenholm *et al.* (2008).

Table 2.4 Comparison of different SO definitions and prevalence

Study	Definition of SO	Number of participants (N)	Mean age in years (SD)	Prevalence
Baumgartner *et al.* (2004)	− Sarcopenia: skeletal muscle mass -2 SD below mean of young population or <7.26 kg/m^2 in men and < 5.45 kg/m^2 in women. − Obesity: percentage body fat greater than median or >27% in men and >38% in women.	831	60 and over	M: 4.4% F: 3.0%
Davison *et al.* (2002)	− Sarcopenia: two lower quintiles of muscle mass (<9.12 kg/m^2 in men and <6.53 kg/m^2 in women). − Obesity: two highest quintiles of fat mass (>37.16% in men and >40.01% in women).	M: 1391 F: 1591	M: 76.3 (1.7†) F: 77.3 (2.2†)	M: 9.6% F: 7.4%
Zoico *et al.* (2004)	− Sarcopenia: two lower quintiles of muscle mass index (<5.7 kg/m^2). − Obesity: two highest quintiles of fat mass (>42.9%), women only.	F: 167	71.7 (2.4)	F: 12.4%

** Age and gender adjusted prevalence. †Standard error. F female. M male. SD standard deviation. (Adapted from Stenholm et al., 2008).*

2.4.5.3 Health consequences of sarcopenic obesity

Obesity and sarcopenia in the elderly may potentiate each by maximising their effects on disabilities, morbidity and mortality (Zamboni *et al.*, 2008). Davison *et al.* (2002); Zoico *et al.* (2004) and Baumgartner *et al.* (2004) reported that limited literature regarding the health consequences of SO shows that sarcopenic-obese individuals are at an increased risk of functional impairments and physical disabilities. Nicklas *et al.* (2004) maintain that obesity, particularly abdominal and visceral obesity, contributes to numerous cardiometabolic health problems, such as insulin resistance, type 2 diabetes, dyslipidaemia and CVD. Likewise, a low muscle mass and low strength are associated with CVD risk factors, including arterial stiffness, glucose intolerance and the metabolic syndrome (Nicklas *et al.*, 2004).

Since both obesity and low muscle mass/low strength predict cardiovascular risk factors and outcomes in the elderly, it is possible that a combination of obesity and sarcopenia can be associated with an even greater risk of reduced physical functions (Baumgartner *et al.*, 2004). Fat infiltration into muscle is associated with lower muscle strength and lower leg muscle performance (Stenholm *et al.*, 2008). Table 2.5 presents the different characteristics of the phenotype of body composition adapted from Waters *et al.* (2010). The link between sarcopenia and obesity during aging is shown in Figure 2.1, adapted from Zamboni *et al.* (2008).

Table 2.5 Body composition phenotype characteristics

	Sarcopenic	**Obese**	**Sarcopenic obese**
Body mass (kg)	Low	High	Normal
Fat mass (kg)	Low/ normal	High	High
SMM (g)	Low	Normal/ high	Low
BMI (kg/m^2)	Low	High	Normal
Waist circumference (cm)	Low/ normal	High	Normal/ high

SMM: skeletal muscle mass; BMI: body mass index. (Adapted from Stenholm *et al.*, 2008).

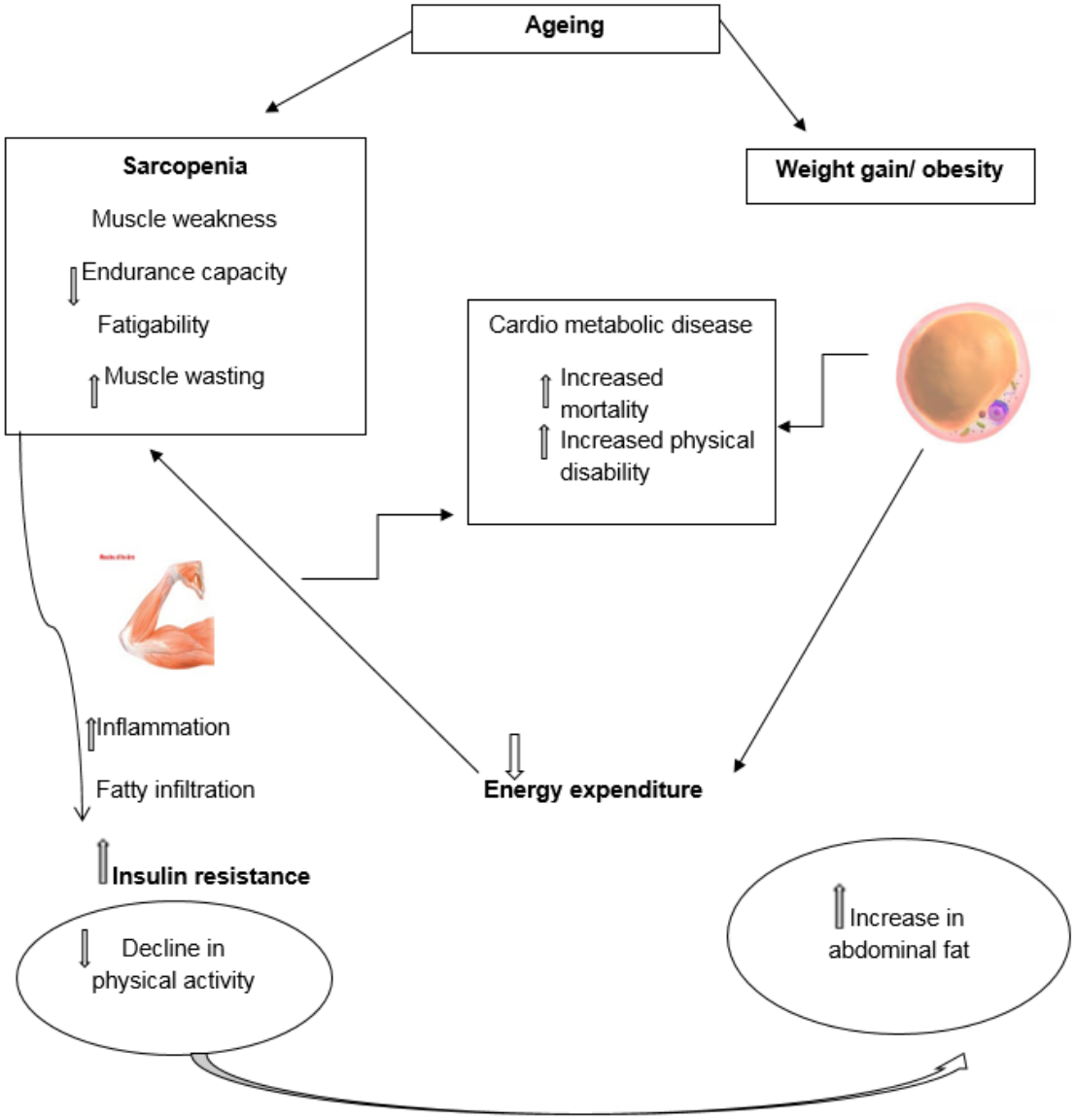


Figure 2.1 **The link between sarcopenia and obesity with sarcopenic obesity during ageing. (Adapted from Zamboni *et al.*, 2008).**

2.5 The measurement of body composition

2.5.1 Anthropometry

Anthropometry is the study of measurements of the size, proportions and composition of the human body (World Health Organisation, 2002). It involves collecting statistics or measurements relevant to the human body, called anthropometric data. Anthropometric measurements are a set of non-invasive, quantitative techniques used to measure, record, and analyse the dimensions of a human body, such as height and weight, skin-fold thickness and body circumference at the waist, hip and chest in adults (Zamboni *et al.*, 2008). These measurements are then compared to reference standards to assess weight status and the risk for various diseases. An anthropometric evaluation is an essential feature of the nutritional evaluations of elderly individuals for determining malnutrition, being overweight or obese; to determine muscular mass loss, fat mass gain and adipose tissue redistribution. Anthropometric indicators are used to assess the prognosis of chronic and acute diseases and to guide medical intervention in the elderly (Sánchez-García *et al.*, 2007). Landi *et al.* (2014) reported that lean body mass loss has been indicated as a reliable marker of frailty and poor physical performance among older individuals.

Calf circumference correlates positively with muscle mass (Landi *et al.*, 2014; Díaz-Villegas *et al.*, 2016) and is a potential marker of physical function. Calf circumference is regarded as an inexpensive, simple, non-invasive measurement performed by clinicians and relevant in the screening for sarcopenia (Landi *et al.*, 2014). Furthermore, Díaz-Villegas *et al.* (2016) are of the opinion that CC is related to sarcopenia in older people and this condition is associated with falls. However, Tsai *et al.* (2012) maintain that the role of CC in the incidence of falls is still unclear but a clinical association between frailty and sarcopenia and nutritional or anthropometric variables is frequently recognised. In patients suffering from malnutrition, CC is considered as a good muscle measuring approach, because the lower limbs contain almost half of the body's muscle mass and has a direct impact on walk performance (Tsai *et al.*, 2012). Landi *et al.* (2014) suggest that among older subjects living in a community, a high CC is associated with a lower level of frailty and better functional performance. Their findings support, therefore, the hypothesis that muscle mass is strongly implicated in the process of independent living during aging. CC, therefore, correlates with muscle mass and a CC value of 31 cm or less is usually associated with a lack in functional capacity (Landi *et al.*, 2014).

2.5.2 Dual-energy X-ray absorptiometry

Dual-energy X-ray absorptiometry is widely applied as the standard method to measure appendicular skeletal muscle (ASM) mass in evaluating sarcopenia, and is an important pointer for determining sarcopenia. However, the DXA method is inappropriate for health checks in a field setting or large epidemiological studies due to the costly, non-portable equipment that is required and the danger of radiation exposure (Kawakami *et al.*, 2015). A simplified tool is, therefore, necessary for the clinical assessment of sarcopenia. Stenholm *et al.* (2008) state that although there are no generally accepted criteria for low muscle strength, measuring strength is easier and cheaper than measuring muscle mass. The use of more sophisticated methods, such as DXA or computed tomography, should also be considered an option in more thorough clinical examinations and especially in establishing the effectiveness of interventions. Previous studies have shown that CC has a positive correlation with DXA used to measure ASM (Landi *et al.*, 2014). Calf circumference is, therefore, a valuable tool for guiding public health policies and clinical decisions. Table 2.6 presents body composition measurement methods used for assessing sarcopenia:

Table 2.6 Measurements of muscle mass, strength and function in research and practice (Adapted from Cruz-Jentoft *et al.,* 2010).

Variable	Research	Clinical practice
Muscle mass	Computed tomography (CT)	BIA
	Magnetic resonance imaging (MRI)	DXA
	Dual-energy X-ray absorptiometry (DXA)	Anthropometry
	Bio impedance analysis (BIA)	
	Total or partial body potassium per fat-free soft tissue	
Muscle strength	HGS	HGS
	Peak expiratory flow	
	Flexion/extension: knee, hip, shoulder and elbow motions	
Muscle endurance	Knee flexion/extension, isokinetic testing	Isokinetic testing
Physical performance	Short Physical Performance Battery (SPPB)	SPPB
	Usual walk speed	Usual walk speed
	Timed get-up-and-go test	Get-up-and-go test

Variable	Research	Clinical practice
	Stair climb power test	

2.6 Physical performance

Physical performance is an indication of the size, shape, sex and age of individuals. In addition, physical performance is the capacity of individuals to execute specific actions that are needed for daily living activities or PA (Caspersen *et al.*, 1985; van Lummel *et al.*, 2015). Physical performance includes balance, muscle strength and endurance and has increasingly been recognised as a powerful factor in the prevention and treatment of a number of health conditions in older adults and can be measured objectively with physical performance tests (Haskell *et al.*, 2009; Roshanravan *et al.*, 2013; van Lummel *et al.*, 2015).

2.6.1 Link between physical performance and physical activity

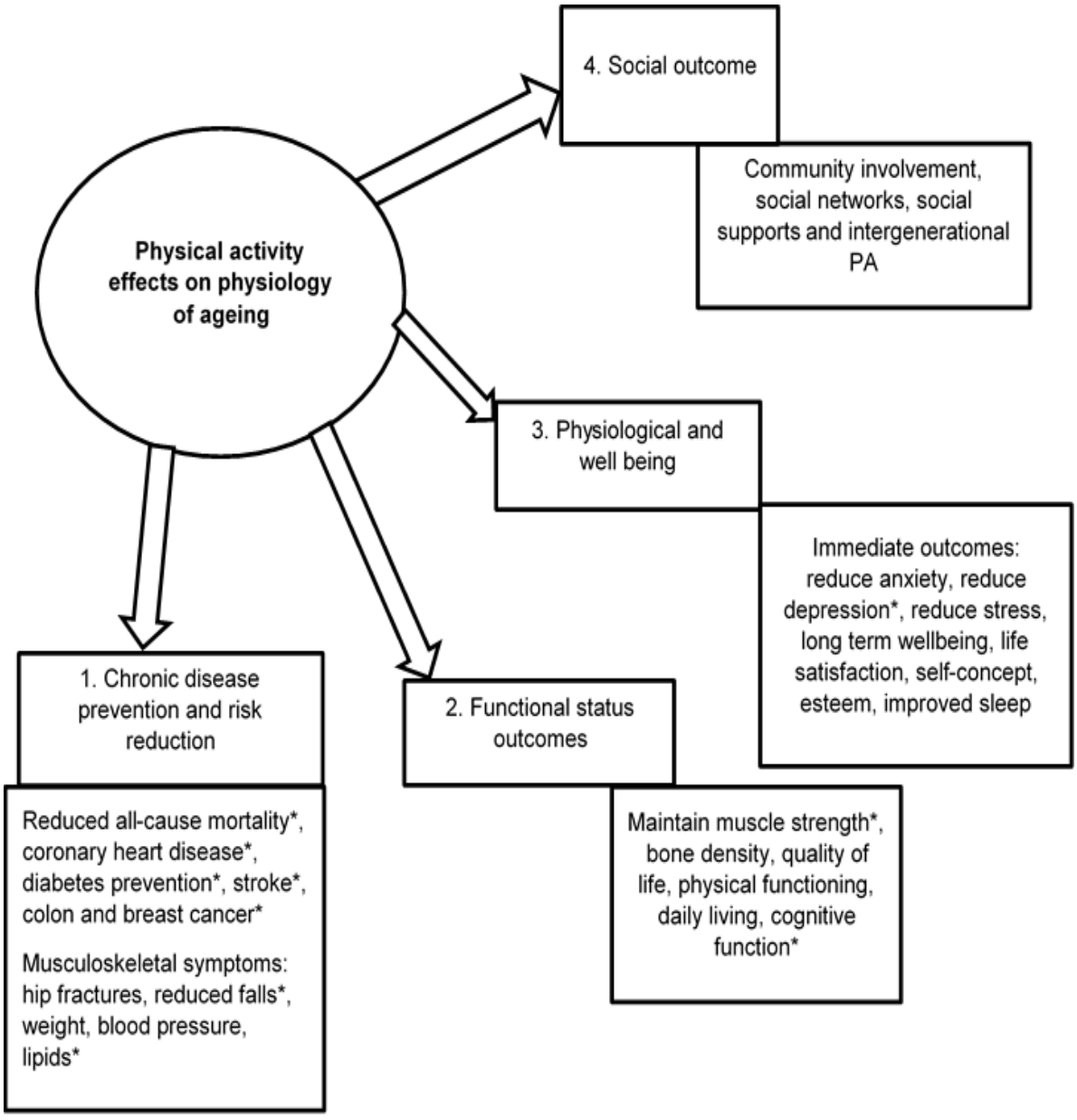
Physical performance and PA both signify the associated but separate domain of physical function and this domain proposes that an improvement in physical performance does not automatically indicate an increase in PA (Haskell *et al.*, 2009; van Lummel *et al.*, 2015). PA, exercise and physical fitness are terms that define different theories and are often confused with one another and sometimes used interchangeably (Caspersen *et al.*, 1985; Gibney *et al.*, 2004). PA is defined as any bodily movement produced by skeletal muscles that result in the spending of energy. In daily life, PA can be categorised into occupational, sports, conditioning and household activities (Waters *et al.*, 2010). Exercise is a subset of PA that is deliberate, organised and repetitive and the intermediate objective is the improvement or maintenance of physical fitness. Physical fitness is a set of traits that are either health-related or skill-related and the degree to which individuals have these attributes can be measured with specific tests (Caspersen *et al.*, 1985).

2.6.2 Physical activity

Physical activity can be positively linked to lower fat mass and an increase in muscular strength and function and has been recognised as a key lifestyle factor to prevent and delay muscle loss and obesity during ageing (Cauley, 2015; Lee *et al.*, 2016). Shisana *et al.* (2013) revealed from the South African National Health and Nutrition Examination Survey (SANHANES-1) that 27.9% males and 45.2% females between the ages of 18-40 years are physically unfit. However, the PA levels of participants were not measured. These high unfit levels in the SA populations is an indication of low levels of PA. A total physical activity index (PAI) can be calculated by combining indices, such as commuting, stair climbing, sport participation, occupational activities and leisure time activities (Kruger *et al.*, 2000; Kruger *et*

al., 2002a). In the THUSA study, Kruger *et al.* (2002a) found that 29% of the participants were physical inactive and 28% were moderately active. In addition, women in urban areas were more physically active than women in rural areas.

Physical activity is associated with many health and psychological benefits (Warburton *et al.*, 2006) as illustrated in Figure 2.2:



**Strong epidemiological evidence.*

Figure 2.2 **A conceptual framework to illustrate the benefits of PA *(Adapted from Warburton et al., 2006).***

Participation in PA is associated with a low risk for coronary heart disease, type 2 diabetes, obesity, hypertension, osteoporosis, depression and anxiety (Martínez-González *et al.*, 2005). Low levels of PA are associated with a higher BMI and both factors contribute to the risk of developing obesity due to low energy expenditure and a negative influence on energy balance (Fogelholm & Kukkonen-Harjula, 2000; Stessman *et al.*, 2000). This in turn increases the risk of obesity and other related chronic diseases (Vorster *et al.*, 2000; Kruger *et al.*, 2005; Bennell *et al.*, 2011). Moreover, PA is associated with a decreased burden of diseases, particularly chronic diseases, such as coronary artery disease and osteoporosis and offers health benefits to people of all ages (Fogelholm & Kukkonen-Harjula, 2000; Stessman *et al.*, 2000; Stephen, 2008). Waters *et al.* (2010) state that PA can slow the loss of skeletal muscle and function. The most compelling evidence to combat sarcopenia is either PA alone or in combination with nutritional supplements (Waters *et al.*, 2010). Lack of PA can show disuse atrophy with sarcopenia and associated impaired physical performance as an endpoint (Sowers *et al.*, 2005; Kruger *et al.*, 2016). In a South African study, sarcopenic participants showed significantly lower HGS and the trend of a lower walk speed than non-sarcopenic women. PA can, therefore, be viewed as a protective measure against sarcopenia in these black women (Kruger *et al.* (2016). In the THUSA study, Kruger *et al.* (2002b) found that PA shows a significant negative association with BMI and may be one of the most important factors affecting BMI as an index of obesity among black South African women. The relationship between PA and SO is presented in Figure 2.3:

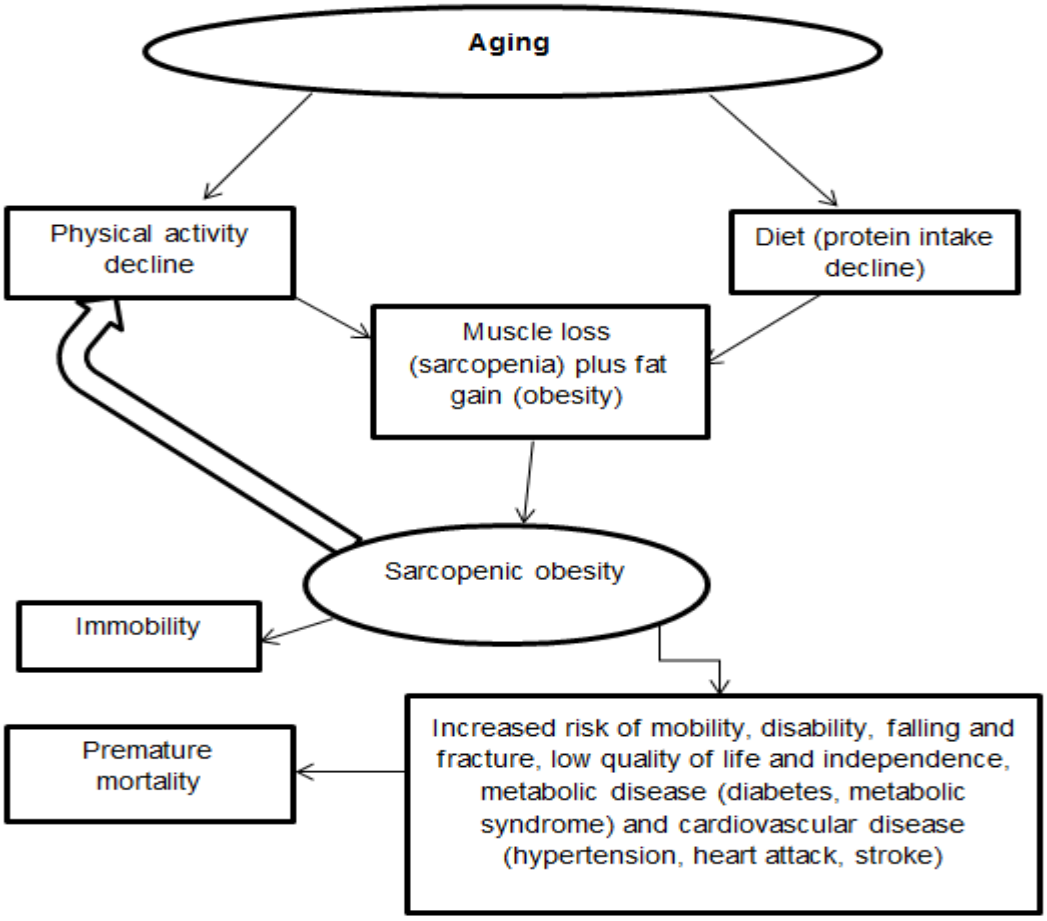


Figure 2.3 Relationship between PA and SO *(Adapted from* Waters *et al.,* 2010).

The Centers for Disease Control and Prevention (2014) in the United States of America provide PA guidelines for older adults (65 years and older). These guidelines recommend that in order to stay healthy, adults should try to be active on a daily basis and should do at least 150 minutes of moderate aerobic activity such as cycling or fast walking every week combined with strength exercises on two or more days a week that work all the major muscles (legs, hips, back, abdomen, chest, shoulders and arms). The same guidelines also recommend 75 minutes of vigorous aerobic activity, such as running or a game of singles tennis every week and strength exercises on two or more days a week that work all the major muscles (legs, hips, back, abdomen, chest, shoulders and arms) (Bauman *et al.*, 2016). A mix of moderate and vigorous aerobic activity every week, for example, two 30-minute runs plus 30 minutes of fast walking equates to 150 minutes of moderate aerobic activity, and strength exercises on two or more days a week that work all the major muscles (legs, hips, back, abdomen, chest, shoulders and arms) is highly recommended. A good rule is that one minute of vigorous activity provides the same health benefits as two minutes of

moderate activity (World Health Organization, 2008). One way to do the recommended 150 minutes of weekly PA, is to do 30 minutes per day in one week. In general, 75 minutes of vigorous activity can provide similar health benefits as 150 minutes of moderate activity. Older adults with chronic diseases should be as physically active as their abilities and conditions allow (Sparling *et al.*, 2015).

PA questionnaires are the most frequently used method to estimate PA and this method is considered reliable for large epidemiological studies, because the duration of PA can be reported in terms of time spent in each activity (Martínez-González *et al.*, 2005). Berlin *et al.* (2006) are of the opinion that PA assessments are necessary to identify the presence of physical inactivity, to set goals for physical therapy interventions to increase PA, to provide incentives to propose recommendations for increasing PA, and to utilise PA as an outcome measure for physical therapy interventions.

2.6.3 Physical performance tests

The chair stand test is used in research studies (Lee *et al.*, 2016) to measure lower limb muscle functional strength (Tiedemann *et al.*, 2008). Participants are asked to rise from a chair to a standing position five times without using their hands. Timing is started as soon as participants rise from the chair the first time and ends when participants are standing for the fifth time. Each completed stand is counted and the success of the test and time to complete five chair stands is recorded. When participants are unable to stand even once, then the result is recorded as a fail (Rikli & Jones, 1997; Blair *et al.*, 2013). In the United States of America, neither height nor body mass was related to the time it took to get up from a chair in either males or females when healthy subjects were used between the ages of 20 to 85 years (Csuka & McCarty, 1985).

Walk speed is a popular physical function and performance test in clinical practice and research studies, because it is a fast, simple and easy way to measure predictors of mobility limitations and mortality in general populations (Toots *et al.*, 2013). Walk speed is associated with survival in older adults, both female and males (Studenski *et al.*, 2011). Alley *et al.* (2014) analysed the results of 20 847 participants who participated in 14 different studies. Strong evidence shows a threshold effect in the association between strength and walk speed, suggesting that increases in strength may have positive effects on physical function across the spectrum of strength observed in community-dwelling older adults (Alley *et al.*, 2014). The walk speed test can serve as a useful integrated measure of mobility (Harada *et al.*, 1999). The total adiposity and associated fat infiltration into muscle are important predictors of walk speed decline (Beavers *et al.*, 2013). A slow walk speed in older adults is

associated with an increased risk for disabilities and mortality (Stenholm *et al.*, 2009). Furthermore, poor muscle function is an important risk factor for reduced walk speed and is also associated with an increased risk of disabilities and death (Santanasto *et al.*, 2017).

Handgrip strength is widely used for muscle strength measurements as it is inexpensive, easy to use and well-associated with relevant health outcomes and mortality (Leong *et al.*, 2015). HGS provides a measure of muscle strength, and correlates with leg strength (Cruz-Jentoft *et al.*, 2010). HGS is strongly related with lower extremity muscle power (Cruz-Jentoft *et al.*, 2010).A small HGS is a clinical indicator of poor mobility and a better predictor of clinical outcomes than low muscle mass. A HGS declines with age and has been reported as a predictor of physical functioning and disabilities (Waters *et al.*, 2010). Leong *et al.* (2016) maintain that individual HGS measurements should be interpreted by making use of region/ethnic-specific reference ranges. Furthermore, HGS values are usually low in middle income countries, such as South Africa, compared to high income countries, such as Canada, when 125 462 participants between the ages of 35-70 years in 21 different countries were measured (Leong *et al.*, 2016). In 1997 and 1999, Taekema *et al.* (2010) conducted a study in The Netherlands with 599 patients who were 85 years and older. They concluded that a poor HGS predicts an accelerated dependency with regard to daily activities and a cognitive decline in the oldest age group. In the BELFRAIL study in Belgium, Legrand *et al.* (2013) found that low physical performance remains associated with a low HGS even after considering other risk factors for sarcopenia in the oldest age group and they support the hypothesis that low muscle strength is a better indicator of sarcopenia than low muscle mass in participants older than 80 years. Measuring HGS can be a useful instrument in geriatric practice to identify patients at risk of developing sarcopenia (Taekema *et al.*, 2010). Moreover, the international PURE study reported that HGS was associated with increased risk of mortality (Leong *et al.,* 2015).

2.7 Summary of the literature review

Few studies have determined changes in anthropometric measures over time in black adults in LMIC (Hughes *et al.*, 2004; Newman *et al.*, 2005; Chantler, 2014). No published studies have determined an association between anthropometric measures and the physical performance of black men and women in LMIC. Descriptive cross-sectional studies were recently done with only black women from South Africa (Kruger *et al.*, 2015b; Sotunde *et al.*, 2015; Kruger *et al.*, 2016). The prevalence of overweight and obese individuals in both HIC and LMIC keeps growing despite adopted policies in place to reduce individuals being overweight or obese (World Health Organization, 2013). Important functional implications are caused by obesity in both older men and women. Obesity worsens an age-related decline in

physical function and causes frailty or SO (Villareal *et al.*, 2005). Age-related changes in body composition can differ considerably with regard to age, gender, race and ethnicity (Cruz-Jentoft *et al.*, 2010; Kruger *et al.*, 2015b). Several definitions of sarcopenia are proposed by different authors (Morley *et al.*, 2005; Pathy *et al.*, 2006; Cruz-Jentoft *et al.*, 2010; Malafarina *et al.*, 2012; Batsis *et al.*, 2014) but accepted definitions include muscle mass, strength and function (Studenski *et al.*, 2014). The prevalence of sarcopenia and SO varies in study populations even when similar methods are applied. Black women are found not to be protected from sarcopenia when South African cut-off points are applied using DXA to measure ASM (Kruger *et al.*, 2016). A combination of high muscle mass and low fat mass is considered a healthy body composition while obesity represents a high fat mass and sarcopenia represents a low muscle mass and low strength (Lee *et al.*, 2016).

Calf circumference is a valuable tool for guiding public health policies and clinical decisions (Díaz-Villegas *et al.*, 2016). Unlike DXA, is CC inexpensive and suitable for use in cohort studies and a reliable tool in the screening for sarcopenia (Deurenberg *et al.*, 2002; Landi *et al.*, 2014). Moderate weight loss in conjunction with PA improve physical function and a health-related quality of life in obese older individuals (Villareal *et al.*, 2005). Future research is, however, needed to diagnose obesity and sarcopenia in both black men and women by making use of research methods described by Cruz-Jentoft *et al.* (2010), such as BIA and DXA in order to determine a possible association between muscle mass and physical performance tests in black populations in LMIC. Currently, a paucity of information exists regarding the relationship between sarcopenia, obesity and physical performance among African populations (Moreira *et al.*, 2016b). The aim of the study was, therefore, to determine an association between anthropometric measures and physical performance in adult black men and women in the North West Province, South Africa.

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CHAPTER 3 METHODOLOGY

3.1 Introduction

This chapter describes in detail the methods that were used in this study to collect and analyse the data, including the study design, sample size, inclusion and exclusion criteria, data collection procedures, statistical methods and ethical considerations. All of the Prospective Urban and Rural Epidemiology Study South Africa (PURE-SA) measurements were completed in 2015. The protocol for the larger study (see Addendum A) was used for this affiliated study. The PURE-SA study received ethical approval from the Ethics Committee of the North-West University, Potchefstroom Campus, Faculty of Health Sciences in 2005 and 2010 and from the Health Research Ethics Committee (HREC) and the North West Department of Health in 2015. Only the 2015 ethical clearance is attached (see Addendum B). In 2016, the affiliated study also received ethical clearance from the HREC and the certificate is attached (see Addendum C).

3.2 Study design

A prospective cohort study design was followed. Spark *et al.* (2015) state that cohort or follow-up studies follow a large number of people over time to study the information gathered. Moreover, in prospective cohort studies, a large number of people are grouped together and followed over a period of time to compare outcomes concerning those with the highest exposure to particular conditions and those with the lowest rates of exposure (Spark *et al.*, 2015). The strength of this study design is that it enables researchers to assess a number of diseases or outcomes associated with the exposure being studied and the exposure is measured before these diseases have occurred. Components of strengths tests performed in 2015 and changes in BMI, CC and self-reported PA over ten years were determined in this affiliated study. Quantitative research methods were used.

3.3 Population and setting

In this cohort study, black adults who were HIV negative (n=803) (559 women and 244 men aged between 32–93 years) participated in the PURE-SA study at baseline from both rural and urban areas in 2005. Participants were followed-up annually by fieldworkers to ensure retention in this longitudinal study. Body mass, height, BMI, CC and PA were collected from participants in the North West Province, Ganyesa rural areas and Ikageng urban areas at baseline in 2005 and in 2010. Participants returned for follow-up visits in 2015. A total of 742 individuals (512 women and 230 men) were followed up after ten years. In 2015, the participants completed chair stand, six (6) meter

walk and HGS tests together with the measurements done in 2005 and 2010 (body mass, height, BMI, CC and PA).

The main criterion for selection was the migration stability of the selected urban and rural communities. Participant recruitment was conducted in four different areas. Community A is a rural community located 450 km west of Potchefstroom on the highway to Botswana. Community B is a deep rural community that can only be reached via a gravel road 35 km east of Community A. Community C (Ikageng) forms part of the greater Potchefstroom and Community D the surrounding informal settlements. The Ikageng urban area lies within the boundaries of Tlokwe Municipality, one of the four municipalities in the Dr Kenneth Kaunda District. Tlokwe Municipality is situated about 120 km from Johannesburg and 45 km from Klerksdorp. Ganyesa is in the far North Western area of the North West Province and falls under Dr Ruth Segomotsi Mompati District in the Kagisano or Molopo Municipality. The local language is Setswana and Ganyesa is dominated by black people. The estimated population living there was around 19 000 in 2005. Ganyesa is 70 km from Vryburg − the seat of the district in the North West Province, South Africa − 70 km from the Botswana border and 30 km from the Tlakgameng rural area.

3.4 Recruitment of participants

A household census concerning the number of people, their ages and health profiles was conducted randomly in 6000 houses (1500 in each community) by trained fieldworkers. Two questionnaires were completed during the household census – a family questionnaire and a household questionnaire. The family questionnaire contained questions concerning the number of people in a household, their ages and health profile (Leong *et al.*, 2015). This questionnaire was necessary so that all participants eligible to participate in the study could be identified. The household questionnaire included questions regarding the socio-economic status of a household. Signed consent was given by every head of a household. In the case where an individual refused to take part or was not home, the fieldworkers filled in a non-compliance questionnaire and moved on to the next house. This process was repeated until 1500 households from each community were included.

3.5 Inclusion and exclusion criteria

In 2005, the census provided the necessary data to perform a paper-based selection of possible participants and was based on inclusion and exclusion criteria. Table 3.1 presents the criteria used for including and excluding participants in the study. Inclusion criteria included participants in the age range of 29-93 years in 2005. A large percentage

of the participants used chronic medication for hypertension and a smaller percentage used chronic medication for type 2 diabetes.

Table 3.1 Inclusion and exclusion criteria for the PURE-SA project

Inclusion criteria	Exclusion criteria
≥35 years of age	<35 years of age
≤70 years of age	>70 years of age
Males and females	
No reported diseases of lifestyle, TB or HIV positive	Use chronic medication
No chronic medication	Existing chronic conditions
Eligible participants should reside in households in Communities A, B, C or D	

The reason for including participants on chronic medication was that the exclusion of these individuals would have resulted in a biased sample, because almost 60% of the older adult population in these areas were already using antihypertensive medication. For the statistical analysis of the affiliated study, participants who were HIV positive were excluded from the study due to the known effects of an HIV infection on body composition and physical performance (Greene *et al.*, 2014). After the exclusion of participants who were HIV positive, the data consisted of 1057 participants who were HIV negative (368 men and 689 women) between the ages of 32–93 years from both the rural and urban areas who participated in the PURE-SA study at baseline in 2005. Participants who were HIV positive were, however, included in the PURE-SA larger study.

Inclusion criteria for the current study

- Between the ages of 32–93 years
- HIV negative in 2015
- Males and females
- Resides in the study communities for the PURE North West Province, South Africa study.

Exclusion criteria for the current study

- Below 32 years or older than 93 years
- HIV positive in 2015.

3.6 Sample and sampling procedure

The target population was 2000 black men and women from the Ganyesa rural area (n=1000) and Ikageng urban area (n=1000). Stratified sampling was used to ensure that different groups (gender, age, communities) within the target population were recruited on purpose to become part of the sample. This sampling method is one of the probability random sampling methods that ensure that the sample is representative of the population and each individual in the study setting has an equal chance to form part of the study. According to Spark *et al.* (2015), this method provides a more precise estimate of a target population. It also ensures a representative sample by including all strata-specific and stratum-specific estimates (Naidoo, 2015). Door to door home visits were done by fieldworkers in both the rural and urban areas to recruit individuals from selected households to participate in the study. In 2005, a total of 2010 individuals from the rural (n=1006) and urban (n=1004) areas between the ages of 32 and 93 years participated in the PURE-SA study. 1428 participants were available after excluding the participants who were HIV positive, displaying incomplete data and women who were pregnant. In 2015, 926 individuals returned for a follow-up and 774 participants remained after participants who were HIV positive were excluded.

To determine the changes in anthropometric measures from 2005 to 2015 (three repeated measurements) and assuming the correlation among repeated measurements is equal to at least 0.5, the study should have been able to detect an effect size of 0.04 with a power of 80% given a sample size of 774 and a significance level set at 0.05.

3.7 Informed consent and instruments

Both the fieldworkers and researchers explained the research to the participants. Continual consent was obtained every five years as a symbol of showing respect to each of the participants. The fieldworkers discussed informed consent with the participants and the form was also left with the participants. When the participants indicated interest, appointments were made to visit the research site where they were once again informed of the research and time was made available for questions. Informed consent was then signed by each of the participants with an independent person being present at the same time in 2005, 2010 and 2015 (see Addendum D). A translator was present at all times.

After all the measurements were completed and all of the participants signed their informed consent form, measurements were recorded on the data collection form (see Addendum E). Privacy was ensured by using a special closed off area and two people were present at all times during measurements. Body mass, height, CC, chair stand, six meter walk and HGS were recorded. A questionnaire was used to measure a PA index score as described in section 3.8.3.

3.8 Data collection procedure

3.8.1 Anthropometric measurements

After all of the measurements were taken at least twice, according to the International Society for the Advancement of Kinanthropometry (ISAK) guidelines, the average of the two closest measurements was recorded (Beneke, 2009). The measurements were recorded on the anthropometric data collection form (see Addendum E).

- **Body mass**

The Tanita Ironman Inner Scan BIA (model BC-554) was used for measuring body mass. The scale was placed on an even, uncarpeted area and levelled with the aid of its in-built spirit level and calibrated prior to each measurement day. The researchers switched on the scale and waited for a zero indication (0.00) before each of the participants were weighed. The participants were weighed (after fasting and preferably after emptying their bladder) and with the minimum of clothing on and no shoes.

The participants were asked to step onto the scale while standing still in an upright position in the middle of the platform. They were requested to face forward while looking straight ahead with their arms hanging freely at their sides ISAK, 2001. After the readings were recorded in the space provided on the form, the participants were then asked to step off the scale. Weight was recorded to the nearest 0.01 kg. Weight measurement was repeated and when the two readings varied by more than 10 g, the measurements were repeated until two similar weight readings were obtained.

- **Height**

Height was taken by making use of a stadiometer (Leicester Height Measure, model MkII). The participants were asked to remove their heavy clothes, shoes and hats. The stadiometer was placed on an even, uncarpeted area. In cases where the hair of participants was tied up on the top of their head, participants were asked to release their hair. The participants were asked to step on the stadiometer facing forward with their head in the Frankfort horizontal plane: shoulders relaxed with shoulder blades, buttocks and heels touching the measuring board; arms relaxed at their sides; legs straight; knees together; feet flat; and heels touching each other. The headpiece was slid down until it touched the crown of the head of participants. Height was taken twice and recorded to the nearest 0.1 cm after participants inhaled fully and maintained an erect position without altering their feet load (ISAK, 2001). When two measurements differed by more than 1 cm, a third measurement was taken and the two measurements nearest to each other were recorded and the average was used for the analysis. BMI was derived by dividing body mass in kilogrammes over height in meter squared (W (kg)/H (m^2)).

- **Calf circumference (CC)**

A non-stretchable tape measure (KDS measure, model F10-02DM 2m) was used to take measurements. The participants were asked to remove their shoes and socks prior to measuring their CC and the participants wore minimal clothing. Measurements were taken while participants were standing relaxed with their arms hanging at their sides and their feet separated feet—the right foot placed on the floor (ISAK, 2001). CC was measured at the maximal right calf girth while participants were standing. The measuring tape was placed around the calf and moved to locate the maximum circumference in a plane perpendicular to the long axis of the calf. The zero was held on the end of the tape below the measurement value—snugly, but not too tight—and the results were recorded to the nearest 0.1 cm. Two measurements were taken and when these two measurements differed by more than 3 cm, a third measurement was taken. The two measurements nearest to each other were recorded and the average was used for the analysis (ISAK, 2001).

3.8.2 Demographic and health information

Questionnaires were administered in the preferred language of the participants (Afrikaans, English or Setswana) by trained fieldworkers residing in the study setting. Information regarding age, ethnicity, gender, marital status, level of education, occupation and employment status were collected. Socio-economic background, lifestyle practices, physiological health and support, current habits, such as the use of tobacco, alcohol and medication, were also collected by trained fieldworkers from participants in 2005, 2010 and 2015 (Richter *et al.*, 2014; Kruger *et al.*, 2015b).

3.8.3 Physical activity questionnaire

A PA questionnaire is the most frequently used method to estimate PA and is useful during large epidemiological studies (Martínez-González *et al.*, 2005). The Transition of Health during Urbanization in South Africa (THUSA) physical activity questionnaire (THUSA-PAQ) was compiled from a form of the Baecke PA questionnaire, which was used to determine the PA levels of Tswana-speaking people in the North West Province (Baecke *et al.*, 1982; Kruger *et al.*, 2000; Kruger *et al.*, 2005). The questionnaire reports PA in the form of commuting, stair climbing, sport participation, occupational activities and leisure time activities and the total PAI is calculated by combining the above-mentioned indices. A PAI score of 1-3.33 is classified as low, 3.34–6-67 as moderate and >6.67 as high (Kruger *et al.*, 2002a). Duration, frequency and intensity of these activities were reported by trained biokinetic students in the preferred language of the participants (see Addendum F).

3.8.4 Physical performance tests

Physical performance was assessed by making use of three different tests: chair stand test, walk speed (gait speed) over 6 m and HGS. The researcher described and demonstrated each test, and then observed and assessed the ability of each participant in attempting to complete these tasks. The results of the tests were recorded in the section for anthropometric data on the form (see Addendum E).

- **Chair stand test**

A 45 cm high straight, armless back chair was placed against the wall in order to avoid any sliding movements. A stopwatch was used for this test. The participants were requested to wear comfortable footwear or could complete this test barefoot. The participants were instructed to sit on the chair with folded arms crossed at the wrists and held close to their chest (across their chest) with their feet flat on the floor, shoulder width apart and their knees flexed slightly more than 90 degrees. The researcher stood close to the side of the chair as a safety precaution. From a sitting position, the participants were asked to stand up completely with their hips and knees fully extended, and were then asked to completely sit back down touching the seat. The participants were asked to rise from the chair to a standing position five times without using their hands to support themselves. Timing was started as soon as the participants rose the first time and ended when the participants were standing for the fifth time. Each completed stand was counted and the success of the test and time to complete five chair stands were recorded. When the participants could not stand even once, then the results were recorded as a fail (Rikli & Jones, 1997; Blair *et al.*, 2013). This test measures lower limb muscle functional strength and is used to assess how long it takes for individuals to stand up from a chair and return to a seated position five times consecutively (Tiedemann *et al.*, 2008).

- **Walk speed over 6 m**

This test was performed on a flat surface with the participants wearing comfortable footwear and they were allowed to make use of their customary walking aid if needed. For those who needed to sit down during the test due to exhaustion, a chair was provided in the test area. The participants started with both feet on the starting line and on start the participants had to walk as fast as they could—safely and not running—to the 6 m line. The time it took the participants to complete a 6 m walk was recorded with a stopwatch to calculate walk speed in m/s: the distance divided by the time it took the participants to reach 6 m (Rikli & Jones, 1997; Bennell & Hinman, 2011; Studenski *et al.*, 2011).

- **Handgrip strength**

The handgrip Jamar dynamometer (Model 78010 & 78011, Lafayette Instruments), a straight-backed chair and a stopwatch were used for the HGS test. The handgrip dynamometer was set to “0” (zero) for each measurement. The dynamometer can be adjusted was adjusted to avoid any discomfort. The participants used their dominant hand to perform this test while seated on the chair. They were asked to hold the dynamometer slightly away from the chair so that it does not rest on their thighs. The participants were then asked to press the dynamometer as hard as they could and they were asked to sustain the pressure for 5 seconds. They were asked to repeat the measurement twice at intervals of at least 30 seconds (a total of three measurements). When the first and second tests were more than 5 kg apart, the first and second results were recorded. HGS was measured by making use of the dominant hand and a maximum of three repeated measurements were recorded (Taekema *et al.*, 2010; Cooper *et al.*, 2013; Alley *et al.*, 2014). HGS is a measure of maximum voluntary force of the hand, and can be described as the simplest method to assess muscle function (Bohannon, 2001). HGS is also an appealing method to stratify the risk of individuals of developing CVD or their susceptibility to death from an incident illness (Leong *et al.*, 2016).

3.9 Data management system

3.9.1 Research monitoring

Research was regularly monitored by trained fieldworkers to improve the sustained quality of collected data. The study leader and coordinators of the larger study made sure that all of the participants who came on a particular day completed all of the measurements and questionnaires by checking the checklist card on the participant forms. This was done after all the measurements and questionnaires were completed. The researchers and fieldworkers signed the checklist to indicate that the participants completed all of the tests, questionnaires and measurements. When the participants did not complete all of the measurements, the study leader and coordinator took these participants to the right station so that all of the measurements were completed. The principal investigator of this affiliated study also paid visits to the research facilities ensuring the correctness of measurements taken, and that all anthropometric measurements were taken according to the ISAK principles and the protocol of the larger study. The principal investigator of this affiliated study provided clarity and guidance when necessary.

Every morning before the first participant was measured, the instruments (weighing scale and stadiometer) were calibrated in a secured, stable and horizontal position on the floor.

A 10 kg weight was used for the calibration of the weight scale and a calibration rod of 100 cm was used to calibrate the stadiometer. The calliper and dynamometer were set to zero. Prior to taking measurements, the procedures of taking measurements were explained to the participants. After all the measurements were completed for the day, the instruments, such as the weight scale, stadiometer and non-stretchable tape measure, were cleaned with wet wipes and securely packed. The batteries were removed over weekends. The research team adhered to the North-West University's monitoring guideline provided by the HREC. An HREC annual progress report was completed. Researchers also adhered to the HREC's guidelines with regard to amendments.

3.9.2 Data entries

Microsoft Excel 2010 was used for data entries in 2015. The anthropometric data were entered by a trained data capturer. Prior to the analysis, the data were checked for missing values, inconsistencies, the presence of outliers and carefully cleaned to ensure quality and consistency and were then exported to the computer programme, Statistical Package of Social Sciences (SPSS version 23.0). Furthermore, data collection forms were viewed to check if outliers were a result of wrong values being entered or wrong measurements. All of the data were cleaned in Excel by removing invalid values and zeros and marking missing values.

3.9.3 Statistical analysis

The statistical analysis was planned in consultation with statistical consultants. The distribution of the variables was determined by making use of histograms, Q-Q plots and the Shapiro Wilk test. Descriptive statistics for continuous variables, such as means and standard deviations, were used to present data with a normal distribution; medians and interquartile ranges were used to present data with a non-normal distribution. Frequencies and percentages were used to present results according to categories. Table 3.2 provides each objective with the accompanying statistical method applied.

3.9.4 Data archiving

All of the hard copies of the anthropometric measurements and other data forms used in the study from 2005–2010 and in 2015 are locked in the PURE-SA study office and electronic data were archived on a password-protected computer and backed up on an external hard drive. Data were recorded and saved by numbering the participants to ensure confidentiality. Data integrity is being monitored by the PURE-SA study leader for the next ten years. All data were cleaned by the different groups who contributed data and sent to the PURE-SA study office. All of the data were checked again and the final dataset was locked away. The cleaned data are only released to PURE-SA researchers

after a motivated request for the specific data is received. All of the hard copies of the completed forms are stored for seven years and will then be shredded, according to the North-West University's rules and regulations.

3.10 Quality control during all of the stages of the study (collection, analysis, capturing, storage)

The data were collected and analysed by the research team. All the individuals who performed the anthropometric measurements were trained, according to ISAK standards by the principal investigator (Prof. HS Kruger) of the affiliated study, who also monitored the measurements on a weekly basis for accuracy. The instruments (measuring scales and stadiometer) were checked and calibrated before use to ensure quality measurements. Captured data were checked and cleaned to ensure accuracy. Data were stored in an Excel file and the computer program, Statistical Package of Social Sciences (SPSS version 23 program), was used. Data were cleaned and checked by the researcher, the supervisor and the biostatistician.

Table 3.2 Description of how the statistical analysis was performed by providing the objectives and methods

Objective	Method
To determine the magnitude of changes in anthropometric measures (body mass, BMI and CC) in 2005, 2010 and 2015.	Linear mixed modelling.
Changes in BMI and CC from 2005 to 2010 and in 2015.	Wilcoxon signed rank test.
To compare the baseline and end CC of the participants. Proportions of men and women, according to BMI category in 2005 and 2015.	McNemar test.
To determine the association between CC and the components of the physical performance tests in adult black men and women in 2015. The means of each of the physical performance tests in each CC tertile group were compared to determine differences between the components of strength tests according to CC.	Analysis of variance (ANOVA). Post hoc tests with a Bonferroni correction for multiple comparisons.
To determine the association between anthropometric measures (BMI and CC, respectively) and the physical performance tests measured in 2015 with an adjustment for potential confounding variables.	Linear regression models for each physical performance parameter with the physical performance parameter as a dependent variable using the stepwise method.

3.11 Ethical considerations

The PURE-SA study has been approved by the North-West University, Potchefstroom Campus, by the HREC—ethics number NWU-000160-10-A1 for 2005-2010 and during 2015 (see Addendum B). Institutional approval was sought from the Centre of Excellence for Nutrition (CEN), the scientific review committee, the CEN journal club and the HREC for this part of the data analysis of the affiliated study (ethics number NWU-00055-16-A1) (see Addendum C).

- **Anticipated risks and precautions**

The participants were requested to remove the top layer of their clothing (remained in their underwear and light clothes, barefooted) in order for the researcher to conduct the necessary anthropometry measurements. This may have made some of the participants feel uncomfortable. In order to minimise discomfort, the areas where these measurements took place were enclosed off to ensure privacy and only the researcher and assistant were present. Gowns were provided in the "anthropometry room" to make the participants feel at ease and comfortable.

The participants were requested not to eat anything before coming to the research facility so that blood samples could be collected. However, some of the participants felt uncomfortable or lightheaded. A light breakfast was provided to the participants as soon as the blood sample and anthropometry measurements were collected. The measurements usually took the whole day to complete and at the end of a day the participants were exhausted. Lunch was provided and tea/juice/water were available for the duration of each day at the waiting area as a precautionary measure. Research assistants helped the participants to move to the next station to improve time management and to assist participants who did not know where to go.

The only possible risk concerning this affiliated study was that the data could have been stolen and that the password on the computer was bypassed. As a precautionary measure, the participants remained anonymous. No personal data were transmitted to the research team. For the purpose of this study, all of the data were coded to ensure anonymity and were not accessible for interpretation at an individual level. Nobody will be able to identify the individuals who have participated in this study.

- **Benefits**

The participants benefited from the daily measurements in the sense that feedback was immediately provided to them. The principal investigators visited the local hospital and clinics to inform them about the upcoming follow-up visit and to make arrangements for possible referrals in the larger study. For this affiliated study, there were no direct benefits as the data were already collected in 2005-2010 and in 2015. New knowledge concerning changes in anthropometric measures over time and associations with PA and the physical performance of black adults in the North West Province may help in the design and adoption of prevention programmes of lifestyle diseases. The data provided information for future studies concerning changes in anthropometric measures and the components of physical strength.

- **Risk/benefit ratio analysis**

The benefits outweigh the risks as there were no risks to the participants. The data were already collected and no precautionary measures were necessary.

- **Privacy and confidentiality throughout the research process**

The privacy of participants was ensured by making use of private rooms that were closed off from the general research area. In cases where the measurements required participants to partially undress, only the researcher and assistant researcher were present. Furthermore, gowns were provided for participants who did not feel comfortable. Privacy was also guaranteed by ensuring that the conversations between participants and interviewees were not overheard by other individuals. A special closed-off area was used and two individuals were present at all times during measurements. The identifier list of the coded data was kept separate by the PURE-SA project leader.

Confidentiality was ensured by assigning each of the participants a unique number during the initial baseline data collection in 2005. This unique number was used in all of the stages of data gathering. Upon arrival on the day of the measurements, the participants produced their SA identity document in order to verify their number against their unique participant number. That was done by the project coordinators and no other researcher had access to this information. It was not required of the participants to provide personal information to any other researcher or assistant except in cases where their date of birth was required for research input. The captured data were entered by making use of a unique participant number. Electronically captured data were handed to the principal investigator of the study to match the new data with existing data in the master data set. For this affiliated study, the datasets that were received from the PURE-SA study leader contained no personal information and there was no risk attached of information being exposed during a secondary data analysis. The datasets only contained data on the community the participants lived in, their age, smoking habits, education, weighted PAI score, weight, height, BMI and CC. The confidentiality of the participants who participated in the primary studies remained guaranteed due to the protocols and conditions set by those studies.

- **Anonymity and respect**

Respect for individuals recognises the dignity, well-being and safety interests of all research participants and should be the primary concern in research that involves human participants. Appointments were always made before home visits took place to show respect to the participants. Informed consent was confirmed on a continual basis before any measurements were taken. The participants were treated with respect and were permitted to exercise self-determination. Furthermore, efforts were made to

accommodate the participants who lacked capacity or who had a diminished capacity concerning their choices to protect them against harm from irresponsible choices. This affiliated study involved data that were already collected and included all of the participants with valid data based on the larger studies. The information of the participants was not disclosed to anyone as the research team only had their unique number and the participants could not be identified. If necessary, only the study leader of the larger study could have identified them. A financial compensation of R100 was made to each of the participants. This was done as a token of appreciation and respect for their time spent at the research facility.

- **Justice (fair recruitment and burden evenly distributed)**

The recruitment, selection, exclusion and inclusion of participants for the study were just and fair. Participants were not excluded unreasonably or unfairly. The participants were reminded that they could withdraw from the study at any point before the data analysis took place without any consequences. Participants with missing data for any one of the indicators were excluded from the affiliated study.

- **Management of vulnerability**

Transport arrangements were made for all of the participants from their homes to the research facility and back on a daily basis. A light breakfast, lunch and refreshments were provided to the participants on the day of the study. When participants were referred to a hospital or clinic, funds were made available for transport when needed. This was done during the data collection in 2005, 2010 and 2015. These management procedures were not applicable to this affiliated study as data were already collected.

- **Data sharing**

Electronically captured data were stored on a central computer that is password protected. Only the principle investigator has access to the data. A back-up of all electronic data was made on an external hard drive locked away in a cupboard within a locked office at the African Unit for Transdisciplinary Health Research (AUTHeR) in 2005, 2010 and 2015. The AUTHeR offices at the North-West University, Potchefstroom Campus, are used as a storage facility for the hard copies of data from the start of the study in 2005 to 2015. The hard copies contain data that may identify participants and strict control is, therefore, exercised with regard to the accessibility of data and only supervisors have access to the data. All hard copies will be stored for at least seven years after the conclusion of the PURE-SA study after which the data will be destroyed, according to the rules and

regulations of the data/record management of the North-West University. For this affiliated study, electronically captured data of PURE-SA 2005, 2010 and 2015 were

used. If outliers were detected, the hard copies were checked by PURE-SA staff, as the data forms are locked in the PURE-SA study office.

- **Conflict of interest**

No conflict of interest was reported in the larger study or in this affiliated study from the start of the study in 2005 to the end in 2015.

3.12 Reporting, dissemination and notification of results

3.12.1 Dissemination of results: academics, volunteers, communities and authorities

The researcher presented the study protocol at the Centre of Excellence for Nutrition's (CEN) journal club and the results of the study will also be presented at the CEN's journal club. Feedback on the disease burden within these communities will also be given to the North West Department of Health. The publication of results is presented in the form of a mini-dissertation. An article will be published in a peer-reviewed academic journal and presented at conferences. Results from measurements that were immediately available on the day of the study were verbally reported to the participants at the end of the day in 2005, 2010 and 2015. It was done privately and if abnormalities were present, a referral letter was provided to the local clinic/hospital of a particular participant. The research leader explained the results to the participants in detail.

3.13 Protocol violations

The research team strove to minimise protocol deviations during the collection of data. The set protocol was not violated.

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CHAPTER 4 ARTICLE

The association between anthropometric measures and physical performance in black adults of the North West Province, South Africa.

The association between anthropometric measures and physical performance in black adults of the North West Province, South Africa

Phumudzo Mamphwe[1], Herculina Salomé Kruger[1, 2]*, Sarah Johanna Moss[3], Marike Cockeran[4], Cristian Ricci[1] and Iolanthé Marike Kruger[5]

[1]Centre of Excellence for Nutrition, [2]Medical Research Council Unit for Hypertension and Cardiovascular Disease, [3]Physical Activity, Sport and Recreation Research Focus Area, [4]Computer Statistical and Mathematical Sciences, [5]Africa Unit for Transdisciplinary Health Research: North-West University, Potchefstroom, South Africa

*Corresponding author: Email salome.kruger.@nwu.ac.za

Abstract

Objective: Few studies have investigated the association between anthropometric measurements and physical performance over time in black adults in low and middle income countries (LMIC). This study investigated the associations between anthropometric measures and physical performance in black adults.

Design: Longitudinal study where, age, body mass and height, body mass index (BMI), calf circumference (CC), physical activity (PA), education level, and smoking status were measured at baseline in 2005. In 2015 chair stand, 6-metre walk and handgrip strength (HGS) tests were performed. Linear regression models were used to evaluate the association between anthropometric measurements and physical performance.

Setting: The Prospective Urban and Rural Epidemiology (PURE-SA) study in the North West Province, South Africa

Participants: Black HIV negative adults (n=1428, 538 men and 890 women); aged 32-93 years in 2005.

Results: The combined overweight and obesity prevalence of both men (p=0.02) and women (p<0.001) increased significantly over 10 years, with significant increases over time in BMI and CC in the women, whereas PA decreased significantly over time in both men and women (p<0.0001). BMI and CC were positively associated with HGS in the men (p=0.02, p<0.0001, respectively) and women (p<0.0001 for both), while CC was positively associated with walk speed in the men only (p=0.006) in the cross-sectional analysis of 2015 measurements.

Conclusion: BMI and CC in both men and women were positively associated with HGS, but CC was associated with walk speed in the men only. CC may be a useful predictor of physical performance in black adults.

***Keywords*: calf circumference; physical performance; handgrip strength; walk speed**

4.1 Introduction

South Africa, like many low and middle income countries, is undergoing urbanisation with a rapid socio—economic and nutritional transition that may affect the body composition and physical activity patterns of individuals (World Health Organisation, 2013; World Health Organisation, 2015). Modifiable risk factors that contribute to the development of non-communicable diseases (NCD), such as obesity and physical inactivity, require attention. Approximately 5% of deaths globally can be attributed to obesity and 3.2 million deaths each year are due to insufficient physical activity (World Health Organisation, 2008). Urgent action is needed in order to understand and address the effects of lifestyle changes on the needs of aging populations (Tucker & Buranapin, 2001).

Being overweight and obesity have been defined as conditions in which excessive body fat increases with adverse effects on the well-being of individuals (World Health Organisation, 2013). Body mass index (BMI) is easy to measure and used as a measure of whole body obesity, but does not differentiate between muscle mass and fat mass (Lee *et al.*, 2016). Being overweight (BMI>25 kg/m^2) and obese (BMI>30 kg/m^2) are major problems in both high income countries and low and middle income countries (World Health Organisation, 2013). South Africa has the highest overweight and obesity prevalence in Sub-Saharan Africa with up to 70% of women and a third of men classified as overweight or obese (Mungal-Singh, 2012). In South Africa, the age-standardised mean BMI increased in men from 21 kg/m^2 to 24 kg/m2 and in women from 26 kg/m^2 to 29 kg/m^2 from 1975 to 2014 (NCD Risk Factor Collaboration, 2016). Obesity is associated with numerous adverse health problems, including impaired physical performance and quality of life, the development of type 2 diabetes, hypertension, dyslipidaemia and cardiovascular diseases (Villareal *et al.*, 2005).

Studies have shown that physical activity is associated with a lower fat mass and an increase in muscular strength and function and has been recognised as a key lifestyle factor to prevent and delay muscle loss and obesity during ageing (Cruz-Jentoft *et al.*, 2010; Lee *et al.*, 2016). A low level of physical activity is associated with a higher BMI (Fogelholm & Kukkonen-Harjula, 2000). Furthermore, physical inactivity contributes to sarcopenia in a

vicious cycle by causing the elderly to become weaker and less able to participate in daily living activities (Kruger *et al.*, 2016). Maintaining or increasing physical activity levels may decrease the decline of age-associated physical performance (Martinez-Gomez *et al.*, 2017). Physical performance measurements assess physical function and can be used to investigate association with mortality and disability in the elderly (Roshanravan *et al.*, 2013).

Ageing is considered as the primary risk factor for many diseases and chronic conditions (Buffa *et al.*, 2011). A critical change associated with human ageing is a progressive decline in skeletal muscle mass—a downward spiral that may lead to a decrease in physical strength and performance (Cruz-Jentoft *et al.*, 2010). Sarcopenia is a gradual loss of lean muscle mass and strength coupled with ageing, often associated with a progressive increase in body fat leading to sarcopenic obesity (Batsis *et al.*, 2014). The loss of muscle mass starts at around the age of 40 years with an estimated decrease of 8% every decade. Thereafter, muscle mass shows an accelerated loss rate of 15 % after the age of 70 years (Moreira *et al.*, 2016a).

In the North West Province of South Africa, 8.1% of black women are reported to be sarcopenic (Kruger *et al.*, 2015a). Sarcopenia is generally defined in terms of dual-energy X-ray absorptiometry (DXA) that measures muscle mass. However, the cost of DXA measurements and the lack of availability in remote areas necessitate alternative measurements (Deurenberg *et al.*, 2002). Anthropometric measurements, such as calf circumference, is an inexpensive, simple and non-invasive method that can be used as a muscle mass indicator (Landi *et al.*, 2014). In previous studies, calf circumference was positively related to higher muscle strength and physical performance (Landi *et al.*, 2014). Physical performance is assessed with a chair stand test, 6 m walk speed test and a handgrip strength. These tests are inexpensive, simple and non-invasive and are regarded as predictors of physical performance and possible disabilities (Studenski *et al.*, 2011).

Sarcopenia and obesity have been independently associated with a decline in physical performance (Chantler, 2014). The direct and indirect economic consequences of being underweight, overweight or obese in South Africa are high and require interventions directed at achieving normal BMIs (Kengne *et al.*, 2013). Few studies have assessed anthropometric measures over time in black adults in low and middle income countries (Hughes *et al.*, 2004; Chantler, 2014). Little information is currently available on the relationship among sarcopenia, obesity and physical performance among African populations (Moreira *et al.*, 2016a). The aim of this study was, therefore, to determine the association between anthropometric measures and the physical performance of black adult men and women in the North West Province, South Africa.

4.2 Methodology

4.2.1 Study population

A stratified random sampling was used to recruit participants from two rural communities and two urban communities to participate in the Prospective Urban and Rural Epidemiology (PURE-SA) study in 2005. Follow-up visits were completed in 2010 and 2015. Anthropometric measurements, socio-demographic and physical activity information were collected in 2005, 2010 and 2015. Physical performance tests were added in 2015. A total of 2 010 individuals between the ages of 32 and 93 years participated in the PURE-SA study in 2005 from rural (n=1006) and urban (n=1004) areas of which 1 428 participants were available after participants who tested HIV positive, those with incomplete data and pregnant women were excluded. In 2015, 926 individuals returned for a follow up and 774 participants remained after participants were excluded who tested HIV positive. A detailed description of the study population and assessment was published elsewhere (Kruger *et al.*, 2015b). This study is nested in the South African leg of the multi-national PURE cohort study. The PURE study was approved by the Health Research Ethics Committee (HREC) of the Faculty of Health Science, North-West University, Potchefstroom Campus, with the following ethics number: 04M10 and NWU-00016-10-A1. All of the participants gave informed written consent.

4.2.2 Procedures

Anthropometric measures were performed, namely height (m) using a stadiometer (Leicester height measure, Seca, UK), body mass (kg) using an electronic weight scale (Seca, Hamburg, Germany) and calf circumference (cm) was measured on the right calf at maximum calf girth of each participant standing upright using a non-stretchable tape measure (KDS measure, model F10-02DM 2m, Kyoto, Japan). Semi-structured questionnaires were administered in the preferred language of participants by trained fieldworkers residing in the study communities. Basic demographic information regarding age, ethnicity, gender, marital status, level of education (no school education versus school education), smoking status (current smoker versus non-smoker) and occupational status of the participants were collected. The Transition of Health during Urbanisation in South Africa (THUSA) physical activity questionnaire developed from the Baecke physical activity questionnaire was used to determine physical activity scores (Kruger *et al.*, 2000). Physical activity scores were reported for the domains of commuting, stair climbing, sport participation, occupational activities and leisure time activities. A total physical activity score

was calculated by combining the above-mentioned indices. The questionnaire derived a physical activity score (range 0–20) (Kruger *et al.*, 2000).

4.2.3 Outcome measurements

A functional performance was determined by the following measurements: a chair stand time test, walk speed performance and a handgrip test. A 45 cm high armless chair with a straight back was used for the chair stand time test and placed against a wall to avoid the chair from sliding back. The participants were requested to perform five consecutive sit to stand movements. The number of completed stands was counted and the time to complete the five chair stands was recorded in seconds using a stopwatch. The inability of participants to complete one chair stand was recorded as a "fail" (Rikli & Jones, 1997). The walk speed performance over 6 m was performed on a flat surface. The participants were asked to wear comfortable footwear and customary walking aids were allowed. The participants started with both feet on the starting line and walked as fast and safely as they could—not running—to the 6 m line. The time it took to complete a 6 m walk test was recorded in seconds with a stopwatch. The walk speed was calculated in m/s (Studenski *et al.*, 2011). The Jamar dynamometer (Model 78010 & 78011, Lafayette Instruments, Sagamore Parkway North, USA) was used to test handgrip strength with the participants seated and their elbow at a 90-degree angle. Handgrip strength measures the maximum voluntary force of a hand and is regarded as a measure of muscle function (Bohannon, 2001). Handgrip strength was measured for the dominant hand. A maximum of three repeated measurements in kilogram were recorded.

4.2.4 Statistical analysis

Descriptive statistics were used to present demographic information and anthropometric measures together with physical activity and physical performance data of the participants. The normality of data was assessed by making use of histograms, Q-Q plots and a Shapiro-Wilk test. Descriptive statistics with a normal distribution was presented as a mean ± standard deviation (SD) of continuous variables and frequencies and percentages for categorical variables. Non-normally distributed data were presented as the median and interquartile range. Proportions of men and women, according to their BMI category in 2005 and 2015 were compared using the McNemar test. Linear mixed models were used to evaluate changes in anthropometric measurements (BMI and calf circumference) over ten years. Age, physical activity score, smoking status and education level were adjusted for use in separate models for BMI. Differences between the results for the physical performance test of the tertile groups of calf circumference were compared by making use of an analysis

of variance (ANOVA) and post hoc tests were performed with a Bonferroni correction for multiple comparisons. The Wilcoxon signed rank test was used to compare baseline and the end calf circumference of the participants. Multivariable linear regressions were used to determine the cross-sectional association between anthropometric measures (BMI and calf circumference, respectively) and the physical performance tests as a dependent variable (chair stand, walk speed and handgrip strength, respectively) in 2015. The following potential confounders were added in a stepwise regression model: age, physical activity (continuous variables), education and smoking (categorical variables). Confounding variables were selected based on theoretical considerations and existing literature relevant to the topic (Kostka & Bogus, 2007). Statistical tests were two-sided and a statistical significance was set at $p< 0.05$. All the statistical analyses were conducted using SPSS statistical software version 23 (IBM, Armonk, NY, USA).

4.3 Results

The basic demographic characteristics of the participants are presented in Table 4.1. A higher BMI was observed in the women compared to the men. Figure 1 presents the BMI categories for both men and women in 2005, 2010 and 2015. The prevalence of obesity in men was very low (<7%) in 2005, 2010 and 2015 while the prevalence of being overweight increased from 14.3% in 2005 to 17.5% in 2015. In women, the prevalence of being underweight decreased over the years while the prevalence of obesity in women increased from 34.2% to 39.8% over the same time frame. The prevalence of both being overweight and obesity in men (p=0.02) and women ($p< 0.001$) increased significantly from 2005 to 2015. Table 4.2 presents the anthropometric changes in continuous variables for ten years. There is a significant increase over time in body mass (p=0.014), BMI (p=0.001) and calf circumference (p<0.0001) in women whereas physical activity decreased significantly in both men and women (p<0.0001). Table 4.3 presents the BMI change of the participants adjusted for confounding variables in 2005. The participants (men and women) who smoked at baseline had a smaller increase in BMI over the ten year period than those who did not smoke (p<0.05). BMI increased more in the participants with high school education than in participants with no school education (p<0.0001). The education level at baseline (2005) was, therefore, a significant predictor of an increase in BMI in this study.

Table 4.4 presents a correlation among possible confounding factors, such as age and PA score, and the physical performance tests measured in 2015. A physical activity score correlated positively with handgrip strength in both men (p<0.0001) and women (p=0.015) while age correlated negatively with walk speed (p=0.002 and p<0.0001, respectively) and handgrip strength (p<0.0001 and p<0.0001, respectively) in both men and women. Chair

stand time correlated positively with age (p=0.007 and p=0.004, respectively) but negatively with physical activity (p=0.001 and p=0.001, respectively) in men and women. Table 4.5 presents the results of the physical performance strength tests by calf circumference tertile groups in 2015. Statistically significant differences between handgrip strength in the tertile groups of calf circumference were found in both men (p=0.002) and women (p<0.0001). Table 4.6 presents the association between anthropometric measures and physical performance in 2015. Chair stand time was not significantly associated with BMI or calf circumference and this phenomenon was observed in both men and women. The walk speed of the men and women was not significantly associated with BMI, even after adjusting for possible confounders. However, walk speed was positively associated with calf circumference in the men (p=0.006) but not in the women. A significant positive association was found among handgrip strength, BMI and calf circumference in both men and women. A positive association was maintained in all of the models after adjusting the models for age, physical activity, education status and smoking status (p<0.05).

4.4 Discussion

This is the first study to the knowledge of the researcher that investigated an association between anthropometric measures and the physical performance of black adults over a time span of ten years in South Africa. The study indicated that there is an increase in BMI and calf circumference in women over ten years but not in men. BMI and calf circumference can be positively associated with handgrip strength in men and women, whereas calf circumference can be positively associated with walk speed in men only. Calf circumference can, therefore, be a useful measure of physical performance in black men.

The results of this study concur with the findings of other studies: In South Africa, the prevalence of obesity in women is higher than in men (Shisana, 2014; Kruger *et al.*, 2015b). The prevalence of obesity increases with time but more rapidly for women than men. Black women in particular are noted to harbour misperceptions of weight gain and they underestimate their weight (Kruger *et al.*, 2002b). The nutrition transition is reported as a reason behind the increasing prevalence of obesity in low and middle income countries—including South Africa (Bourne *et al.*, 2002). Fat accumulation in older persons occur due to hormonal changes and a loss of muscle mass caused by a decrease in physical activity, which reduces the basal metabolic rate that decreases the total energy expenditure (Stenholm *et al.*, 2009).

Despite the general increase of overweight and obese participants in the study, no inverse associations between BMI and physical performance tests were found. These results differ

from other studies suggesting that a higher BMI is associated with poor physical performance (Jensen & Friedmann, 2002; Zoico *et al.*, 2007). Chair stand time was not associated with BMI or calf circumference in men and women in this study. However, the results of this study are similar with the findings of a study in the United States of America concerning healthy subjects between the ages of 20 to 85 years: Neither height nor body mass was related to the time it took to get up from a chair (men and women) (Csuka & McCarty, 1985). However, low muscle strength and *not* low muscle mass was found to be associated with poor physical performance in older men and women in a study in the Netherlands (Visser *et al.*, 2000). BMI is generally considered a suitable measure to categorise the status of individuals with regard to being underweight, normal, overweight or obese in epidemiological studies. It is easy to measure and interpret. However, BMI does not differentiate between body fat and lean mass and different cut-points can be applicable to different ethnic groups (Deurenberg *et al.*, 2002; Kruger *et al.*, 2015b).

BMI did not show a linear negative association with walk speed among men and women in the present study. This may be due to the fact that BMI is a measure of both underweight and overweight individuals, and the prevalence of being underweight in men was relatively high in this study. Underweight individuals may show a low fat mass and low muscle mass and may, therefore, be associated with a weaker physical performance among the men in the present study. A walk speed test serves as a useful, integrated measure of mobility (Harada *et al.*, 1999). The total adiposity and associated fat infiltration into muscle were important predictors of a walk speed decline in black and white men and women of the Health Aging, and Body Composition (ABC) study in the United States of America (Beavers *et al.*, 2013). In the South African study, women with a high BMI presented both a high fat mass and high muscle mass (Kruger *et al.*, 2015a). A high BMI may not, therefore, be associated with a slower walk speed or a longer chair stand time as reported in other studies where a higher BMI is normally associated with poor physical performance (Jensen & Friedmann, 2002; Zoico *et al.*, 2007). A positive association was found between BMI and handgrip strength of both men and women in the present study. In the Finnish population-based Health 2000 Survey, handgrip strength cut-points for mobility increased together with BMI in men (p=0.02) (Sallinen *et al.*, 2010). This finding (Sallinen *et al.*, 2010) supports the notion that underweight individuals show both a low fat mass and low muscle mass and, therefore, a low BMI may be associated with a weaker physical performance, particularly concerning men in the present study.

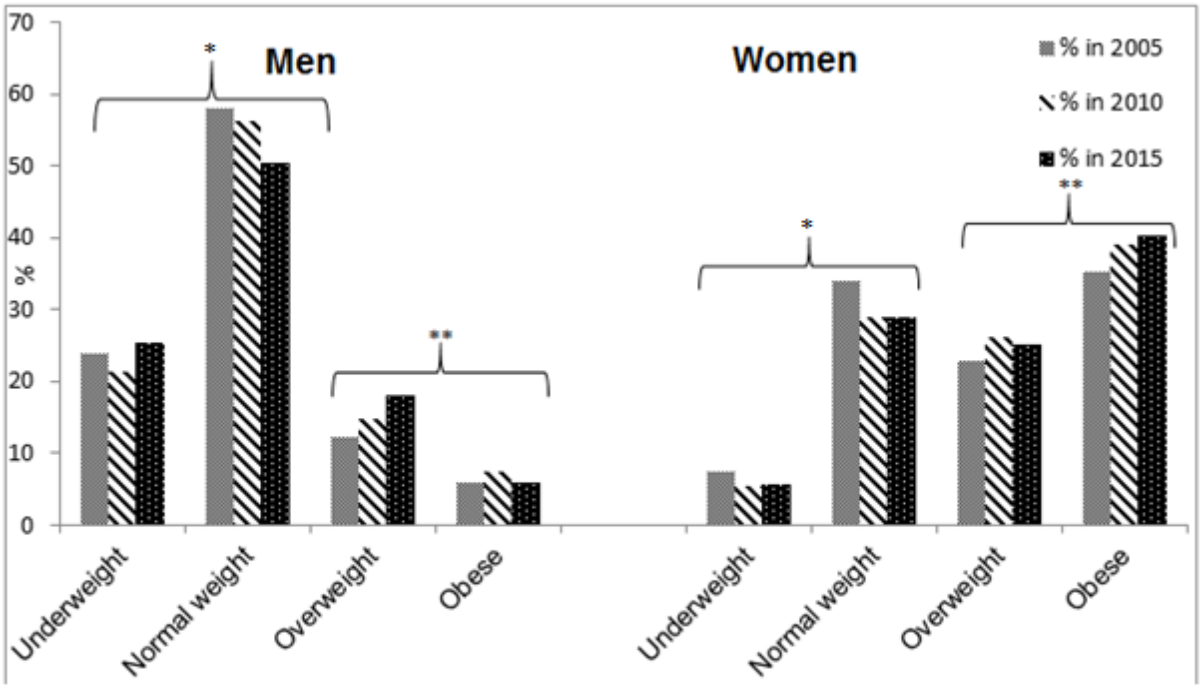
Calf circumference provides a relatively accurate estimation of lower limb muscle mass and it has, therefore, been suggested to be used as proxy for muscle mass, although it measures

the muscle area and subcutaneous fat (Rolland *et al.*, 2003; Landi *et al.*, 2014). The predictive power of calf circumference to assess lean body mass can also be influenced by leg oedema (Kawakami *et al.*, 2015). A calf circumference of <31 cm was associated with disabilities (Landi *et al.*, 2014). The relationship between calf circumference and lean body mass was stronger in men than in women and may possibly be due to the fact that women distribute more fat mass on their lower extremities (Kawakami *et al.*, 2015). This may be the reason why calf circumference increased significantly over the time frame of ten years in the women of the present study but not in the men. The results of this study are in contrast with another study from Ireland (Corish & Kennedy, 2003), where the calf circumference of women decreased over time with aging. This may be due to the fact that most women in the present study were between the ages of 45 to 65 years while all of the women in the Irish study were older than 65 years (Corish & Kennedy, 2003). In this study, the calf circumference of women increased in line with their general increase in body mass and BMI over the time span of ten years.

Calf circumference was positively associated with handgrip strength over tertile groups in men and women. This is an indication that calf circumference can be a useful predictor of physical performance in black men and women. A handgrip strength test is a useful tool to identify individuals at risk for mobility limitations and is a good measure of muscle strength and correlates with leg strength (Cruz-Jentoft *et al.*, 2010). Low handgrip strength is a clinical indicator of poor mobility and a better predictor of clinical outcomes than low muscle mass. In the present study, calf circumference was associated with both handgrip strength and walk speed in men. Calf circumference has been reported as more effective in predicting long-term mortality risks, and is more accessible and time efficient to measure than BMI (Tsai & Chang, 2011). This study confirmed that increased age is associated with a weaker performance in physical performance tests—indicating declining muscle strength (Eremenko *et al.*, 2016). This study found that age has a negative association with walk speed and handgrip strength while a chair stand time has a positive association with age. This can be viewed as an indication that physical performance in all three tests declines during aging.

The strength of this study lies in the repeated body composition measures taken of apparently healthy men and women over time. The longitudinal design established a temporal relation in changes concerning the anthropometric measures. A wide range of variables was measured in the PURE-SA study and this enabled the researchers to account for several potential confounding variables. Limitations include that the PURE-SA study was composed exclusively of black adult men and women from four communities in the North

West Province and the generalisability of the results was, therefore, limited. A longitudinal design is vulnerable to bias due to the loss of follow up. Some of the participants were lost to follow up, resulting in 926 participants returning for a follow up in 2015. The physical performance tests were only performed at the end of the study as an outcome of longitudinal exposures. No changes in anthropometric measures were found in men and only cross-sectional associations between anthropometric measures and physical performance at the end of the study were, therefore, assessed. Self-reported physical activity also lends to possible errors and bias. Although BMI is widely used as a measure of obesity, it is insensitive to body fat and muscle mass. It is possible that changes in BMI do not fully capture adiposity-related and muscle-related changes. Further interventions and longitudinal research will be needed to understand these relationships better. Additional measures, such as Dual energy X-ray absorptiometry (DXA) and a bio-electric impedance analysis, can be helpful in future investigations to more precisely understand the nature of the observed associations in the present study.



McNemar test, ⌐ increase or decrease from 2005 to 2015; *: significant decrease in underweight/normal weight; **: significant increase in overweight/obesity (p<0.05); Two by two table; underweight and normal weight=0; overweight and obese=1.

Figure 4.1 Body mass index categories in men and women over the span of ten years (2005, 2010 and 2015) in rural and urban areas of the North West Province, South Africa

Table 4.1 Anthropometric measurements of the participants, according to gender in 2005, 2010 and 2015

Variables		Men (n=188)			Women (n=422)		
		2005	2010	2015	2005	2010	2015
Age (years)†		50.8(44.3–58.3)	55.3(48.8–62.7)	60.8(54.3–68.3)	50.32(44.0–57.5)	54.9(48.5–62)	60.4(54–67.5)
Body mass (kg)†		56.6(50.4–66.6)	57.3(52–67.7)	57.8(51.2–67.9)	65.2(54–81.5)	68.8(57–83.3)	68.9(55.8–83.7)
Height (m)*		1.7±0.1	1.7±0.1	1.7±0.1	1.6±0.06	1.6±0.06	1.6±0.06
Body mass index (kg/m^2)†		20(18.6–23)	20.5(18.6–24.4)	20.5(18.4–24.6)	26.5(22–32.7)	27.7(23.3–33.9)	28(23–33.6)
Waist circumference (cm)†		75.3(70.5–82.6)	77(70.6–85.9)	79.3(72–91.4)	82.4(72–93.3)	84.7(74.9–95)	93.4(81.3–103)
Hip circumference (cm)†		86.2(82.5–91.8)	83.8(76.7–91.3)	89(84.5–96.7)	102.1(91.4–112.4)	99.5(87.1–112.5)	104.5(94–117.1)
Calf circumference (cm)*		32.3±3.4	~	32.1±3.7	34.6±4.7	~	35.1±5.1 **
Physical activity score†		2.9(2.5–3.3)	3(2.7–3.2)	2.4(1.9–2.9)	2.9(2.6–3.3)	3(2.7–3.1)	2.1(1.9–2.5)
Urbanisation area (n/%)	**Rural**	105(55.9%)	105(55.9%)	105(55.9%)	252(59.7%)	252(59.7%)	252(59.7%)
Educational status (n/%)	**High School**	107(56.9%)	107(56.9%)	107(56.9%)	259(61.4%)	259(61.4%)	259(61.4%)
Tobacco user (n/%)	**Smoking**	105(55.9%)	93(49.7%)	92(48.9%)	182(43.1%)	180(43.1%)	279(66.1%)

n: number of participants with complete data in all three years; †: Data are presented as a median and IQR; or *: as mean ± standard deviation; ~: Measurements done in 2005 and 2015 only; **: Significant difference between 2005 and 2015 (Wilcoxon signed rank test). The *p*-values for other significant changes are presented in Table 5·

Table 4.2 **Change over time (2005, 2010 and 2015) in continual variables using linear mixed models in men and women (crude models)**

	Men (n=220)			Women (n=559)		
Variable	**β estimate**	**95%CI**	***p-value***	***β estimate**	**95%CI**	***p-value***
Body mass(kg)	0.27	-0.4 ;0.94	0.46	0.76	0.15;1.37	**0.014**
BMI (kg/m^2)	0.19	-0.05;0.43	0.12	0.42	0.17;0.66	**0.001**
PA score	-0.30	-0.39;-0.22	**<0.0001**	-0.37	-0.40;-0.33	**<0.0001**

BMI, body mass index; PA, physical activity; Linear mixed models; estimates of fixed effects; separate models for each variable; one unit is equal to five years.

Table 4.3 **Body mass index change over ten years adjusted for age, physical activity score, smoking status and education level using linear mixed models**

Anthropometric measures	Men (n=220)			Women (n=559)		
	β estimate	**95%CI**	***p-value***	**β estimate**	**95%CI**	***p-value***
Dependent variable: BMI adjusted for confounding variables						
Age (years)	0.09	0.05;0.13	**<0.0001**	0.07	0.03;0.12	**0.001**
Physical activity score	-0.12	-0.30;0.07	0.23	0.25	-0.03;0.52	0.08
Smoking (smoking as reference)	0.45	0.10;0.79	**0.01**	0.74	0.40;1.07	**<0.0001**
Education (high school education as reference)	-1.52	-2.39;-0.65	**0.001**	-2.83	-3.71;-1.94	**<0.0001**

Linear mixed models; estimates of fixed effects; one unit is equal to five years; adjusted for age, physical activity score, smoking status & education level.

Table 4.4 The correlation between predictor variables and dependent variables (physical performance) in men and women in 2015

Physical performance tests	Men (n=220)			Women (n=559)		
	Age (years)	Physical activity score	Body mass index (kg/m^2)	Age (years)	Physical activity score	Body mass index (kg/m^2)
Chair stand time(s)	*r*=0.20 ***p*=0.007**	*r*=-0.24 ***p*=0.001**	*r*=0.07 *p*=0.33	*r*=0.13 ***p*=0.004**	*r*=-0.16 *p*=0.001	*r*=0.06 *p*=0.15
Walk speed (m/s)	*r*=-0.32 ***p*=0.002**	*r*=0.20 ***p***=0.06	*r*=0.10 ***p***=0.34	*r*=-0.44 ***p*<0.0001**	r=0.03 ***p***=0.63	*r*=0.02 *p*=0.78
Handgrip strength (kg)	*r*=-0.28 ***p*<0.0001**	*r*=0.14 ***p*<0.0001**	*r*=0.24 ***p*=<0.0001**	*r*=-0.33 ***p*<0.0001**	*r*=0.11 ***p*=0.015**	*r*=0.19 ***p*<0.0001**

*: Correlation significant at the 0.01 level 2-tailed) using Pearson correlation coefficient.

4.5 Conclusion

BMI and calf circumference in men and women were associated with handgrip strength, but calf circumference was associated with walk speed in men only. Calf circumference may be a useful predictor of physical performance in black men and to a more limited extent in black women. In conclusion, there was a stronger association among calf circumference, handgrip strength and walk speed in men than in women, but no associations were found with chair stand performance. Intervention and longitudinal research are needed to gain a better understanding of these relationships between anthropometric measures and physical performance.

Table 4.5 Results of physical performance tests in calf circumference tertile groups of men and women measured in 2015

	Men (n=226)				Women (n=501)			
Calf circumference (cm) t*ertile groups*	***1(<30.4 cm)***	***2(30.5-35.5 cm)***	***3(>35.6 cm)***	***p-value***	***1(<32.3 cm)***	***2(32.4-37.2 cm)***	***3(>37.3 cm)***	***p-value***
Chair stand time(s)	17.43±4.32	17.11±3.34	17.40±3.93	0.708	17.7±3.84	17.95±5.19	18.27±4.70	0.59
Walk speed (m/s)	1.25±0.33	1.39±0.43	1.44±0.31	0.122	1.22±0.30	1.20±0.27	1.26±0.26	0.46
Handgrip strength (kg)	29.14±7.6[a]	31.93±9.4[a]	34.85±11.12[b]	**0.002**	22.03±5.99[a]	24.28±7.26[b]	25.38±6.82[b]	**<0.0001**

a, b variables with different subscript differ significantly (ANOVA, Bonferroni with post hoc test); Data presented as mean and standard deviation.

Table 4.6 **Cross-sectional association between anthropometric measures and physical performance test measured in men and women in 2015, adjusted for confounding factors**

		Chair stand(s)		Walk speed (m/s)		Handgrip strength (kg)	
		Standardised coefficient	*p*-value	Standardised coefficient	p-value	Standardised coefficient	*p*-value
Men		***n=209***		***n=92***		***n=266***	
Body mass index (kg/m^2)	Crude model	0.08	0.25	0.15	0.15	0.21	**0.001**
	Model 1	0.07	0.27	0.11	0.24	0.21	**0.001**
	Model 2	0.04	0.53	0.15	0.12	0.23	**<0.0001**
	Model 3	0.09	0.18	0.18	0.09	0.21	**0.02**
	Model 4	0.10	0.16	0.18	0.09	0.20	**0.02**
Calf circumference (cm)	Crude model	0.03	0.70	0.26	**0.01**	0.30	**<0.0001**
	Model 1	0.04	0.27	0.20	**0.04**	0.28	**<0.0001**
	Model 2	0.02	0.78	0.25	**0.01**	0.30	**<0.0001**
	Model 3	0.06	0.35	0.29	**0.006**	0.28	**<0.0001**
	Model 4	0.07	0.33	0.31	**0.006**	0.27	**<0.0001**
Women		***n=469***		***n=187***		***n=496***	
Body mass index (kg/m^2)	Crude model	0.04	0.37	-0.02	0.20	0.20	**<0.0001**
	Model 1	0.03	0.27	-0.03	0.61	0.20	**<0.0001**
	Model 2	0.04	0.44	-0.03	0.62	0.20	**<0.0001**
	Model 3	0.05	0.24	-0.05	0.45	0.19	**<0.0001**
	Model 4	0.06	0.19	-0.07	0.29	0.18	**<0.0001**
Calf circumference (cm)	Crude model	0.04	0.31	-0.01	0.87	0.22	**<0.0001**
	Model 1	0.05	0.26	-0.04	0.49	0.21	**<0.0001**
	Model 2	0.04	0.28	-0.04	0.50	0.21	**<0.0001**
	Model 3	0.06	0.19	-0.06	0.38	0.20	**<0.0001**
	Model 4	0.07	0.12	-0.07	0.25	0.19	**<0.0001**

Model 1: crude model adjusted for age; Model 2: model 1+physical activity score; Model 3: model2 + smoking (smoking as reference); Model 4: model 3+ education (school education as reference); multiple linear regression method; standardised coefficient.

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- **Conflict of interest**

None.

- **Authorship**

PM and HSK conceptualised the study, drafted the manuscript and conducted all of the statistical analyses with input from MC and CR. SJM, IMK and HSK made substantial contributions to the drafts and were involved in critically reviewing the manuscript and interpreted the results. PM, HSK and IMK contributed to data collection. All of the authors have reviewed and approved the final version for publication.

- **Ethics of human participation**

The PURE study was approved by the Health Research Ethics Committee of the Faculty of Health Science, North-West University, Potchefstroom Campus. The ethics number is NWU-00016-10-A1 and this project was also approved by the same committee with the following ethics number: NWU-00055-16-A1.

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CHAPTER 5 CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

The aim of the study was to determine an association between anthropometric measures and the physical performance of black adult men and women in the North West Province, South Africa. The objectives of the study were to determine changes in anthropometric measures (body mass, BMI and CC) from 2005 to 2015 of the study participants and to determine an association between anthropometric measures (BMI and CC, respectively) and physical performance tests measured in 2015 with an adjustment made for potential confounding variables. The purpose of this chapter is to summarise the results of this study and to provide recommendations for future studies.

Changes, such as a decline in muscle mass and an increase in fat mass, occur during ageing and can lead to a decrease in physical performance (Cruz-Jentoft *et al.*, 2010; Cruz-Jentoft *et al.*, 2014). Obesity has important functional consequences for both older men and women as it worsens the age-related decline in physical function (Villareal *et al.*, 2005). Moderate weight loss in conjunction with PA improves physical performance and the health-related quality of life of obese older individuals (Villareal *et al.*, 2005). Physical performance measurements assess physical function and its association with mortality and disabilities in older adults (Roshanravan *et al.*, 2013). A chair stand test, walk speed and HGS are regarded as predictors of physical performance and disabilities (Waters *et al.*, 2010; Studenski *et al.*, 2011; Lee *et al.*, 2016). CC is a potential anthropometric marker of physical performance, it's easy to measure and less expensive than DXA or a BIA (Deurenberg *et al.*, 2002; Landi *et al.*, 2014).

5.2 Main findings

It was hypothesised that body mass, BMI and CC will increase from 2005 to 2015 in the participants and that there will be a positive association between CC, HGS and walk speed, respectively. It was also hypothesised that there will be a negative association between CC and chair stand test times taken in 2015. The body mass, BMI and CC of black women increased significantly over the time span of ten years, but no increases were found in the men. As the participants (black men and women) aged, their PA score decreased over the ten years. Smoking black men and women showed a higher increase in BMI over the ten years compared to non-smoking participants. Participants (black men and women) who have obtained a school education showed a higher increase in BMI than participants with no school education. In 2015, a positive correlation was found between age and chair stand

time in both men and women. A weak, positive correlation was found between PA scores and walk speed in both men and women while age showed a negative correlation to HGS in both men and women. CC was divided into three tertile groups in men and women and only HGS was positively associated with CC over tertile groups. A statistically significant association was found in both men and women between BMI, CC and HGS. Moreover, CC was positively associated with walk speed performance in men only while BMI and CC were not associated with chair stand time in men and women.

Based on these results, the hypothesis of an increase in body mass, BMI and CC from 2005 to 2015 in women only but not in men can be accepted. In addition, the hypothesis of a positive correlation between BMI and CC, respectively, and HGS in the participants can also be accepted. Furthermore, a positive association was found between CC and walk speed performance in men only. The hypothesis of a negative association between CC or BMI and chair stand test time in men and women was, therefore, rejected.

Few studies have evaluated changes over time in the anthropometric measures of black adults in LMIC. However, some recent descriptive cross-sectional studies were done on black women in South Africa (Kruger *et al.*, 2015b; Sotunde *et al.*, 2015; Kruger *et al.*, 2016). To the knowledge of the researcher, no published studies have yet determined an association between anthropometric measures and the physical performance of black men and women in LMIC. With the likely growth taking place in the adult population, preventing or delaying frailty and promoting healthy lifestyles have become national goals. A loss of function associated with physical inactivity in later years can be reduced by monitoring physical weakening and PA behaviour. The aging process can lead to a loss in muscle mass and strength. It is, therefore, of the utmost importance to maintain a normal BMI and muscle mass through the various life stages by practicing an active lifestyle and healthy dietary habits.

5.3 Conclusion

Significant anthropometric changes (body mass, BMI and CC) were observed over the time frame of ten years in women but not in men. PA scores decreased over the same period in both men and women. BMI and CC were positively associated with HGS in men and women but this was not the case with a chair stand test. CC had a positive association with the walk speed of men only. Positive associations amongst CC and HGS and walk speed performance in men and HGS in women remained the same after adjustments were made for age, PA score, education level and smoking status. The cross-sectional association between anthropometric measures and physical performance tests cannot establish

causality and should be interpreted with caution. In summary, it can be concluded that CC can be a useful predictor of physical performance in black men and to a more limited extent in women.

5.4 Recommendations

Lifestyle programmes should be designed and implemented for the prevention of NCDs to improve PA scores and also to prevent weight gain during ageing when the body fat percentage increases and muscle wasting starts. Obesity interventions in older populations need to be improved. The majority of obese adults remain obese over time during aging. Further intervention and longitudinal research are needed to gain a better understanding of these relationships between anthropometric measures and physical performance. Additional measures, such as DXA and BIA, can be helpful in future investigations to precisely understand the nature of the observed associations found in this study.

Future longitudinal studies that focus on black adult people are needed to clarify how body composition affects physical performance in older adults. Such studies should be designed to explain the longitudinal changes in BMI and CC and physical performance tests by also taking into consideration possible confounding factors. Randomised controlled trials are needed to clarify the biological mechanisms leading to a decline in physical performance among obese persons with low muscle strength. Randomised controlled trials can also be useful to test the effect of interventions designed to reduce body fat and increase muscle mass in older persons.

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ADDENDA

ADDENDUM A PURE-SA 2015 PROTOCOL

PROSPECTIVE URBAN AND RURAL EPIDEMIOLOGICAL STUDY FOR SOUTH AFRICA (PURE-SA)

Principle Investigators:

Prof Annamarie Kruger
E-mail: annamarie.kruger@nwu.ac.za
Tel: 018 299-2095

Dr Lanthe Kruger
E-mail: lanthe.kruger@nwu.ac.za
Tel: 018 299-2093

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1 Introduction

This project is the South African arm of a global research study called PURE: Prospective Urban Rural Epidemiology Study; and the South African arm is referred to as PURE-SA. The main question of PURE global is aimed to answer the question: "How do societal transitions cause changes in the lifestyles of populations that predispose or protect them from chronic diseases, such as obesity, its consequences such as diabetes and cardiovascular diseases (coronary heart disease, strokes, and other atherothrombotic vascular diseases)?"

The overarching hypothesis is that lifestyle (activity and nutrition) and psychosocial transitions secondary to urbanization and industrialization (primordial determinants) are associated with obesity, elevated blood pressure, glucose and lipid levels. These factors interact with tobacco and alcohol use, leading to an increase in cardiovascular disease. These processes are partially mitigated by adaptive changes that "cushion" the harmful effects of the primordial determinants.

Therefore, PURE-SA explores societal, population and genetic level factors that lead to the development of these risk factors. Most causal risk factors available to date have been collected in Western countries. PURE-SA is addressing a need to study urban and rural populations in South African countries at different stages of the health transition. The health transition has several components, which are summarized here.

1. **The Urban Transition** is one of the most dramatic shifts in environment that populations around the world have experienced in the last century.

2. **The Nutrition Transition.** Economic growth and media influences have been hypothesized to change the traditional diet of populations previously living in subsistence conditions, to a Western style diet – high in fats, meats, refined carbohydrates, and low in fibre (6). This has also been found in THUSA (3).

3. **The Activity Transition.** Mechanization and impact on physical activity: Reduced physical activity and sedentariness have been associated with obesity, diabetes, and cardiovascular disease (CVD), especially in high-income countries (HIC).

4. **The Psychosocial Transition** includes anxiety and depression, in response to changing types and frequency of acute and chronic life events, which may be modified by inherent characteristics of an individual (coping), and by external factors (social disparity, social services, social support and networks). Depression, social isolation, and lack of social support are related to acute myocardial infarction (AMI) in HIC (7), middle-income countries (MIC), and low-income countries (LIC) (unpublished data from INTER-HEART). However, there are few data as to how stress and its impact differs between urban and rural populations.

5. **Variations in the Use of Tobacco and Potential Impact on CVD.** A large body of evidence indicates that smoking is the most common risk factor for CVD, but these data are largely from HIC (8), MIC and LIC (unpublished data from INTER-HEART).

6. **Interaction between Societal Transitions and Genetics.** Data from family studies initially suggested that genetic factors may explain up to 50% of the susceptibility to CVD. However, population based studies (including INTER-HEART), increasingly suggest that the majority (80% to 90%) of CVD susceptibility can be explained by a relatively small number of "classical" risk factors. Therefore, it seems likely that the most important susceptibility genes with regard to population health will be those influencing these risk factors. Genes with the largest effects on population risk will be those which determine differences in the physiological response of individuals to the environmental transition. Although many studies have attempted to study gene-environment interaction in CVD, few robust conclusions have resulted (9-12).

PURE-SA has established a unique cohort suitable for examining whether interactions between a variety of candidate genes for hypertension, dyslipidaemia, diabetes/glucose intolerance and CVD, and the rural or urban lifestyle is of similar strength, and due to the same or different alleles, in different populations.

SA is a developing country with limited resources and a large proportion of its people suffer from poverty, HIV/AIDS and under-nutrition. It is therefore of the utmost interest to limit the burden of NCD in this population. This study is providing SA with a direct estimate of the health / disease burden attributable to established and

emerging risk factors (such as obesity, diabetes, and hypertension) for non-communicable diseases (NCD) as well as CVD. The challenge will be to design and develop appropriate educational and health promoting programs with the emphasis on prevention rather than cure for these disadvantaged communities where rapid urbanisation still takes place.

Findings from PURE-SA will facilitate the development of effective public health policies in SA, which in turn should decrease the burden of disease for SA. Because societal changes are included in PURE-SA, other National, Provincial and Local Departments working in the fields of education, environmental affairs, housing, labour, public works, social development and sports could use information obtained within PURE-SA for policy development.

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2 Aims of the study

PURE-SA aims to understand the different lifestyles and health transitions of individuals, in response to societal changes, in order to elucidate societal and individual adaptive strategies that could diminish the adverse health effects of industrialization and urbanization on health, while retaining its benefits. Collection of data within PURE-SA helps to facilitate the development of effective public health policies in SA, which in turn could decrease the burden of disease for SA. The ultimate goal of this project will be to ensure transition of South Africa's disadvantaged people from an inadequate diet directly to an optimal / prudent diet and lifestyle rather than the current trend during which this transition is via a phase of a more adequate but imprudent diet and lifestyle.

2.1 Specific objectives of PURE-SA

1. To document urban versus rural differences in prevalence and incidence of rates of chronic diseases (such as obesity), cardiovascular risk factors (hypertension, elevated lipids, haemostasis, smoking), diabetes and CVD.

2. To determine the relative contributions of changes in physical activity and nutrition to chronic diseases, CV risk factors and CVD, and whether this varies between rural and urban communities.

3. To determine whether societal changes over time affect health behaviours of communities, which in turn affect rates of chronic diseases, cardiovascular risk factors, and CVD within communities?

4. To determine the societal influences that affect changes in psychosocial factors in multiple and diverse settings.

5. To determine if changes in health care affect health outcomes.

6. To determine how individual risk factors (tobacco, obesity, lipids, BP, glucose) relate to chronic diseases and CVD in settings where their average levels would be considered to be "low" (bottom half of the distribution).

7. To determine whether individuals at low risk for CVD are at higher risk of other non-communicable diseases.

8. Are genes which predispose individuals to the development of chronic diseases and CVD, the same in different populations, and are the fractions of disease attributable to specific causative alleles similar between populations? Is there any differential genetic susceptibility between ethnic groups to the environmental "stressors' (lower physical activity and increased caloric intake) associated with the transition from rural to urban living, and could these genetic factors mediate differences in chronic diseases and CVD risk?

3 Research methodology

3.1 Research design

PURE-SA is designed as a prospective epidemiological study, which means firstly that it is an observational study (the investigators have no control over the way in which subjects are exposed) and secondly that the exposure is measured in the present (recruitment phase) and that the outcome is recorded in the future (follow-up phase). Having said this, it should be noted that the recruitment phase itself can be regarded as a cross-sectional study where both exposure and outcome are measured in the present and at the same point in time. Exposure in PURE-SA is defined as the degree of urbanization.

3.2 Research sampling

The main selection criteria were that there should be migration stability within the chosen communities. All the baseline data for South Africa were collected during August to November 2005. The rural community (A) was identified 450 km west of Potchefstroom on the highway to Botswana. A deep rural community (B), 35 km east from A and only accessible with a gravel road, was also included. Both communities are still under tribal law. The urban communities (C and D) were chosen near to home due to financial constraints. Community C was selected from the established part of the Township next to Potchefstroom and D from the informal settlements surrounded community C.

Please see Section 4.1 and 4.2 regarding permissions that were received before entering the abovementioned communities.

A household census regarding the number of people, their ages and health profile was done in 6 000 houses (1 500 in each community) starting from a specific point. Every head of household signed written informed consent to fill out the questionnaire. If a person refused or was not at home, the next house was taken and a non-complier questionnaire was filled out.

3.3 Participant recruitment

3.3.1 Selection process - 2005

From the data obtained from the census a paper-based selection of possible subjects was made based on the following inclusion and exclusion criteria:

Inclusion criteria:

1. ≥ 35 years of age
2. ≤ 70 years of age
3. Males and females
4. No reported diseases of lifestyle, TB or HIV
5. Not using any chronic medication
6. Eligible participants have to reside in the households

Exclusion criteria:

1. < 35 years of age
2. > 70 years of age

3. Using chronic medication
4. Existing chronic conditions

Approximately 1 000 subjects from each community were selected. These 4 000 subjects were visited at home by a trained fieldworker (**See Section 4.4**) also acting as our mediators (**See Section 3.3.3**) within the communities.

After giving voluntary and informed consent **(Addendum 6)**, an extensive questionnaire regarding physical and psychological health, socio-economic background, lifestyle practices and support systems available were filled out by the participant. A total of 3 750 questionnaires were completed. At the time of baseline data collection (2005) a total of 2010 participants agreed to participate further within the study.

3.3.2 Role of the gatekeepers

Please refer to **Section 4.2** for details regarding the gatekeepers.

3.3.3 Role of the mediators

The fieldworkers act as the mediators between the research team and the participants. The live within the communities involved within the study. They fulfil an important role; not only do they track the participants enrolled in the study, but they act as advisors and offer support to the participants regarding basic health issues and health education.

3.4 Research procedures and data collection

Data collection occurs at three levels: 1) community, 2) household / family, and 3) individual).

1) Community level forms record the level of "urbanization" of rural communities, and a description of the "built" environment in urban and rural communities.

2) A Family Census Questionnaire records demographics, tobacco use, education and morbidities in all inhabitants of the household. A Household Questionnaire covers domains related to house structure, amenities, access to water and sanitation.

3) In all consenting and eligible individuals detailed additional information is recorded using the Adult-, Food Frequency-, and Physical Activity questionnaires.

Furthermore, at the individual level physical measures (anthropometry) are performed, blood and urine are collected; and ECGs, spirometry and grip strength are obtained. These methods were developed, standardized and tested in about 12 000 people in 10 countries. All physical exams and tests are done in a clinic setting utilizing standard methods; blood and urine samples are collected in the early morning with subjects fasting. Blood and urine samples are immediately stored in ice filled insulated containers and are centrifuged, aliquoted and stored at -20 degrees C within 2 hours of collection. Samples are then transferred to centralized long-term storage in –70oC freezers connected to power sources that can run independent of the local grid.

3.4.1 Data collection for: January 2005 – January 2015

During August until the end of November 2005, an appointment with each person who completed the questionnaire was made, and they were voluntarily picked up by taxi and brought to where a team of expert researchers were where they again gave informed consent for the measurement of lung function, ECG, and anthropometry, and for an urine, hair and a blood sample to be taken. They were asked to be in a fasted state for approximately 10 hours. Everyone was tested for HIV, but was given the choice whether they wanted to know their status or not. However, everyone received pre-test counselling in groups of 10 persons before the blood sample was taken and post-test counselling was done individually while giving the results on blood pressure, lung function, ECG and blood glucose to individuals before going home. Every individual identified with an abnormality regarding tested markers, were referred to the nearest clinic or hospital. A total of 2010 subjects were tested (approximately 500 from each community). Data on these 2010 subject's physical activity levels and habitual diets were also obtained by questionnaires. All the questionnaires and home visits were done by 16 intensively trained fieldworkers from the four different communities. Each fieldworker is responsible for 125 subjects for the next 10 years. During 2006 home visits to each subject (2010) were done by the authors of this paper together with the fieldworkers with the main aim to follow-up on who attended the clinic or hospital after being tested positive for HIV.

IN LIGHT OF THE LATEST ETHICAL GUIDELINES PRESENTED TO RESEARCHERS PERFORMING RESEARCH ON HUMAN SUBJECT, THE DATA COLLECTION METHODOLOGY FOR THE PERIOD 2015 HAS BEEN AMENDED ACCORDINGLY, AND ALL ETHICAL CONSIDERATIONS HAVE BEEN INCLUDED AND ADDRESSED APPROPRIATELY.

3.4.2 Data collection for: February 2015 – December 2015

From February until July 2015 the fieldworkers will perform house visits at every active participant to inform him / her about the upcoming follow-up measurements planned for the period of August until November 2015. The fieldworkers will be trained intensively (**See Section 4.4**) regarding the research procedures to fully and comprehensively inform the participants about all of the procedures in order for the participant to make an informed decision regarding continuing participation. Ample time (1 week) will be given to participants to consider participation.

Since this is a longitudinal study and research is on-going, out of respect for the participants, the fieldworker will obtain re-consent from all current active participants prior to the study (**See Section 4.3**). In the case where a participant has refused in the past to further participate or there is an event where a participant has moved out of the community, and has recently returned, these participants will also be visited again to re-invite them back to the study. If they are willing to participate / return to the study, they will be fully briefed about the upcoming study and re-consent will be obtained by the fieldworker, after which the researcher will sign the written informed consent form. Participants will also be given the opportunity to ask questions directly to the researcher.

Each participant will be picked up by a taxi on a pre-arranged date that suits the participant, and will be brought to the research facility (**See Section 4.6**). An independent person will reconfirm consent and will again emphasise that participation is completely voluntarily and that they may withdraw from the study at any point of time without being penalised in any way. If the participant does not re-consent or later withdraw from the study it will be brought to the attention of the participant that the data collected in 2005 and 2010 will still be used, and only new data collected in 2015 will be disregarded.

It will be expected of the participant to be in a fasting state for approximately 10 hours; therefore, upon arrival (after confirming written informed consent has been given) the participant will first give a blood sample (33 ml). Some of this blood sample will be used to obtain genetic material (DNA and RNA). Only genetic factors that are associated with non-communicable diseases will be investigated. Genetic analyses will include genotyping, gene expression and epigenetic analyses of these genes. No extra blood will be drawn for these analyses, rather more effective use of the blood

sample will be made i.e. aliquoting the buffy coat from the EDTA tube after centrifugation instead of discarding it.

After the blood sample is taken, participants will receive a light breakfast. Thereafter, in no specific order they will proceed to the following stations:

1. Cardiovascular measurements
    a. Electrocardiograph – non-invasive technique (Check by qualified person for abnormalities)
    b. Blood pressure – non-invasive technique
    c. Pulse wave velocity – non-invasive technique
    d. Intima-media thickness – non-invasive technique

2. Physical measurements
    a. Body composition – non-invasive technique
    b. Anthropometry – non-invasive technique
        i. Triceps skinfold
        ii. Bicep skinfold
        iii. Subscapular skinfold
        iv. Supra-iliac skinfold
        v. Height
        vi. Weight
        vii. Hip circumference
        viii. Waist circumference
        ix. Upper arm circumference
    c. Strength test - non-invasive technique
        i. Handgrip strength
        ii. Chair stand/rise test
        iii. 6m walk test (Potchefstroom only)
    d. Bone mineral density – non-invasive technique

3. Spirometry (lung function test) – non-invasive technique

4. Midstream urine sample

5. Validated questionnaires (**See addendums 9 – 16)**
    a. Household questionnaire

b. Participant questionnaire
c. Physical Activity Index (PAI) questionnaire
d. International Physical Activity Questionnaire (IPAQ)
e. Quantitative Food Frequency questionnaire
f. Bone health questionnaire
g. HIV and stigma questionnaire
h. Psychological questionnaires

6. PURE-FORT
    i. MHC-SF
    ii. SWLS
    iii. Affectometer
    iv. MLQ
    v. PHQ-9
    vi. K6
    vii. MMSE

7. Information regarding medication usage (**See section 4.10**).

8. HIV testing and CD4 count if the participants consent to this (individual pre- and post-counselling will be performed by professional and experienced counsellors). During the process of obtaining written informed consent from the participant, the participant will be asked whether or not they would like their status to be disclosed to them.

All of the measurements and questionnaires will be done by experienced and professional members of the research team (**See Section 4.4**)

When a participant has finished for the day, results that are immediately available (**See Section 4.11**) will be reported back to each participant individually **(See Section 4.6 and Section 4.5**). This will be done by one of the experienced researchers. Every individual identified with an abnormality regarding tested markers, will be handed a referral letter and referred to the nearest clinic or hospital. The principle investigator will visit the local hospital and clinics to inform them about the upcoming follow-up study and to make pre-arrangements for possible referrals.

4 Ethical considerations

4.1 Legal authorisation

This study gained permission from the North West Department of Health **(See Addendum 3**). Ethical approval was obtained from the Ethics Committee of the North-West University for the period January 2005 – December 2009 (ethical number 04M10) **(See Addendum 1 and 2)** as well as for the period 2010 – January 2015 (ethical number NWU-0016-10-A1) **(See Addendum 4)**. Additional ethical clearance was also obtained from the ethic committee to include additional measurements of bone mineral density (**See Addendum 5**) in all of the participants. An extension of the current ethical approval was obtained from the Health Research Ethics Committee (HREC) of the Faculty of Health Sciences from the North-West University until December 2020 (ethical number NWU-00016-10-A1). This HREC is registered at the National Health Research Ethics Council (NHREC) of South Africa.

4.2 Goodwill permission

The principle investigator (PI) of PURE made appointments with the Mayors of both Potchefstroom and Ganyesa. During the meetings the PI fully informed them about the aims of the study and what the possible outcomes and benefits of the study are. The research procedures were also explained, and permission was granted to proceed with the planned study

After permission was obtained from the Mayors, the *inkosi* (tribal chief) of the rural communities in Ganyesa and the community leaders in the urban areas (acting as the gatekeepers for each community) were approached. Verbal permission was obtained from the gatekeepers to perform the study within their communities. This will be done again prior to the 2015 follow-up study as an act of respect.

4.3 Participant: written informed consent

It is a legal obligation to attain written informed consent form participants before participating in any research. Since this is a longitudinal study and research is on-going, out of respect for the participants, the fieldworker will obtain re-consent from all current active participants prior to the study. The fieldworkers (mediators) will perform house visits to each individual at least three (3) months prior to the start of the study. During these visits they will inform the participants about the upcoming follow-up study. All of the procedures / measurements that will be performed on the study day will then be discussed and explained in full to each individual by the

fieldworker, they will also be given an opportunity to ask questions. This will process will be done in the participant's preferred language (Tswana, English or Afrikaans). A repeat visit will be done one month prior to the start of the study. During this visit, the fieldworkers will again fully inform the participant about the study and give them opportunity to ask questions. The participant will be given 1 week to consider further participation within the study. After a week the fieldworker will go back to the participant, and if the participant agrees to partake in the study, the fieldworker will obtain re-consent. In the case where a participant is illiterate, the right thumb print will be taken as substitute for a signature.

They will again be reminded that participation is completely voluntarily and that they can withdraw from the study at any point before data analyses without any consequences or being penalised. The fieldworkers will then schedule an appointment, that suits the participant, and logistical arrangements will be made. The day before the participant is scheduled to arrive at the research facility, the fieldworker will do one last house visit, to make final arrangements with the participants regarding pick-up time and to remind and explain to them to bring along all necessary documentation (**See Section 4.5.2 and 4.10**). The fieldworkers will once more remind the participants to be in a fasting state and ensure that they understand that this entails that they should not eat or drink anything from 22:00 onwards, except water.

At the day of the study, upon arrival, the lead researcher of the day will collect the signed written informed consent forms and again remind the participants that participation is completely voluntarily and that they may with draw at any time (up to data analyses) without being penalised. The fieldworker as well as the researcher will make sure that the participant understands everything before they sign the written informed consent.

In the case where a participant has refused in the past to further participate or there is an event where a participant has moved out of the community, and has recently returned, these participants will also be visited again to re-invite them back to the study. If they are willing to participate / return to the study, they will be fully briefed about the upcoming study and re-consent will be obtained by the fieldworker.

4.4 Expertise, skills and legal competencies

All of the researches and assistants (nurses, anthropometrists, counsellors, students) that are part of this study are all experienced in their fields and all staff members are standardised in terms of data collection and completion of questionnaires prior to the study. Physical and anthropometric measures are gathered by staff using standardized protocols. Key staff (principal investigator, coordinator, and nutritionists) attended initial training. They in turn trained local staff. These staff were trained and tested on "mock" subjects in order to ensure that measured values between interviewer and a local certified "expert" (supervisor) are within an acceptable range. If between interviewers variation compared to the supervisor is unacceptable, the staff member is retrained. A random 20% of all ECGs and all positive ECGs are checked by a second physician for accuracy.

The fieldworkers are re-trained intensively every time prior to any form of data collection, *inter alia* all the procedures of the study, in order to give the participants a comprehensive overview of what will be expected of them on the day of the study. The fieldworkers will also be responsible for completing the following questionnaires on the study days: 1) Household questionnaire, 2) Adult questionnaire, and 3) the HIV and stigma questionnaire. They will be intensively trained beforehand on how to complete these questionnaires.

Blood samples will be collected by professional registered nurses, with experience in collecting blood samples for research purposes, minimising risk / harm to the participants and themselves.

4.5 Privacy and confidentiality

People, whether or not in a research setting, should always be treated in such a way that they can exercise their right to autonomy. This includes their right to privacy and confidentiality. Through maintaining privacy and confidentiality, participants are protected from potential harm such as psychological harm, social harm or even stigmatization.

4.5.1 Privacy

Privacy refers to *inter alia* how information is gathered from a participant, i.e. the circumstances under which a participant has to expose / share themselves physically

(physical measurements such as anthropometry) or intellectually (questionnaires) with the researcher(s).

Privacy of the participants will be ensured by using either private rooms or dedicated areas that will be closed off from the general research area (**See Section 4.6**). In the case where a measurement requires the participant to partially undress, it will be ensured that there are two people present (researcher and an assistant) in the room or dedicated area. It will also be ensured that the participant is comfortable with the gender of the researcher and assistant taking the measurements.

During the completion of questionnaires, only the researcher and / or assistant will be present. Any other members of the research team or participants will not be allowed within these dedicated areas. Privacy will further be guaranteed by ensuring that the conversation between the participant and interviewee will not be overheard by any other person or passer-by.

4.5.2 Confidentiality

Confidentiality pertains to how information is treated after it has been disclosed to the researcher, whether it is verbal information or physical information.

Each participant was assigned a unique participant number during the initial baseline data collection in 2005. This unique number is used in all stages of data gathering. Upon arrival on the day of the study, the participant has to produce their South African identity document, in order to verify the ID number against their unique participant number. This is done only by the project coordinators. No other researcher and / or assistant will have access to this information or be involved in the process.

Furthermore, participants are not required to provide their personal information to any other researcher or assistant, except in some cases date of birth is required for input into research apparatus. All of the data captured will be done so by using the unique participant number. The data that has been electronically captured will be handed to the PI of the study, and he / she will match the new data with existing data in the master data set.

See **Section 4.12.2** on confidential handling of electronic data.

4.6 Facilities

4.6.1 Urban facilities

Participants will be collected on a pre-arranged date at a central point within the community by a taxi, and brought to the Lipid Clinic at the North-West University. The Lipid Clinic has several private rooms where all the stations will be set-up for measurements. Some of the measurements will not be performed at the Lipid Clinic premises, and will be performed at the campus's Healthcare Centre as well at the Hypertension Clinic, all which have private rooms.

The HIV counsellors will also have a private room that will be secluded from the rest of the research area to ensure complete privacy for pre- and post-counselling.

4.6.2 Rural facilities

Participants will be collected on a pre-arranged date at a central point within the community by a taxi, and brought to the research facility situated at Setlhare Lodge which is located within the rural community. Tents and gazebos will be erected on the premises of Setlhare Lodge and will serve as the research facility. Each researcher will receive a dedicated area which will be closed off and private to set up for performing their measurements.

Sensitive measurements (required to remove top layer of clothing) such as anthropometry, body composition, ECG, and pulse wave velocity will be performed within the lodge's seminar room. Within the seminar room dedicated areas will be set up which will also be closed off to ensure privacy.

The HIV counsellors will also have a private room that will be secluded from the rest of the research area to ensure complete privacy for pre- and post-counselling.

4.7 Benefits

4.7.1 Direct benefits

Participants partaking in the study will directly benefit from the day's measurements in the sense that feedback will be given to them regarding results that are immediately available. This includes:

- Blood pressure
- Blood glucose levels
- Pulse wave velocity

- ECG
- Intima-media thickness
- HIV status (this will be done only by professional counsellors)
- Anthropometry
- Bone mineral density
- Lung function
- Strength tests

In the case of any abnormalities that are picked up on any of the measurements, the lead researcher for the day will provide the participant with a referral letter that they should take to their nearest hospital or local clinic. The principle investigator will visit the local hospital and clinics to inform them about the upcoming follow-up study and to make pre-arrangements for possible referrals.

4.7.2 Indirect benefits

SA is a developing country with limited resources and a large proportion of its people suffer from poverty, HIV/AIDS and under-nutrition. It is therefore of the utmost interest to limit the burden of chronic diseases in this population. Through participating within the PURE study, they will help to provide SA with a direct estimate of the health/disease burden attributable to established and emerging risk factors for obesity, diabetes and CVD.

Ultimately, a large proportion of the South African population should benefit from this project, because the long-term goal of PURE is to ensure transition of South Africa's poor people from an inadequate diet directly to an optimal/prudent diet and lifestyle rather than the current trend during which this transition is via a phase of a more adequate but imprudent diet and lifestyle.

Findings from the PURE study will help to facilitate the development of effective public health policies in SA, which in turn should decrease the burden of disease for SA, hence indirectly benefiting the overall population.

4.8 Dangers / risks / discomforts and precautions

As with any research involving human participants, there is always some form of risk involved. Although most of the techniques and procedures that are going to be used

during the study are non-invasive, there are some discomforts that might be experienced during some of the measurements:

1. Participants will be asked to give a blood sample (which is an invasive procedure) which might cause some discomfort or anxiety. As a precaution to the latter mentioned and to minimise risks of possible injuries to the participants as well as staff members we will make use of professional and registered nurses to collect blood samples (**See section 4.4**). The nurse will explain every step of the blood collection procedure to the participant as they go along, in order to put them at ease.

2. During some of the measurements (anthropometry, body composition, ECG, and pulse wave velocity) the participants are requested to remove the top layer of their clothes (remaining only in their underwear or light clothing) in order for the researcher to conduct the necessary measurements. This might make the participant feel uncomfortable. In order to minimize any discomfort the areas dedicated to these measurements will be closed off and private (**See Section 4.6**) and only the researchers and / or assistant will be present.

3. Participants will have to arrive at the research facility in a fasting state for blood samples to be collected. Being in a fasting state might make the participant feel uncomfortable or perhaps light headed. A light breakfast will be provided to them as soon as the blood sample is collected to relieve their fasting state.

4. Concluding all of the measurements mentioned in **Section 3.4.2** will take approximately a whole day, which might be very exhaustive for some participants. In order to minimize their discomfort participants will be provided with a lunch as well as tea / coffee / juice / water throughout the duration of the day at the seating / waiting area.

5. After finishing at a measurement station, research assistants will help the participants along to the next station to avoid them not knowing where to go and hence wasting their time and energy.

6. HIV testing will also be performed on the day of the study (with the participants consent). Being newly diagnosed with a chronic disease such as HIV might

cause some anxiety within some participants. Participants might also refuse to have their status disclosed to them due to them being in denial. As precautionary steps a registered HIV counsellor will perform pre-counselling on the participants as a group. Professional counsellors will perform the testing. After each testing, regardless the outcome, individual post-counselling will be performed on an individual level. During the post-counselling session, the counsellor will provide necessary information regarding HIV/AIDS and support to each participant. In the event where a participant agrees to have their status disclosed to them, they will also receive a referral letter to their nearest clinic or hospital for further treatment.

7. With regard to the genetic analyses, the applicants are focussing on genes that are involved in non-communicable disease. As such we will be dealing with genetic susceptibility analyses. As these results are unlikely to be definitive markers of disease development, due to the complex nature of these diseases, it is not ethically justified to give individual results to the participants directly although information about the consolidated findings will be made available in general. It is unlikely that any reportable i.e. diagnostic genetic findings will be determined due to the nature of the analysis.

4.9 Incentive and reimbursement

Participants will be conveyed by transport provided by the research study (North-West University) and no travelling expenses are foreseen.

Participants are required to arrive in a fasting state (at least 10 hours) at the research facility in order to provide a blood sample. After the blood sample was collected a breakfast will be provided to the participants. Furthermore, in order to complete all of the measurements and questionnaires, participants will have to be at the research facility approximately the whole day, thus, lunch will also be provided. Tea / coffee / juice / water will be available throughout the day.

Participants will also be financially compensated to the amount of R100.00 (one hundred rand) per day for any expenses or loss of income incurred due to their attendance at the study, for example if they are referred to the local hospital / clinic they will have some funds available.

If a participant is fulltime employed, their employer will be contacted and employment will be confirmed. Daily remuneration will also be confirmed with the employer and the participant will be compensated for loss of income for their attendance at the study. Only one day will be compensated for.

4.10 Access to privileged data / information

Participants will be asked to bring along their medication that they are currently using for any chronic or non-chronic conditions as well as their clinic books and / or any other medical records within their possession to confirm any reported medical / health events (such as heart attack, stroke, asthma attack, injury etc.). Participants have to provide written informed consent in order for researchers to obtain and access this privileged information.

Furthermore, in the case of HIV-infected participants access to hospital records / patient files will also be requested to obtain information regarding history of the type of anti-retroviral therapy (ART) used, year of diagnoses, years since diagnoses, history of CD4 counts, viral load and history of renal function.

To access this privileged information, written informed consent will be obtained from the participant well as additional permission from the hospitals' and / or clinics' supervisors will be obtained.

4.11 Announcements of results

Measurements that are immediately available on the day of the study will be reported back verbally and individually. This will take place privately in the form of a referral letter and include the following:

- Blood pressure
- Pulse wave velocity
- ECG
- Intima-media thickness
- HIV status
- Anthropometry
- Lung function
- Strength tests

The information will be discussed and explained to them by the lead researcher of the day. If any abnormalities are present, it will be discussed with the participant and they will be referred to their nearest hospital or local clinic.

Feedback will also be given to the North West Department of Health in the form of an official report regarding the disease burden within these communities.

Results will also be published in peer-reviewed academic journals, conference proceedings and health reports.

4.12 Storage and archiving of data

4.12.1 Hard copy data

All hard copies will be stored in a locked office within AUTHeR at the North-West University (Potchefstroom Campus). Since the hard copies contain identifiable data (personal information) of each individual participant, strict control over the hard copies will be applied. Hence, only the supervisors will have access to the hard copies. The hard copies will be securely stored for 5 years after the study has finished. After 5 years it will be destroyed according to the North-West University's rules and regulation for data / record management.

4.12.2 Electronic data

Data that has been electronically captured will be stored on a central computer and will be password protected. The data set will only be accessible to the principle investigator. For research and dissemination purposes, data will be made available to other team members (researchers) via the PI and only upon request. Data will be handed to them in a format that contains no personal information regarding the participants (de-identified data set) and thus researchers will not be able to identify any participants based upon the data received.

All electronic data will be backed-up on an external hard drive which will be locked up in a cupboard within a locked office at AUTHeR at the North-West University.

4.12.3 Access to data

First most, it is important to note that this is an international study which includes 25 countries. PURE is supervised by the Public Health Research Institute (PHRI), Hamilton, Canada, under the administration and supervision of Prof Salim Yusuf. We

are under contractual agreement to send some of the data to PHRI on an annual basis. As a research institute, PHRI, complies and accords to all research ethics to ensure data is handled private, secure and confidential.

Furthermore, no data will be accessed by any person unless permission is granted by the principle investigator / project leader, and even then only the necessary data will be provided.

4.12.4 Sample storage and analyses

Blood and urine samples collected up to 31 December 2015 will be stored for further analyses. These analyses will only take place as financial funding becomes available. Samples may be sent to laboratories outside of South Africa for analyses if expertise and / or equipment are not locally available. This will however not be done without HREC approval as well as the relevant permits from the Department of Health and only if the participant has indicated on their written informed consent form that their samples may be sent overseas. This will result that samples will be stored for an unspecified period of time. To ensure the integrity of the samples while in storage, blood and urine samples will be stored at -80 degrees C in secure lockable bio-freezers until determination of the variables examined in this study. Access to these bio-freezers is limited to key personnel. These bio-freezers are constantly monitored via a cellular-based monitoring system. Sample integrity **is** furthermore maintained via the connection of the freezers to uninterrupted power supplies and centralised power generators.

4.12.5 Declaration

We declare that no participant will be re-approached after 31 December 2015 to collect new additional data under the newly extended ethical approval. Only data that was collected up to 31 December 2015 will be used for primary and secondary analyses. Primary and secondary analyses will only be performed if they are in line with the original scope and aims of the PURE study as stipulated within the umbrella application. In the case of secondary analyses, the researchers will apply for individual ethical approval for these analyses / studies.

ADDENDUM B PURE-SA 2015 HREC APPROVAL

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT

Private Bag X6001, Potchefstroom
South Africa 2520

Tel: (018) 299-4900
Faks: (018) 299-4910
Web: http://www.nwu.ac.za

Ethics Committee
Tel +27 18 299 4849
Email Ethics@nwu.ac.za

ETHICS APPROVAL OF PROJECT

The North-West University Research Ethics Regulatory Committee (NWU-RERC) hereby approves your project as indicated below. This implies that the NWU-RERC grants its permission that provided the special conditions specified below are met and pending any other authorisation that may be necessary, the project may be initiated, using the ethics number below.

Project title: PROSPECTIVE URBAN AND RURAL EPIDEMIOLOGY STUDY (PURE STUDY)

Project Leader: Prof A Kruger

Ethics number:

N	W	U	-	0	0	0	1	6	-	1	0	-	A	1
Institution				Project Number						Year			Status	

Status: S = Submission; R = Re-Submission; P = Provisional Authorisation; A = Authorisation

Approval date: 2015-01-20 **Expiry date**: 2020-01-20

Special conditions of the approval (if any): None

General conditions:

While this ethics approval is subject to all declarations, undertakings and agreements incorporated and signed in the application form, please note the following:

- *The project leader (principle investigator) must report in the prescribed format to the NWU-RERC:*
  - *annually (or as otherwise requested) on the progress of the project,*
  - *without any delay in case of any adverse event (or any matter that interrupts sound ethical principles) during the course of the project.*
- *The approval applies strictly to the protocol as stipulated in the application form. Would any changes to the protocol be deemed necessary during the course of the project, the project leader must apply for approval of these changes at the NWU-RERC. Would there be deviated from the project protocol without the necessary approval of such changes, the ethics approval is immediately and automatically forfeited.*
- *The date of approval indicates the first date that the project may be started. Would the project have to continue after the expiry date, a new application must be made to the NWU-RERC and new approval received before or on the expiry date.*
- *In the interest of ethical responsibility the NWU-RERC retains the right to:*
  - *request access to any information or data at any time during the course or after completion of the project;*
  - *withdraw or postpone approval if:*
    - *any unethical principles or practices of the project are revealed or suspected,*
    - *it becomes apparent that any relevant information was withheld from the NWU-RERC or that information has been false or misrepresented,*
    - *the required annual report and reporting of adverse events was not done timely and accurately,*
    - *new institutional rules, national legislation or international conventions deem it necessary.*

The Ethics Committee would like to remain at your service as scientist and researcher, and wishes you well with your project. Please do not hesitate to contact the Ethics Committee for any further enquiries or requests for assistance.

Yours sincerely

Linda du Plessis

Digitally signed by Linda du Plessis
DN: cn=Linda du Plessis, o=NWU, Vaal Triangle Campus, ou=Vice-Rector: Academic, email=linda.duplessis@nwu.ac.za, c=US
Date: 2014.12.02 18:42:40 +02'00'

Prof Linda du Plessis
Chair NWU Research Ethics Regulatory Committee (RERC)

ADDENDUM C AFFILIATED STUDY APPROVAL LETTER

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT

Private Bag X6001, Potchefstroom,
South Africa, 2520

Tel: (018) 299-4900
Faks: (018) 299-4910
Web: http://www.nwu.ac.za

Institutional Research Ethics Regulatory Committee
Tel: +27 18 299 4849
Email : Ethics@nwu.ac.za

2016/07/26

ETHICS APPROVAL CERTIFICATE OF STUDY

Based on approval by **Health Research Ethics Committee (HREC)** on **19/07/2016** after being reviewed at the meeting held on **08/06/2016**, the North-West University Institutional Research Ethics Regulatory Committee (NWU-IRERC) hereby **approves** your study as indicated below. This implies that the NWU-IRERC grants its permission that provided the special conditions specified below are met and pending any other authorisation that may be necessary, the study may be initiated, using the ethics number below.

Study title: **The association between anthropometric measures and physical performance in black adults of the North West Province, South Africa.**

Study Leader/Supervisor: **Prof HS Kruger**
Student: **P Mamphwe**

Ethics number:

N	W	U	-	0	0	0	5	5	-	1	6	-	A	1
Institution				Study Number						Year			Status	

Status: S = Submission; R = Re-Submission; P = Provisional Authorisation; A = Authorisation

Application Type: Single Study
Commencement date: 2016-07-19 **Risk:** Minimal

Continuation of the study is dependent on receipt of the annual (or as otherwise stipulated) monitoring report and the concomitant issuing of a letter of continuation up to a maximum period of three years.

Special conditions of the approval (if applicable):

- Translation of the informed consent document to the languages applicable to the study participants should be submitted to the HREC (if applicable).
- Any research at governmental or private institutions, permission must still be obtained from relevant authorities and provided to the HREC. Ethics approval is required BEFORE approval can be obtained from these authorities.

General conditions:

While this ethics approval is subject to all declarations, undertakings and agreements incorporated and signed in the application form, please note the following:

- *The study leader (principle investigator) must report in the prescribed format to the NWU-IRERC via HREC:*
  - *annually (or as otherwise requested) on the monitoring of the study, and upon completion of the study*
  - *without any delay in case of any adverse event or incident (or any matter that interrupts sound ethical principles) during the course of the study.*
- *Annually a number of studies may be randomly selected for an external audit.*
- *The approval applies strictly to the proposal as stipulated in the application form. Would any changes to the proposal be deemed necessary during the course of the study, the study leader must apply for approval of these amendments at the HREC, prior to implementation. Would there be deviated from the study proposal without the necessary approval of such amendments, the ethics approval is immediately and automatically forfeited.*
- *The date of approval indicates the first date that the study may be started.*
- *In the interest of ethical responsibility the NWU-IRERC and HREC retains the right to:*
  - *request access to any information or data at any time during the course or after completion of the study;*
  - *to ask further questions, seek additional information, require further modification or monitor the conduct of your research or the informed consent process.*
  - *withdraw or postpone approval if:*
    - *any unethical principles or practices of the study are revealed or suspected,*
    - *it becomes apparent that any relevant information was withheld from the HREC or that information has been false or misrepresented,*
    - *the required amendments, annual (or otherwise stipulated) report and reporting of adverse events or incidents was not done in a timely manner and accurately,*
    - *new institutional rules, national legislation or international conventions deem it necessary.*
- *HREC can be contacted for further information or any report templates via Ethics-HRECApply@nwu.ac.za or 018 299 1206.*

The IRERC would like to remain at your service as scientist and researcher, and wishes you well with your study. Please do not hesitate to contact the IRERC or HREC for any further enquiries or requests for assistance.

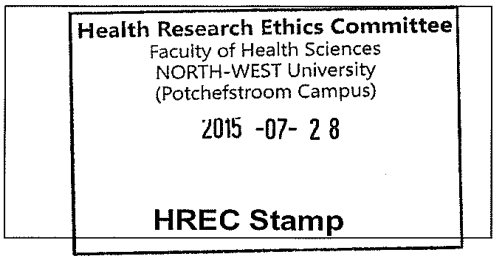
Yours sincerely

Prof LA Du Plessis
Digitally signed by Prof LA Du Plessis
Date: 2016.08.04 08:47:16 +02'00'

Prof Linda du Plessis
Chair NWU Institutional Research Ethics Regulatory Committee (IRERC)

ADDENDUM D PURE-SA 2015 CONSENT FORM

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT
POTCHEFSTROOM CAMPUS



INFORMATION LEAFLET AND WRITTEN INFORMED CONSENT FORM FOR PARTICIPANTS OF THE PURE STUDY

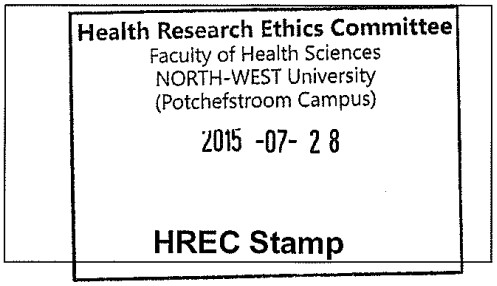
TITLE OF THE RESEARCH PROJECT: Prospective Urban and Rural Epidemiology (PURE) study

REFERENCE NUMBERS: NWU-00016-10-A1

PRINCIPAL INVESTIGATORS: Prof A Kruger and Dr IM Kruger

ADDRESS: North-West University (Potchefstroom Campus), Africa Unit for Transdisciplinary Health Research (AUTHeR), Building E8, Office G03.

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT
POTCHEFSTROOM CAMPUS



INFORMATION LEAFLET AND WRITTEN INFORMED CONSENT FORM FOR PARTICIPANTS OF THE PURE STUDY

TITLE OF THE RESEARCH PROJECT: Prospective Urban and Rural Epidemiology (PURE) study

REFERENCE NUMBERS: NWU-00016-10-A1

PRINCIPAL INVESTIGATORS: Prof A Kruger and Dr IM Kruger

ADDRESS: North-West University (Potchefstroom Campus), Africa Unit for Transdisciplinary Health Research (AUTHeR), Building E8, Office G03.

Dear participant

You have been part of the PURE research since it started in 2005. Whether you took part in the research every year or even only some of the years, we would like to invite you once more to be part of this research.

This information document will provide you with all the information that you need to know about the research. A fieldworker who lives within your community will discuss all of the information in this document with you in order for you to understand why this research is done and why you are invited to be part of this research.

What is this research about?

This research has already started in 2005 and will finish in December 2015. This research study wants to look at different risks to your health and how these risks can develop over time.

What are some of the risks to your health?

- Being too fat (overweight or obese) or too thin (underweight),
- Having high blood pressure (hypertension) or too low blood pressure (hypotension),
- Having too high blood sugar levels (hyperglycaemia) or too low blood sugar levels (hypoglycaemia),

What might cause you to develop some of these risks?

- The type of foods you eat, for example too much salt or too much fat;
- If you don't do any exercise;
- Smoking or using tobacco products;
- Drinking alcohol;
- Some factors (genetic characteristics) that you inherit from your parents or even your grandparents,

Why have you been invited to take part in the study?

You have been invited to be part of the study because:

- In 2005:
    - you were between the ages of 35 and 70 years
    - you were a healthy man or woman

- you did not have any chronic disease or illness
- you permanently lived in a household within the community

Even though you might have developed some illness since 2005, you can still be part of the study. If you are part of the study now we want to see how you are doing.

Do you have to take part in the study?

You are not forced to take part in this research. It is important that you understand that you don't have to be part of this research study. You are invited, and therefore you can choose if you want to be part or not. You can agree to be part of the research now and change your mind later. If you do not want to be part of the research anymore, you will not be treated differently and you will not be punished or judged for not wanting to be part of the research.

This research was approved by a group of people (known as a committee) from the North-West University. These people looked at all the procedures of the research to make sure that if you decide to be a part of the research, you will not be hurt or harmed in any way. These people are known as the Health Research Ethics Committee of the Faculty of Health Sciences of the North-West University on the Potchefstroom campus. It might happen that during the research one or more of these committee members may come to check that the researchers are keeping to the procedures that was explained to you and no unnecessary procedures are performed on you.

What will you have to do if you decide to be part of the study?

If you decide to be part of the study the following will be done:

- A fieldworker that lives within your community will visit you at your house and he / she will explain everything to you and let you ask any questions if you don't understand anything. You will then be given 7 days to think about whether you want to continue to be part of the research.

- If you, after 7 days, agree to continue to be part of the research and you understand everything, you will sign a form, known as a written informed consent form, with the fieldworker.

- Once you have signed the written informed consent form an appointment will be made with you for you to come to the research facility. The date that will be scheduled with you, will be one that suits you the best. All of the arrangements will be made with you to bring you to the place where the research will take place.

- On the day of the appointment one of the taxis involved in the research will pick you up from a place that was arranged with you.

- When you arrive at the place where the research will take place the following will be done with your permission / consent:
    - A small amount of blood (33 ml) will be drawn from the inside of your arm.
    - Your blood pressure will be measured.
    - Your heart function will be checked (electrocardiogram). For us to be able do this test, you will be asked to take off your shirt or blouse to reveal your chest. If you are a women, you are allowed to keep on your underwear. Little round stickers will be placed on your skin all around the area of your heart.
    - The speed that the blood travels through your blood vessels will be measured (pulse wave velocity). This will be done by placing a thing that looks like a pen on the skin of your neck while placing another one on the skin near your pubic area. For us to be able to do this test, the researcher will gently pull down your pants or skirt to reveal just a small area between the inside of your leg and your private area (pubic area) where the pen-like device will be placed.
    - Your blood vessels in your neck will be checked for any blockages or deposits (intima-media thickness) by placing some liquid gel on the skin of your neck and then by using a thing that looks like a torch to take a picture (sonar) of your blood vessels.
    - You will be weighed and your body length will be measured. You will be asked to remove your shoes and all of your extra clothing. You will be allowed to keep on your pants / skirt and your shirt / blouse.
    - The amount of body fat and amount of muscles you have will be measured. You will be asked to remove just your shirt / blouse. If you are a women, you may keep your underwear on. The thickness of your skin on

your stomach, arms and back will be measured using a tong-like instrument. The researcher will pinch the skin between their fingers and place the tong over the skin to measure how thick the skin fold is. A measuring tape will also be used to measure the circumference of your hip, waist and upper arm.

- The amount of fat and muscle will also be measured using a special machine called the Bodpod. You will be asked to climb into the machine and sit on a little bench. A see-through lid will close around you. You will be asked to sit very still and make no movements at all. The machine will blow some air around you and this will then measure the amount of fat and muscle in your body. You will need to wear a tight pants and tight shirt. We will also give you a swimming cap to put on your head while you are in the machine.
- A photo (X-ray) will be taken of your forearm to see if the bones are still hard and strong (bone mineral density).
- Your lung function will be measured. A little plastic pipe will be placed between your lips. Then you have to take a deep breath and blow out the air as hard and as fast as you can through the little pipe.
- You will perform a test to see how strong you're muscles in your hands / forearm (hand grip strength) and legs are (chair stand / rise and walk test). To test how strong your muscles in your hand is you will be asked to squeeze your hand very tight around an instrument with a handle. To test the strength of your muscles in your legs you will have to sit down on a chair and then stand up without using your hands and arms. You will also be asked to walk on a straight line for 6 metres without any help.
- You will complete several questionnaires.
- You will be asked information regarding all the medicines that you currently use.
- You will be asked to give a little bit of urine in a small bottle.
- If you agree and give permission, a HIV test will be performed (If you do not want to be tested for HIV, you can still be part of the study). A needle will be used to prick one of your fingers to get a small drop of blood. This drop of blood will be used to do the HIV test.
- If you are newly diagnosed with HIV, or if you are currently HIV positive we will test your CD4 count. This test will show us how many CD4 cells

there are in your body. These cells keeps your body healthy and prevents you from getting sick. If the number of cells are too low then you will need medicine (anti-retroviral therapy (ART)). This test is done by a small prick on one of your fingers to get a drop of blood. The drop of blood will be used to count the number of CD4 cells in your body.

- If you are HIV positive, and you agree and give permission, personal information will be collected from your personal files that are kept at the hospital or clinic that you attend. This will provide us with information to better understand how HIV and the treatment you receive for HIV influence your health.

What do you have to do before coming to the study?

- We ask that you do not eat or drink anything (except for water) from the previous night 22:00 (ten o'clock). This will help to see if your blood sugar levels are normal.
- Please bring along all the medication that you are currently drinking
- Please bring along your South African ID document
- Please bring along your clinic book or medicine sheet that contains all your medication that is prescribed to you

Will you benefit from taking part in this research?

When you are finished for the day, some of the results will be given back to you. This will include:

- Blood pressure
- Blood sugar levels
- Heart function (electrocardiogram)
- Lung function (spirometry)
- How hard the bone in your forearm is (bone mineral density)
- How strong your muscles in your hand / forearm (hand grip strength) and legs (chair stand / rise and walk test) are
- Your height and weight
- Your HIV status and most resent CD4 count – if you gave permission for the test to be done and you want to know your status

If you participate you will also help us to understand what the risks are to your health. If we know what the risks are we can help the government to set up policies that will address this health risks in order to help other South Africans, like you, to have better health.

Are there any dangers involved in you taking part in this research?

Most of the measurements that will be performed won't hurt or harm you in any way, but you might experience the following:

1. If you give permission to a blood sample, you might feel uncomfortable or scared. We want to make sure that you are not hurt in any way and therefore we will use a qualified nurse that has a lot of experience. She will talk to you and explain to you everything that she is going to do in order for you to feel at ease. Some of this blood will be used (tested) to help us to understand what the reason(s) are that some people get non-infectious (non-communicable) diseases (such as heart attack and stroke) as well as high blood sugar (Type 2 Diabetes) and high body weight (obesity) and others may not. All the blood tests and experiments will only look at the reasons that change your chance of getting non-communicable diseases of lifestyle.

2. Some of this blood will also be used to get genetic material (DNA and RNA) to look at genetic factors. Genetic factors (inherited from your parents) are like a book that tells your body how to work. Sometimes there are mistakes (genetic alterations) that cause an increase in your chance of getting non-communicable diseases (these are diseases of the heart and blood vessels (such as heart attack and stroke) as well as high blood sugar (Type 2 Diabetes) and high body weight (obesity). We want to look at these genetic mistakes to better understand how these diseases develop. We promise that all genetic tests and experiments will only focus on genetic factors that contribute to your chance of getting non-communicable diseases of lifestyle.

3. During some of the measurements (weight and height, body composition, ECG, and pulse wave velocity) you will be asked to remove some of your clothes keeping only your underwear or light clothing on. This might make you feel uncomfortable or shy. To help you feel less shy and uncomfortable the area where these measurements will be done will be private and closed off. This

means that no one will be able to see you and that only the person that will take the measurements and someone to help him / her will be with you.

4. You will be asked to do a test (strength test) in order to see how strong the muscles in your hand / forearm and legs are. Although this is not a very hard test to do, and it does not take very long (only a few minutes) you might get tired. The researcher will ask you to rise / stand up from a chair as well as to walk 6 meters. If you feel that you cannot do the test, you will not be forced to do it, and you can move on to the next station.

5. You will be asked not to eat or drink anything from 22:00 (ten o'clock) the night before you come to the study. You will only be allowed to drink water. You should also not eat any breakfast on the morning of the study and not drink coffee, tea, juice or cold drink. Not eating or drinking anything might make you feel uncomfortable or light headed (dizzy or faint). As soon as you arrive at the research study, we will take a blood sample (if you give us permission) and then we will give you a light breakfast to make you feel better.

6. Doing all of the measurements on the day of the study, will take the whole day. This might make you feel very tired. We will give you a lunch as well as tea / coffee / juice / water throughout the duration of the day at the seating / waiting area.

7. Being part of such a big study can be frightening and overwhelming. To prevent us from wasting your time and to make sure that you know where to go and what to do, there will be people available at all times to help you and show you where you have to go every time.

8. HIV testing will also be performed on the day of the study (with your permission). Being newly diagnosed with a long-lasting disease such as HIV might cause you to worry. To help reduce the worry, there will be a professional person (counsellor) that will come and talk to the whole group about HIV and the test they will do. They will explain everything to you. The counsellor will then take you alone to a private room where nobody can hear you when you talk to the counsellor. When they do the test, a small needle is used to prick your finger and

a little drop of blood is used to test for HIV. You can decide if you want to know your status. Whether the test is positive or negative, the counsellor will talk to you alone and give you all of the information that you need to know. If you are positive and you want to know your status, you will receive a letter that you can take to your clinic or hospital and they will help you with treatment.

There are more benefits than dangers / risks when you partake in the study.

Who will see my personal information (data)

When you arrive at the study, you will be given a unique number, and only this number will be used when you provide us with any personal information or when we do the measurements. No one, except the supervisor of this research will be able to identify you. All your information will be kept safe and secret and will be locked away. No one will have access to your information except the supervisors of this study. All of the information will be stored for 5 years after the study has finished.

The PURE study also takes place in other countries. The main country that is supervising this study is Canada. Because we have a contract with them, we have to share the data with them. Only the information you provide us within the questionnaires and the body measurements will be shared with them. We won't share your information from your HIV status or DNA with them. They will also keep your information safe and secret. They will not share your information with anyone else.

Will you be paid to take part in this study and are there any costs involved?

You will be provided with a breakfast when you arrive at the study. Furthermore, the measurements will take about a whole day, and therefore we will also provide you with lunch. Water / juice / coffee / or tea will also be provided.

There will not be any travel costs for you, since we will arrange for transport for you to the research facility and back to the point where you were picked-up. You will also receive R50.00 (fifty rand) for any expenses due to your attendance at the study. If you are referred to the hospital or clinic you can use this money for any expenses.

If you are fulltime employed we will make special arrangements with your employer for you to be able to take part in the study. If you lose your work income for the day you will be compensated for the day (one day of work).

Is there anything else that you should know or do?

- If you have any questions that the fieldworkers cannot answer you can ask that the researcher explains it to you. You can contact the researcher, Dr Lanthé Kruger at 018 299 2093 or lanthe.kruger@nwu.ac.za. You can also contact the researcher if you have any problems with the research.

- You can contact the Health Research Ethics Committee via Mrs Carolien van Zyl at 018 299 2089 or carolien.vanzyl@nwu.ac.za if you have any concerns or complaints that have not been fully addressed by the researcher.

- You will receive a copy of this information and consent form for you to keep with you.

How will you know about the findings?

Results that are immediately available will be given to you in private and in person on the day of the study. Other results of the research will be shared with you as a group (everyone that was a part of this study) and with your community leaders verbally during a personal visit from the lead researchers. When we share the results with the community leaders and with the group we will never share personal information. This means that people will not be able to identify you, and you will be safe from any harm such as stigmatization.

Storage of blood and urine samples

The blood and urine samples that we collect from you will be stored in a special freezer that will protect it. Only we will have access to your blood and urine samples, and no one else. The samples will be kept in these freezers for an unlimited period of time until we have money available to test (analyse) them. All of the tests (analyses) will be related to this study (PURE) and what you give permission for. Some of your blood samples may be sent to laboratories outside of South Africa for analysis if it cannot be done here. If we are finished with the tests of the blood, we will destroy it so that no one else can use it.

Declaration by participant

By signing below, I ..... agree to take part in a research study entitled:

Prospective Urban and Rural Epidemiology study (PURE)

I declare / confirm that:

- I have read this information and consent form and it is written in a language that I understand and is comfortable with.
- I have had a chance to ask questions and all my questions have been answered to my satisfaction.
- I understand that taking part in this study is completely my choice and I have not been forced to take part.
- I may choose to leave the study at any time and will not be penalised or judged in any way.
- I may be asked to leave the study before it has finished, if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

If you want to get tested for HIV you have to give permission here below:

Yes, I want to get tested for HIV ☐

No, I don't want to get tested for HIV ☐

If you want to know your HIV status you have to indicate it to us here below:	
Yes, I want to know my HIV status	☐
No, I don't want to know my HIV status	☐

Do you give permission that we may have access to your medical records at the hospital or clinic?	
Yes, I give permission	☐
No, I don't give permission	☐

Do you give permission that we may collect your genetic material from your blood sample?	
Yes, I give permission	☐
No, I don't give permission	☐

Do you give permission that your genetic samples may be analysed outside of South Africa if it cannot be done here?	
Yes, I give permission	☐
No, I don't give permission	☐

Do you give permission that some of your blood samples may be analysed outside of South Africa if it cannot be done here?	
Yes, I give permission	☐
No, I don't give permission	☐

Do you want to be contacted when there are any NEW research studies that will take place within your area?	
Yes, I want to be contacted	☐
No, I don't want to be contacted	☐

Signed at (*place*) ..... on (*date*) ..... 20....

....

Signature of participant **Signature of witness**

Declaration by person obtaining consent

I *(name)* ..... declare that:

- I explained the information in this document to .....
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use an interpreter.

Signed at (*place*) ..... on (*date*) ..... 20....

....

Signature of person obtaining consent **Signature of witness**

Declaration by researcher

I *(name)* ..... declare that:

- I explained the information in this document to .....
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use an interpreter.

Signed at (*place*) ..... on (*date*) ..... 20....

....

Signature of researcher **Signature of witness**

ADDENDUM A

SUMMARY FOR DATA COLLECTION (2005 – 2015) AND INTENDEND FUTURE USE FOR THE PROSPECTIVE URBAN AND RURAL EPIDEMIOLOGIC (PURE) STUDY

WHAT WAS COLLECTED?	WHAT INFORMATION DOES THIS GIVE US?
1. Blood sample	1.1 DNA damage due to environmental factors 1.2 Genetic factors related to non-communicable diseases 1.3 Indication of liver function 1.4 Clotting factors related to non-communicable 1.5 Risk markers for non-communicable diseases 1.6 Indication of bone health 1.7 Indication of nutritional status
2. Urine sample	2.1 Indication of kidney function 2.2 Indication of salt intake 2.3 Hypertension markers
3. Hair sample	3.1 Presence of toxins (fumonisin mycotoxins)
4. Body composition (Anthropometrics)	4.1 Height 4.2 Weight 4.3 Amount of fat in the body 4.4 Amount of muscles in the body 4.5 Amount of water in the body 4.6 Waist circumference 4.7 Hip circumference 4.8 Head circumference 4.9 Arm circumference 4.10 Leg circumference 4.11 Skinfolds
5. Blood pressure	5.1 To see if the blood pressure is too high or too low.
6. Pulse wave velocity	6.1 Indication of the flexibility of the arteries.
7. Electrocardiograph	7.1 Indication of heart function.
8. Vascular sonar (intima-media thickness)	8.1 Indication of blockages in the blood vessels.
9. Bone mineral density	9.1 Indication of the strength of the bones in the arm.
10. Lung function test (spirometry)	10.1 Indication of lung function.
11. Hand grip strength	11.1 Indication of the strength of the muscles in the hand.
12. Chair rise/stand test	12.1 Indication of the strength of the muscles in the legs.
13. 6 metre walk test	13.1 Indication of the strength of the muscles in the legs.
14. HIV test and CD4 count	14.1 Test for HIV and to test for the levels of CD4 cells in the body.
15. PURE Adult questionnaire	15.1 Provides demographic information. 15.2 Provides information regarding tobacco and alcohol use.

	15.3 Provides information regarding the use of medication. 15.4 Provides information regarding your health. 15.5 Provides information regarding violence and injuries. 15.6 Provides information on major personal events. 15.7 Provides information on female health. 15.8 Provides information on support systems used. 15.9 Provides information on consumer habits. 15.10 Provides information on work-, financial-, and home related stress. 15.11 Provides information regarding your neighbourhood. 15.12 Provides non-personal information regarding people living close to you who have HIV/AIDS.
16. PURE Family census questionnaire	16.1 Provides demographic- and health information on family members currently living within the household.
17. PURE Physical activity questionnaire	17.1 Provides information on the type, duration and frequency of physical activity.
18. International Physical Activity Questionnaire (IPAQ)	18.1 Provides additional information on the type, duration and frequency of physical activity.
19. PURE Health Services questionnaire	19.1 Provides information on health services, health related expenditures, medication use and health knowledge.
20. PURE Annual contact form	20.1 Provides mortality and morbidity information regarding participant and members of household.
21. PURE Event reports	21.1 Provides information regarding new diagnoses of non-communicable disease(s).
22. PURE Verbal Autopsy questionnaire	22.1 Provides information regarding death of participants.
23. PURE: EPOCH 1: Environmental Profile of a community's health	23.1 Provides information regarding community.
24. PURE: EPOCH 2: Environmental Profile of a community's health	24.1 Provides information regarding community.
25. PURE Community profile questionnaire	25.1 Provides information regarding community.
26. Assessing neighbourhood walkability	26.1 Provides information regarding community.
27. Mental health questionnaire: MHC-SF	27.1 Provides information on emotional-, social-, and psychological wellbeing.
28. Mental health questionnaire: SWLS	28.1 Provides information regarding satisfaction with life.
29. Mental health questionnaire: AFM	29.1 Affectometer provides information regarding positive mental health.
30. Mental health questionnaire: MLQ	30.1 Measures to what extent respondents feel their lives are of meaning. Measures how engaged and motivated respondents are in efforts to find meaning or deepen their understanding of meaning in their lives.
31. Mental health questionnaire: PHQ-9	31.1 Provides information on possible mental health disorders.

32. Mental health questionnaire: K6	32.1 Provides information psychological distress (depressive and anxiety symptoms).
33. Mental health questionnaire: MRG	33.1 Provides information on the most meaningful things, most important relationships and most important goals.
34. Mental health questionnaire: MMSE	34.1 Provides information on positive impairment.
35. Bone health questionnaire	35.1 Provides information regarding risk factors for bone health. 35.2 Provides information regarding bone fractures.
36. HIV and stigma questionnaire	36.1 Provides information regarding attitudes and stigma on HIV/AIDS.
37. Medicine use questionnaire	37.1 Provides information regarding use of chronic medication.
38. Quantitative Food Frequency Questionnaire (QFFQ)	38.1 Provides quantitative information regarding frequency of dietary intake. 38.2 Provides quantitative nutrient information. 38.3 Provides quantitative information on nutritional status.
39. 24-hour recall dietary intake	39.1 Provides information of dietary intake over the past 24 hours.

Declaration by participant

By signing below, I ....., ID number: ..... give permission that all of my data (information obtained from questionnaires, personal communication and interviews, physical measurements, and biological samples) that was voluntarily collected from me during the entire duration of the **Prospective Urban and Rural Epidemiology study (PURE) study** (between January 2005 - December 2015) may be used for any further analyses (primary and secondary), however, with the understanding that any analyses and its related results will only be relevant to the scope of the **Prospective Urban and Rural Epidemiology study (PURE) study**, and for which I gave permission (written informed consent).

I further agree to the secure storage and archiving of all of my data on the premises of the North-West University, Potchefstroom Campus. I understand that all of my data that was collected between January 2005 and December 2015, will be stored for an unspecified period until such time is suitable for appropriate further analyses (primary and secondary), and that it will be kept anonymously to everyone except the principle investigator.

Signed at (*place*) ..... on (*date*) ..... 20....

.....	.....
Signature of participant	**Signature of witness**
.....	.....
Signature of researcher	**Signature of witness**

ADDENDUM E ANTHROPOMETRIC DATA COLLECTION FORM

Participant's nr:——— M/F: ——— Test date —/— 2015

			Measure 1	2	3
1	Weight	kg			
2	Height	cm			
Circumferences					
3	waist circumference	cm			
4	Hip circumference	cm			
5	Calf	cm			
Skinfolds					
6	Triceps	mm			
7	Subscapular	mm			
BODPOD					
8	Mass	kg			
9	Fat %	%			
10	Fat mass	kg			
11	Lean mass	kg			
Bio-electrical Impedance					
12	Fat %	%			
13	Total water %	%			
14	Fat mass	kg			
15	Muscle mass	kg			
16	Physique rating				
17	Visceral fat	kg			
18	Bone mass	kg			
19	Metabolic age	Y			
Strength					
1	Chair stand test	sec		failed	
2	Walk speed over 6m	sec			m/s
			Measure 1	2	3
3	Grip strength (dominant hand)	kg			

ADDENDUM F PHYSICAL ACTIVITY QUESTIONNAIRE

PURE-SA Project (Prospective Urban and Rural Epidemiology)

Physical activity questionnaire

Date: Place: Interviewer:

The information on this questionnaire is confidential

1.	Subject number						(1-4)
2.	Gender	Male 1			Female	2	(5)
3.	What is your main occupation?.....						
	Low level: office work, housework, scholar					1	
	Middle level: factory work, carpentry, farming, hospital nurse, plumber					2	(6)
	High level ("sweat work"): construction work, digging, manual labour					3	
4.	At work I sit	1. never	2. seldom	3. sometimes	4.often	5.always	(7)
5.	At work I stand	1. never	2. seldom	3. sometimes	4.often	5.always	(8)
6.	At work I walk	1. never	2. seldom	3. sometimes	4.often	5.always	(9)
7.	At work I lift heavy loads	1. never	2. seldom	3. sometimes	4.often	5.always	(10)
8.	At work I am tired	1.never	2.seldom	3. sometimes	4.often	5.always	(11)
9.	At work I sweat	1.never	2.seldom	3. sometimes	4.often	5.always	(12)
10.	If you work away from home, how do you get to work/school?				walk	1	
					cycle	2	(13)
					car/taxi	3	
11.	How long does it take you to walk/cycle to work/school? (or to the taxi rank/ bus stop/ train station)				0-15 min	1	
					16-30 min	2	
					31-60 min	3	
					1-2 hours	4	(14)
12.	If you walk or cycle to work/school, what is your usual pace? (or to taxi rank/bus stop/ train station)				casual strolling	1	
					fairly brisk	2	
					brisk/fast	3	(15)
13.	Do you climb stairs often?				yes	1	
					no	2	(16)
14.	If yes, how many flights of stairs do you climb each day? (1 flight = 10 steps)						(17)
15.	How many days per week do you climb steps?						(18)
16.	Do you play sport?				yes	1	
					no	2	(19)
17.	Which sport do you play most frequently?	low level: bowling, golf, billiards				1	0.76*1
		middle level: tennis, athletics, cycling				2	1.26
		high level: soccer, rugby, netball, boxing				3	1.76(20)
18.	How many hours per week do you practice? <1/ 1-2/ 2-3/ 3-4/ >4 (Write appropriate code in space) 0.5, 1.5, 2.5, 3.5, 4.5*2					.	(21-23)
19.	How many months per year ? <1/ 1-3/ 4-6/ 7-9/ >9 (Write appropriate code in space) 0.04, 0.17, 0.42, 0.67, 0.92*3					.	(24-26)

*1 intensity code of sport, *2 time code for sport, *3 proportion of year

ADDENDUM G LANGUAGE EDITING CERTIFICATE

DECLARATION OF LANGUAGE EDITING

I, Mari Grobler, hereby declare that I have language edited the mini-dissertation with the title:

The association between anthrometric measures and physical performance in black adults of the North West Province, South Africa

for **Phumudzo Mamphwe** for the purpose of submission as a research study.

Changes were suggested in the form of electronic track changes and comments. Implementation was left to the discretion of the author.

Please contact me, should there be any questions concerning the language editing of this study.

Yours sincerely

Mari Grobler
SATI membership no: 1002808