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THE ASSOCIATION BETWEEN PHYSICAL ACTIVITY, BODY COMPOSITION AND CARDIO-METABOLIC DISEASE RISK IN MIDDLE-AGED MEN FROM SOWETO

Melikhaya A Soboyisi

A dissertation submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in the fulfilment of the requirements for the degree of Master of Science in Medicine

Johannesburg, 2020

DECLARATION

I, Melikhaya Agnitia Soboyisi declare that this dissertation report is my own, unaided work. It is being submitted for the degree of Master of Science in Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

_____

Candidate's signature

Signed on……day of…….2020

DEDICATION

To

My Lord and Saviour Jesus Christ

Acknowledgements

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Abstract

South Africa has the highest obesity prevalence in sub-Saharan Africa, and this is associated with a high prevalence of metabolic syndrome (MetS). Regular physical activity has been shown to reduce obesity and the risk of cardio-metabolic diseases such as hypertension and diabetes. The aim of this dissertation was to investigate the associations between objectively measured physical activity, sedentary behaviour and sleep, and the MetS and its components, in middle-aged black South African men, and to determine whether this relationship was independent of body mass index (BMI). The participants included in this study comprised a sub-sample of men (n=286, mean age 56.6±6.3 years) who were part of a larger study. Socio-demographic factors (age, level of education, employment status, marital status, and socioeconomic status) were obtained via questionnaire. Participants underwent the following measurements: weight, height, waist circumference, blood pressure, fasting blood glucose, HDL-C, LDL-C, Triglycerides. Thereafter, physical activity was measured by accelerometer (Actigraph GT3X-plus) using Troiano (2008) cut-points. Participants spent on average 35% of the day in sedentary behaviours. However, 75% of study participants met WHO physical activity recommendations (engaging in at least 150 minutes of moderate intensity activity per week or 75 minutes of vigorous intensity activity per week). Sedentary time was significantly associated with higher odds of having MetS (OR≥1.004 (1.00-1.00) p≤0.000, however when adjusted for BMI, it was no longer significant p=0.499. Moderate to vigorous intensity physical activity (MVPA) and daily step count were both significantly associated with lower odds of metabolic syndrome, however after adjusting for BMI, daily step count was no longer significant. Promotion of physical activity while reducing sedentary time should be encouraged to reduce obesity and cardio-metabolic disease risk outcome and type 2 diabetes.

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PAG	Physical Activity Guidelines
MVPA	Moderate to Vigorous Physical Activity
CVD	Cardiovascular Disease
CVM	Cardiovascular Mortality
WHO	World Health Organization
HDL-C	High-Density Lipoprotein Cholesterol
LDL-C	Low-Density Lipoprotein Cholesterol
PA	Physical Activity
LPA	Light Intensity physical activity
SB	Sedentary Behaviour
T2D	Type 2 Diabetes
GPAQ	Global Physical Activity Questionnaire
MetS	Metabolic Syndrome
SADHS	South African Demographic Health Survey
SANHANES 1	South African Health and Nutrition Examination Survey
BMI	Body Mass Index
IDF	International Diabetes Federation
AHA	American Heart Association
NCEP ATP III	National Cholesterol Education Program Adult Treatment Program
WHS	World Health Survey
Bt20	Birth to Twenty
WC	Waist Circumference
T2D	Type 2 Diabetes
OR	Odds Ratio
HIC	High Income Countries
MET-min	Metabolic Equivalent of Task

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CHAPTER 1: Literature Review

1.1 Introduction

The United States Department of Health devised recommendations that formed the American Physical activity guidelines (U.S. Department of Health and Human Services, 2008). These guidelines suggested that having some activity was better than no activity, while focussing on spending time in MVPA for improved health benefits (U.S. Department of Health and Human Services, 2008). The update physical activity guidelines remain the same, however, provides further benefits for how people function, feel, and sleep. Also, elimination of the requirement for PA of adults to occur in bouts of at least 10 minutes, with tested strategies that can be used to get the population more active (U.S. Department of Health and Human Services, 2018). Also, people who sit for prolonged amount of time have an increased risk for cardiovascular disease mortality and type 2 diabetes, this increased risk is not observed among people who do 60 to 75 minutes of MVPA a day. However this amount of activity is far more than what most people attain, therefore, reducing sitting time and increasing PA will provide health benefits. PA accumulated in bouts of at least 10 minutes can improve a variety of health- related outcomes, however, new research indicates that bouts of any length of MVPA contribute to health benefits associated with the accumulated volume of PA (U.S. Department of Health and Human Services, 2018). To this day, South Africa has adopted the World Health Organisation physical activity guidelines for adults, which stipulates that; people participate in at least 150 minutes of MVPA per week; or at least 75 minutes of vigorous activity in a week; or an equal combination of MVPA (U.S. Department of Health and Human Services, 2018). Subsequently, the WHO adopted these recommendations with the hope to increase physical activity (PA) plus reduce disease risk globally (WHO, 2010). Physical activity reduces the risk of cardiovascular mortality (CVM) and cardiovascular disease (CVD), high blood pressure and diabetes mellitus (Welch *et al.*, 2019) (Powell *et al.*, 2019). Bouts of any length contribute to these health benefits associated with accumulated volume of physical activity, even a brief episode of PA like going up a few flights of stairs counts (U.S. Department of Health and Human Services, 2018). People who are sufficiently active, that is, people who do some MVPA, but who do not yet meet the key guidelines target range, small increase in MVPA can provide health benefits. There is no threshold that must be exceeded before benefits begin to occur (U.S. Department of Health and Human Services, 2018). People who sit for prolonged periods have an increased risk for chronic disease; this increased risk is not observed among people who do 60 to 75 minutes of MVPA a day, however this amount of activity is far more than what most people attain, (U.S. Department of Health and Human Services, 2018).

Therefore, reducing sitting time and increasing PA provides health benefits. PA accumulated in bouts of at least 10 minutes can improve a variety of health- related outcomes, however, new research indicates that bouts of any length of MVPA contribute to health benefits associated with the accumulated volume of PA (U.S. Department of Health and Human Services, 2018).

Cardiometabolic risk factors, includes; elevated glucose and elevated blood pressure, obesity, high triglycerides, and low high-density lipoprotein-cholesterol (HDL-C), incline patients to develop diabetes or CVD (Watson, 2007). Metabolic syndrome (MetS) is a composite syndrome, comprised of five criteria: elevated blood pressure (systolic ≥130 and/or diastolic ≥85 mmHg, or on medication), high fasting glucose (≥5.6mmol/l) and/or use of oral hypoglycemic drugs, high waist circumference, elevated triglycerides (≥1.7 mmol/l), (≥94cm for men), low HDL-C (≤1.0 mmol/l) for men or if patient is on HDL drug treatment). The occurrence of any 3 of these 5 risk factors indicates the presence of MetS (K G M M Alberti *et al.*, 2009). Black African women (mean age 40±10 years) who were caregivers of the birth to twenty participants, had the occurrence of MetS (42.1%) (Crowther and Norris, 2012). Moreover, a study of black African women with (mean age 41±7 years) living in Soweto, Johannesburg, who were previously shown to have a high prevalence of MetS, 75% of participant met the WHO physical activity guidelines (Gradidge *et al.*, 2014). Black South African women (27±7 years of age), meeting physical activity guidelines was related to reduced risk for T2D and CVD (Dickie *et al.*, 2014), although this was not related to a reduction in weight in the cohort after 5.5-years. To our knowledge the relationship between sleep, physical activity and sedentary time has not been specifically examined in middle-aged black South African men. Before, most studies conducted to assess PA and sedentary behaviour (SB) in adult populations were based on subjective measurements, which include self-administered questionnaires, diaries, and recalling past activities by participants (Prince *et al.*, 2008) (WHO, 2010) (Bull, Maslin and Armstrong, 2014) (Guthold *et al.*, 2008) (Riley *et al.*, 2016). GPAQ has been used in HICs (Bull, Maslin and Armstrong, 2014) and LMICs (Guthold *et al.*, 2008), and is advantageous due to its ability to provide sphere specific PA data during transport, leisure, and work time (WHO, 2010), which is particularly relevant in LMICs. Although these subjective measures have been beneficial in understanding PA patterns, technological advancements have enabled the application of devices such as accelerometers and pedometers to objectively measure PA and SB (Cook, 2007)(Cook *et al.*, 2010)(Cook,

Alberts and Lambert, 2012). South Africa is experiencing a rapid environmental transition that includes urbanisation and cultural modernisation (Popkin et al, 2013), which has resulted in unhealthy ways of living including an 0.2% upsurge in overweight and obesity occurrence amongst African mature men from 27.2% (SADHS, 2007) to 27.4% (STATS SA, 2017). Black South African women (18-45 years) who utilized accelerometers, sedentary time was positively related to triglyceride (r=0.36, p=0.01) independent of body fat, while, light intensity activity not MVPA was inversely related to trunk fat mass (r=0.25, p=0.03) (Kasha Dickie *et al.*, 2016). Therefore it is essential to observe the association between accelerometers and metabolic syndrome in middle aged South African of African descent to see if this trend persists in men.

1.2 Physical Activity

The definition of physical activity is as any bodily movement resulting from emaciated muscle contractions that results in energy being used (Caspersen, Powell and Christenson, 1985), if done regularly it has benefits (U.S. Department of Health and Human Services, 2008). The benefits of physical activity on the prevention and control of NCD has been presented in some studies (Durstine *et al.*, 2013) (Nelson *et al.*, 2007) (Haskell *et al.*, 2007).

According to the World Health Survey (WHS) (2003) in 38 developing countries, SA had the 3rd highest prevalence of inactivity (43%) among adult men (≥15 years), after Mauritania and the United Arab Emirates (Guthold *et al.*, 2008). In 2010 20 percent of the African American population was classified as physically inactive, men had low levels of inactivity (17.3%) then women (24.4%).The WHO Global strategy for food and physical activity for well-being (WHO, 2005) identified importance for having national surveillance for levels of physical activity. The most recent reported national surveillance information from 2003 SADHS (Department of Health, Medical Research Council and OrcMacro, 2007) where they used the validated (Bull, Maslin and Armstrong, 2009) and reliable GPAQ (WHO, 2012), previously introduced as part of the WHO Step-wise approach to surveillance (Guthold *et al.*, 2011). The 2016 SADHS did not include physical activity measures (Statistics South Africa, 2017). The SADHS (2003), used GPAQ physical activity categories defined as follows; Insufficiently active (0-<600 metabolic equivalent of task), minimally active (600-<300 metabolic equivalent of task); and sufficiently active (>=3000 metabolic equivalent of task) (Pate and Tudor-Locke, 2005). In black South African men, aged >15 years of age, 47.7% were insufficiently active, 27.6% minimally active, and 24.6% sufficiently active (Department of Health, Medical Research Council and OrcMacro, 2007). The prevalence of sufficiently active adults decreased

from 34% among 15-24-year-olds to 7% among the 65+ year old age group. The prevalence of inactive category increased with age and sufficiently active decreased with age. While this decrease with age may be the result of functional limitations that occur with ageing, the high prevalence of inactivity even with those with younger ages is a public health concern. Specific barriers to physical activity in older adults have been identified and includes poor health, reduced mobility, and fear of personal safety due to crime incidence and traffic (Schutzer and Graves, 2004).In a convenience sample of 44 men (10) and women (34) older than 50 years, recruited from 2 areas representing a low socioeconomic area and high socioeconomic are according to property value. Neighbourhood aesthetics was positively associated with leisure-time physical activity, while safety from traffic was inversely associated with travel related physical activity (Kolbe-Alexander *et al.,* 2015). People living in rural settlements partake in high levels of daily physical activity, as most of them chop wood, carry water, and walk to work on a regular basis, and are therefore more likely to meet the physical activity guidelines of 150 minutes of MVPA per day (Tshabangu and Coopoo, 2001). Dikgale Demographic Surveillance System site (DDSS) of rural black South African women (mean age 32±10 years), 39.7% engaged in (≥10000 steps/day) and steps/day was inversely related to BMI (Cook, Alberts and Lambert, 2008). In the urban study of SA women (aged 18-45 years) using objective measure of physical activity, it was found that majority (59.4%) of time was consumed in sitting time (8.5 hours a day)(K Dickie *et al.*, 2016), and most time was spent participating in LPA, while no time was spent being vigorous or very vigorous (K Dickie *et al.*, 2016). Studies in SA have shown very small amounts of vigorous intensity activity using the GPAQ (Gradidge *et al.*, 2014)(Gradidge *et al.*, 2015). To my knowledge there have not been studies that have objectively measured sleep, sedentary time, physical activity and MetS in middle aged black men in SA. Other studies in South Africa assessed behavioural and physiological influences that influence the development of MetS (Crowther and Norris, 2012)(Schutte and Olckers, 2007)(Jennings *et al.*, 2009)(Motala *et al.*, 2011), although physical activity and the association with individual metabolic syndrome components or metabolic syndrome risk was not assessed.

1.3 Urbanisation

Informal and formal black South African societies in the past faced differing public health challenges, from infectious diseases related to malnutrition occurring mostly in informal societies (Vorster, 2010), and increasing occurrence of NCD related with overweight and obesity in formal societies (Bradshaw, 2006). In the 2016 SADHS, the occurrence of

overweight & obesity among black urban and rural adult men (aged >15 years) was 34.2% and 26.1%, respectively (Statistics South Africa, 2017). Food-related NCD accounts for 28% of the load of disease in SA (Bradshaw, 2006), and has been linked to the social change from old-fashioned rural lifestyle to the acceptance of westernised foods (Vorster *et al.*, 2005; Food and Agriculture Organization (FAO), 2006; Vorster, 2010). The word nutritional transition is usually used to talk about the alterations in food that arise from urbanisation (Raschke *et al.*, 2007). The change becomes a consequence in change and neglect of traditional food habits which are healthier in comparison to westernized way of food ingestion (Raschke *et al.*, 2007). Other data has reported this transition in formal dwellings, possibly explaining the occurrence of obesity in LMICs (Bourne, Lambert and Steyn, 2002; Fezeu *et al.*, 2008; Keding *et al.*, 2011) (Micklesfield *et al.*, 2013). In a study of sub-Saharan African countries (aged 18-45 years), SA was the country with the highest occurrence of overweight and obesity (85%)(Ajayi *et al.*, 2016). This prevalence was higher than the reported prevalence of the SANHANES-1 (65%)(Shisana *et al.*, 2013). In the multi-country study the prevalence of obesity was 56%, this shows an increasing trend when comparing the different obesity prevalence's 23.5% (2008) and 27.2% (2012), reported from the National Panel survey, 2008-2012 (Sartorius *et al.*, 2015). The multi-country study has shown that urbanisation is an essential determinants of obesity and overweight, and as urbanisation and nutritional transition is certain to continue, the need to halt the increasing occurrence of obesity and obesity in SA is important (Ajayi *et al.*, 2016).

1.4 Sedentary Behaviour

Sedentary behaviour in some studies was well-defined obtaining a MET value between 1 and 1.5 (equal to lying or sitting down, watching TV, and other forms of screen-based entertainment) (Owen *et al.*, 2010)(Pate, O'Neill and Lobelo, 2008)(Tremblay *et al.*, 2017). Some studies reported consistent and significant relations amongst sitting behaviour and metabolic risk for cardiovascular disease and diabetes in adults (Bankoski *et al.*, 2011). In a cross-sectional of adult non-Hispanic blacks (mean age 71±8 years) from the NHANES, 8.1% had metabolic syndrome and sitting behaviour was associated with greater odds of MetS (Ford *et al.*, 2005)(Sisson *et al.*, 2010)(Bankoski *et al.*, 2011). A randomised control trial study, of men with mean age 58.2±8.6 years, prolonged sedentary behaviour (per 30min/day) meaningfully connected with greater chances of high waist circumference and BMI (Healy *et al.*, 2015). Other cross sectional studies showed significant relationships between sedentary behaviour and serum lipid concentrations, glucose concentrations, and resting blood pressure (Healy *et al.*, 2008) (Wijndaele *et al.*, 2014) (Gradidge *et al.*, 2014). In the ProActive study of

30-50 year old adult men, sedentary behaviour confidently related to triglycerides (Wijndaele *et al.*, 2014). In the study of urban females mean age 41±7.8 years old, sitting time was assessed using GPAQ, the mean sitting time was 3 hrs, sedentary behaviour was definitely related to triglycerides, diastolic blood pressure and HDL-C, (Gradidge *et al.*, 2014). Moreover, study of 35-55 year old men and women from Uganda, those with sedentary work style was definitely related with systolic blood pressure (Twinamasiko *et al.*, 2018). Most studies from high income countries as demonstrated above with a few in low-middle income countries. These studies demonstrate the harmful relationship of high sedentary behaviour, (BMI) and cardio-metabolic disease risk for type 2 diabetes and CVD.

1.5 Sleep Duration

Sleep is very essential for our health, yet most people do not get enough rest that is recommended seven to nine hours of sleep each night (Hirshkowitz *et al.*, 2015). There has been a consensus statement on recommended sleep duration and seven to eight hours of sleep was associated with low MetS in adults (Watson *et al.*, 2015)(Chaput *et al.*, 2013). In the NHANES among adults mean age 49.9±18.6 years, sleep time was assessed with a survey which categorized responses as "very short" (<5 hrs), short (5-6 hrs), normal (7-8 hrs), or long (9 hrs) (Grandner *et al.*, 2015). In the black African/American group, majority of participants had short sleep (22%), and this was related with obesity and positively associated with fasting glucose (unadjusted for confounders) (Grandner *et al.*, 2015). Sleeping for 7 hours each night was related to low cardio-metabolic risk score in African American population from the NHANES (Kanagasabai and Chaput, 2017). In the UK Biobank Cohort of women mean age 56.9±7.9 years, long sleep was more prevalent (58.4%), and obesity and high WC was higher in those with who slept >9 hours sleep,34.2% and 96%, respectively (Celis-morales *et al.*, 2017). Relationship between sleep and cardiometabolic danger might be modified by age, ethnicity, sex and lifestyle factors, that were well-thought-out as confounders (Cappuccio *et al.*, 2011)(Chaput *et al.*, 2013). Again these associations have been reported from HICs and need to be assessed in middle aged black South African men.

1.6 MetS and cardiometabolic syndrome components

1.6.1 MetS

According to the International Diabetes Federation, MetS is defined a multiple of interconnected risk causes for cardiovascular disease and T2D (Alberti, Zimmet and Shaw, 2006). The five criteria that are incorporated in the MetS are: waist circumference in the context of South African men (≥95cm) (Owolabi *et al.*, 2018), serum triglycerides ≥1.7 mmol/l, HDL-C ≤1.0 mmol/l for men or being on medication for low HDL and elevated serum triglyceride, hypertension (≥130and/or 85 mmHg) and fasting glucose ≥5.5mmol/l, and elevated BMI, the occurrence of somewhat 3 of 5 risk causes specifies the occurrence of metabolic syndrome (K G M M Alberti *et al.*, 2009).

Metabolic syndrome prevalence data from across Africa and selected developed countries are outlined on Table 2.1 and 3.1. Some South African studies have reported on the prevalence of MetS in black males and females of various ages, using the harmonised and IDF criteria for MetS (Table 1.1). Metabolic syndrome prevalence was reported higher among females than males in all regions accept in Australia were white males had a higher prevalence (39.2%) vs 27.9% for females (Cameron *et al.*, 2009). Men and women have different waist circumference cut-points, where studies show that different WC cut-points can overestimate or underestimate true prevalence. In South Africa MetS prevalence has been reported lower in rural settings males (11.6%), and females (30.2%) (Motala *et al.*, 2011) vs males (16.5), females (43%)in urban settings (Peer *et al.*, 2015) using the harmonized guidelines (K G M M. Alberti *et al.*, 2009). Also, the prevalence of MetS in other African countries such as Ghana were also higher in females than males, 34.4% and 14%, respectively (Van Der Linden *et al.*, 2019). In Nigeria, prevalence higher prevalence was also higher among females (25%) than males (13%) (Adejumo *et al.*, 2017). MetS prevalence was almost similar in adult men and women from the U.S , 32.8 vs 34.9, respectively (Aguilar *et al.*, 2015).

The IDF definition for a person with MetS, is well-defined as follows; central obesity (waist circumference that is ethnic specific), in addition to 2 of subsequent factors: high serum triglycerides (1.7mmol/l), low HDL-C (1.03mmol in males), high blood pressure (systolic ≥130 or diastolic ≥85 mmHg or on high blood pressure medication), elevated fasting glucose ≥5.6mmol/l or previous diagnosis of type 2 diabetes and/or use of medication (K G M M Alberti *et al.*, 2009). Some observational studies that have evaluated physical activity patterns

and metabolic syndrome in adult men and women (Healy *et al.*, 2008) (Ekelund, Griffin and Wareham, 2007)(Sisson *et al.*, 2010). In a study of participants who were diagnosed with type 2 diabetes and obesity, objective measure of sedentary time, light, MVPA was evaluated (Healy *et al.*, 2008). sedentary time was positively associated with metabolic syndrome (IDF criteria) while time spent in light intensity physical activity was inversely associated with MetS (Healy *et al.*, 2008). Also, in a randomized control trial investigating the efficacy of a family-based intervention to increase physical activity among people who were defined as high-risk through paternal history of type 2 diabetes (Ekelund, Griffin and Wareham, 2007). MVPA was inversely associated with clustered metabolic risk. (Ekelund, Griffin and Wareham, 2007). To our knowledge no study has examined the association between sedentary time and physical activity, and metabolic syndrome in middle aged South African men.

Table 1. 1 Prevalence of MetS in black African male and females in South Africa

Table 1 Prevalence of MetS in black African male and females in South Africa								
Reference	Study design (name of study)	Criteria	N [year]	Gender	Mean age (SD)	Country	Metabolic syndrome Prevalence (%)	
							men	women
(Schutte and Olckers, 2007)	Cross sectional (urban)	IDF	102	females	31.3±8.64	Potchefstroom, South Africa	-	24.8
(Kalk and Joffe, 2008)	Cross-sectional (urban; type 2 diabetics)	IDF	500	Male (209) and female (291)	48.3±8.7	Johannesburg, South Africa	46.5	85.2
(Jennings *et al.*, 2009)	Cross-sectional (urban)	IDF	225	Females	27.0±7.0	Cape Town, South Africa	-	9.9
(Motala *et al.*, 2011)	Cross-sectional (rural)	Harmonized	947	Male (189) and female (758)	46.4±20.6	KwaZulu-Natal, South Africa	11.6	30.2
(Crowther and Norris, 2012)	Cross sectional (urban)	Harmonized	1251	females	40.0±10.6	Soweto, South Africa	-	42.1
(George *et al.*, 2013)	Cross sectional (urban)	Harmonized	373	Male (181) and females (192)	18-70 years	Soweto, South Africa	19.3	39.2
(Peer *et al.*, 2015)	Cross-sectional (urban)	Harmonized	1099	Male (392) Female (707)	25-74 years	Cape Town, South Africa	16.5	43
(Gradidge *et al.*, 2016)s	Cross-sectional (urban)	Harmonized	702	females	51±5 years	Soweto, South Africa	-	14%
(Kruger and Nell, 2017)	Cross sectional (urban)	IDF	188	Male (41) Female (147)	38.8±0.8	Cape Town, South Africa	29.0	46%

(Owolabi *et al.*, 2017)	Cross sectional (healthcare facility based)	IDF	979	Male (313) Female (666)	18-66 years	East London	15.6	24.8
Age range or mean (SD) of participants as provided by respective journal articles. IDF, International Diabetes Federation								

Table 2. 1 Prevalence of MetS in selected developed countries

Reference	Study design (name of study)	Criteria	N [year]	Gender	Mean age (SD)	Country	Metabolic syndrome Prevalence (%)	
							Male	female
(Aguilar *et al.*, 2015)	NHANES, 2003-12; Cross-sectional	Modified NCEP	2015	Male and female	>20 years	United States (African American)	32.8	34.9
(Tillin *et al.*, 2005)	Cross-sectional (urban)	Modified NCEP	2005	Male (455), female (348)		United kingdom (African Caribbean)	15.5	23.4
(Jeppesen *et al.*, 2007)	Cross-sectional (urban)	Modified NCEP	2007	Male (1229), female (1264)	41-71 years	Denmark (White)	18.6	14.3
(Cameron *et al.*, 2009)	Cross-sectional (urban)	IDF	2009	Male (2751), Female (3321)	50.5±11.7	Australia (White)	39.2	27.9

Table 3. 1 Prevalence of metabolic syndrome in selected African countries

Reference	Study design (name of study)	Criteria	N [year]	Gender	Mean age (SD)	Country	Metabolic syndrome Prevalence (%)		Overall prevalence of metabolic syndrome
							Male	Female	
(Kerie, Menberu and Geneto, 2019)	Cross-sectional (urban)	NCEP-ATP III	2019	Male (271), Female (263)	≥18 years	Ethiopia	-	-	9.6
(Van Der Linden *et al.*, 2019)	Cross sectional (urban)	JIS	2019	Male (415), Female (1034)	25-70 years	Ghana	14.9	34.4	-
(Marbou and Kuete, 2019)	Cross sectional (urban and rural)	JIS	2019	Male (257), Female (347)	43.7±17.2 years	Cameroon	-	-	32.5
(Adejumo *et al.*, 2017)	Cross-sectional (urban)	JIS	2017	Male (146), Female (389)	47.1±14.7	Nigeria	13	25	-
(Kann *et al.*, 2015)	Cross-sectional (urban)	IDF	2015	Male (18), Female (42)	46.3±11.3 years	Namibia	-	-	31.7

1.6.2 Waist Circumference

The prevalence of overweight and obesity from the recent South African demographic and health survey was 34.2% in adult black men (STATS SA, 2017). Waist circumference has been identified as one of the strongest predictive tool for MetS (K G M M Alberti *et al.*, 2009). Waist circumference is easy to measure central obesity, inexpensive and non-invasive and is applied in clinical practice. The Africa Wits-INDEPTH partnership for Genomic Research (AWIGEN) study, which constitutes study sites in South Africa, Kenya and Ghana found that waist circumference was significantly associated with increased odds of being hypertensive in African men (Pisa *et al.*, 2018). Elevated waist circumference (WC) cut-points are population- and country- specific, although the IDF cut-point of 94cm is recommended for non-Europeans until more data is available (K G M M Alberti *et al.*, 2009). **Owolabi *and collegues (*2018) determined the optimal WC cut-points for predicting Metabolic syndrome among low-income adults in the Eastern Cape, South Africa, and recommended using a WC cut-point of ≥ 95cm (Owolabi *et al.*, 2018)** instead of the recommended non-European cut-off of 94cm (K G M M Alberti *et al.*, 2009). WC cut-off for South African blacks need to be determined to assist with correctly identifying the MetS prevalence in this population and develop appropriate interventions (Owolabi *et al.*, 2018).The Sympathetic Activity and Ambulatory Blood Pressure in Africans (SABPA) study recommended a country specific WC cut point of 90cm for men (Prinsloo *et al.*, 2011) and in a 3 year follow up study using the SABPA data recommended 92cm (Hoebel *et al.*, 2014); Motala et al recommended the Joint Interim Statement (JIS) cut-point of 86cm for black African women (Motala *et al.*, 2011), while Crowther and Norris, using data from the caregivers of the Birth to Twenty (Bt20) cohort recommended 91.2cm for middle aged black women (Crowther and Norris, 2012). The Cardiovascular Risk in Black South Africans (CRIBSA) study recommended a WC of 84cm for black African women (Peer *et al.*, 2015), while Kalk et al recommended (≥90cm) black adult South African men (mean age 50±8 years) (Kalk, Joffe and Sumner, 2011). In the study of black South African women (aged 34±7 years), light intensity physical activity and step count were inversely associated with waist circumference (K Dickie *et al.*, 2016). In the cross sectional study of urban black women from Soweto, Johannesburg (mean age 41±7 years) trunk fat-free soft-tissue mass (FFSTM) in the trunk increased the risk of MetS, while subcutaneous fat in the abdominal region was associated with lower risk of MetS (Gradidge, 2017). To our knowledge no studies have examined physical activity, sedentary time, sleep and association to waist circumference in middle-aged black South African men.

1.6.3 Blood pressure

The blood pressure component of the metabolic syndrome is defined as having either systolic blood pressure ≥130mmHg and/or diastolic blood pressure ≥ 85mmHg, or on antihypertensive drug treatment with a history of high blood pressure (K G M M Alberti *et al.*, 2009). High blood pressure is responsible for a high burden of disease in South Africa (including morbidity and mortality) (Peltzer and Phaswana-mafuya, 2008; Mayosi *et al.*, 2009; Phaswana-mafuya *et al.*, 2013).The prevalence of elevated blood pressure from the 2016 SADHS, using the WHO guidelines (≥140/90mmHg), was 40.9% in adult black South African men (STATS SA, 2017). Based on data from the H3Africa AWIGEN (H3A) collaborative centre study, which was established to examine genomic and environmental factors that influence body composition, body fat distribution and cardiometabolic disease risk in low-middle income countries, SA had the highest prevalence of blood pressure (≥140/90 mmHg) (33.7%) compared to other developing countries; Ghana (27.3%), Kenya (28.7%), and Burkina Faso (29.4%) (Gómez-Olivé *et al.*, 2017). Hypertension was higher among black South African men in Soweto (54.7%) than black South African women (53.4%) (Gómez-Olivé *et al.*, 2017). The Urban and Rural Epidemiology (PURE) study of adult black men from the North West, and Free State province, reported a high prevalence of hypertension blood pressure (50.1%) (>130/85mmHg) (Kruger *et al.*, 2017). In the Cardiovascular Risk in Black South Africans (CRIBSA) study of black South African men and women (mean age 50±11 years) conducted in a township in Cape Town reported prevalence of hypertension 37.5% (men) and 38.9% (women) (Peer *et al.*, 2013). There was also a sharp increase in hypertension prevalence for ≥45 year old men (58%) and those between 55-64 years of age (63%) (Peer *et al.*, 2013). Regional hypertension prevalence differences were also noted within all AWIGEN study sites and South African men in Soweto had the highest prevalence of hypertension 54% even higher than women (53%) (Gómez-Olivé *et al.*, 2017). Studies which objectively measured sedentary behaviour did not show significant relationship between sedentary behaviour and blood pressure (Healy *et al.*, 2008) (Healy *et al.*, 2011) (Bankoski *et al.*, 2011). These studies did not exclude people who were on antihypertensive medication during analysis which could have confounded their results. In a cross sectional study of black African adult males from Peri-urban location in Mbarara Uganda, sedentary work style was associated with higher odds of hypertension (OR=2.68 (1.47-4.88), p=0.001)) among people who have sedentary work style. In the cross sectional study of urban black women (mean age 37±7 years) no physical activity variables, sedentary time were associated with resting blood pressure (Kasha Dickie *et al.*, 2016).

Moreover, in a cross sectional of urban black women in Soweto, Johannesburg, sitting time was associated with diastolic and not systolic blood pressure (Gradidge *et al.*, 2014). In black South African men these associations have not been examined.

1.6.4 High Density Lipoprotein Cholesterol

The cut-off for HDL-C according to the harmonised guidelines is <1.0mmol/l in males or being on drug treatment for reduced HDL-C (K G M M Alberti *et al.*, 2009). The British Regional Heart Study, a longitudinal landmark study which provided a unique opportunity to assess Coronary Heart Disease (CHD) and association to HDL-C (Gordon *et al.*, 1988). The study reported than an increase of 0.06 mmol/l in HDL-C was associated with a 2-3% reduction in CHD. This was the same in another landmark study from the American Framingham heart study which focused on Cardiovascular Disease (CVD) risk in residents of Framingham and revealed that there were increases in CHD events in patients who had low HDL at all levels of LDL (Castelli, 1988). A cross sectional study of healthy black South African adults aged 25-76 years from the North West and Free State province reported a prevalence of low HDL (≤1.0mmol/l) of 20% in men (Kruger *et al.*, 2017). It was also reported that men with a BMI >22kg/m2 had increased odd of low HDL (OR 3.22, p<0.001) (Kruger *et al.*, 2017). In the Heart of Soweto study conducted at Chris Hani Baragwanath Hospital, data on patients with structural and functional heart disease was examined and there were no differences in HDL-C values across ethnicities (Sliwa *et al.*, 2012). Prevalence's of low HDL-C in women of African descent, white European, mixed ancestry and Indian as; 63%, 66%, 57% and 62%, respectively (Sliwa *et al.*, 2012). In cross sectional study of black African women in Soweto, Johannesburg (mean age 41±7 years) sitting time was positively associated with HDL-C. While a cross sectional study of urban black women (mean age 37±7 years) from Cape Town, South Africa found no association between sedentary time and HDL-C, however light-intensity physical activity, MVPA and step count was inversely associated with HDL-C (K Dickie *et al.*, 2016). Kruger et al (Kruger *et al.*, 2017) showed low HDL-C prevalence in black South African men. However, associations of this cardiometabolic risk component in relation to sedentary time and physical activity and sleep has not been investigated in middle aged men in South Africa.

1.6.5 Serum triglycerides

The presence of high serum triglycerides is another of the metabolic syndrome components that is associated with a high risk of heart disease and stroke and according to the harmonized criteria elevated serum triglycerides is having ≥1.7mmol/l or being on treatment for elevated serum triglycerides (K G M M Alberti *et al.*, 2009). In the AusDiab cross sectional sub study

of adult men and women (mean age 53.4 years) moderate-to-vigorous physical activity was associated with lower serum triglycerides (Healy *et al.*, 2008). Data from the PURE study reported 12% of adult men had elevated serum triglyceride levels (Kruger *et al.*, 2017) and in the same study, participants with a BMI ≥22kg/m^2 had 6.22 greater odds of elevated serum triglycerides. In South Africa, a cross sectional study assessed independent associations of physical activity and cardio metabolic risk factors for cardiovascular disease and type 2 diabetes in middle aged back South African women (K Dickie *et al.*, 2016). Sedentary time was positively associated with serum triglycerides (r=0.36, P=0.01) (K Dickie *et al.*, 2016).In the Birth to Twenty cohort of biological mothers, 22% had elevated serum triglycerides levels (Crowther and Norris, 2012). In the Heart of Soweto cohort, African women (56±15 years) prevalence of elevated serum triglycerides was 23% in women of African descent, and they also showed a positive association between serum triglycerides and BMI (Sliwa *et al.*, 2012).When comparing the prevalence of elevated serum triglycerides from men with other ethnicities, African men have the least prevalence, 23% vs 36% (white Europeans), 41% (mixed ancestry) and 56% (Indians) (Sliwa *et al.*, 2012). Data from the third National Health and Nutrition Examination Survey was examined and the prevalence of elevated serum triglyceride in African American men was 21.4% (Ford, Giles and Dietz, 2002). In a cross sectional study of rural African (black) community aged >15 years in KwaZulu Natal in South Africa, serum triglyceride prevalence was 13.8% for males (Motala *et al.*, 2011). **These variations in ethnic triglyceride prevalence was reported from the NHANES, where prevalence was lowest in African American black men (21.4%) vs 36.9% (white), 39.7% (Mexican American) and 29.4% (Other) (Ford, Giles and Dietz, 2002).** Regular exercise can help to improve lipid disorders including lowering serum triglycerides (Ekelund and Griffin, 2007). In the randomized controlled trial examining the efficacy of family-based intervention to increase physical activity among individuals defined as high-risk due to their family history of type 2 diabetes, this study reported total body movement (counts/day) had a significant and independent association with serum triglyceride and other metabolic syndrome components (Ekelund and Griffin, 2007). This investigation suggest that increasing the amount of physical activity in sedentary and overweight individuals has benefits on metabolic risk (Ekelund and Griffin, 2007). In urban black South African women (mean age 37±7 years), sedentary time was inversely associated with serum triglycerides (r=-0.25, p=0.03) (Kasha Dickie *et al.*, 2016). Moreover, a study of black women in Soweto, South Africa (mean age 41±7 years), sedentary time was also positively associated with serum triglyceride (Gradidge

et al., 2014). To our knowledge no studies that have investigated physical activity, sedentary time and these associations in black South African men.

1.6.6 Glucose

In the determination of MetS, using the harmonised guidelines, fasting blood glucose ≥ 5.6mmol/l pose as one of the risk factors for MetS (K G M M Alberti *et al.*, 2009). Diabetes is a major public health challenge in this 21st century. Before the 1990s, diabetes was considered rare in sub-Saharan Africa, post 1990, Sub-Saharan Africa has witnessed a rise in the burden of diabetes (Mbanya *et al.*, 2010) (Levitt, 2008). Rapid uncontrolled urbanization and lifestyle changes could be the driving cause of the epidemic (Mbanya *et al.*, 2010). Insulin resistance is present in most patients with metabolic syndrome, many of whom develop impaired glucose tolerance (Bonora *et al.*, 2002). When impaired glucose tolerance progresses to type 2 diabetes, increased glucose level constitutes a major independent risk factor coronary heart disease (Bonora *et al.*, 2002). In 40 black subjects (54±8 years) with documented coronary artery disease, insulin resistance was linked with coronary heart disease (Ntyintyane *et al.*, 2014). In the Cardiovascular Risk in Black South Africans (CRIBSA) study the prevalence of elevated fasting glucose was 15.4% among 392 African adult men (25-74 year old) in Cape Town, who had a mean fasting glucose of 5.2mmol/l (Peer, Steyn and Levitt, 2016). Another cross-sectional study of adults (>15 years of age) in a rural African community in Kwa-Zulu Natal reported the prevalence of elevated fasting glucose to be 13.8% using the same cut-point (>5.6mmol/l); and of those with elevated glucose, 50% had metabolic syndrome (Motala *et al.*, 2011). A study that assessed diabetes mellitus patient data from Johannesburg Hospital, South Africa, reported a median fasting glucose of 6.8mmol/l (5.9, 9.1 mmol/l) among African men with median HOMA-IR of 2.45 (1.90, 3.48) (Kalk and Joffe, 2008). Black South African women are more insulin resistant that their white counterparts (Goedecke *et al.*, 2009). In a prospective observational study conducted among black African diabetic patients at Chris Hani Baragwanath Hospital (age 18-65 years), an increase of ≥7000 steps per day had a significant effect on HbA1c ($p<0.001$)(Siddiqui, Bhana and Daya, 2018). However the cross sectional study of black African women (mean age 41±7 years) found no significant association between physical activity (light, MVPA, and step count), sedentary time and fasting glucose (Gradidge *et al.*, 2014). In black South African women (mean age 34±7 years), fasting glucose was not associated sedentary time and physical activity (Dickie *et al.*, 2016).

1.7 Aim

This study aimed to investigate the association between objectively measured physical activity, sedentary behaviour, sleep time, BMI and metabolic syndrome components in middle-aged black South African men.

1.7.1 Objectives

- To investigate the association between objectively measured physical activity, sedentary behaviour, sleep time, and individual metabolic syndrome components in middle-aged black South African men
- To investigate the association between objectively measured physical activity, sedentary behaviour, sleep time, and presence of metabolic syndrome in middle-aged black South African men
- To determine whether the relationship between physical activity, sedentary behaviour, sleep time, and metabolic syndrome is independent of body composition in middle-aged black South African men.

1.7.2 Hypothesis

Objectively measured physical activity, sedentary time, and sleep time will be associated with a greater odds of having metabolic syndrome, in middle-aged black men, and this association will be independent of BMI.

CHAPTER 2: METHODS

2.1 Ethical Approval

Ethical approval for this study was obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, (Ethics clearance number: M160973) (Annexure A). The study was therefore conducted following the laws and regulations controlling the use of human participants. All participants signed an informed consent and were free to leave the study at any time.

2.2 Study participants

The study participants comprised a sub-sample of men (n=286, 40-65 years of age) who were originally part of the AWIGEN-H3A study conducted in 2014/15, and who were now included in a more extensive follow-up study entitled: 'Determinants of type 2 diabetes mellitus (T2D) risk in middle-aged black South African men and women: dissecting the role of sex hormones, inflammation and glucocorticoids'. The inclusion criteria were men between 40 years and 65 years of age, who consented to give a blood sample and signed informed consent. **The initial study sample was 300, and participant's variables had to all be present to be included for data analysis. There was 14 participants who either, did not have all clinical measures (lipids, fasting glucose, and blood pressure) (4) and anthropometry data (weight, height, waist and circumference) (2) or physical activity data (8) (>4 full days, >10 hours of data per day). These participants were recruited in a form of Cohort sampling. Cohort selection is an alternative form of sampling to randomisation, which were used for the sample of 300 participants**. **Only, 286 participants had full results for triglycerides, fasting glucose, LDL-C, HDL-C and total cholesterol.** All data collection took place at the SAMRC/Wits Developmental Pathways for Health Research Unit research unit located at the Chris Hani Baragwanath Academic Hospital in Soweto, Johannesburg. I assisted with conducting interview questions, anthropometry measures, initializing and downloading of physical activity (Actigraph) data.

2.3 Sociodemographic and Lifestyle Questions

A sociodemographic questionnaire was administered by interviewers (age, education, marital status, and employment). Participant's date of birth was obtained from their identification document (ID), and age was generated. A physical asset-based household SES measure was used. The physical assets SES measures were; electricity, television, radio, motor vehicle, bicycle, microwave, washing machine, DVD, telephone/cell phone, tablet/laptop/personal computer, DSTV/Satellite, and MNET. **MNET is a paid TV channel in South Africa**. Participants were asked if they had any of those items and an asset score was computed from all the 'yes' answered and were categorised into a categories namely: low(1), medium (2), and high (3)(McVeigh, Norris and De Wet, 2004). Household assets ≤4 (low), between 5-8 (medium) and 9-12 (high). Highest level of education attained was asked and categorised as; no education, grade 1-7, grade 8-12. Marital status was categorised as single, married/cohabiting, widowed, or separated/divorced. Participants were asked if they were currently employed (Yes/No), and if they were taking any/specific medication (name of medication, and what it are used for). If participants were on medication, they were asked to bring it with, and a picture was taken for verification purposes and identified in terms of its use. Participants were asked if they currently smoked (Yes/No).

2.4 Anthropometric measurements

2.4.1 Height

Standing height was measured to the nearest mm using a calibrated stadiometer (Seca 264). Participants were either barefoot or wearing thin socks. Participant's buttocks, shoulders and the back of the head were touching the wall or the vertical board of the stadiometer. If this was not possible, a straight posture was maintained with at least the buttocks and heels touching the vertical board. Shoulders were relaxed but straightened, and arms were allowed to hang freely alongside the body with palms facing inwards and the head positioned in the Frankfurt Horizontal Plane (Lohman et al., 1988). Height was then converted from mm to cm by dividing mm/10 and rounded off to one decimal place.

2.4.2 Weight

Participants were weighed using a calibrated Seca 813© electronic scale (Seca GmbH Company, Hamburg, Germany) (Boua *et al.*, 2018). Participants removed shoes, heavy clothing, and jewellery, and also emptied their pockets before being weighed. Participants were measured standing still in the centre of the platform, with a 10cm gap between their heels, and arms hanging loosely at their sides. Weight was recorded in kg to one decimal place.

2.5 Body Mass Index (BMI)

Body mass index (BMI) was calculated as weight (kg) divided by height (m) squared. Underweight was defined as a BMI <18.5 kg/m^2; normal weight as a BMI between 18.5-24.9 kg/m^2, overweight as a BMI between 25–29.9 kg/m^2 and obesity was defined as BMI ≥30 kg/m^2, according to the WHO guidelines (WHO, 1999).

2.6 Waist circumference measure

Waist circumference (WC) was measured using a material tape measure under clothing, were tape was positioned correctly. The participant was asked to relax, and stand up straight with arms slightly abducted, and to breathe normally with the feet and heels together. The tape was placed horizontally around the waist, between the iliac crest in the mid-axillary plane and the lowest rib margin. Measurement was taken at the end of a normal expiration without compression of the tape. Waist circumference was measured three times in mm and later converted to cm by dividing the average of the three waist circumference measures by 10.

2.7 Clinical tests

2.7.1 Blood pressure

Blood pressure was measured three times in millimetre of mercury (mmHg) at two-minute intervals using a digital blood pressure device (Omron) with an appropriately sized cuff after the participant had been seated for five minutes. The average of the 2nd and 3rd blood pressure measurements was used. Smoking, heavy exercise, and alcohol use may affect the accuracy of measurement, therefore participants were notified to abstain before their appointment. The analysis was taken from the left arm for all participants, with the arm resting either on the desk or armrest; with the antecubital fossa level with the heart and palm facing upwards.

2.7.2 Glucose

Fasting glucose analysis was performed on samples collected from participants in the morning after an 8 – 10 hour overnight fast. Serum glucose was measured in plasma. The glucose sample was collected in a grey top tube (2ml). Glucose analysis was completed at the DPHRU laboratory using the Randox Daytona Plus. A trained lab technician performed all these analyses.

2.7.3 Lipids

All analysis were performed according to good laboratory practice. Lipids were analysed using a Randox plus Clinical chemistry analyser (UK) using colorimetric assays. The coefficient of variance was 1.3%. The concentrations for triglycerides, total cholesterol, and HDL-C were determined directly from the essay, with measuring ranges of 0.13-5.60 mmol/l, 0.30-17.20 mmol/l, and 0.05-380 mmol/l respectively. The coefficient of variance for LDL-C, HDL-C, and triglyceride were 0.8%, 1.7% and 1.4%, respectively. The concentration of LDL-C was measured directly with a measuring range 0.40-4.90 mmol/l, but was also calculated using the Friedewald equation (Friedewald, W, Levy and Fredrickson, Donald, 1972). Fasting blood (serum and plasma) biomarker assays were performed at the laboratory at the MRC/WITS DPHRU in Soweto under the guidance of trained lab technician. The coefficient variance (CV), for LDL-C was 0.8%, HLD-C (1.7%), serum triglyceride (1.4%), and fasting glucose (1.3%). Fasting samples were collected in a 5ml yellow tube for the analysis of HDL, LDL, serum triglycerides and total cholesterol and all samples were analyses on the Randox Daytona Plus by a trained lab technician. Regression for low density lipoprotein was not completed because it not one of the metabolic syndrome outcomes.

2.8 Metabolic syndrome

The harmonised guidelines require the presence of 3 or more of the following to determine the diagnosis of MetS (K G M M. Alberti *et al.*, 2009):

- Waist circumference: ≥94cm for sub-Saharan African males
- Serum triglycerides: ≥1.7 mmol/l or specific management
- High-density lipoprotein cholesterol: <1.0 mmol/l
- Blood pressure: ≥130 mmHg systolic and/or ≥85mmHg diastolic blood pressure, or diagnosed hypertension and on medication
- **Fasting glucose: ≥5.6 mmol/l and/or those previously or currently diagnosed with diabetes and/or on diabetes medication were included in the metabolic syndrome definition**

Variables for all the components of metabolic syndrome were created and coded as follows:

- Waist circumference <94 cm was coded as 0, and ≥94cm =1
- Serum triglycerides <1.7 mmol/l = 0 and ≥ 1.7 mmol/l = 1

- **Fasting glucose <5.6mmol/l was categorised as 0 and those ≥ 5.6 mmol/l; and/or on diabetes medication were categorised as1**
- Blood pressure: systolic blood pressure <130mmHg and/or diastolic blood pressure <85mmHg = 0; and systolic blood pressure ≥130mmHg and/or diastolic blood pressure ≥85mmHg; or on medication = 1.

Once all these component variables were categorised, an additional variable was created by summing the score's to assess the participants with metabolic syndrome. Those who scored three or more were classified as having metabolic syndrome.

Study procedure and flow

The study procedure and flow of data collection are outlined on Appendix 5.

Study flow and procedures were as follows: Informed consent process, consent form signing, OGTT, fasting blood samples, Anthropometry measurements, DXA scans, participant questionnaire, dietary intake questionnaire, and accelerometer procedure. Once all data is collected, participant were offered refreshments and reimbursed for transport.

Data collection procedure for abnormal results

Participants who presented undiagnosed conditions were provided a referral letter from the nurse or medical doctor to present at their closest local clinic. The casualty SOP and abnormal results form have been added as an appendix 5. Oral glucose tolerance test was conducted and if fasting glucose was ≥ 7.0 mmol.l and/or 2 hr post glucose load ≥11.1 mmol/l, participant was given a referral letter to present at their closest local clinic.
Blood pressure in mmHg (Systolic BP≥140 and/or diastolic BP ≥90) was repeated and if still elevated a referral letter to local clinic was also provided.

2.9 Objectively measured physical activity

2.9.1 Actigraph GT3X-Plus

Physical activity was assessed using Actigraph GT3X-Plus triaxial accelerometers. ActiLife v6.13.3 software was used to initialise and download data from the accelerometer. The device was fully charged to 100% before initialising. The initialisation sample rate was set at 80Hz. The start date/time, and end date/time was entered to ensure that data was collected for seven full days, including the weekend. That is:

- The accelerometer was fitted based on the start date/time and end date and time, and we ensured that the start time was midnight of that day (i.e. 12.00AM), and the end date and time was midnight after seven days (i.e. 12.00AM)
- The minimum wear time per day was 600 minutes (10 hours) with allowance for 1-2 minutes of zero activity intensity counts between 0 and 100 (Troiano *et al.*, 2008), and a minimum of 4 days of valid wear time was required for inclusion. Those participants who did not wear the device for the required minimum four days and each day having at least 600 minutes of data were excluded from the data analysis.

Student role in data collection

I was involved in conducting informed consent, administering interview questions, initialising Actigraph and downloading Actigraph data, ensuring that participants recorded >4 days in a week with at least >10 hours of awake time data before downloading data. I had to monitor a data activity log, and was also responsible for management of the Actigraph database which included: tracking of devices, the date the participant took the device and expected date of return of the device, and date of the actual return. I was also responsible for the measurement of blood pressure.

The Actigraph is not waterproof, so participants were asked to remove the device when showering bathing and swimming. Figure 1.2. Shows how the device was worn on a Velcro belt which is placed around the waist. The participant placed the accelerometer on the centre of their right hip.



Figure 1. 1 Actigraph GT3X-Plus triaxial illustration on how the device was placed https://www.actigraphcorp.com/

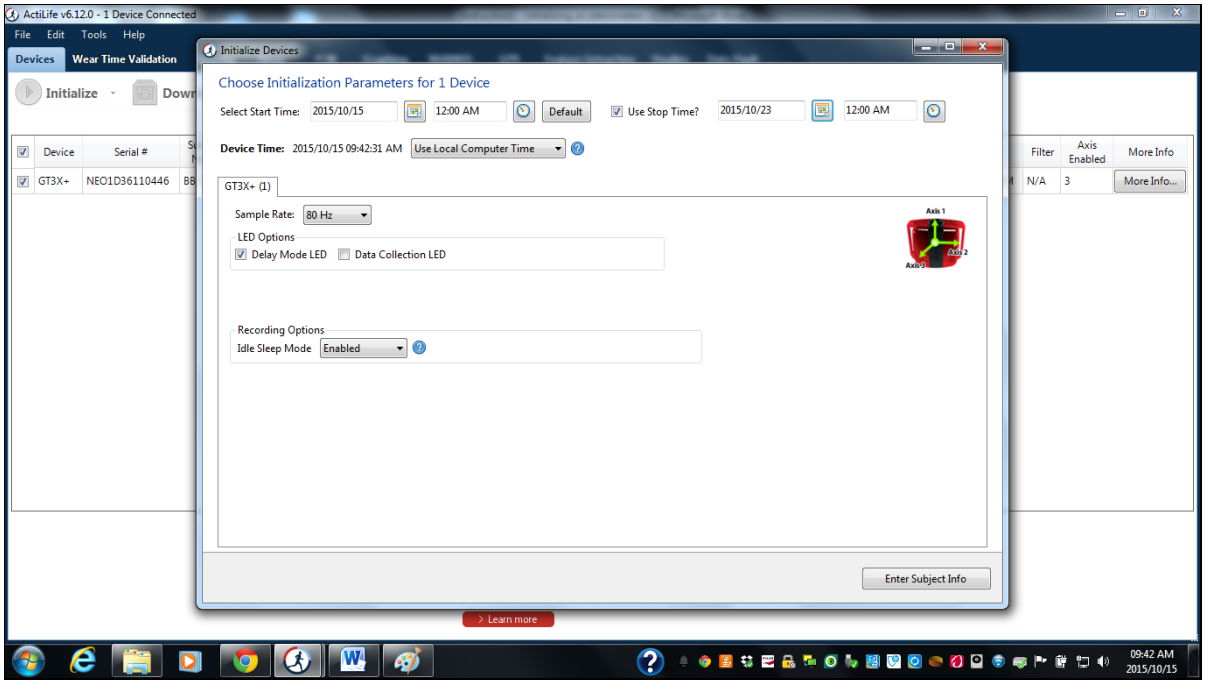

Figure 1. 2 ActiLife software during initialising device and ensuring the start and end date is correct

The Troaino 2007 cut point values were used to determine sedentary, light, moderate, vigorous, very vigorous intensity physical activity; i.e.: sedentary (0-99 counts per minute), light (100-1951), moderate (1952-5724), vigorous (5725-9498), and very vigorous (≥9499) (Troiano *et al.*, 2007). Moderate, vigorous and very vigorous intensity activity was added to get moderate-to-vigorous intensity physical activity (MVPA).

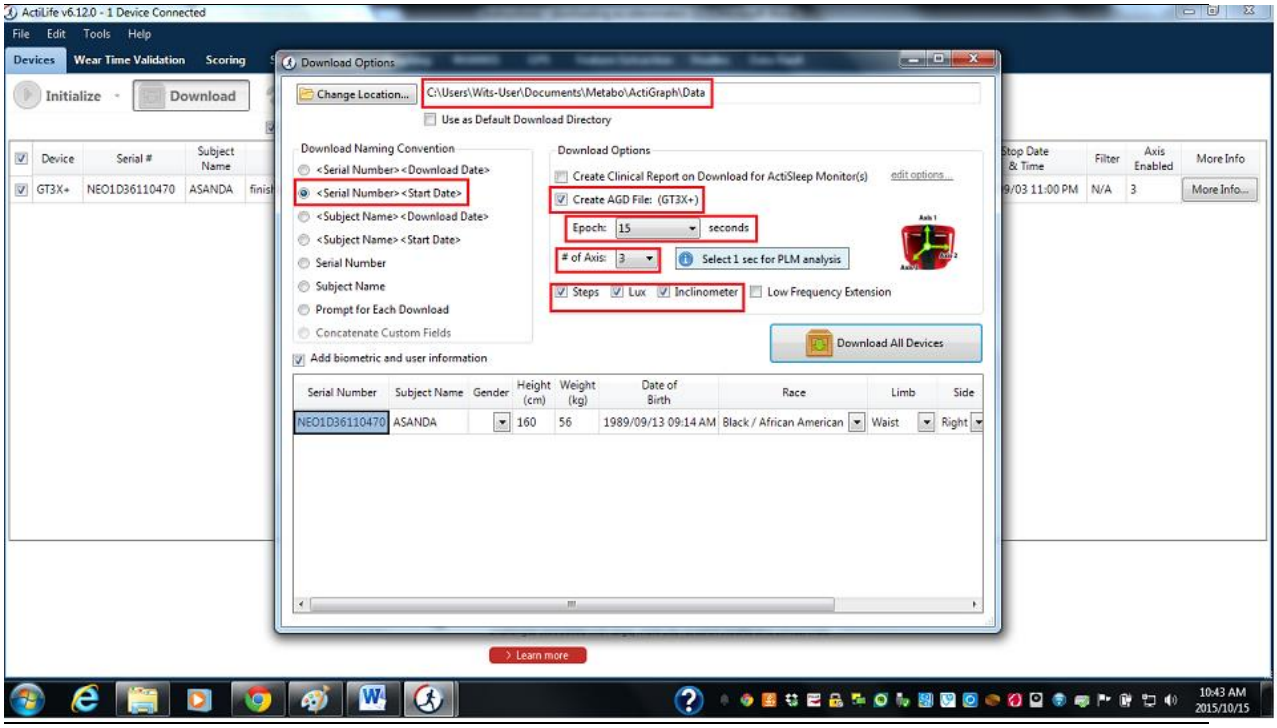

Figure 1. 3 ActiLife software downloading data of the participant

2.9.2 Sleep measurement

The ActiGraph's monitoring system delivers 24-hour information about sleep/wake behaviour. ActiGraph was capturing high-quality continuous sleep/wake data for the number of days the accelerometer was worn. The participants were given sleep diaries and were asked to document their sleep/wake up time each day. Participants' nap time was also included in the document. After participant data was downloaded, sleep/awake time was incorporated into the accelerometer data set. For those participants who had missing sleep diary data, sleep time was manually entered using visual inspection. Thus, sleep time was removed from the data. Sleep time is also reported in Table 2. Short sleep time was recorded as (<7 hrs/day), normal sleep time (7-9 hrs/day) and long sleep time (>9 hrs/day) (Celis-morales *et al.*, 2017).

2.10 Statistical Analysis

Data analysis was performed using STATA software version 14, StataCorp LP, USA**)**. A copy of the questionnaire has been added to the Appendices 4. However, for this analysis when it comes to smoking, participants were only asked if they smoked or not, and only currently smoking were recorded.

Categorical variables (e.g. SES, marital status, smoking, metabolic syndrome risk) were presented as frequencies and percentages. All data were tested for normality, where after continuous variables (e.g. age, height, weight, BMI, waist circumference, glucose, systolic and diastolic blood pressure) were presented using means (and standard deviations) if normally distributed, or medians (interquartile range) if not normally distributed. Metabolic syndrome risk components are; waist circumference (≥94cm), serum triglyceride (≥1.7mmol/l), HDL-C (<1.0mmol/l), blood pressure (≥130 mmHg systolic and/or ≥85mmHg diastolic blood pressure, or on medication), and fasting glucose (≥5mmol/l). The presence of 3 or more components indicate the presence of metabolic syndrome. Linear and multiple linear regression models were then used to determine the linear and independent contribution of physical activity and sedentary behaviour to each of the metabolic syndrome risk factors. Three regression models were conducted: Model 1 was a univariate regression between the one PA variable and the outcome (unadjusted), model 2 was a multivariate regression model adjusted for age and SES, also model 3 was a multivariate regression adjusted for age, ses and BMI. All of these are separate models. I still need to figure this out;

The current study aims to determine whether the relationship between physical activity, sedentary behaviour, sleep time, and metabolic syndrome components and metabolic syndrome is independent body composition, hence adjustment in the regressions. A logistic regression was used to determine whether exposure to physical activity sedentary time and sleep time is a risk factor for metabolic syndrome outcome in middle-aged black South African men. OR equals to 1 means the exposure does not affect odds of outcome, and OR greater than one means exposure is associated with higher odds of the outcome. OR less than 1 means exposure associated with lower odds of outcome (Szumilas, M. 2010).

CHAPTER 3: RESULTS

3.1 Sociodemographic, anthropometric measurements, and metabolic syndrome components descriptive data

The detailed characteristics of the 286 men who participated in the study are presented in Table 2. **There was 14 participants who either did not have all clinical measures (lipids, fasting glucose or blood pressure) (n=4), anthropometry data (weight, height, waist and circumference) (n=2) or physical activity data (n=8) (>4 full days, >10 hours of data per day). The mean age of excluded sample was 50±6.4 years, versus mean age of 56±6.3 years from the included sample. Mean SES score for the excluded sample was 9.2±1.8; (min/5 and 12/max) (p=0.498) vs 8.7±2.2 (min/2 and 12/max) for the included sample (p=0.037). Clinical measures and anthropometry cannot be compared from the two samples, as there were missing information from those excluded sample.**

In the current study 80% of participants had a primary school education, with 19% having secondary school education and 1% had no formal education. Describing socioeconomic status (SES), 57% had high SES, 38% medium SES, and 5% had low SES. The majority (59%) of this study population were married.

3.2 Anthropometric measurements and metabolic syndrome components

Anthropometric and metabolic syndrome components are presented in Table 2. A high proportion of the study sample were either overweight or obese (52%). Even with this high prevalence of overweight and obesity, undernutrition still existed (10%). half (44%) of the participants had a high waist circumference (≥94cm) which is the measure for central obesity in populations of African ancestry (K G M M. Alberti *et al.*, 2009).. The prevalence of lipid metabolic syndrome components were as follows; prevalence of high serum triglyceride was 13%, and low HDL-C prevalence was 25%. **The prevalence of elevated fasting glucose was 16%, and 66% had elevated blood pressure (≥130 systolic and/or 85 diastolic mmHg) with 13% being on hypertension medication.**

Table 4. 1 Descriptive characteristics of the middle aged black men in Soweto (n=286)

Variables	**Mean**	**Std. Dev**
Age (years)	53.6	6.3
Height (cm)	170.9	7.6
Weight (kg)	75.3	18.0
BMI (kg/m^2)	24.7	7.9
Waist circumference (cm)	92.5	18.7
Glucose (mmol/l)	5.1	1.8
Total Cholesterol (mmol/l)	4.3	1.1
Low-Density Lipoprotein (mmol/l)	2.4	1
Serum triglycerides (mmol/l)	1.1	0.9
High-Density Lipoprotein (mmol/l)	1.2	0.5
Systolic Blood Pressure (mmHg)	131.7	20.2
Diastolic Blood Pressure (mmHg)	87.3	13.2
Categorical	**%**	**(n)**
BMI Category		
Underweight (<18.5 kg/m^2)	10	29
Normal (18.5-24.9 kg/m^2)	38	109
Overweight (25-29.9 kg/m^2)	29	82
Obese (≥30 kg/m^2)	23	66
Marital status		
Single	24	69
Married	59	168
Widowed	4	10
Divorced	14	39
Socioeconomic status		
Low	5	13
Medium	38	109
High	57	164
Employment		
Yes	56	160
No	44	126
Education		
No education	1	1
Grade 1-7	80	230
Grade 8-11	15	43
Completed high school	4	12

Continuous values are presented as means ± standard deviation, and categorical data as %

Table 5.1 and Figure 1.4 show the physical activity and sedentary behaviour patterns of study participants. On average 35% of the day was spent in sedentary time, yet the distribution of sedentary behaviour amongst study participants was widely spread (Figure 1.4). However, 23% of the time of the day was spent in light physical activity. While only 3% of the time per day was spent on moderate to vigorous activity with 1% time per day spent in vigorous activity. Even with the high average sedentary time spent a day, 75% met the WHO adult physical activity guidelines (engaging in at least 150 minutes of moderate intensity activity per week or 75 minutes of vigorous intensity activity per week) with 25% considered inactive. Moreover, 32% of the study sample engaged in ≥10000 steps a day. Sleep time was reported, and more than half of the sample had a moderate sleep (7-8 hours a day), with 10% having a long sleep (>9 hours) and 31.8% experiencing short sleep (<7 hours). The minimum sleep time reported was 251.1 minutes (4.1 hours) and maximum being 660.5 minutes (11 hours) per day.

Table 5. 1 Time (minutes/day) engaging in different intensity activities n=286

Different activities	Median	IQR	
		25th percentile	75th percentile
Daily sedentary (min/day)	492	416	592
Daily Light (min/day)	316	261	375
Daily MVPA (min/day)	37	22	65
Daily Step counts (steps/day)	8156	5649	10780
Daily Sleep (hours/day)	7.5	4.1	11.0
Daily (%) time spent in sedentary, light , moderate, vigorous, very vigorous and sleep			
Daily Sedentary	35	28.9	41.1
Daily Light	23	19.2	27.8
Daily Moderate	3	1.6	4.7
Daily Vigorous	0.1	0	0.1
Daily Very Vigorous	0	0	0
Daily Sleep	31	28	35

MVPA-moderate to vigorous physical activity, min/day- minutes per day;

Values expressed in median (IQR-Interquartile range) or percentage (%).

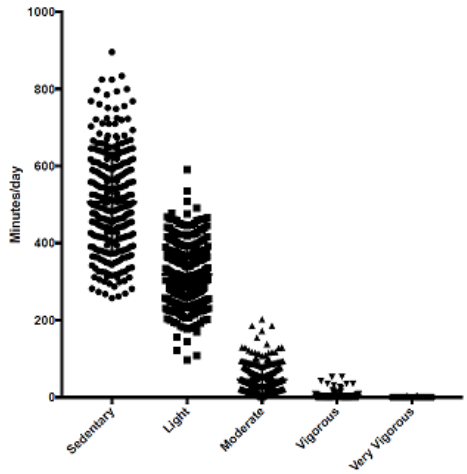

Figure 1. 4 Graphical physical activity patterns of middle-aged black African men in Soweto, South Africa

3.4 Associations between sedentary time, physical activity and metabolic syndrome components outcome

The associations between sedentary time; physical activity, sleep time and metabolic syndrome components outcomes, unadjusted (model 1), adjusted for age and SES (model 2), adjusted for age, SES, and BMI (model 3), are presented in Table 6.1. Daily sedentary time was positively associated with BMI, before and after adjusting for age and SES, while waist circumference had no significant association with sedentary time. Light intensity physical activity, MVPA, step count, and sleep time were inversely associated with BMI even after adjusting for SES and age, while waist circumference was inversely associated with MVPA and step count before and after adjusting for age and SES. Step count was inversely associated with fasting glucose and positively associated with HDL-C after controlling for all confounders, while sedentary time was inversely associated with serum triglycerides and light intensity activity was positively associated with serum triglycerides. It was of interest that see sleep time was inversely associated with systolic blood pressure before and after adjusting for BMI.

The current study aims to determine whether the relationship between the exposures (physical activity, sedentary behaviour, sleep time, and metabolic syndrome components) and the outcome (metabolic syndrome) are independent of body composition, hence adjustment for body composition in the regressions. Furthermore, age and SES were included in the models as these are known confounders of physical activity.

Table 6. 1 Univariate and Multivariate regression results for body composition and cardio-metabolic risk factors

	Model 1				Model 2				Model 3			
Body Mass Index (kg/m^2)	β	P-value	95% [CI]		β	P-value	95% [CI]		β	P-value	95% [CI]	
Sedentary (min/day)	0.014	**0.000***	0.00	0.01	0.011	**0.000***	0.00	0.01				
Light (min/day)	-0.010	**0.021***	-0.01	-0.00	-0.00	**0.033***	-0.17	-0.00				
MVPA (min/day)	-0.035	**0.000***	-0.05	-0.01	-0.019	0.058	-0.03	0.00				
Step count (steps/day)	-0.000	**0.000***	-0.00	-0.00	-0.000	**0.006***	-0.00	-0.00				
Sleep (hrs/day)	-0.003	**0.016***	-0.00	-0.00	-0.002	**0.024***	-0.02	-0.00				
Waist circumference												
Sedentary (min/day)	0.032	**0.000***	0.01	0.05	0.002	0.715	-0.01	0.01				
Light (min/day)	-0.013	0.320	-0.04	0.01	-0.012	0.352	-0.03	0.01				
MVPA (min/day)	-0.118	**0.000***	-0.17	-0.06	-0.064	**0.031***	-0.12	-0.00				
Step count (steps/day)	-0.001	**0.000***	-0.00	-0.00	-0.000	**0.004***	-0.00	-0.00				
Sleep (hrs/day)	-0.004	0.271	-0.01	0.00	-0.003	0.348	-0.01	0.00				
Glucose (mmol/l)												
Sedentary (min/day)	0.001	0.206	-0.00	0.00	0.000	0.383	-0.00	0.00	0.000	0.707	-0.00	0.00
Light (min/day)	-0.000	0.792	-0.00	0.00	-0.000	0.761	-0.00	0.00	-0.000	0.980	-0.00	0.00
MVPA (min/day)	-0.006	0.02	-0.01	-0.00	-0.004	0.146	-0.01	0.00	-0.003	0.226	-0.00	0.00
Step count (steps/day)	-0.000	**0.004***	-0.00	-0.00	-0.000	0.761	-0.00	0.00	-0.000	0.980	-0.00	0.00
Sleep (hrs/day)	-0.008	0.388	-0.02	0.01	-0.006	0.471	-0.02	0.01	-0.004	0.625	-0.02	0.01
HDL-C (mmol/l)												
Sedentary (min/day)	-0.000	**0.000***	-0.00	-0.00	-0.000	**0.000***	-0.00	-0.00	-0.000	**0.021***	-0.00	-0.00
Light (min/day)	0.000	0.560	-0.00	0.00	-0.000	0.545	-0.00	0.00	-0.000	0.860	-0.00	0.00
MVPA (min/day)	0.001	**0.033***	0.00	0.00	0.001	**0.035***	0.00	0.00	0.000	0.132	-0.00	0.00
Step count (steps/day)	0.000	**0.003***	5.85e-06	0.00	0.000	0.545	-0.00	0.00	-0.000	0.860	-0.00	0.00
Sleep (hrs/day)	0.002	0.200	-0.00	0.00	0.002	0.211	-0.00	0.00	0.001	0.521	-0.00	0.00

Table 6. 2 Continued

Model 1					Model 2				Model 3			
Serum triglyceride (mmol/l)	β	P-value	95% [CI]	β	P-value	95% [CI]	β	P-value	95% [CI]	β	P-value	95% [CI]
Sedentary (min/day)	-0.000	0.259	-0.00	0.00	-0.000	0.139	-0.00	0.00	-0.000	**0.028***	-0.00	-0.00
Light (min/day)	0.001	0.073	-0.00	0.00	0.001	**0.045***	0.00	0.00	0.001	**0.016***	0.00	0.00
MVPA (min/day)	-0.000	0.561	-0.00	0.00	-0.000	0.713	-0.00	0.00	-0.000	0.958	-0.00	0.00
Step count (steps/day)	0.000	0.073	-0.00	0.00	0.001	**0.045***	0.00	0.00	0.001	**0.016***	0.00	0.00
Sleep (hrs/day)	0.003	0.467	-0.01	0.00	-0.003	0.505	-0.12	0.00	-0.001	0.704	-0.01	0.00
Systolic Blood Pressure (mmHg)												
Sedentary (min/day)	0.028	**0.002***	0.01	0.04	0.026	**0.005***	0.00	0.04	0.018	0.058	-0.00	0.03
Light (min/day)	-0.025	0.088	-0.05	0.00	-0.026	0.073	-0.05	0.00	-0.018	0.199	-0.04	0.00
MVPA (min/day)	-0.066	**0.030***	-0.12	-0.00	-0.044	0.180	-0.10	0.02	-0.027	0.387	-0.09	0.03
Step count (steps/day)	-0.025	0.089	-0.05	0.00	-0.026	0.073	-0.05	0.00	-0.018	0.199	-0.04	0.00
Sleep (hrs/day)	-0.271	**0.010***	-0.47	-0.06	-0.257	**0.014***	-0.46	-0.05	-0.210	**0.038***	-0.41	-0.01
Diastolic Blood Pressure (mmHg)												
Sedentary (min/day)	0.011	0.060	-0.00	0.02	0.011	0.072	-0.00	0.02	0.006	0.325	-0.00	0.01
Light (min/day)	-0.017	0.067	-0.03	0.00	-0.017	0.079	-0.03	0.00	-0.012	0.185	-0.03	0.00
MVPA (min/day)	-0.013	0.490	-0.05	0.25	-0.013	0.530	-0.05	0.02	-0.004	0.841	-0.04	0.03
Step count (steps/day)	-0.017	0.067	-0.03	0.00	-0.017	0.079	-0.03	0.00	-0.012	0.185	-0.03	0.00
Sleep (hrs/day)	-0.110	0.108	-0.24	0.02	-0.109	0.114	-0.24	0.02	-0.082	0.225	-0.21	0.05

Model 1, comprises of univariate regression (unadjusted) between the one PA component and the outcome and;
Model 2, include multivariate regression (adjusted) between PA components controlled for age and SES only cardio-metabolic outcome variables were controlled for age and SES and;
Model 3, include multivariate regression (adjusted) between PA components controlled for age, SES, BMI and cardio-metabolic outcome variables
Min/day, minutes per day; Hrs/day, hours per day

3.4 Logistic regression for the association between sedentary time, physical activity, and sleep, and metabolic syndrome outcomes

Results before and after adjusting for BMI are presented in Table 5. Sedentary activity was significantly associated with higher odds of metabolic syndrome (OR≥1, p≤0.001), however, when adjusted for BMI, SES, and age, this was no longer significant. MVPA and daily step count were both significantly associated with lower odds of metabolic syndrome, however after adjusting for age, SES and BMI, only MVPA remained significant. Neither light intensity physical activity nor sleep were significantly associated with metabolic syndrome. Sedentary behaviour was significantly associated with higher odds of metabolic syndrome and this associated was dependent on BMI. OR is close to 1.0 which shows a weak association because of BMI.

Table 7. 1 Logistic regression results for metabolic syndrome

Model 1					Model 2				Model 3			
Metabolic Syndrome	OR	P-value	[95% CI]		OR	P-value	[95% CI]		OR	P-value	[95% CI]	
Sedentary	1.004	**0.000***	1.00	1.00	1.004	**0.000***	1.00	1.00	1.001	0.499	0.99	1.00
Light	0.998	0.314	0.99	1.00	0.998	0.368	0.99	1.00	1.001	0.429	0.99	1.00
MVPA	0.977	**0.000***	0.97	0.99	0.982	**0.000***	0.97	0.99	0.980	**0.012***	0.96	0.99
Sleep	0.984	0.150	0.96	1.00	0.987	0.253	0.96	1.00	1.001	0.932	0.96	1.03
Step count	0.999	**0.000***	0.99	0.99	0.999	**0.000***	0.99	0.99	1.001	0.429	0.99	1.00
Variables in model 1 were not adjusted, while variables for model 2 were adjusted for age and SES; and model 3 variables were adjusted for age, SES, and BMI OR, Odds Ratio; 95% CI, Confidence Interval												

CHAPTER 4: DISCUSSION

The current study investigated the association between objectively measured physical activity, sedentary time and sleep time, metabolic syndrome components and metabolic syndrome in a sample of black South African men between the ages of 40 and 65 years, living in Soweto. The main findings of this study were that objectively measured sedentary time was significantly associated with a higher odds of having metabolic syndrome, **however this was a weak association and was not independent of BMI.** Moderate to vigorous intensity physical activity was associated with a lower odds of having metabolic syndrome, and this was independent of BMI. The prevalence of metabolic syndrome in this sample was 49%. There was a high prevalence of overweight (29%) and obesity (23%) in this middle-aged sample of men, yet those who were underweight still existed (10%). This study has also shown that sedentary time was positively associated with BMI before and after adjusting for age and SES, while all other intensities of physical activity, daily step count and sleep time were inversely associated with BMI.

The majority of waking hours was spent in sedentary behaviour (35%; 8.4 hrs/day), while 23% (5.5 hrs) of the day was spent in light intensity physical activity, and 3% of the day was spent in moderate intensity activity, with 1% of the day spent in vigorous intensity activity. The majority of time spent in sedentary time was similar (8.4 hrs/day) to that of urban black women in a study from Cape town (aged 37±7 years), where time spent in sedentary time was (8.5 hrs/day)(K Dickie *et al.*, 2016). **Our data confirms that sedentary time constitutes the bulk of waking hours in this sample, also in countries like Belgium (55%)(13 hours) (Spittaels *et al.*, 2012). (Spittaels et al., 2012) had a sample of n=441 adult men from the Belgium study with mean age of 41.5 ±11.0 years, while (Kasha, Dickie et al., 2016) had 76 adult black women with mean age of 34±7 (Kasha Dickie *et al.*, 2016) compared to 53.6± 6.3 mean age of reported in the current study.** Moreover, In the ProActive study from the UK **Men aged 40±6 years spent significantly more time (p=0.003) in sedentary behaviour and more time in MVPA (P=0.002) than women (Ekelund, Griffin and Wareham, 2007)**. **(Spittaels et al., 2012) and (Ekelund, Griffin and Wareham, 2007) used the ActiGraph GT1, while (Kasha Dickie et al., 2016) used the Actigraph MTI 7164 accelerometer, and the current study used the Actigraph GT3X-plus. It is reasonable to compare data derived either from the GT1M, MTI and GT3X-plus when collected in uniaxial mode (Kaminsky and Ozemek, 2012)(Kozey *et al.*, 2010).** High sedentary time was

also noted from study of apparently healthy urban black adult women in Cape Town South Africa (Kasha Dickie *et al.*, 2016), however this comparison was between those who did not complete secondary school versus those who completed secondary/tertiary. It is important to note that no one had tertiary education in our study sample (n=286). **All the respective studies above (Kasha Dickie *et al.*, 2016) (Spittaels *et al.*, 2012) (Ekelund, Griffin and Wareham, 2007) were cross-sectional and had a small sample sizes.**

In this sample of middle aged black men, sedentary time was high yet the majority of participants met the physical activity guidelines, showing that individuals can be highly sedentary yet still be physically active according to the WHO physical activity guidelines.

The present study also showed that moderate-to-vigorous intensity activity and step count was associated with lower odds of having metabolic syndrome. **The prevalence of metabolic syndrome in this sample was 49%, from those with metabolic syndrome 48% were overweight with 46% obese. This prevalence is very high particularly among African black males. Metabolic syndrome prevalence has consistently been reported higher among females than males in all regions accept in Australia were white males had a higher prevalence (39.2%) vs 27.9% for females (Cameron *et al.*, 2009). In South Africa MetS prevalence has been reported lower in rural settings males (11.6%), and females (30.2%) (Motala *et al.*, 2011) vs urban in settings males (16.5), females (43%) (Peer *et al.*, 2015) using the harmonized guidelines (K G M M. Alberti *et al.*, 2009). In black residential areas from Cape Town South Africa, the prevalence of metabolic syndrome was high in black females (45%) vs males (32.6%) (Peer *et al.*, 2015). Among males with metabolic syndrome (≥2 MetS components) 52% were overweight with 67.9% who were obese (Peer *et al.*, 2015).** Moderate-to-vigorous intensity activity and step count were significantly associated with lower odds of metabolic syndrome, before and after adjusting for potential confounders (age, ses and BMI). **MVPA is very important to the prevention and control of metabolic syndrome and its related component.** Consistent with our study, moderate-to-vigorous intensity physical activity was inversely associated with reduced metabolic risk, even after adjusting for age, SES, and BMI in 30-50 year old men and women who were part of a family based intervention that aimed to increase physical activity in the United Kingdom (Ekelund, Griffin and Wareham, 2007).

Despite 75% of this sample meeting physical activity recommendations the prevalence of overweight and obesity was 52%. The national prevalence of overweight and obesity from the recent 2016 South African Demographic and Health survey was 27.4% in adult black men (aged ≥15 years) (Statistics South Africa, 2017). Men between the ages of 45 and 54 years had a prevalence of 42.7% and between 55 and 64 years this increased to 53.2%. Central body fatness has been associated with a higher cardiometabolic risk (Gradidge, 2017). In current study, men who had a waist circumference ≥94 cm spent significantly less time in moderate to vigorous intensity physical activity (33±26 min/day) than those with a lower waist circumference (60±43 min/day). In the Sympathetic Activity and Ambulatory Blood Pressure in Africans study, a WC cut-off of 94cm was associated with an increased odds of elevated glucose (OR: 3.23) and elevated serum triglycerides (OR: 1.70), while a WC between ≥90cm-96cm was associated with increased odds of elevated serum triglycerides (OR: 4.41) and high blood pressure (OR: 9.50) (Prinsloo *et al.*, 2011). **In our present study comparing both (Owolabi et al., 2018) (≥95cm) (Owolabi *et al.*, 2018) and (Alberti et al., 2009) (≥94cm) (K G M M Alberti *et al.*, 2009) cut-points, the prevalence of high waist circumference was 45% and 43%, respectively. The International Diabetes Federation (IDF) (Alberti *et al.*, 2005), and the new harmonized guidelines (K G M M Alberti *et al.*, 2009) for diagnosing metabolic syndrome include population specific cut-points for waist circumference. It has been recommended that cut points derived from European population groups are used for African subjects (Alberti *et al.*, 2005) (K G M M Alberti *et al.*, 2009).**

Other South African studies have reported high WC prevalence in black South African men using different cut-points (18.5%, ≥94cm). (Motala et al., 2011) (Motala *et al.*, 2011) reported a prevalence of 18.5%, using a cut-point of ≥94 cm while (Peer et al., 2015) (Peer, Steyn and Levitt, 2015), using the same cut point reported a prevalence of central adiposity of 20.1%. It has been suggested that country, ethnic and gender-specific waist circumference cut off points are needed, as adopting other countries cut-points may either under-or-overestimate the prevalence of metabolic syndrome (Owolabi *et al.*, 2018). In the present cut-off of ≥94cm was used and sedentary time was positively associated with waist circumference, and moderate-to-vigorous intensity physical activity and step count were both inversely associated with waist circumference. In black African women in South Africa (mean age 33±7 years), light intensity physical activity and step count were inversely associated with waist circumference (Kasha Dickie *et al.*, 2016). Results from the present study shows that moderate-to-vigorous intensity activity, but not light intensity physical activity was associated with lower waist circumference in men. Black South African men need to engage more in moderate-to-vigorous intensity

activity to lower central obesity. Policy makers in South Africa need to identify ways of eliminating barriers to physical activity practices such as safety , cost and accessibility to sports facilities to encourage more physical activity (Hill *et al.*, 2020).

The prevalence of high blood pressure in this sample of black South African men was 66%. Sedentary behaviour was positively associated with systolic blood pressure before and after adjusting for BMI. Similar results were reported from African adult males from Peri-urban location in Mbarara Uganda, who's work involved mostly sitting or standing for no more than 10 minutes at a time (p=0.0034) (Twinamasiko *et al.*, 2018). In a sub cohort study from the Osteoarthritis Initiative of adults with or at high risk for developing knee osteoarthritis, objectively measured sedentary behaviour was associated with higher systolic but not diastolic blood pressure, and associated with elevated blood pressure (≥130 systolic and/or ≥85 diastolic mmHg) independent of age and moderate-to-vigorous physical activity (p=0.046) (Sohn *et al.*, 2015). Sedentary lifestyles are modifiable and targeted interventions for middle aged black men can be used to prevent hypertension and reduce risk of metabolic syndrome (Twinamasiko *et al.*, 2018). In our study sample, moderate-to-vigorous intensity activity, and daily sleep time were inversely associated with systolic blood pressure however when adjusted for BMI, only sleep time remained inversely significant. This is consistent with findings from African women living in rural Limpopo South Africa, where longer sleep time was associated with lower systolic and diastolic blood pressure (Gradidge, Phaswana and Cohen, 2018).

In the current study, the prevalence of low HDL-C was 24% with a mean HDL-C of 1.2mmol/l. In the PURE study of healthy black South African men (aged 41±10 years) the prevalence of low HDL was 20%, with mean HDL-C of 1.45 mmol/l (Kruger *et al.*, 2017) which was then reported in the current study. In the present study, sedentary behaviour was inversely associated with HDL-C, and MVPA and step count were positively associated with HDL-C. However, after adjusting for BMI, only sedentary time and step count remained significant, therefore the relationship with MVPA and HDL-C was moderated by body composition. A cross sectional study of urban black South African women (aged 33±7 years) found no significant association between physical activity, sedentary time and HDL-C (K Dickie *et al.*, 2016). In another study by Cook et al (2009) (Cook, Alberts and Lambert, 2009), even though the relationship between physical activity and HDL-C was in the expected direction, it did not reach statistical significance.

According to the harmonised criteria serum triglycerides ≥1.7mmol/l or being on treatment for elevated serum triglycerides contribute to the presence of metabolic syndrome. The prevalence of elevated serum triglycerides in the present study was 13%. The prevalence of elevated serum triglycerides has been well reported in other South African studies including Kruger et al (2017) (Kruger *et al.*, 2017) who reported prevalence of 12.1% in men mean age 41±10 years, and Motala et al (2011) (Motala *et al.*, 2011) who reported a prevalence of 13.8% in a sample of black African men mean age 46±20 years. In the caregivers from the Birth to Twenty cohort, 22% of the women had elevated serum triglyceride levels (≥1.7mmol/l) (Crowther and Norris, 2012). The prevalence of elevated serum triglycerides in the heart of Soweto study among women of African descent was 23% (Sliwa *et al.*, 2012). It has been reported that black South African men who have a BMI ≥22kg/m^2 (overweight) had 6.22 odds of elevated serum triglycerides (Kruger *et al.*, 2017). In the present study, sedentary time was inversely associated with serum triglyceride, and light intensity physical activity was positively associated with serum triglyceride but only after adjusting for age, SES and BMI. **This unusual association with serum triglycerides may be due to other confounders such as lipid lowering medication or other medication use (Hamer *et al.*, 2014) which was not adjusted for in the present study affecting the association between physical activity, sedentary time and serum triglycerides**. Genetic factors could influence each individual component of the metabolic syndrome and itself (Chagnon *et al.*, 2003). A family history of type 2 diabetes and/or insulin resistance, obesity can increase chance of a person to develop the metabolic syndrome. The single-nucleotide polymorphism (SNPs) rs9939609 in the FTO (fat mass and obesity associated) gene altered the risk of being overweight or obese in white European (Frayling *et al.*, 2007) and African Americans (Hassanein *et al.*, 2010) adults compared to people who are normal weight (<25 kg/m^2). However, in African population of Gambia, no associations between FTO and weight-for-height z scores were found (Hennig *et al.*, 2009). In South African adolescents, SNPs were significantly associated with BMI: FTO rs17817449 (p=0.022), MC4R rs17782313 (p=0.045), LEP rs10954174 (p=0.000), and LEP rs6966536 (p=0.012) (Lombard *et al.*, 2012). The current study aims was not to identify these genetic associations, however it is important to acknowledge genetic contributions to overweight and obesity as a potential confounder**.** In the ProActive Study of men mean age 40.9±6.4 years, light intensity physical activity was inversely associated with serum triglycerides (Ekelund, Griffin and Wareham, 2007). We did not show an association between moderate-to-vigorous intensity activity, step count and sleep time, and serum triglycerides, while some studies have reported step count to be associated with lower odds of high serum triglycerides (OR, 0.92,

p≤0.05)(Sisson *et al.*, 2010), whereas other studies did not show any associations (Healy *et al.*, 2015). It is important for future research studies to examine what other confounding variables may influence the association between physical activity, sedentary time and serum triglycerides.

The mean fasting glucose level in our sample was 5.1mmol/l, with 16% of participants having glucose level ≥ 5.6mmol/l. This prevalence is similar to the prevalence reported in black African adult men from the CRIBSA study who had elevated fasting glucose of 15% (Peer *et al.*, 2015). High glucose levels are more prevalent in men who are overweight and obese (Peer *et al.*, 2015). In the present study, only step count was significantly associated (inversely) with fasting glucose, however this was not independent of confounders including BMI. In the National Health and Nutrition Examination Health survey (Sisson *et al.*, 2010) increased steps per day were associated with lower odds of elevated fasting glucose (OR,0.95, p≤0.05), however that survey did not adjust for BMI. Other studies have reported significant associations between light intensity activity and fasting glucose (Sisson *et al.*, 2010) (Healy *et al.*, 2015).In the Living Well with Diabetes (LWWD) randomized control trial of men (aged 58±8 years) light intensity activity was associated with reduced odds of elevated fasting glucose (OR,0.98, p≤0.05)(Healy *et al.*, 2015).To our knowledge the present study is the first to assess the association between objectively measured physical activity and fasting glucose levels among middle aged black men in Soweto, South Africa. In middle aged black women in South Africa, step count was not associated with fasting glucose (K Dickie *et al.*, 2016). In this study there was no significant associations between fasting glucose, while Dickie et al (2016) (K Dickie *et al.*, 2016) showed a significant association between sedentary behaviour and light intensity activity, and fasting glucose.

In the present study, sedentary time was significantly associated with higher odds of metabolic syndrome (OR >1, p ≥0.00), however when controlled for BMI, sedentary time no longer had significant association. Men who were overweight and obese, 81% and 96% had metabolic syndrome, respectively. In a cross sectional study of African males and females (aged ≥ 45 years) physical inactivity (<150 minutes per week) was positively associated with metabolic syndrome (Longo-Mbenza *et al.*, 2010). In the present study daily step count was associated with lower odds of metabolic syndrome, however was no longer significant after adjusting for BMI, age and SES. Other studies observed similar associations. In the Health and Nutrition Examination Health Survey (Sisson *et al.*, 2010), steps/day were associated with lower odds of

metabolic syndrome in men (OR, 0.90, $p \leq 0.05$) and this was controlled for age, smoking and ethnicity. Whereas in the current study, lifestyle factors were not accounted for. **To our knowledge this is the first study to investigate the association of objective measured physical activity in urban black SA men, who have prevalence of obesity, to determine if these criteria distinguished overall metabolic risk in this sample independent of BMI.** The current study only focused on black South African men as this was the sample of interest, so these findings are not necessarily relevant for South African females but only of great interest to black middle aged SA men.

CHAPTER 5: Conclusion, Strengths, Limitations and Recommendations

Conclusion

This study has shown that sedentary time was significantly associated with higher odds of having metabolic syndrome, however, this association was not independent of BMI. On average 35% (8.4hrs/day) of the day was spent in sedentary time, while, 23% of the time of the day was spent in light intensity physical activity, and 3% of the day was spent only on moderate intensity activity with only 1% of the day spent in vigorous intensity activity. People who sit for a prolonged period of time have an increased risk for cardiovascular disease mortality and type 2 diabetes, this increased risk is not observed among people who do 60 to 75 minutes of MVPA a day. However this amount of activity is far more than what most people are able to do, therefore, reducing sitting time and increasing PA will provide health benefits. Light intensity physical activity replacement of sedentary time can reduce risk of cardiovascular mortality by 16% per 30 min/day of sedentary time. **This was a sub-Study from a larger Cohort, and was cross-sectional. The low sample (n=286) may not be representative of the entire population of middle-aged black men in South Africa. These findings should be confirmed in larger independent cohorts, that include women, and future studies should consider the contribution of other lifestyle factors, including dietary intake, to cardio-metabolic risk**. Our study shows that 23% of the time of the day was spent in light intensity physical activity in this age group. The majority (75%) of study participants met the WHO adult physical activity guidelines. However, was still highly sedentary (35%). We have shown that despite most of the urban dwelling black South African men being classified as physical active, the high prevalence of overweight and obesity (52%) and metabolic syndrome (49%) is of concern in this sample. This would suggest that interventions studies could focus on increasing step counts as a means to reduce fasting glucose. From a public health perspective, this study has shown that metabolic syndrome and its related components are influenced by sedentary behaviour, sleep time and physical activity. Metabolic syndrome adds a major challenge to the overburdened primary health care system in South Africa. A more holistic and inclusive approach to managing these factors is needed, especially given that metabolic syndrome can be managed by individual behaviour. This study highlighted potential targets for intervention in this context, which are important to consider in future studies of this field.

6.1 Limitations

A key limitation when using accelerometers is the wide range of potential cut-points (Troiano *et al.*, 2008)(Choi *et al.*, 2011), meaning that data may not be comparable to studies who chose different cut-points. This was a cross sectional study design, which cannot be used to infer causality. The study only focused on black South African men as this was the sample of interest, so these findings are not necessarily relevant for South African females but only of great interest to black middle aged SA men. The low sample (286) may not be representative of the entire population of middle aged black men in South Africa. OR's in this sample were all close to 1.0, showing weak association, perhaps the candidate should have used robust regression would have overcome some limitations of traditional parametric and non-parametric data. Sedentary time was positively associated with serum triglycerides while light intensity activity was inversely associated with serum triglycerides, meaning high sedentary time increases triglyceride levels and higher PA time lowers triglycerides. However, lifestyle factors such as alcohol use, smoking and diet were not explored as they are potential confounders. The use of a 7 day sleep diary to determine sleep time may have been subject to recall bias, as we are not certain if participants forgot to fill in their diaries at the correct times or not. Also, the participants were part of a follow-up study from a larger sample, and may have sampling bias. The sample was collected in a manner that enabled some members of the intended population to have a higher sampling probability than others. +-This study did not include modifiable risk factors such as unhealthy diet.

6.2 Strengths

The strengths of this study include the use of objective measure of physical activity which provides robust and high precision assessment of free-living physical activity. Furthermore, this has allowed us to sedentary time, and physical activity over 24 hour periods. The study highlights objective measured light intensity physical activity as it the activity that most middle-aged participants engage in, and its association on metabolic syndrome and related components. Light intensity physical activity was not associated with metabolic syndrome, however was inversely associated with triglyceride independent of BMI, age and SES. Also, light intensity physical activity was significantly associated with BMI. Higher obesity levels are fuelling the metabolic syndrome epidemic and predicted higher obesity levels in future. This study provides the evidence and emphasis on replacing sitting time with more light intensity activity and encouraging more MVPA in this aging population. This may assist with halting obesity levels and metabolic syndrome and its related components in this sample group.

6.3. Recommendations for future studies

The current study investigated the association between objectively measured physical activity, sedentary time and sleep time, and metabolic syndrome in a sample of black South African men between the ages of 40 and 65 years, living in Soweto. The main findings of this study were that, sedentary time was significantly associated with a higher odds of having metabolic syndrome, however this association was not independent of body composition (BMI). Sitting time is an essential target behaviour to be targeted in health behaviour change programs. Physical activity measured as MVPA was associated with lower odds of metabolic syndrome, and this associations was independent of overall BMI. The low sample (n=286) may not be representative of the entire population of middle aged black men in South Africa. These findings should be confirmed in larger independent cohorts, that include women, and future studies should also consider the contribution of other lifestyle factors, including dietary intake, to cardio-metabolic risk. Previous studies have shown that sedentary behaviour is associated with increased risk for obesity (Spittaels *et al.*, 2012), CVD and T2D (Gennuso *et al.*, 2015)(Grunseit *et al.*, 2017). Our results showed that time spent in sedentary behaviour was associated with increased odds of MetS, however these findings were not independent of BMI. Physical activity guidelines focus mainly on increasing MVPA, with little focus on decreasing sedentary behaviour, therefore it is important for policy makers to devise sedentary guidelines that discourages time spent in sedentary activities with health promotion strategies centred around awareness of harmful effects on sedentary behaviour. Noting also that central body fatness is associated with a higher cardiometabolic risk, programmes encouraging MVPA should be initiated to lower this risk. We acknowledge that lifestyle factors such as diet play a significant role with obesity, CVD and T2D management. Sedentary behaviour interventions should be accompanied with dietary programmes that control of existing diseases such as high blood pressure, diabetes and dyslipidaemia, can be vital in communities (van Zyl *et al.*, 2012). Physical activity programmes can facilitate weight control and promote overall health. Patients with MetS can benefit intensively from dietary and exercise programmes to improve blood glucose levels, waist circumference, lower blood pressure, and lower lipid profile (Lichtenstein *et al.*, 2006). **Future intervention studies for cardio-metabolic disease prevention in urban black African men must aim to reduce daily sitting time and to increase physical activity (light ad MVPA) in order to prevent obesity. Soweto is an urban Township with many socioeconomic disparities with some areas that have been gentrified due to tourism**

attracted by the rich history it has. Creation of built environment that support physical activity is a sustainable strategy to encourage people to adopt, or increase levels of physical activity (McCormack and Shiell, 2011). Some barriers to physical activity among older adults have been identified and includes reduced mobility, poor health and fear for personal safety because of crime and traffic (Schutzer and Graves, 2004). The current study did not assess these barriers as this could explain the majority of time spent in sedentary behaviour. In addition interventions and strategies focused on reducing metabolic syndrome should focus on preventing obesity through good diet and avoiding excessive sedentary behaviour and encouraging more moderate-to-vigorous physical activity.

CHAPTER 7: References

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CHAPTER 8: Appendices

Appendix 1

R14/49 Mr Melikhaya Soboyisi et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160973

NAME: (Principal Investigator)	Mr Melikhaya Soboyisi et al
DEPARTMENT:	Paediatrics MRC/Wits Developmental Pathways for Health Research Unit Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	The Association between Physical Activity, Body Composition and Cardio-Metabolic Disease Risk in Middle-Aged Men from Soweto
DATE CONSIDERED:	30/09/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	A/Prof Lisa Micklesfield
APPROVED BY:	Professor P. Cleaton-Jones,Chairperson, HREC (Medical)
DATE OF APPROVAL:	19/04/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004,10th floor, Senate House/2nd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated,from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially review September and will therefore be due in the month of September each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature Date

Appendix 2

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

03 November 2016
Person No: 1343672
PAG

Mr MA Soboyisi
1651 Tolomo Street
Kanana
Orkney
2619
South Africa

Dear Mr Soboyisi

Master of Science in Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *The association between physical activity, body composition and cardio-metabolic disease risk in middle-aged men from Soweto* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 3

PARTICIPANT INFORMATION SHEET

September 2016

The association between physical activity, body composition and cardio-metabolic disease risk in middle-aged men in Soweto

Invitation

Hello, my name is Melikhaya Soboyisi and I am a Masters student at the MRC/Wits Developmental Pathways for Health Research Unit (DPHRU) from the University of the Witwatersrand.

I would like to invite you to participate in the research study entitled; **The association between physical activity, body composition and cardio-metabolic disease risk in middle-aged men in Soweto**

Before, agreeing to participate, it is important that you understand the purpose of the study, the study procedures, benefits and risks as well as your right to withdraw from the study at any time. If you have any questions, do not hesitate to ask me. You should not agree to take part unless you are satisfied with all the procedures involved. If you decide to take part in this study, you will be asked to sign this document to confirm that you understand the study. You will also be given a copy to keep.

Why is the study being done?

Studies have shown that body composition (the amount of muscle and fat in your body) and body fat distribution (where the fat is located in your body, for example, fat around your stomach) changes as one gets older, and that this is associated with an increased risk of certain diseases such as type 2 diabetes (sugar disease). However, most of these studies were undertaken in white populations from developed countries. It is important to study this in the black African population as many factors such as socio-economic status, physical activity and nutrition, are specific to this population, and may have an important impact on how your body works and how this is changed with aging. Further, Physical activity plays an important role in obesity and overweight reduction, although there is limited data describing physical activity levels in South African men. Few studies in South Africa have investigated obesity in relation to physical activity in rural African population and have relied on questionnaires to estimate physical activity. Although, objectively measured physical activity not only provides comparable unit-based output but also greatly reduces the impact of language and cultural influences on physical activity estimates, as opposed to questionnaires. Therefore, considering

the limited data on physical activity in middle aged South African men, and the high prevalence of obesity in this group, as well as the apparent associations between adiposity, physical activity and metabolic health; it would be interesting to measure physical activity levels in this population and determine whether these associations exist in this group

Who can participate?

We are going to be testing men who participated in the H3Africa/AWIGEN study in 2014.

You will only be eligible for this follow-up study if you participated in the H3A/AWIGEN study.

What will happen if you decide to take part in the study?

If you meet the criteria and decide to take part in the study, you will be required to complete two testing session described below, at DPHRU at Chris Hani Baragwanath Hospital in Soweto.

You are under no obligation to take part in the study and are not required to give a reason if you do not wish to participate. If you decide to take part in the study, you are free to withdraw at any time and without giving a reason and without prejudice. If you decide to withdraw from the study, we will discuss with you what will happen to any information or samples that you have provided. If the incomplete samples and information can usefully contribute to the study, we will ask your permission to store them and use them in our analysis. Alternatively, on your request all your information and samples will be destroyed.

Testing Session 1: Testing at any time of the day and will take 2 hours of your time.

You will be requested to complete a series of questionnaires by interview, which will include questions on measures of socioeconomic status (i.e. housing, employment and income), personal and family history of disease (e.g. diabetes, obesity, high blood pressure, and cardiovascular disease), reproductive history, access to food, and stress. In addition, questions on lifestyle factors, including smoking and alcohol intake, medication and supplement use will be included. You will also be asked to wear two small devices, one on your hip and one on your thigh, for 7 days to measure your physical activity and sedentary time. Your weight and height will be measured, as well as your waist and hip circumferences. In addition, you be required to undergo a scan to measure your body fat, muscle mass, and bone density, using a special X-ray scan. If there is any risk that you may be pregnant, you will be requested to have a pregnancy test prior to the scan, as the scan will expose you to a small amount of radiation. Your blood pressure will also be measured and you will also be requested to have an HIV test. You will also be required to bring your ID document, clinic card as well as any medication that you are currently taking.

Further details of these procedures are provided below**:**

Demographic, socioeconomic status and lifestyle questionnaire

You will be asked questions about various measures of social and economic status (e.g. if you are employed or not, what do you do at work, your source (s) of income) and questions about whether there are people in your family with diseases such as high blood pressure or heart problems. You will also be asked questions about your personal health, stress and reproductive history. In addition questions on lifestyle factors including smoking and alcohol intake, medication and supplement use will be included. We will fill in the answers for you. You can skip any questions that make you uncomfortable.

Body composition and DXA (dual-energy X-ray absorptiometry) measurements

Your weight, height, waist and hip circumference will be measured as part of your body composition assessment. In addition, you will undergo a special X-ray scan (DXA) that will tell us about your muscle mass, body fat and bone density. The scan will take approximately 20 minutes to perform during which you will lie quietly on the scanning table in a medical gown provided. The only risk associated with the DXA scan is exposure to radiation. However, the radiation exposure with a DXA scan is less than half that of a chest x-ray.

Blood pressure:
After a 5-minute relaxation period, blood pressure will be measured 3 times in a row, separated by 5 minutes of relaxation between readings. A standard blood pressure monitor will be used.

Physical activity

You will be asked to wear two motion sensors (accelerometer and activPAL) for 7 days, to measure your activity and sedentary patterns. They are the size of a small matchbox and one is worn on the waist with a lightweight belt and the other is attached to the thigh using a waterproof plaster. You will be instructed on how to use the monitors. There are no side-effects associated with wearing the monitors.

HIV test

We would like to test your HIV status. This is very important as it may have effects on your body composition, risk for diabetes and the factors that we will measure in your blood. The HIV test is voluntary, however If you have previously been tested as HIV positive this is not necessary. If you refuse the test, you will not be able to participate in the study. It is also important to note that if you decide to test, you will be given pre-test counseling. This test is always strictly confidential and can only happen if you agree. There is no way in which anyone can link your HIV status to your name as all results in this study are coded with a number. No one including your doctor, family, or work colleagues will be told about this test without your permission. The advantage of a rapid test is that you do not have to return to get your test result. Results will be available when your check out, after all the other tests, measurements and questionnaires are completed.

You will have your finger pricked with a sterile needle and the drop of blood will be tested on specific HIV testing kits to check for HIV antibodies. Test results will be given to you in private by a registered trained counsellor. If the report states negative it means that there are no antibodies to HIV. The window period will be explained. If the report states positive, it means that you are HIV positive and that there are antibodies to HIV. You will be given a letter to refer you to a clinic specialising in HIV treatment and you will be given a second test at the clinic to confirm this result. Sometimes we cannot clearly tell if the results are negative or

positive. We will then refer you to a clinic specialising in HIV treatment and you will be given a second test at the clinic to confirm this result.

There is a chance that some of the questions in the questionnaire might trigger some emotional distress. If this happens, we will refer you to our counseling nurse on site and she will make the necessary appointment for you to see a psychologist at the Psychology Unit at Chris Hani Baragwanath Hospital

Testing session 2: Testing in the early morning (between 7:30 and 8:00 am) and will take 2½ hours of your time

You will be requested to visit the DPHRU offices at the Chris Hani Barangwanath Hospital between 7:30 and 8:00 am in the morning approximately 7 days after testing session 1, but after an overnight fast (nothing to eat or drink, except water, from 10pm the night before). You will be asked to donate a sample of blood and then undergo an oral glucose tolerance test (OGTT) to determine whether you are at risk for developing diabetes. You will also be required to return the two physical activity monitors that were given to you in the first testing session.

Blood sampling and oral glucose tolerance test (OGTT)

Blood sampling and the OGTT can only be performed in the morning after an overnight fast. Therefore it is important that you do not eat or drink anything (except water) from 10 PM the night before, or for 10-12 hours before your test begins. You are not allowed to take any medication, food or drink, chew gum or sweets, before your blood test.

Blood sampling will be performed by inserting a small plastic tube into a vein in your arm and a small plastic tap or valve will be attached onto it so that blood samples can be drawn before the 2 hour OGTT test. The first blood sample (50 ml) will be drawn for the measurement of blood lipids (fats), glucose (sugar) and various hormones (e.g. insulin and cortisol) and inflammatory markers in the fasted state (i.e. before you eat anything). You will then be asked to drink a cup of water containing 75 g of glucose (sugar). Thereafter, blood samples (5 ml or 1 teaspoon each) will be drawn from your arm at 30, 60, 90 and 120 min after the glucose ingestion (total 20ml, 4 teaspoons) for the later measurement of changes in glucose and insulin levels. After your test you we will give you something to eat and drink.

What are the risks and discomforts of this study?

There are no risks or discomforts associated with the administration of the questionnaires. Strict confidentiality of results will be maintained. Your name will be removed from all data, and you will be assigned a number, which will be used to identify data relating to you. All records will be kept in a locked room and in a secure computer database in the research unit. Your name will not be used in any publication of the results.

There are no risks associated with the use of the physical activity monitors. The only risk associated with the DXA scan is exposure to radiation. However, the radiation exposure with a DXA scan is less than half that of a chest x-ray (11.3 microSieverts).

There are no appreciable risks associated with the fasting blood sampling and OGTT, other than those associated with routine blood sampling. Sometimes when blood is taken you may feel a prick at the place where the needle enters your body. Afterwards there may be a little bruise, and pain (which are associated with normal blood sampling), and in very unusual circumstances, local infection. Very occasionally participants may 'faint'. This is a stress

response to a trigger (e.g. the sight of blood) and has no long-term effects. This test is used routinely for both research and medical purposes. The total amount of blood drawn will be 70 ml, which is substantially less ($1/7^{th}$) than that of a standard blood donation (500 ml). All procedures will be supervised and carried out by a nursing sister and appropriately trained medical personnel using sterile techniques to minimise any risks of infection.

If we discover that you have any health problems based on our tests, you will be contacted and referred to the appropriate clinic for treatment and/or management.

Are there any benefits to you for being in the study?

You will receive your own results from the study, including your body composition (e.g. muscle and fat mass), and blood pressure. This information can be used to provide evidence for future strategies for the prevention, treatment and management of cardio-metabolic risk in middle-aged black South African men.

What will happen when the study is over?

Detailed analysis of your results will take some time, but once these analyses have been completed, the final results of the study will be shared with you. In addition, the results of the study will be published in scientific journals, as well as in the local media. Your name will not be used in any publication of the results.

Will you receive reimbursement for transport?

You will receive R150 to cover transport costs to DPHRU for each of the two testing sessions. The transport money will be paid to you at the end of each session.

Who will see the information that is collected about you during the study?

Strict confidentiality of results will be maintained. Your name will be removed from all data, and you will be assigned a number, which will be used to identify data relating to you. All records will be kept in a locked room and in a secure computer database in the research unit. Your name will not be used in any publication of the results.

Who do I contact if I have any questions about the study?

If you have any questions or you experience any problems during or after the tests, please contact Associate Professor Lisa Micklesfield or Dr Alessandra Prioreschi

Associate Professor Lisa Micklesfield (PhD)

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Appendix 4

INFORMED CONSENT 1

The association between physical activity, body composition and cardio-metabolic disease risk in middle-aged men in Soweto

Consent to participate in the study:

"I, _____, hereby give consent to participate in this research trial to be conducted by DPHRU, within the Department of Paediatrics at the University of Witwatersrand.

I understand that the study will involve completion of questionnaires by interview, an HIV test, routine body measurements (i.e. height, weight, hip and waist circumference), an X-ray scan to measure my body fat and muscle mass, and bone density, blood pressure, collection of blood samples after an overnight fast (10-12 hours) and during a 2-hour oral glucose tolerance test, as well as wearing an accelerometer and ActivPAL for 7 days to measure physical activity and sedentary time, respectively. The purpose and all the details of this study have been explained to me.

I have read and have had explained to me the procedures described. I have had an opportunity to ask questions and my questions have been answered in a satisfactory way.

I understand that all the information collected during the study will be treated with the strictest confidentiality and will only be used for scientific research purposes. All samples will be kept in a freezer in a secure facility with access limited to research personnel. All records will be kept in a locked room and in a secure computer database in the research unit. My name will not be used in any publication of the results. I understand that for data verification and quality

control purposes regulatory authorities and/or members of the Wits Human Research Ethics Committee (Medical) may be allowed access to my personal data under conditions of strict confidentiality.

I understand that I may be contacted for a follow-up study.

I agree to participation in the study on the condition that:

1. I can withdraw voluntarily from the study at any time and that no adverse consequences will follow on withdrawal from the study.

2. I have the right not to answer any or all questions posed in the questionnaire.

3. The University of the Witwatersrand's Human Research Ethics committee has approved the study protocol and procedures.

4. All results will be treated with the strictest confidentiality.

5. Only group results, and not my individual results, will be published in scientific journals and in the media.

6. The study scientific team are committed to treating participants with respect and privacy through interviews conducted in private and follow-up counselling available on request.

7. I will receive a referral note to psychological services if I experience any psychological distress during the study.

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and my questions have been answered to my satisfaction. I consent voluntarily and understand that I have the right to withdraw my consent without this affecting the current research study or my medical care.

Print Name of Participant _____

Signature of Participant _____

Date _____

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

RESEARCH ASSISTANT:

Printed Name Signature/Mark or Thumbprint Date and Time

Copy provided to participant _____ (initialed by researcher)

WITNESS: (If applicable)

Printed Name and Time	Signature/Mark or Thumbprint	Date

PARTICIPANT INFORMATION SHEET 2

The association between physical activity, body composition and cardio-metabolic disease risk in middle-aged men in Soweto

Information sheet:

Will any of your blood samples be stored and used for research in the future?

The researchers will ask your permission to store your blood samples for future research indefinitely. Also, we will be extracting DNA from your blood and this will be stored indefinitely. All samples will be kept in a freezer in a secure facility with access limited to research personnel only; all records will be kept in a locked room and in a secure computer database in the research unit. Your name will not be used in any publication of the results. For data verification and quality control purposes regulatory authorities and/or members of the University of the Witwatersrand Human Research Ethics Committee may be allowed access to your personal data under conditions of strict confidentiality.

Future research analyses on the stored blood samples and DNA will be based on new research that we are at present not aware of, but may be important in our understanding of the risk for disease. Any research done in the future will only be executed once it has been approved by the Human Research Ethics Committee (Medical) of the University of Witwatersrand that is set up to determine that the research is done according to accepted standards. You will not be penalized in any way for not allowing the use of your blood or tissue for future research. If you decide not to donate blood for future research, it will be destroyed on completion of this study.

When entering into the study, you will receive a unique code that will be used for sample and data analysis, which serves to maintain your confidentiality. When storing samples, you may

choose that we keep the unique code on the sample so that we can link any new results to your existing data. If any clinically relevant information relating to this sample is found, we will inform you of the results. Alternatively, you can remove the identifying number, so that your information will not be linked to the sample and you will not be informed of any clinical results relating to the new analyses.

Associate Professor Lisa Micklesfield (PhD)

Supervisor

MRC/Wits Developmental Pathways for Health Research Unit

Chris Hani Baragwanath Hospital

Soweto Johannesburg

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Human Research Ethics Committee contact details:

Prof P Cleaton-Jones, Tel 011 717 2301, email peter.cleaton-jones1@wits.ac.za or Ms Zanele Ndlovu/ Mr Rhulani Mkansi/ Mr Lebo Moeng Administrative Officers 011 717 2700/2656/1234/1252 zanele.ndlovu@wits.ac.za; Rhulani.mkansi@wits.ac.za; and Lebo.moeng@wits.ac.za

PARTICIPANT INFORMATION SHEET 2

INFORMED CONSENT 2

The association between physical activity, body composition and cardio-metabolic disease risk in middle-aged men in Soweto

Certificate of Consent:

1) If any of the **BLOOD** that I have provided for this research project is unused or leftover when the project is completed

   _ I give permission for my **blood** sample to be stored indefinitely

   AND if my **blood** sample is to be stored:

   _ I give my permission for my **blood** sample to be stored and used in future research of any type, which has been properly approved

   AND if any research on my **blood** sample cannot easily be done in South Africa:

   _ I give my permission for a portion of my **blood** sample to be sent out of the country for analysis if appropriately approved

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and my questions have been answered to my satisfaction. I consent voluntarily and understand that I have the right to withdraw my consent without this affecting the current research study or my medical care.

Print Name of Participant _____

Signature of Participant _____

Date _____

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

RESEARCH ASSISTANT:

Printed Name Signature/Mark or Thumbprint

Date and Time

Copy provided to participant _____ (initialed by researcher)

WITNESS: (If applicable)

Printed Name Signature/Mark or Thumbprint

Date and Time

INFORMED CONSENT 3

The association between physical activity, body composition and cardio-metabolic disease risk in middle-aged men in Soweto

The information around the blood sample taken from me and the DNA that will be extracted from the blood is clear and the purpose of consent is for me to inform the study what they can or cannot do with these samples.

I understand that all procedure/tests on the stored blood and DNA samples will be approved by the Human Research Ethics Committee of the University of the Witwatersrand.

YES ☐ NO ☐

I am in agreement that my DNA may be stored and used for the purposes described above.

YES ☐ NO ☐

I am in agreement that the data generated from my DNA may be made available as stated above.

YES ☐ NO ☐

I am in agreement that the information I have supplied in the list of questions and the information from the tests and measurements taken from me may be used as stated above.

YES ☐ NO ☐

I agree that a small bit of my DNA may be sent out of the country if the research cannot easily be done in South Africa.

YES ☐ NO ☐

I agree that a portion of my DNA may be stored in a biobank (laboratory) and that some data may be stored in a database as stipulated and that these may be shared according to the processes and procedures of the H3Africa initiative by using my study code or another code that de-identifies my sample and data.

YES ☐ NO ☐

I understand that every time a new study is done on my DNA, permission will be obtained from the ethics committee for the study to make sure that it is used only for the purposes stated above.

YES ☐ NO ☐

I understand that I will not benefit directly from the research done on my DNA.

YES ☐ NO ☐

I understand that I may withdraw from the study at any time.

YES ☐ NO ☐

PARTICIPANT

_____

Printed name Signature/Mark or Thumbprint

Date and Time

RESEARCH ASSISTANT:

_____

Printed Name Signature/Mark or Thumbprint

Date and Time

Copy provided to participant _____ (initialed by researcher)

WITNESS: (If applicable)

_____

Printed Name Signature/Mark or Thumbprint

Date and Time

Appendix 5



University of the Witwatersrand, Johannesburg

Developmental Pathways for Health Research Unit

Department of Paediatrics and Child

The association between physical activity, body composition and cardio-metabolic disease risk in middle-aged men in Soweto

DATE: Day | | | **Month** | | | **Year** | | | | |

BTT ID NUMBER: | | | | | | | |

Components	Tick

Study information sheet	
Consent form	
ID COPY	
Participant Questionnaire	
Anthropometric Measurements	
DXA scan	
Fasting bloods samples	
OGTT	
Accelerometer (ActiGraph)	
ActivPAL	
Dietary intake	
Reimbursement	
Feedback (comment)	
Date : _____	
Signature: _____	

IDENTIFICATION AND CONTACT DETAILS	
Name _____ ID number: _____ Date of Birth : _____ Age: _____ Physical Address: _____ _ _____ _ Postal Address: _____ _____ _ E-mail: _____ Tel No's: _____ (h) _____(w) _____ (Cell) _____	**SUBJECT CODE:**

Contact details of a relative or a friend who will <u>always</u> know where you live:

Alternative contact Person: _____
Relationship:_____

Tel No's: _____ (h) _____(w) _____ (Cell)
_____

TO BE KEPT SEPARATE FROM QUESTIONNAIRE DATA

SECTION A: DEMOGRAPHIC AND SOCIEO-ECONOMIC DETAILS

1. CURRENT MARITUS STATUS (tick option that applies)

Single	
Married/cohabiting	
Widowed	
Separated/Divorced	

2. HIGHEST LEVEL OF EDUCATION ATTENDED (tick options that applies)

No education	
Grade 1-2	
Std (1-3) Grade (3-5)	
Std (4-5) Grade (6-7)	
Std (6-7) Grade (8-9)	
Std (8) Grade (10)	
Std (9) Grade (11)	
Matric Grade (12)	
Post Matric qualification	
Diploma	
Tertiary education (university / technikon)	

3. CAREGIVER'S CONFIRMATION DETAILS

Question	**Answer**
Where were you born? (City/Town & Province SA) (Country & Rural/Urban)	
Where did you spend most of your school years, which includes primary and high school?	

How many years have you been living in Gauteng?	

4. GENERAL HOUSEHOLD INFORMATION

Questions	Answers
4.1 How many people live in your house including you?	
4.2 How many rooms are in your house (including kitchen, dining room, bedrooms, excluding bathrooms)	
4.3 How many bathrooms are in your house?	
4.4 How many rooms are there for sleeping?	

5. WHICH OF THE FOLLOWING DO YOU HAVE IN YOUR HOUSEHOLD (Tick for YES and X for NO)?

Electricity		Television		Radio	
Motor vehicle		Fridge		Washing machine	
Telephone/Cell phone		Microwave		Bicycle	
Tablet/ Laptop/Personal Desktop		DSTV/Satellite		MNet	

6. HOW WOULD YOU DESCRIBE YOUR HOME (tick the one that best describes it)?

House		Flat/Cottage/Townhouse		Residence/hostel	
Shack/Zozo		Government housing (e.g. municipal/RDP housing)		Room in backyard of house (or shared house)	

7. WHAT ARE THE WALLS OF YOUR HOUSE MADE OF? (tick appropriate box)

Brick/concrete		Mud/ cement		Plastic/cardboard	
Clay/Mud		Corrugated iron/zinc		Other	
Prefab		Plaster/finished			

8. WHAT IS THE **ROOF** OF YOUR HOUSE MADE OF? (tick appropriate box)

Straw/Thatch		Galvanised iron		Other (specify)	
Earth/sand/Mud		Wood/planks			
Concrete		Tiles/slates			

9. WHAT IS THE **FLOOR** OF YOUR HOUSE MADE OF (tick one box only)

Earth/sand/mud		Stone/Brick		Cement	
Wood		Vinyl/linoleum		Other	
Carpet		Ceramic tiles			

10. WHAT IS THE MAIN SOURCE OF DRINKING WATER IN THE HOUSE? (Tick one box only)

Bottled water		Protected dug out well		Public tap/standpipe	
Running water (tap water)		Unprotected dug well		Tanker truck/cart with small tank	
Piped water into yard/plot		Protected spring		Piped water into dwelling	
Surface water		Rain water		Other	

11. WHAT IS THE TYPE OF TOILET FACILITY IN THE HOUSE (tick one box only)

Flush to piped sewer system		Protected dug out well		Bucket system	
Flush to septic tank		Ventilated improved pit (VIP) latrine		Other	
Traditional pit toilet		No facility or bush or field			

12. HOUSEHOLD FOOD INSECURITY ACCESS SCALE

1. In the past four weeks, did you worry that your household would not have enough food?			
1. No	2. Rarely	3. Sometimes	4. Often
2. In the past four weeks, were you or any household member not able to eat <u>the kinds of foods you preferred</u> (i.e. VEGETABLES, FRUIT, MEAT/CHICKEN <u>NOT</u> "luxury" food such as pizza, burgers or fried chicken) because of a lack of resources?			
1. No	2. Rarely	3. Sometimes	4. Often
3. In the past four weeks, did you or any household member have to eat a <u>limited variety of foods</u> (e.g. Pap with <u>NO meat</u> OR pap with sweetened water) due to a lack of resources?			
1. No	2. Rarely	3. Sometimes	4. Often
4. In the past four weeks, did you or any household member have to eat some foods that you really did not want to eat because of a lack of resources to obtain other types of food?			
1. No	2. Rarely	3. Sometimes	4. Often
5. In the past four weeks, did you or any household member have to eat a smaller meal than you felt you needed because there was not enough food?			
1. No	2. Rarely	3. Sometimes	4. Often
6. In the past four weeks, did you or any other household member have to eat fewer meals in a day because there was not enough food?			
1. No	2. Rarely	3. Sometimes	4. Often
7. In the past four weeks, was there ever no food to eat of any kind in your household because of lack of resources to get food?			
1. No	2. Rarely	3. Sometimes	4. Often
8. In the past four weeks, did you or any household member go to sleep at night hungry because there was not enough food?			
1. No	2. Rarely	3. Sometimes	4. Often
9. In the past four weeks, did you or any household member go a whole day and night without eating anything because there was not enough food?			
1. No	2. Rarely	3. Sometimes	4. Often

13. EMPLOYMENT AND INCOME

13. 1 Are you currently employed? (tick)	YES NO
13.2 If YES TO 13.1, what type of employment?	FORMAL INFORMAL

13.3 If YES to 13.1, which best describes the work that you are employed to do? (tick relevant option)

Skilled manual work (i.e. sewing, beadwork, arts and craft, administrative assistants)	
Unskilled manual work (i.e. hotel maids, cleaner, sweepers or farm worker, domestic work)	
Clerical support, service or sales (i.e hairdresser, taxi service)	
Managerial/professional	
Own business	
Other (specify)	

15.4 Other household incomes (tick appropriate box):

Grants(PLUS number of people receiving grant)			
Child support grant		Support from a partner	
Disability grant		Support from family	
Care dependency Grant		Other (specify)	
Grants for older persons			
Foster care grant			

Income is a sensitive question to many people. However, it is very important for the study to have an idea of your monthly income.

13. 5 Monthly Household Income (including all sources of income e.g. grant, spousal support or family support) (Tick appropriate range):

R 1 to 2499		R 10 000 to 14 999		No income	
R 2500 to 4999		R 15 000 to 19 999		Not willing to disclose	
R 5000 to 7499		R 20 000 to 29 999			
R 7500 to 9999		Give other range			

13.6 How many people do you support with this income? _____Adults _____Children

SECTION B: GENERAL HEALTH

1. Are you pregnant?

Y	N

2. Have you had a hysterectomy (i.e. ovaries removed)?

Y	N

2.1 If YES, what date was it?_____

3. Do you have regular periods?

Y	N

3.1 If YES to 3, when was the start date of your last menstrual period?

3.2 If NO to 3, when was your LAST period?

3 months ago	6 months ago	1 year ago	More than 1 year

Y	N

3.3 How would you classify your menopausal stage?

Pre-menopausal	
Peri-menopausal “menopausal transition” e.g. menstrual irregularity, hot flashes, mood changes	
Post-menopausal (e.g. 12 month period without menstruation)	

4. How many children do you have?_____

5. How many pregnancies have you had? _____

6. When was your last pregnancy?_____

7. Contraception and fertility control

Contraceptive method	**Tick the appropriate box (give name where appropriate)**	**Duration**
None		
Oral contraceptive pill		

Injection (state frequency of injection)		
Female sterilisation		
IUD “Intra-Uterine Device” loop		
Patch		
Other and specify		

8. MEDICATION AND SUPPLEMENT USE

8.1	Do you use any medicine regularly or daily that a doctor or nurse has prescribed?	YES..... NO.....
8.2	Please provide the following information of your medication (s): **Name of medication(s)?** **What are they used for?** **What is the dosage and frequency of use of use? (e.g. 3 tablets per day)** **What long have you been using the medication?** **Examples of medical conditions that you could be using the medication (s) for:** high blood pressure, heart attack or angina (chest pains), stroke, high cholesterol (fats in the blood), diabetes, emphysema, bronchitis, asthma, osteoporosis, TB, epilepsy, cancer OR state don’t know if you are unsure what	
8.3	Do you use nutritional or other supplements?	YES..... NO.....
8.4	If YES to 8.3, Name the supplement, what is it used for, dosage, frequency and duration of use.	

8.6	Do you use any herbal medicine?	YES..... NO.....
8.7	Name of herbal medicine, what you are using for, state the dosage, frequency and duration of use.	
8.8	Have you been sick in the past week?	YES..... NO.....
8.9	If YES, what sickness? 8.9.1 Did you take medicine? (yes/no) What medication(s) did the nurse or doctor prescribe you? State the dosage, frequency and duration of use.	YES..... NO.....

9. CLINICAL CONDITIONS

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES
9.1	Would you say your health is poor, average, good, or very good/excellent?	POOR..... AVERAGE ..... GOOD ..... VERY GOOD/EXCELLENT.....

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES
9.2	Do you personally think that you are underweight, normal weight or overweight?	UNDERWEIGHT..... NORMAL WEIGHT ..... OVERWEIGHT. ..... OBESE..... DON'T KNOW.....
	Has a **doctor** or **nurse** or **health worker** at a **clinic** or at **hospital told you** that you had or have any of the following conditions:	
9.3	High Blood Pressure?	YES ..... NO ..... DON'T KNOW.....
9.4	Heart attack or angina (chest pains)?	YES ..... NO ..... DON'T KNOW.....
9.5	Stroke?	YES ..... NO ..... DON'T KNOW.....
9.6	High blood cholesterol or fats in the blood?	YES ..... NO ..... DON'T KNOW.....
9.7	Diabetes or Blood Sugar?	YES ..... NO ..... DON'T KNOW.....
9.8	Emphysema/Bronchitis?	YES ..... NO ..... DON'T KNOW.....

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES
9.9	Asthma?	YES ..... NO ..... DON'T KNOW.....
9.10	Sore joints, e.g. Arthritis, gout?	YES ..... NO ..... DON'T KNOW.....
9.11	Osteoporosis?	YES ..... NO ..... DON'T KNOW.....
9.12	Epilepsy / fits?	YES ..... NO ..... DON'T KNOW.....
9.13	TB?	YES ..... NO ..... DON'T KNOW.....
9.14	How many episodes of TB have you ever been treated for?	NUMBER OF TB EPISODES……..... Are you currently on TB medications? ……..... When was your last TB episode: ……....

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES
9.15	Cancer?	YES ..... NO ..... DON'T KNOW..... If yes, what? ……..

10. FAMILY AND MEDICAL HISTORY

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES
	Now I would like to ask you about your family. Do you have a **close blood relative** (father, mother, brother, sister or child) who has ever had any of the following conditions:	
8. 1	High Blood Pressure?	YES..... NO..... DON'T KNOW ..... If yes, who? …… …… …… …….....
8.2	Heart attack or angina or chest pain when exerting himself/herself?	YES..... NO..... DON'T KNOW .....

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES
		If yes, who…….. …… …… ……..
8.3	Was this relative younger or older than 50 years old when they first had a heart attack, angina or chest pain?	YOUNGER THAN 50 YEARS ..... …… …… OLDER THAN 50 YEARS..... …… …… DON'T KNOW ..... …… ……..
8.4	Stroke?	YES..... NO..... DON'T KNOW ..... If yes, who? …….. …… …… …… …….....
8.5	Diabetes?	YES..... NO..... DON'T KNOW ..... If yes, who? …… …… …… …… Adult/ child onset? …… …… ……

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES
8.6	Obesity? (Were they abnormally large? Or have difficulty moving?)	YES..... NO..... DON'T KNOW ..... If yes, who? …… …… …… …… …… …… ……

SECTION C: LIFESTYE

	1. TOBACCO USE (WHO STEPwise Questionnaire)	
1.1	Do you **currently smoke** any tobacco products, such as cigarettes, cigars, or pipes?	YES..... NO .....
1.2	Do you currently smoke tobacco products **daily**?	YES..... NO .....
1.3	**How old** were you when you first **started** smoking daily?	YEARS OLD _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ IF "YOU DON'T REMEMBER",.....
1.4	If you do not remember how old you were, do you remember how long ago it was?	WEEKS AGO_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ ──
		MONTHS AGO _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
		YEARS AGO_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
1.5	On average, how many of the following items do you smoke each day?	MANUFACTURED CIGARETTES _ _ _ _ _
	(CHECK EACH ITEM, IF NOT SMOKING AN ITEM, CODE 00)	HAND-ROLLED CIGARETTES _ _ _ _ _
		PIPES FULL OF TOBACCO _ _ _ _ _ _ _ _ _ _ _ _

		CIGARS/CHEROOTS/CIGARILLOS _ _ _ _ _ _ _ _
		OTHER_ _
1.6	**In the past,** did you ever smoke daily?	YES..... NO .....
1.7	**How long ago did you stop** smoking daily?	WEEKS AGO_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ MONTHS AGO _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
		YEARS AGO_ _ _ _ _ _ _ _ _ _ _ _ _ _ __

2. Do you use snuff?

2.1 IF YES, how often do you use snuff?

Once a day	
Twice a day	
Three times a day	
More than three times a day	
Other: Specify _____	

3. Do you use e-cigarettes (electronic cigarettes?)

3.1 IF YES, how often do you use e-cigarettes?

Once a day	
Twice a day	
Three times a day	
More than three times a day	
Other: Specify _____	

4. ALCOHOL INTAKE

1 standard drink is equal to 10 g of pure alcohol:

- 200 ml of beer
- 1 glass of wine
- 1 tot (25 ml) spirits
- 1 small glass (50ml) of sherry/port

4.1 How often do you have a drink containing alcohol?

Never		2-3 times per week	
Monthly or less		4 or more times per week	
2-4 times per month			

4.2 On a typical WEEK day, how many drinks containing alcohol do you drink? (how many standard drinks)

1 or 2		7, 8 or 9	
3 or 4		10 or more	
5 or 6		0	

4.3 On a typical WEEKEND day, how many drinks containing alcohol do you drink? (how many standard drinks)

1 or 2		7, 8 or 9	
3 or 4		10 or more	
5 or 6		0	

SECTION D: Clinical measurements (OGTT, Anthropometry, DXA and BP)

Date of testing: _____ Time of testing: _____

Time of last meal/drink: _____ Hours fasted: _____

How would you describe your health TODAY? (How are you feeling?):

Good ☐ Fa☐ Poo☐

If POOR, explain why:
_____

Date of last menstrual cycle:
_____

OGTT:

Fasting blood sample: Tubes 5 x SST – 27 epp (500µL each); 3 x EDTA – 9 epp (500µL each); 1 x LH – 1 epp (500 µL); 1 x FO – 1 epp (500µL)

Drink: ☐ Time: _____ Comments:
_____

30 min: ☐ Time: _____ Comments:
_____

60 min ☐ Time: _____ Comments:
_____

90 min: ☐ Time: _____ Comments:
_____

120 min: ☐ Time: _____ Comments:
_____

DXA: ☐ Full Body ☐ Half Body

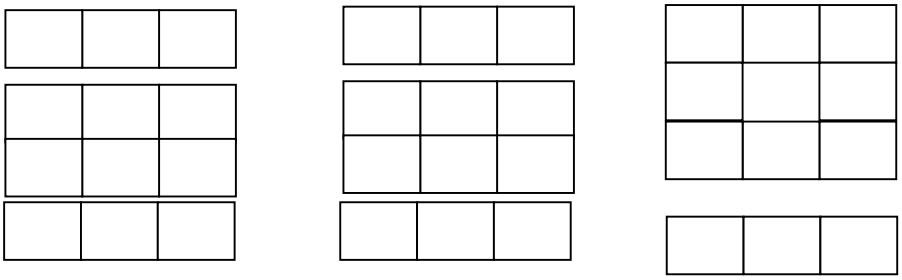
Comments:

_____

_____

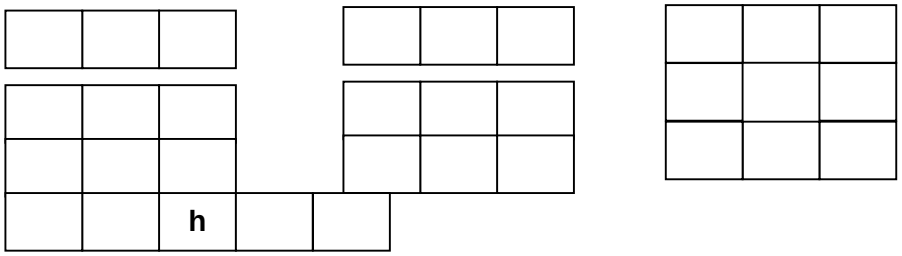
Anthropometry **(1)** **(2)** **(3)**

- Height (cm)
- Weight (kg)
- Waist (cm)
- Hip (cm)



BLOOD PRESSURE **(1)** **(2)** **(3)**

- SYSTOLIC BP
- DIASTOLIC BP
- PULSE
- TIME OF BP



PHYSICAL ACTIVITY SHEET

1. Accelerometer

1.1 Serial number of the monitor:_____

1.2 Date collected:_____

1.3 Date returned:_____

	Intensity

RECORDING DAY	Total moderate intensity	Total vigorous intensity	Moderate-to-vigorous intensity
DAY 1			
DAY 2			
DAY 3			
DAY 4			
DAY 5			
DAY 6			
DAY 7			

2. ActivPAL

1.1 Serial number of the monitor:_____

1.2 Date collected:_____

1.3 Date returned:_____

RECORDING DAY	**Sedentary time**
DAY 1	
DAY 2	
DAY 3	
DAY 4	
DAY 5	
DAY 6	
DAY 7	