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A comparison of self-report versus objectively measured physical activity in African-origin adults and the role of adiposity: a prospective cohort study

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Preamble

Declaration

I, Jessica Davies, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part has been, is being, or is to be submitted for another degree in this or any other university. I authorise the University to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

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Dissertation Abstract

Understanding physical activity (PA) patterns, including the domain, duration, and intensity, among different populations where the prevalence of obesity varies may provide insight into the role of PA in obesity prevention.

This thesis consists of two parts; Part A includes the rationale, aims and objectives of the current study, and the methodology, data analysis plan and ethical considerations. Part B consists of a manuscript which outlines and discusses the findings of the study.

The study presented in this thesis is a secondary data analysis from the Modeling the Epidemiologic Transition Study (METS)-Microbiome. Approximately 2,000 men and women of predominantly African-origin, between the ages of 35 and 55, were recruited and enrolled in the METS-Microbiome study between January 2017 and December 2019. Participants were previously enrolled in a prospective study of weight change (METS) and included 5 countries spanning the epidemiologic transition; rural Ghana; peri-urban South Africa; urban Jamaica; the Seychelles; and suburban Chicago, USA. PA was measured using objective PA monitoring and the self-report Global PA Questionnaire (GPAQ). Adiposity was measured using bioelectrical impendence analysis (BIA), which calculates fat and fat free mass. A basic health history was obtained from the participants, including the health history and socio-demographic information.

Using objectively measured PA, it was found after adjusting for site and sex, that Ghanaians do 76 min/day more PA compared to those in the US (95% CI: 42.51, 108.67, $p<0.05$). Similarly, females perform 64 min/day less PA than males (95% CI: -88.44, -39.84, $p<0.05$). Overweight/obese people do 31 min/day less PA than normal weight people adjusting for sex (95% CI: -55.48, -6.69, $p=0.01$). Finally, females perform 54 min/day less PA than males (95% CI: -78.57, -29.32, $p<0.05$). Regarding the influence of adiposity or site on the association between objectively measured PA and self-reported PA, overall, there is a very weak but

statistically significant correlation between using the GPAQ and PA measured using an accelerometer (0.223, 95% CI 0.16, 0.28; p-value<0.05). However, using the Bland-Altman method, we were unable to confirm these findings. When calculating the mean PA difference across all five sites, it was discovered that on average, people self-reported 142 minutes more activity than was objectively measured. When refitting the model without the interaction of adiposity, it is found that a 1 min/day increase in objectively measured PA results in a 1 min/day increase in self-reported PA adjusting for sex (95% CI: 0.58, 1.31, p<0.05). When investigating the role of adiposity on the association between the two measures within each country, no interaction was found in any of the five sites adjusting for sex.

Taken together, it is not possible to reject the null hypothesis, that with increasing adiposity, there is an increase in self-reported PA. Further investigations are therefore required to determine which factors influence the reporting of PA across different settings. Finally, it is evident that the PA policy and recommendations, may need to be tailored to individual settings as a result of discrepant PA perceptions.

List of Abbreviations

ADA – American Diabetes Association

ADL – activities of daily living

BIA – bioelectrical impedance analysis

BMI – body mass index

BP – blood pressure

cm - centimeter

CPM – counts per minute

CRF – cardiorespiratory fitness

CVD – cardiovascular diseases

FFM – fat free mass

FM – fat mass

GBD – Global Burden of Disease (study)

GPAQ – Global Physical Activity Questionnaire

HbA1C – glycosylated haemoglobin

HDI – Human Development Index

HIV – Human Immunodeficiency Virus

kg – kilogram

LMIC – low- and middle-income countries

m – meter

METS – Modeling the Epidemiologic Transition Study

MVPA – moderate-vigorous physical activity

NCDs – non-communicable diseases

PA – physical activity

PAQs – physical activity questionnaires

SSA – Sub-Saharan Africa

T2DM – type II diabetes mellitus

US – United States

VO_2peak – peak oxygen consumption

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Part A: Research Protocol

Purpose of the study

The purpose of this study is to determine whether adiposity moderates the relationship between self-reported physical activity (PA) and objectively measured physical activity. Further, a sub-aim will be to explore whether this association is altered based on location/site. The goal is to correlate self-reported PA and objectively measured PA, and the moderating effect of adiposity on this relationship in the ~2000 people in five countries spanning the epidemiologic transition. We hypothesize that with an increase in adiposity, there is an increase in self-reported PA and the error in self-reported PA compared to objectively measured PA will increase.

Background

The importance of studying/measuring physical activity:

Physical activity (PA) is defined as any bodily movement that requires/results in energy expenditure (1, 2), and these can be undertaken in different ways (1). Non-communicable diseases (NCDs), including Type II diabetes mellitus (T2DM), heart disease, stroke, and breast and colon cancer are making a presence across the globe (3), and this in turn is highlighting the effect which limited PA and physical inactivity can have on these particular types of disease (4). PA which is performed habitually has shown to prevent and treat NCDs such as those mentioned above (5). PA also plays a role in hindering hypertension, overweight and obesity, and can be influential in improving mental health, quality of life and ones well-being (1, 6). Physical inactivity is linked with the initial commencement of NCDs which in turn can result in health problems and all-cause mortality, but it is very importantly also a primary health risk factor for NCDs in all age groups which can be changed/altered (6, 7).

PA is advised for all ages, and can and should be incorporated into everyday lives (1). Although PA can be done by choice, this is not always the case. It is important for all types of PA, including

for means of transport, household chores, or other domestic activities, to be done frequently and be of satisfactory duration and intensity (1).

As is reported by the World Health Organization (WHO), worldwide, 25% of adults, and 75% of adolescents (11-17 years old), do not adhere to the WHO global guidelines for PA (1, 8). Levels of inactivity are seen to increase (6) as countries develop for reasons including a change in transportation modes, increased use of technology, and urbanisation (1).

The death of 1.3 million people (17 deaths per 100,000 inhabitants) 25 years of age and older is the ballpark figure provided by the results of the Global Burden of Disease (GBD) study, and these deaths occurred with risk factors including physical inactivity (7). These findings indicate that physical inactivity is of pandemic proportions globally, and emphasizes their support of the *World Health Organization Global Plan of Action for Physical Activity 2018-2030* (1, 7).

National recommendations on PA for health in low- and middle-income countries (LMIC) is vastly inadequate, and this highlights the great need for synthesis of global guidelines which focus on the relationship between the frequency, intensity, duration, type and total amount of time performing PA necessary to counter NCDs (6). It is imperative for policy-makers who wish to focus on PA at population levels, and those involved in formulating guidelines and policies surrounding the prevention and control of NCDs at various levels (including regional and national) to be provided with evidence-based recommendations with an international focus on the factors mentioned above, as well as other improvements derived from PA (6). The *Global Recommendations on Physical Activity for Health* are specific for different age groups, and can be applied for assorted health events, including cardiorespiratory health, metabolic health, musculoskeletal health, cancer, functional health and prevention of falls, and depression (6). It will be important, however, to highlight the differences between known health benefits of PA and the inferred effect of PA on weight change when defining public policies (9).

PA is vital when considering energy expenditure, and it is therefore of great importance to energy balance and weight control (6). “Energy balance is defined by the direct relationship between energy intake and expenditure” (10), and is vital to the maintenance of body weight (11). With the growing global spread of NCDs, populations are seeing a hasty increase in obesity, including sub-Saharan Africa where prevalence was once low (10, 11). PA recommendations to try and prevent weight gain have been included in prevention strategies provided by specialist bodies and government organisations which have until now, been included in the largely failing public health response to the mounting problems faced globally (10). It is important to acknowledge, however, that there is little direct evidence regarding the association (whether partial or primarily) between a decline in PA and the obesity epidemic in particular.

The aetiology of obesity is multi-faceted and complex (9, 12). Factors, including genetic susceptibility, high socio-economic status, and excess caloric consumption, may contribute to predicting obesity, but this is different from the more recent trend (11, 12). In developing LMICs, there has been a movement of inhabitants to urban centres which has provided these people with access to a mechanised lifestyle and cheaper energy sources, encouraging the rapid increase in the obesity crisis (9).

PA is a complex, multi-faceted construct which has no “gold-standard” measuring technique or method, and may therefore be measured using many approaches. Exact quantification of PA may therefore prove to be difficult, and selecting the most correct and objective measure for large populations (13) may be challenging. A combined approach to measuring PA may be most beneficial as essentially all methods for measurements have fundamental strengths and limitations. One important consideration when deciding on a measurement method is the cost that can be expected to arise from using that particular technique, and the level of practicality and convenience for both the participants and the investigators (13). There is evidently an epidemiologic transition occurring across the globe, and investigating the patterns and intensity

of PA in various, different populations which have a widely contrasting prevalence of obesity may provide necessary knowledge on one aspect of this transition (14).

Self-report values:

Self-report techniques can be used in different ways (15), such as through physical activity questionnaires which are a widely used method in monitoring activity levels. Global questionnaires, such as the Global Physical Activity Questionnaire (GPAQ), are simple to administer and complete (13). The WHO devised the GPAQ as a component to aid in observing chronic disease risk factors through the WHO STEPwise approach (16) in order to generate estimates of PA which are accurate, precise, reproducible and consistent for use in developing countries (17). The GPAQ categorises activities into domains, differentiating between PA during recreation time, occupation, or transportation (15) for at least 10 minutes at a time (17). An array of PA elements can be measured through the use of self-report physical activity questionnaires (PAQs) in vast numbers of participants with little expenditure (13). PAQs may be utilised with diverse populations, with the possibility of tailoring the specific questionnaire/measurement tool to meet the requirements of the target population (13, 15). Comparisons of results can be made across locations when the same instrument is used, e.g., GPAQ (13).

Self-report downfalls:

It is no secret that PAQs potentially lead to errors in calculating the total volume and/or intensity of PA due to PAQs oftentimes amplifying vigorous PA and belittling activities of daily living (ADL) and the time spent participating in them (13, 15). The judgment of the dose-response relationship between PA and health may therefore be influenced by this blunder (13). PAQ may enable groups to be categorised as “active” or “inactive” even though very little information is provided about activity. Recall questionnaires, however, are more comprehensive and may contain descriptions of PA with more details, including information on the frequency and duration of PA over an

extended period (13). Some populations, such as children or older participants, may have difficulty with recall. Terminology, such as “moderate- and/or vigorous-intensity”, used in the questionnaires may be ambiguous to some, and therefore pose a problem (13, 15). Answers may not be complete, and PAQs rely heavily on participants responses and their capability to adhere to the directions provided. The activities presented in a PAQ may not be applicable to all populations and therefore pose a problem (13). Due to the large number of measures available, it is not possible to compare results across studies. In studies with a high number of low-literacy participants, it may be required to make use of interviewer-administered surveys, adding to the cost and time of the study. In addition, many self-report measures may be more useful and appropriate when investigating the prevalence of PA in populations as they have not been found to be sensitive to changes in interventions (15).

Measured values:

One method of objectively measuring PA, as was used in this study, is through the use of accelerometres. These devices are able to identify accelerations of a body through their movement detectors. The rate of change in velocity over a given time is what defines acceleration, and because of this, it is then possible for the frequency, intensity and duration of PA to be determined as a behaviour attributed to bodily motions (13). These devices have become increasingly popular as an objective measure of daily PA (13), and may be used to determine whether individuals are meeting moderate-to-vigorous PA guidelines (15). Accelerometers provide improved results when compared with self-report methodologies as they have been proven to be unbiased, practical, exact, and reliable devices for quantifying PA volume and intensity with little discomfort as they are worn on the outside of the body, therefore being completely non-invasive (13). Huge advantages of accelerometers are that they are relatively small in size, their ability to record minute-by-minute information over extended periods of time (15), and the fact that participants are unable to see any information on the device results in a

decline in the chances of fabricating their level of PA (13). Accelerometers are able to objectively measure sedentary behaviour (physical inactivity) (13, 15), by counting the minutes of limited movement (15). This is of great importance because, even amongst those who engage in PA, sedentary behaviour is a risk factor for obesity and diabetes (15). Accelerometers are able to measure sedentary time, as well as PA with greater accuracy and precision than subjective methodologies such as questionnaires or self-report (13).

It is important to include objective measures of PA when attempting to fully acknowledge the role which PA plays in health (18). This is seen through people portraying themselves through surveys as engaging in behaviours which are healthy and beneficial, e.g., engaging in PA, even though they may be over reporting their levels of healthy behaviour. Various factors, such as sex, socio-economic status and other characteristics, may impact this bias (18).

Measured downfalls:

A limitation to the use of accelerometers includes that the device is not accurate in accounting for certain activities, such as bicycling, swimming, and many household chores (19), and they are not able to detect additional loads carried by the user, such as in weight lifting (13, 15). It also cannot determine if there are changes in the incline/gradient of the surface on which a participant is performing PA (13). While accelerometers may be easy for study participants to use, they pose challenges to researchers and evaluators because the data that is generated is of a large volume, and it needs to be checked, cleaned, scored and summarised. In addition to this, there is no standard which indicates how a valid day should be defined, or how the data should be scored (15).

It is of great advantage to include both methods – objective and self-report – to minimise any misreporting of PA, whether intentional or unintentional (13).

Obesity is a risk factor for chronic diseases such as cardiovascular diseases (CVD), and arterial hypertension is strongly associated, as the main risk factor, with these diseases. The prevalence of CVD and arterial hypertension in sub-Saharan Africa has exponentiated. Reducing sedentary time and increasing PA has shown to be protective against obesity, and therefore provides protection against many health risks, including arterial hypertension, associated with obesity. Significant associations have been found between obesity and blood pressure (BP), and obesity and the level of PA. Study results have shown that when weight increases, the risk of high BP increases, and that every 10kg increase in weight may result in systolic BP increasing by 2-6 times. An inverse relationship has been found between body weight and PA, and some epidemiological studies indicate that PA completed at high levels may eradicate the health risk of obesity (20). It is therefore imperative to include high levels of PA or exercise in a treatment plan for those with obesity, regardless of weight loss goals, as there are many cardiovascular benefits. This information agrees with the expanding body of knowledge that there may be a protective effect attainable from increased levels of PA when considering health issues including type 2 diabetes mellitus, overweight and obesity, and hypertension (21).

Evidence of physical activity and obesity:

How to manage the obesity epidemic has become a controversial topic – there are arguments for and against attempting to increase PA at a population-level. Some professionals claim that a decrease in PA, particularly surrounding occupation-related activities, is a large influencer in the obesity epidemic (18). On the contrary, no meaningful relationships between weight gain and PA have been found in prospective longitudinal studies which have used objective measures of PA. Self-report methods, especially questionnaires, are used by many studies interested in the association between weight gain occurring over time and PA. These questionnaires typically significantly over-report daily PA levels. This may be due to participants being required to provide information about specific types of PA levels (i.e., different domains of PA), or inaccuracies arising

because some questionnaires only ask for PA to be reported when the duration has been 10 minutes or longer. It is imperative to have an understanding of the aetiology of obesity when formulating policies, and designating public health funds, which are oftentimes scarce (18). In doing so, it is crucial to differentiate between the known health benefits of PA and the presumed effect of PA on weight changes (9).

Cleven et al reported a prominent relationship (21) between fewer incident cases of obesity and higher levels of PA as approximately 67% of studies reported decreased risks of becoming obese for those individuals who participate in higher levels of PA compared to those with lower levels of PA. One study in their systematic review indicated an elevated risk (142%) for obesity in those who do not participate in PA (21).

The largest health benefits for smaller incremental improvements in cardiorespiratory fitness (CRF) have been experienced in populations of individuals whose fitness levels are low, and those populations whose individuals are obese. It appears that higher levels of CRF are of greater importance for decreasing morbidity and mortality in overweight and obese populations, rather than only weight loss (22).

Elagizi et al., report that while the minimum recommendations for aerobic PA (150 min/week moderate intensity or 75 min/week vigorous intensity PA) can result in better cardiovascular health, these levels of PA are most-times insufficient without a restrictive diet to achieve weight loss or weight maintenance that is clinically significant (22). They also suggest that increasing CRF may be the most impactful method of intervention when compared to weight loss alone, and better CRF is associated with decreased BP, morbidity and mortality in various types of CVD (22).

Evidence of physical activity and Type II Diabetes:

An inactive, sedentary lifestyle is one of the primary reasons for the rise in the incidence and prevalence of T2DM (23). Cleven et al reported findings (21) of a negative association between

PA and diabetes – an increase in PA levels resulted in the risk of new diabetes cases decreasing. A gradual inverse relationship was found in nine of 11 studies, between PA performed at a high/vigorous-intensity and the risk of incident diabetes decreasing, while one study reported an association between moderate-intensity PA and a decreased risk of diabetes (21). Evidence is provided in two of the 11 studies of an increase in the risk of diabetes for those who do not engage in a sufficient amount of leisure time PA compared to the reference group which engaged in high amounts of PA (179% and 145% respectively) (21). Moderate-to-vigorous-intensity PA has been found to be so beneficial as to be able to reverse back most of the known T2DM factors towards healthier levels. PA is clinically beneficial in being protective against T2DM through its ability to improve insulin sensitivity, reduce glycosylated haemoglobin (HbA1C), and increase peak oxygen consumption (VO_2peak) (23). A reduction in adiposity, both visceral and abdominal, is important when considering PA and an improvement in insulin resistance. Intensive lifestyles alterations which focus on increasing PA can protect against the occurrence of T2DM more effectively than pharmacological interventions (23).

The American Diabetes Association (ADA) recommends no less than 150 min/week of PA in order to prevent T2DM. There is a large body of evidence from different countries with varying populations indicating that PA and exercise training are instrumental in increasing insulin sensitivity and altering body mass and composition, thereby preventing T2DM. Epidemiological studies have shown at long-term follow-ups that PA of varying intensity performed across the week had a negative association with the incidence of T2DM, as the incidence was seen to decrease in both genders and in different age groups (23). T2DM is associated with a high prevalence of overweight or obesity, and the metabolic enhancements in those with T2DM caused by PA are mainly attributable to a decrease in visceral adiposity rather than general weight loss (23). An accumulation of visceral adiposity is directly linked to physical inactivity. PA as a means

of decreasing body weight, is effective in rectifying the changes in insulin sensitivity, appetite, and serum omentin-1 concentration induced by overweight and obesity (23).

Amanat et al., report that (23) combined training (rather than aerobic or resistance training alone) is most effective for glycemic control. However, it is imperative to design exercise recommendations specifically for each individual as the challenges relating to blood glucose control are dependent on the type of diabetes and activity, and the presence of diabetes-related morbidities (23).

Evidence of physical activity and hypertension:

In a systematic review conducted by Cleven et al, inconsistent associations were discovered (21) between PA and incident hypertension. Various findings were reported; a gradual inverse association between different levels of PA and incident hypertension, an association found only in a particular age category (51-60 years), no significant association found between PA and incident hypertension, and those who participate in little leisure time PA being more at risk of incident hypertension compared to the comparator group who were highly active (21).

In contrast to the contradictory findings by Cleven et al (21), Seref Alpsoy indicates that hypertension has a significant relationship with being physically inactive, and that PA, both aerobic and resistance, is instrumental in delaying the development of hypertension and reducing BP (24, 25). Regular PA should be endorsed for all individuals, including those with normal blood pressure, those who are pre-hypertensive and those who have hypertension. However, caution should be taken with those on antihypertensive medications. CRF improves when PA is continuous, and reports show a decrease in new-onset/incident hypertension in those with good CRF compared to those with poorer CRF (24, 25).

There is a limited amount of evidence available regarding the effect of physical activity on NCDs in individuals of African-origin. This study/paper aims to fill some of these gaps by investigating using a population comprised solely of people of African-origin.

Methodology

Study design and settings

The modeling the epidemiologic transition study (METS) is the original and very well-established prospective cohort study from which the METS-microbiome study arose (12). Detailed protocols of each study have been published. METS was designed to investigate very diverse population-based samples from five countries and the relationship between body composition, PA, and relative weight, weight gain and cardiometabolic disease risk (12). The Ghanian study site includes a town named Nkwantakese and its surrounding villages (10). Khayelitsha, South Africa's sixth largest township is adjacent to the city of Cape Town (10, 26). The Seychelles study population was recruited from the main island, Mahé (10). Kingston is the capital of Jamaica, and it is the largest city (10). Maywood, in the US, is an African-American working-class community adjoining the western border of Chicago, Illinois (10). These five countries were purposefully selected to represent the "epidemiologic transition" spectrum, with Ghana and the US as opposite poles of the spectrum (12).

Characteristics of the study population

The study population is comprised of people of predominantly African-origin and 50% of each gender. Not only were the sites selected to represent the "epidemiologic transition", but they are also representative of a wide variety of social and economic development which is defined by the United Nations Human Development Index (HDI) 2011: i.e., Ghana at one end of the scale as a low middle HDI country (HDI rank 135 at the time of the original METS study), South Africa as middle (rank 123), Jamaica (rank 80) and the Seychelles (rank 52) as high, and the US at the

opposite end compared to Ghana, as a very high HDI country (rank 4) (10, 14). The population samples from each country were identified with the intention of depicting wide lifestyle characteristics popular in each site, rather than being descriptive of the country as an entire entity (14). The included sample populations varied in body size, with the most notable difference between Ghana (body mass index (BMI) at a low of approximately 24kg/m^2) and the US (BMI at a high of roughly 31kg/m^2) (10).

Recruitment and enrollment

METS-microbiome enrolled approximately two thousand adults (n=2000) between the ages of 35 and 55. A comprehensive protocol for METS-microbiome has been published, but briefly, approximately 400 participants from each of the five sites were admitted into the study between January 2017 and December 2019. Potential participants were excluded from the study if they had any obvious infectious diseases (including active malaria and Human Immunodeficiency Virus (HIV)), pregnant or lactating women, as well as people with issues which impair everyday physical activities, e.g., severe osteo'- or rheumatoid arthritis, or any lower body disability (10, 12, 14).

Investigators from each country site were able to decide the most appropriate method of recruiting a representative sample population from their country through the use of the results of the population-based surveys which had been completed previously in each country (10). The Ghanian team made use of simple random sampling for the correct age group through the results of the population census for Nkwantakese and its nearby villages (10, 14). The teams from both the Seychelles and South Africa made use of the national censuses in order to produce random samples which were stratified according to both sex and age (10). Districts in Jamaica were randomly sampled through beginning from a fixed point in each district and recruiting door-to-door (10, 14). A similar approach was used by the team in the US, as door-to-door recruitment was used once all the city blocks in the Maywood area were randomised (10, 14).

The protocols for METS and METS-microbiome were approved by the Institutional Review Board of Loyola University Chicago, IL, US; the Committee on Human Research Publication and Ethics of Kwame Nkrumah University of Science and Technology, Kumasi, Ghana; the Research Ethics Committee of the University of Cape Town, South Africa; the Board for Ethics and Clinical Research of the University of Lausanne, Switzerland; the Ethics Committee of the University of the West Indies, Kingston, Jamaica; and the Health Sciences Institutional Review Board of the University of Wisconsin, Madison, WI, US. All participants from all five sites involved in the study provided written informed consent (10, 12, 14).

Research procedures and data collection methods

There is an annual health exam completed of the cohort – it is well described and documented, and has been well followed since 2010. Measurements were taken at baseline, 12-months and 24-months for the METS study. Coordinating centre staff from all five sites provided training and certification to the project coordinators for all measurement protocols required for the study. All measurements were completed in the early morning within outpatient clinics that were located in each of the study sites (10, 17). In 2018, the study was refunded to be able to undertake the METS-microbiome study. The METS-microbiome similarly had two follow-up periods.

Anthropometrics and body composition

Measurements involving weight and height were performed once the participants were barefoot and had minimal light clothing on. Weight (in kilograms - kg) was recorded to the nearest 0.1kg and was measured through the use of the same model standard calibrated balance at all five sites (Seca 770, Hamburg, Germany). Height (in centimeters - cm) was recorded to the nearest 0.1cm through the use of a stadiometer (e.g., Invicta Stadiometer, Invicta, London, UK) while the participant maintained their head position in the Frankfort plane. Waist circumference (in centimeters) was measured to the closest 0.1cm at both the umbilicus, and the point of maximum protrusion of the buttocks for the hip. BMI was calculated as kg/m^2 (14).

Body composition was predicted using bioelectrical impedance analysis (BIA). A tetrapolar placement of the electrodes was used on the right hand and foot of a single-frequency (50kHz) impedance analyser (model BIA 101Q; RJL Systems, Clinton Township, MI). An equation validated in the METS cohort made it possible to use the resistance measured in this test to predict the fat-free mass (FFM) and the fat mass (FM) (10, 14).

Physical activity measurements

Physical activity monitoring

The Actical accelerometer (Phillips Respironics, Bend, OR, US) was utilised to objectively measure PA, and it was worn around the waist just behind the right hip. The study participants were requested to keep the monitors on their waist at all times, including while sleeping but excluding while immersed in water (i.e., while bathing, showering or swimming), over an 8-day period (14). Overall, the participants were observed for six full days (i.e., 8 days of wearing the monitor with two partial days on either end of the period taken into account). The original METS study was able to determine, through preliminary work, that this amount of wear time provides a good level of reliability at 0.83-0.92% for all of the five sites (10). The time frame for assessing PA conducted daily was between 07:00 and 23:00 at all five sites, and this was done to standardise the measurements as there are no global guidelines surrounding the definition of sleep-time vs. awake-time for accelerometry data which is collected for a 24-hour period (17).

For data analysis, it was important to first determine non-wear time from 90 or more minutes of continuous zero activity counts by running the raw data from the accelerometers through a SAS macro programme (10). This criterion was formed on visual inspection of the wear/non-wear patterns across a range of difference string-length criteria in a subset of files from each country (17). In order for a days' entry to be valid, the measurement required at least 10 hours of wear time, i.e., wearing the accelerometer for ≥62% of available wear time. The inclusion of participants for analysis was different however, as their files needed to have at least four valid days, i.e., ≥75%

of maximum number of days (14). Published cut-points were used in order to define sedentary, moderate and vigorous activity levels: sedentary <100 counts per minute (cpm), moderate 1535-3959 cpm and vigorous ≥3960 cpm (14). The protocol which served to guide the National Center for Health Statistics in the analysis of accelerometry data in the National Health and Nutrition Examination Survey was used to define minutes (10) as composed of different types of activity (i.e., sedentary, moderate, vigorous, or moderate plus vigorous) which may be presented as the overall time in minutes combined in intervals of either 1- or 10-minutes (17). The METS study made allowances for up to 2 minutes of below threshold count activity before acknowledging that an activity bout has ended, and therefore the 10-minute interval should be regarded as a modified 10-minute bout (10, 17). Data are presented as total activity counts divided by total wear time as an overall measure of average PA intensity (17). Average counts and time 1-minute bouts of moderate-to-vigorous activity (MVPA) and sedentary time are also included. 207 of 2,506 participants were excluded as they have insufficient accelerometer data. For the PA patterns analysis, weekday is defined as Monday through Friday, and weekend days as Saturday and Sunday (17).

Self-report physical activity

Self-reported PA was assessed using the GPAQ (version 2), and it was administered by centrally trained staff. This included determining the number of days per week, and how much time per day was used for: moderate and vigorous occupational activities; vigorous recreational activities; activities for travel purposes (i.e., walking, bicycle riding); sedentary activities (14). Through these findings it was then possible to calculate the daily average number of minutes spent performing activities from the different areas of PA (14).

Questionnaires

A basic health history was obtained from the participants, including a focus on obesity. An occupation questionnaire from the U.K. National Statistics Socio-economic Classification (NS-

SEC), 2000 edition was used to determine in more detail individual occupation (17). Occupation and industry were used to code for manual vs. non-manual labour class. Occupations coded as non-manual class included: senior, middle and junior managers; traditional professional (e.g., dentist, lawyer) and modern professional (e.g., teacher, social worker) occupations; and clerical and intermediate occupations (e.g., secretary, call centre agent). Occupations coded as manual class included technical and craft (e.g., auto mechanic); semi-routine (e.g., postal worker) and routine (e.g., labourer, driver, writer) manual and service; and farming, agriculture, and fishing occupations. Long-term unemployed (i.e., those not working in the past year) were coded as a separate occupation category (17).

Data analysis

Descriptive statistics (e.g., mean levels and distributions of PA, and body size and composition) from each study site will be explored to summarise the characteristics of participants in each of the study sites. Univariable correlation structure for continuous variables will be described, as was done in the original METS study (10). Means and standard deviations will be calculated for continuous measures (e.g., age, weight, % body fat, BMI, minutes of PA, activity counts), and proportions for categorical variables (e.g., overweight/obese, female gender, manual labour).

A mixed-effects model will be used in order to explore the relationship between dependent and independent variables. Exploratory analysis will be completed in order to identify outliers, the distribution of the data, as well as significant covariates. Multiple linear and logistic regression will be used to explore continuous and categorical outcomes, adjusting for age, sex, weight, and site (dummy variable). Bland-Altman and Lin Concordance coefficients will be used to explore the bias and agreement between self-reported PA and objectively measured PA. Adiposity will be considered as a categorical variable according to BMI levels. The analysis will be done across the different sites, as well as within each site. Univariable and multivariable analyses will both be conducted.

Description of risks and benefits

The original informed consent form highlights that it is unknown as to whether the participants themselves will benefit from partaking in the research, but that the knowledge gained from the study may be useful to others. For the purposes of this study, the knowledge gained will be useful in helping others understand the relationship between objectively measured PA and self-reported PA, and how adiposity affects this relationship. There are no risks associated with the tests in this study, including measuring body fat percentage, or wearing an activity or sleep monitor. There is however, a small risk of a loss of confidentiality.

Informed consent process

A comprehensive informed consent form was provided to each participant. All participant from all five study sites were required to provide written consent, which they then received a copy of. They were also provided with contact information specific to their in-country site in the event of complaints or queries (10).

Privacy and confidentiality

The coordinating center at Loyola University Chicago oversees all of the data management. All forms and questionnaires containing any data are scanned and, in conjunction with the electronic Accelerometer data files, are transferred via secure FTP (Bitvise Tunnelier) to the manager responsible for data at the coordinating center. Personnel who are trained and experienced carry out the coding of the scanned forms, and double data entry is completed (10, 12, 14). It is confirmed in the informed consent that while the results from the studies may be used and published, participants will not be identified through the use of their names or any other information which may identify them.

Reimbursement for participation

The reimbursement procedures were site specific in the original METS and METS-microbiome studies. There is no need for reimbursement for this study as it is secondary data analysis.

Emergency care and insurance for research-related injuries

Upon signing the informed consent forms, participants are made aware that they are giving up their legal rights to seek to obtain any compensation from the study for any injuries obtained during the study. However, contact information is provided for any instances when participants feel that they have been injured during the research procedures.

What happens at the end of the study?

At the end of the study, participants are given their results and are given the opportunity to ask questions. The results from the study are then published.

Part B – Manuscript

Title: A comparison of self-report versus objectively measured physical activity in African-origin adults and the role of adiposity: a prospective cohort study

Manuscript type: original research

Key words: obesity, epidemiologic transition, exercise

Abstract word count: 235 words

Manuscript word count: 5,283 (excluding tables, figures); 7,143 including tables, figures.

Abstract

Background: There is a limited amount of evidence available regarding the effect of physical activity on NCDs in individuals of African descent.

Methods: Approximately 2,000 men and women of predominantly African descent, between the ages of 35 and 55, were recruited and admitted into the METS-Microbiome study between January 2017 and December 2019. Participants were previously enrolled in a prospective study of weight change (METS) and included 5 countries spanning the epidemiologic transition; rural Ghana; peri-urban South Africa; urban Jamaica; the Seychelles; and suburban Chicago, USA. PA was measured using objective PA monitoring and the self-report Global PA Questionnaire (GPAQ). A basic health history was obtained from the participants, including the health history and socio-demographic information.

Results: No interaction of adiposity nor site on the association between objectively measured and self-reported PA was found. On average, people self-reported 142 minutes more activity than was objectively measured. Overweight/obese people do 31 min/day less PA than healthy weight people adjusting for sex (95% CI: -55.48, -6.69, $p=0.01$). On average, females perform 54 min/day less PA than males (95% CI: -78.57, -29.32, $p<0.05$). When adjusting for site and sex, it is found that Ghanaians do 76 min/day more PA compared to those in the US (95% CI: 42.51, 108.67, $p<0.05$).

Conclusions: With these results, it is not possible to reject the null hypothesis. Further investigations are required to determine what is influencing the association between the two measures.

Introduction

The prevalence of most commonly reported non-communicable diseases (NCDs), including Type II diabetes mellitus (T2DM), heart disease, stroke, and breast and colon cancers have been increasing throughout the world (3). Obesity and arterial hypertension are two common risk factors for NCDs, which likewise have seen significant increases in Sub-Saharan Africa (SSA) (21). Decreasing levels of physical activity (PA) is one factor which has been identified as a leading cause of obesity and hypertension (4). Consequently, the World Health Organization (WHO) recommends daily PA and has issued a global PA action plan (1). However, PA recommendations as a means of addressing the obesity epidemic is controversial, with both arguments for it, as well as against it (18). For example, Cleven et al., (2020) found that it was not effective for treating hypertension (21), while Alpsoy et al., (2020) found PA instrumental in delaying the development of hypertension and reducing blood pressure (24, 25).

Typically, PA is collected using questionnaires such as the Global Physical Activity Questionnaire (GPAQ) (27). While questionnaires may be simple to administer and complete (13), they may lead to errors in determining the total volume and/or intensity of PA (13, 15). Indeed, PA collected using questionnaires have been shown to generally overestimate a person's PA (13, 15). The GPAQ is designed to establish whether a person is sufficiently active in line with the WHO recommendations of >150 min/week, which is the equivalent of 600 METmin/week (28). Alternatively, PA may be collected using objective PA monitors such as accelerometers, but while more accurate, they are expensive and require trained staff and detailed analyses (13, 15). Accelerometers are able to identify accelerations of a body through the motion detectors (13). These results are unbiased, practical, exact, and reliable when compared with self-report methods (13). A downfall of accelerometers is that they are not able to record certain activities, such as bicycling, swimming, and household chores; activities with added weights; or a change in gradient of the workout surface (13). In situations where feasible, using a combined approach, including

self-report and objective measures, to estimate PA may be the most accurate as all methods of measurement have fundamental strengths and limitations. It may be argued that using both methods will result in more robust PA estimation.

PA contributes to energy expenditure and therefore is an important component of energy balance and may prevent weight regain following weight loss. Its role in NCD prevention has been highlighted, given that obesity is a significant NCD risk factor (6). The global prevalence of obesity continues to increase, with the greatest increases being seen in SSA (10, 11). While the public health response to the increasing problems surrounding obesity across the world has largely failed, specialist and government organisations continue to advocate for increasing PA to prevent weight gain (10). However, this is despite little objective evidence regarding the association (regardless of whether it is partial or primarily) between a decrease in PA and the obesity epidemic. Obesity does not have a single cause, but rather its aetiology is complex and multi-faceted (9, 12). Instead, the movement of people from rural to urban areas in developing low- to middle-income countries, and the concomitant lifestyle changes may be a significant contributor to the increase in obesity worldwide (9).

The purpose of this study was to determine whether adiposity moderates the relationship between self-reported PA and objectively measured PA. Further, a sub-aim was to explore whether this association is altered based on location/site. The goal was to associate self-reported PA and objectively measured PA, and the moderating effect of adiposity on this relationship in approximately 2,000 African-origin adults from five countries spanning the epidemiologic transition. We hypothesized that with an increase in adiposity, there is an increase in self-reported PA and the error in self-reported PA compared to objectively measured PA will increase. The study will help to fill a gap in the knowledge surrounding the effect of PA on NCDs in individuals of African-origin through investigating using a population containing only people of African-origin.

Methodology

Study design and settings

The Modeling the Epidemiologic Transition Study (METS) is a prospective and well-established cohort study and parent study to METS-Microbiome study (12). Detailed protocols of each have previously been published. Originally, METS was designed to investigate the relationship between body composition, PA, and relative weight, weight gain and cardiometabolic disease risk in five African-origin populations (Ghana, South Africa, Jamaica, Seychelles, and the US) (12). The Ghanian study site is in Nkwantakese, including the surrounding villages. Khayelitsha, South Africa's sixth largest township is adjacent to the city of Cape Town (10, 26). The Seychelles study population was recruited from the main island, Mahé. Kingston is the capital of Jamaica, and it is the largest city. Maywood, in the US, is an African-American working-class community adjoining the western border of Chicago, Illinois (10). These five sites were purposefully selected to represent the "epidemiologic transition" spectrum, with Ghana and the US as opposite poles of the spectrum (12).

Recruitment and enrollment

METS-Microbiome enrolled approximately two thousand adults (n=2,000) between the ages of 35 and 55 years. A comprehensive protocol for METS-microbiome has been previously published. Briefly, approximately 400 participants from each of the five sites were enrolled between January 2017 and December 2019. Potential participants were excluded from the study if they had any self-reported infectious diseases (including active malaria and Human Immunodeficiency Virus (HIV)), pregnant or lactating women, as well as people with issues which impair everyday physical activities, e.g., severe osteo'- or rheumatoid arthritis, or any lower body disability (10, 12, 14).

The protocol for METS-Microbiome was approved by the Institutional Review Board of Loyola University Chicago, IL, US; the Committee on Human Research Publication and Ethics of Kwame

Nkrumah University of Science and Technology, Kumasi, Ghana; the Research Ethics Committee of the University of Cape Town, South Africa; the Board for Ethics and Clinical Research of the University of Lausanne, Switzerland; the Ethics Committee of the University of the West Indies, Kingston, Jamaica; and the Health Sciences Institutional Review Board of the University of Wisconsin, Madison, WI, US. All participants provided written informed consent (10, 12, 14). The protocol for this study was approved by the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee (HREC ref: 632/2022).

Research procedures and data collection methods

All measurements were completed in the early morning at outpatient research clinics which were located at the study sites (10, 17). Participants arrived at the clinic following an overnight fast.

Anthropometrics and body composition

Measurements involving weight and height were performed once the participants were barefoot and had minimal light clothing on. Weight (in kilograms - kg) was recorded to the nearest 0.1kg, and height (in centimeters - cm) was recorded to the nearest 0.1cm. Waist circumference (in centimeters) was measured to the closest 0.1cm at both the umbilicus, and the point of maximum protrusion of the buttocks for the hip. BMI was calculated as kg/m^2 (14).

Physical activity measurements

Physical activity monitoring

The Actical accelerometer (Phillips Respironics, Bend, OR, US) was used to objectively measure PA. The accelerometer was worn at the level of the waist just behind the right hip. The study participants were requested to always wear the monitors, including while sleeping but excluding while immersed in water (i.e., while bathing, showering or swimming), over an 8-day period (14). This period yielded six full days (i.e., 8 days of wearing the monitor with two partial days on either

end of the period). The original METS study was able to determine, that this amount of wear time provides a good level of reliability at 0.83-0.92% across the five sites (10). The time period for assessing PA conducted daily was between 07:00 and 23:00, and this was done to standardise the measurements as there are no global guidelines surrounding the definition of sleep-time vs. awake-time for accelerometry data which is collected for a 24-hour period (17).

For data analysis, it was important to first determine non-wear time from 90 or more minutes of continuous zero activity counts by running the raw data from the accelerometers through a SAS macro programme (10). This criterion was formed on visual inspection of the wear/non-wear patterns across a range of difference string-length criteria in a subset of files from each country (17). For a days' entry to be valid, the measurement period should be at least 10 hours of wear time, i.e., wearing the accelerometer for ≥62% of available wear time. The inclusion of participants for analysis requires that their files need to have at least four valid days (14). Published cut-points were used to define sedentary, moderate and vigorous activity levels in counts per minute (cpm): sedentary <100 counts per minute (cpm), moderate 1535-3959 cpm and vigorous ≥3960 cpm (14). The same protocol which was used for the National Center for Health Statistics analysis of accelerometry data in the National Health and Nutrition Examination Survey (NHANES) was used to define minutes (10) as composed of different types of activity (i.e., sedentary, moderate, vigorous, or moderate plus vigorous) which may be presented as the overall time in minutes combined in intervals of either 1- or 10-minutes (17). As is used in the NHANES study protocol, METS made allowances for up to 2 minutes of below threshold count activity before acknowledging that an activity bout has ended, and therefore the 10-minute interval should be regarded as a modified 10-minute bout (10, 17). Data are presented as total activity counts divided by total wear time as an overall measure of average PA intensity (17). Average counts and time 1-minute bouts of moderate-to-vigorous activity (MVPA) and sedentary time are also included.

For the PA patterns analysis, weekday is defined as Monday through Friday, and weekend days as Saturday and Sunday (17).

Self-report physical activity

Self-reported PA was assessed using the GPAQ (version 2) (29), which was administered by centrally trained staff, see Appendix B. This included determining the number of days per week the participant reported being active across three domains; travel, occupation, and leisure or recreational, in minutes per day. This was used to determine: moderate and vigorous occupational; vigorous recreational activities; activities for travel purposes (i.e., walking, bicycle riding); sedentary activities (14). PA was probed by asking participants to recall their PA in the different domains if they accumulated more than 10 minutes in a single bout. These findings made it possible to calculate the daily average number of minutes spent performing activities from the different areas of PA as well as determine if participants were classified as sufficiently active, by meeting the WHO recommendation of 150 min/week of moderate intensity PA, which through the use of the GPAQ, is the equivalent of 600 METmin/week (14, 28).

Questionnaires

A basic health history was obtained from the participants, which included socio-demographic information. An occupation questionnaire from the U.K. National Statistics Socio-economic Classification (NS-SEC), 2000 edition was used to determine in more detail individual occupation (17). Occupation and industry were used to code for manual vs. non-manual labour class. Occupations coded as non-manual class included: senior, middle, and junior managers; traditional professional (e.g., dentist, lawyer) and modern professional (e.g., teacher, social worker) occupations; and clerical and intermediate occupations (e.g., secretary, call centre agent). Occupations coded as manual class included technical and craft (e.g., auto mechanic); semi-routine (e.g., postal worker) and routine (e.g., labourer, driver, writer) manual and service;

and farming, agriculture, and fishing occupations. Long-term unemployed (i.e., those not working in the past year) were coded as a separate occupation category (17).

Data analysis

Descriptive statistics were completed to summarise the participant characteristics at each of the study sites, through medians and interquartile ranges for continuous measures and proportions for categorical variables (**Table 1**).

Exploratory analysis was completed to identify outliers, the distribution of the data, as well as significant covariates. Bland-Altman and Lin Concordance coefficients were used to explore the bias and agreement between self-reported PA and objectively measured PA. Linear regression was used to explore the interaction of adiposity on the association between self-reported PA (continuous outcome) and objectively measured PA. Subsets of the data were created according to site, and the linear regression with the interaction of adiposity was fit again for each site, in order to determine whether there were differences in the interaction between the different countries.

Adiposity was considered as a categorical variable according to BMI levels. Univariable and multivariable analyses were conducted.

Results

Participants' characteristics

METS-Microbiome recruited 2,250 participants with demographic and accelerometer data, of which 1,641 participants had GPAQ data. However, after cleaning and merging the data, the final sample size consisted of 1,505 participants (**Figure 1**). Six observations are missing "sex" data and therefore they have been excluded from the analyses which are stratified by sex but were not removed entirely from the dataset as they still contained other valid information.

Figure 1: Flowchart demonstrating the process of obtaining the final sample size included in this study.

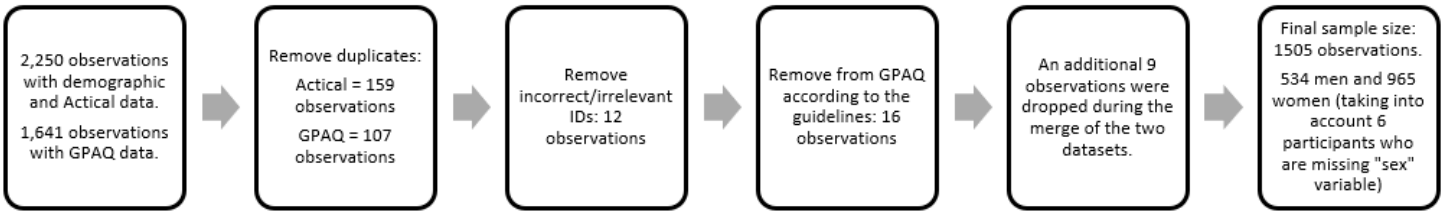


Table 1a shows that the US participants were significantly older (median age 48.0 years (44.0-52.0)), while the South Africans were the youngest (median age 36.0 years, 95% CI:32.0-43.0)). A very small proportion of the Ghanaian men are overweight/obese (6.4%) compared to the US men (44.0%). However, when looking specifically at BMI, the South African men have the lowest BMI (median 21.5 kg/m^2, 19.9-24.8). Interestingly, the Seychelles and the US men have the same BMI of 28.3 kg/m^2, but US has a higher IQR (25.1-34.1 compared to 24.3-31.3 in the Seychelles). South African men have the lowest body fat percentage of 29.0% (27.0-33.0), while the men in the US have the highest (40.0%, 36.0-46.0). Almost all the men across the five sites are employed, and more than 50.0% of all of them report doing manual labour. The proportion of diabetes was high, with the Seychelles having the greatest proportion (23.0%). The US has the

largest proportion of men with hypertension (72.0%). South Africa has the highest proportion of men who smoke (68.0%), while no men in Ghana smoke.

Similar to the men, **Table 1b** shows that the South African women were also the youngest (median age of 37.0 years), while Jamaica and the US women were significantly older (median age of 46.0 years). The adiposity levels are far higher in the women compared to the men. 73.0% of women in the US group classify as overweight/obese (median BMI 35.0kg/m^2, 95% CI: 30-41; median body fat percentage 48%, 95% CI: 41.0-55.0). The Ghanian women have the lowest adiposity with only 35.0% of them being overweight/obese (median BMI 28.0kg/m^2, 95% CI: 24.0-31.0; median body fat percentage 38%, 95% CI: 33.0,42.0). A large proportion of the women are employed, but no more than 55.0% of them participate in manual labour in any given country. South Africa has the fewest diabetic women (2.7%), while the US has the most (19.0%). The US also has the most women who are hypertensive (65.0%), while Ghana has the fewest (28.0%). Unlike the men, the US has the highest proportion of smokers amongst the women (20.0%). As with the Ghanaian men, no Ghanaian women smoke.

Table 1: Participants' characteristics by site for men (*N*= 534) and women (*N*= 965).					
a.	**Men (*N* = 534)**				
	Ghana (*N* = 110)	**Jamaica (*N* = 141)**	**RSA (*N* = 50)**	**Seychelles (*N* = 122)**	**USA (*N* = 111)**
Age (years)	45 (39-50)	46 (39-50)	36 (32-43)	45 (41-48)	48 (44-52)
Weight (kg)	65.0 (59.0-73.0)	74.0 (64.0-85.0)	63.0 (56.0, 72.0)	84.0 (73.0-97.0)	86.0 (76.0-102.0)
Unknown	0	3	0	5	1
Obese					
0 (healthy weight)	103 (94.0%)	120 (85.0%)	46 (92.0%)	81 (66.0%)	62 (56.0%)
1 (overweight/obese)	7 (6.4%)	21 (15.0%)	4 (8.0%)	41 (34.0%)	49 (44.0%)
BMI (kg/m^2)	23.0 (20.8-25.4)	24.6 (20.8-27.9)	21.5 (19.9-24.8)	28.3 (24.3-31.3)	28.3 (25.1-34.1)
Unknown	0	2	0	5	1
Waist circumference (average) (cm)	83.0 (78.0-91.0)	86.0 (75.0-95.0)	81.0 (75.0-87.0)	94.0 (88.0-100.0)	97.0 (84.0-112.0)
Unknown	0	2	0	5	2
Fat free mass (kg)	52.0 (48.0-55.0)	56.0 (50.0-61.0)	47.0 (42.0, 51.0)	60.0 (52.0-64.0)	53.0 (46.0-58.0)
Unknown	0	5	0	8	13
Body fat %	32.0 (30.0-36.0)	35.0 (30.0-39.0)	29.0 (27.0-33.0)	39.0 (34.0-42.0)	40.0 (36.0-46.0)
Unknown	0	2	0	5	1
Employment					
0 (not employed)	3 (2.7%)	10 (7.1%)	10 (20.0%)	5 (4.1%)	6 (5.4%)
1 (employed)	107 (97.0%)	131 (93.0%)	40 (80.0%)	117 (96.0%)	105 (95.0%)
Manual labour					
0 (no manual labour)	23 (21.0%)	39 (31.0%)	15 (31.0%)	49 (45.0%)	37 (36.0%)
1 (manual labour)	84 (79.0%)	85 (69.0%)	34 (69.0%)	60 (55.0%)	67 (64.0%)
Unknown	3	17	1	13	7
Glucose result (mmol/dL)	98.0 (92.0-105.0)	96.0 (88.0-103.0)	94.0 (85.0-100.0)	114.0 (104.0-122.0)	96.0 (89.0-108.0)
Unknown	3	1	0	3	1
Diabetic					
0 (not diabetic)	101 (94.0%)	133 (94.0%)	48 (96.0%)	92 (77.0%)	89 (81.0%)
1 (diabetic)	7 (6.5%)	8 (5.7%)	2 (4.0%)	27 (23.0%)	21 (19.0%)
Unknown	2	0	0	3	1
Systolic BP (mmHg)	120.0 (111.0-128.0)	127.0 (118.0-139.0)	127.0 (114.0-134.0)	126.0 (118.0-138.0)	130.0 (118.0-141.0)
Unknown	0	2	0	6	2
Diastolic BP (mmHg)	66.0 (59.0-72.0)	76.0 (69.0-84.0)	78.0 (68.0-84.0)	80.0 (73.0-88.0)	83.0 (72.0-89.0)
Unknown	0	2	0	6	2
Hypertensive					
0 (not hypertensive)	78 (72.0%)	71 (50.0%)	26 (52.0%)	44 (37.0%)	31 (28.0%)
1 (hypertensive)	31 (28.0%)	70 (50.0%)	24 (48.0%)	76 (63.0%)	80 (72.0%)
Unknown	1	0	0	2	0
Sleep (hours)	8.0 (6.0-8.0)	7.0 (5.0-8.0)	8.8 (7.8, 9.5)	NA (NA,NA)	6.0 (5.0-7.0)
Unknown	19	21	50	122	15
Smoker					
0 (not a smoker)	108 (100%)	120 (85.0%)	16 (32.0%)	84 (71.0%)	65 (59.0%)
1 (smoker)	0 (0.0%)	21 (15.0%)	34 (68.0%)	34 (29.0%)	45 (41.0%)
Unknown	2	0	0	4	1

b.	**Women (*N* = 965)**				
	Ghana (*N* = 208)	**Jamaica (*N* = 290)**	**RSA (*N* = 75)**	**Seychelles (*N* = 166)**	**USA (*N* = 226)**
Age (years)	41 (35-48)	46 (39-52)	37 (29-43)	45 (40-49)	46 (41-51)
Unknown	0	1	0	0	1
Weight (kg)	69.0 (61.0-78.0)	85.0 (72.0-96.0)	82.0 (68.0, 99.0)	77.0 (66.0-92.0)	95.0 (80.0-110.0)
Unknown	3	5	0	0	1
Obese					
0 (healthy weight)	135 (65.0%)	114 (39.0%)	26 (35.0%)	90 (54.0%)	60 (27.0%)
1 (overweight/obese)	73 (35.0%)	176 (61.0%)	49 (65.0%)	76 (46.0%)	166 (73.0%)
BMI (kg/m^2)	28.0 (24.0-31.0)	32.0 (27.0-35.0)	32.0 (27.0-38.0)	29.0 (25.0-34.0)	35.0 (30.0-41.0)
Unknown	3	5	0	0	1
Waist circumference (average) (cm)	94.0 (86.0-102.0)	99.0 (89.0-107.0)	96.0 (90.0-111.0)	94.0 (85.0-102.0)	104.0 (86.0-117.0)
Unknown	2	4	1	0	3
Fat free mass (kg)	44.0 (40.0-49.0)	49.0 (44.0-54.0)	45.0 (41.0, 52.0)	46.0 (42.0-51.0)	46.0 (41.0-53.0)
Unknown	4	9	1	4	28
Body fat %	38.0 (33.0-42.0)	43.0 (38.0-48.0)	42.0 (37.0-48.0)	40.0 (35.0-46.0)	48.0 (41.0-55.0)
Unknown	3	6	0	0	2
Employment					
0 (not employed)	9 (4.3%)	57 (20.0%)	30 (40.0%)	6 (3.6%)	23 (10.0%)
1 (employed)	199 (96.0%)	233 (80.0%)	45 (60.0%)	160 (96.0%)	203 (90.0%)
Manual labour					
0 (no manual labour)	104 (52.0%)	112 (47.0%)	32 (48.0%)	111 (74.0%)	144 (68.0%)
1 (manual labour)	95 (48.0%)	124 (53.0%)	35 (52.0%)	39 (26.0%)	68 (32.0%)
Unknown	9	54	8	16	14
Glucose result (mmol/dL)	101.0 (94.0-109.0)	98.0 (91.0-108.0)	86.0 (80.0-92.0)	105.0 (98.0-116.0)	96.0 (89.0-104.0)
Unknown	5	10	0	2	1
Diabetic					
0 (not diabetic)	188 (90.0%)	242 (84.0%)	73 (97.0%)	138 (83.0%)	182 (81.0%)
1 (diabetic)	20 (9.6%)	47 (16.0%)	2 (2.7%)	28 (17.0%)	44 (19.0%)
Unknown	0	1	0	0	0
Systolic BP (mmHg)	113.0 (104.0-124.0)	124.0 (111.0-137.0)	116.0 (106.0-128.0)	120.0 (111.0-133.0)	121.0 (112.0-134.0)
Unknown	4	11	0	1	2
Diastolic BP (mmHg)	69.0 (62.0-77.0)	79.0 (70.0-86.0)	75.0 (69.0-81.0)	78.0 (71.0-86.0)	80.0 (74.0-87.0)
Unknown	4	11	0	1	2
Hypertensive					
0 (not hypertensive)	150 (72.0%)	126 (44.0%)	46 (61.0%)	78 (47.0%)	78 (35.0%)
1 (hypertensive)	58 (28.0%)	163 (56.0%)	29 (39.0%)	88 (53.0%)	147 (65.0%)
Unknown	0	1	0	0	1
Sleep (hours)	7.0 (6.0-8.0)	7.0 (6.0-8.0)	9.0 (8.0, 9.91)	NA (NA,NA)	6.0 (5.0-8.0)
Unknown	67	41	0	166	42
Smoker					
0 (not a smoker)	208 (100%)	272 (94.0%)	63 (86.0%)	159 (96.0%)	180 (80.0%)
1 (smoker)	0 (0.0%)	16 (5.6%)	10 (14.0%)	7 (4.2%)	45 (20.0%)
median (IQR); n(%)					

Objectively measured PA

As seen in **Table 2a**, Ghanaian men had the highest objectively measured PA levels (median of 38 min/day measured in 1-min bouts). Of this, 66% of them met the WHO guidelines of performing ≥150 minutes of moderate-vigorous PA per week. Men in the US had the lowest objectively measured PA levels (median of 17 min/day measured in 1-min bouts). Only 28% of them met the WHO guidelines.

Table 2c indicates that South African women had the highest objectively measured PA (median of 24 min/day measured in 1-min bouts), but only 26% met the WHO PA guidelines. US women had the lowest objectively measured PA (median of 8 min/day measured in 1-min bouts). Only 6.4% of the US women met the WHO PA guidelines.

Self-reported PA

Among the men, the median self-reported PA was 120 min/day of which the Ghanaian men self-reported the most at 268 min/day (**Table 2b**). This information is used to assess whether participants are sufficiently active. The GPAQ results are used to calculate METmin/week of PA, and the WHO recommends that sufficient PA requires ≥600 METmin/week, the equivalent of 150 min/week (28). Among the men, 95.1% self-reported achieving ≥600 METmin/week. Specifically, the Ghanaians reported the most amount of PA, the majority of which was in the domain of vigorous work (11,520.0 METmin/week), and they did not report any time spent engaging in recreational activity, whether vigorous or moderate. The South African men had the lowest self-reported PA, with a median of 62 min/day, but 85.4% self-reported meeting the PA guidelines of performing ≥600 METmin/week. The largest contributor to this came from moderate work, with a median of 720.0 METmin/week spent in this domain.

Among the women, the median self-reported PA was 51.4 min/day (**Table 2d**). The Ghanaian women, like the men, also self-reported the most PA with a median of 163 min/day. Of them,

88.0% were classified as being sufficiently active by the GPAQ guidelines of performing ≥600 METmin/week. The Jamaican women self-reported the least amount of PA, with a median of 23 min/day, of which only 53.2% were classified as being sufficiently active. The largest contributor of PA for Ghanaians and Jamaicans was from transport, with a median of 1,920.0 METmin/week for the Ghanaians and 310.0 METmin/week for the Jamaicans.

Surprisingly among the men, the greatest discrepancy between self-reported and objectively measured PA was among the Ghanaians, who reportedly overestimated their PA by close to 4 hours (overestimated through self-reporting by 230 min/day). US men had the second largest discrepancy between the two measures (overestimated through self-reporting by 111 min/day of PA). Notably, the South African men had the smallest discrepancy (16 min/day) between their objectively measured and self-reported PA.

Similarly, among the women, the Ghanaians also over-reported their PA by 148 min/day. Jamaican women had the smallest discrepancy between the two measures (overestimated through self-reporting by only 7 min/day). These discrepancies can be seen in **Supplementary Figures 2, 3 (Appendix A)**.

Table 2: Participants' Accelerometer and GPAQ summary findings by site for men (*N*= 534) and women (*N*= 965).					
	Men (*N* = 534)				
	Ghana (*N* = 110)	**Jamaica (*N* = 141)**	**RSA (*N* = 50)**	**Seychelles (*N* = 122)**	**USA (*N* = 111)**
a. Objectively measured PA					
Accelerometer (min/day 10-min bout)	18.0 (7.0-32.0)	4.0 (1.0-20.0)	19.0 (9.0-36.0)	6.0 (0.0-17.0)	3.0 (0.0-15.0)
Unknown	25	76	12	3	14
Accelerometer (min/day 1-min bout)	27.8 (12.6, 48.5)				
By site	38.0 (23.0-67.0)	24.0 (11.0-50.0)	46.0 (28.0-72.0)	23.0 (9.0-39.0)	17.0 (8.0-32.0)
Unknown	25	76	12	3	14
Meets WHO guideline of >=150min MVPA per week	56 (66.0%)	27 (42.0%)	26 (68.0%)	47 (39.0%)	27 (28.0%)
Unknown	25	76	12	3	14
b. Self-reported PA					
Total self-reported PA in male participants (min/day)	120 (34.29,345.0)				
By site	268.0 (86.0-450.0)	66.0 (22.0-302.0)	62.0 (32.0-179.0)	136.0 (36.0-317.0)	128.0 (42.0-326)
Unknown	8	3	2	9	7
Meets GPAQ criteria >600 METmin/week	96 (95.05%)	108 (78.26%)	41 (85.42%)	104 (92.03%)	91 (57.5%)
Does not meet GPAQ criteria >600 METmin/week	5 (4.95%)	30 (21.74%)	7 (3.33%)	9 (7.96%)	13 (12.5%)
Total self-reported PA in each domain (METmin/week)					
Vigorous work	11,520.0 (17,280.0, 1,440.0)	0.0 (0.0, 3,600.0)	400.0 (0.0, 5,400.0)	6,960.0 (2,160.0, 19,200.0)	480.0 (0.0, 4,200.0)
Moderate work	2,160.0 (0.0, 5,880.0)	0.0 (0.0, 1,320.0)	720.0 (190.0, 2,400.0)	4,800.0 (1,440.0, 7,680.0)	700.0 (0.0, 3,600.0)
Transport	2,880.0 (1,200.0, 5,040.0)	600.0 (160.0, 1,680.0)	480.0 (360.0, 1,120.0)	600.0 (300.0, 800.0)	960.0 (360.0, 3,360.0)
Vigorous recreational	0.0 (0.0, 420.0)	0.0 (0.0, 440.0)	0.0 (0.0, 720.0)	1,200.0 (180.0, 1,980.0)	360.0 (0.0, 1,920.0)
Moderate recreational	0.0 (0.0, 0.0)	0.0 (0.0, 80.0)	0.0 (0.0, 0.0)	480.0 (370.0, 960.0)	240.0 (0.0, 900.0)

	Women (*N* = 965)				
	Ghana (*N* = 208)	**Jamaica (*N* = 290)**	**RSA (*N* = 75)**	**Seychelles (*N* = 166)**	**USA (*N* = 226)**
c. Objectively measured PA					
Accelerometer (min/day 10-min bout)	4.0 (0.0-9.0)	4.0 (2.0-10.0)	7.0 (4.0-15.0)	5.0 (0.0-11.0)	0.0 (0.0-5.0)
Unknown	57	227	22	6	54
Accelerometer (min/day 1-min bout)	13.67 (5.87, 24.33)				
By site	15.0 (8.0-25.0)	16.0 (10.0-25.0)	24.0 (14.0-30.0)	16.0 (8.0-27.0)	8.0 (3.0-15.0)
Unknown	57	227	22	6	54
Meets WHO guideline of >=150min MVPA per week	32 (21.0%)	13 (21.0%)	14 (26.0%)	34 (21.0%)	11 (6.4%)
Unknown	57	227	22	6	54
d. Self-reported PA					
Total self-reported PA in female participants (min/day)	51.43 (14.82, 171.43)				
By site	163.0 (58.0-319.0)	23.0 (4.0-69.0)	34.0 (13.0-63.0)	66.0 (31.0-214.0)	39.0 (14.0-148)
Unknown	16	27	10	9	23
Meets GPAQ criteria >600 METmin/week	169 (88.03%)	140 (53.23%)	38 (58.46%)	130 (82.81%)	137 (67.49%)
Does not meet GPAQ criteria >600 METmin/week	23 (11.98%)	123 (46.77%)	27 (41.54%)	27 (17.2%)	66 (32.51%)
Total self-reported PA in each domain (METmin/week)					
Vigorous work	720.0 (0.0, 5,760.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	480.0 (0.0, 2,400.0)	0.0 (0.0, 0.0)
Moderate work	1,560.0 (160.0, 4,440.0)	0.0 (0.0, 240.0)	720.0 (240.0, 1,680.0)	3,600.0 (1,200.0, 6,000.0)	240.0 (0.0, 2,400.0)
Transport	1,920.0 (720.0, 3,840.0)	310.0 (0.0, 840.0)	360.0 (240.0, 720.0)	600.0 (300.0, 900.0)	340.0 (0.0, 975.0)
Vigorous recreational	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 960.0)	0.0 (0.0, 1,080.0)
Moderate recreational	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	480.0 (360.0, 960.0)	80.0 (0.0, 480.0)

The relationship between objectively measured PA, self-reported PA and adiposity

Overweight/obese people do 31 min/day less PA than healthy weight people adjusting for sex (95% CI: -55.48, -6.69, p=0.01). In this same model, females perform 54 min/day less PA than males (95% CI: -78.57, -29.32, p<0.05). When adjusting for site and sex (**Table 3c**), it is found that Ghanaians do 76 min/day more PA compared to those in the US (95% CI: 42.51, 108.67, p<0.05). Similarly in this model, females perform 64 min/day less PA than males (95% CI: -88.44, -39.84, p<0.05). When investigating the role of adiposity on the association between the two measures within each country, no interaction was found in any of the five sites adjusting for sex (**Supplementary Table 1 a-e, Appendix A**).

Upon initial exploration of the data, **Figures 2 and 3** indicate that there is no interaction between adiposity or site on the discrepancy between objectively measured and self-reported PA. Pearson's correlation was used to measure the agreement between the two methods. Overall, there is a very weak but significant correlation between PA estimated using the GPAQ and objectively measured PA using the accelerometer (0.223, 95% CI 0.16, 0.28; p-value<0.05). When calculating the mean PA difference across all five sites using the Bland Altman method, it was found that, participants self-reported 142 minutes more activity than was objectively measured. **Figure 4** confirms that there is no agreement between the two measures, and that there is no adiposity trend, as seen in the general scattering of the different colour points in the plot. This is confirmed in **Figure 5**, using Lin's Concordance Correlation Coefficient.

When fitting the interaction model, there is no evidence of interaction with adiposity but instead there is a weak additive effect of adiposity in both men and women (**Table 3b**) and site (**Table 3c**). When refitting the model without the interaction of adiposity (**Table 3b**), it is found that a 1 min/day increase in objectively measured PA results in a 1 min/day increase in self-reported PA adjusting for sex (95% CI: 0.58, 1.31, p<0.05).

Finally, we explored the proportion of participants meeting the GPAQ classification of sufficiently active (≥600 METmin/week) in accordance with the WHO guidelines (1, 6), by adiposity; overweight/obese or healthy weight (**Table 4**). Among men, substantially more normal weight met the GPAQ PA guidelines, compared to those men classified as overweight/obese. However, this relationship was only seen among the Ghanaian women, whereby the normal weight Ghanaians were the greatest proportion meeting the PA guidelines. Among the overweight/obese Jamaican women, it was equally split between meeting and not meeting the PA guideline. Similarly, in the Seychelles, most women met the PA guideline, but this was not distinguished by adiposity status (40.13% are overweight/obese while 42.68% are healthy weight). Finally, among the South African and US women, the largest proportions of participants meeting the GPAQ guidelines were classified as overweight/obese, however, it must be noted that 65.0% of South African and 73.0% of US females were classified as overweight/obese. When exploring if there existed a protective effect of PA for overweight/obesity, it was found among all sites except for Jamaica and US, the risk ratios were all less than 1.0, confirming that those meeting the GPAQ PA guidelines were less likely to be overweight/obese. The opposite is found for the Jamaican and US women, as the risk ratios indicate that meeting the GPAQ guidelines is more likely in the participants who are overweight/obese. However, while all 95% CI's are relatively narrow, they all cross the null and therefore the null hypothesis cannot be rejected.

Table 3: Coefficient estimates from the linear regression models for the association between objectively measured PA and self-reported PA with additive effects

Model	Variable	Estimate	95% CI	p-value
A. SRPA~OMPA	Intercept	134.55	(119.73, 149.36)	<0.05
	Objectively measured PA (min/day)	1.27	(0.91, 1.62)	<0.05
B. SRPA~OMPA + obese	Intercept	156.51	(137.62, 175.40)	<0.05
	Objectively measured PA (min/day)	1.12	(0.76, 1.48)	<0.05
	Overweight/obese	-44.26	(-68.13, -20.39)	<0.05
C. SRPA~OMPA + obese + site	Intercept	143.47	(115.79, 171.15)	<0.05
	Objectively measured PA (min/day)	1.14	(0.78, 1.50)	<0.05
	Overweight/obese	-31.94	(-56.22, -7.66)	0.01
	Ghana (GH)	66.36	(33.06, 99.66)	<0.05
	Jamaica (JA)	-20.7	(-59.01, 17.61)	0.29
	South Africa (RSA)	-57.07	(-101.24, -12.90)	0.01
	Seychelles (SEY)	-1.41	(-32.37, 29.54)	0.93

Figure 2: Scatter plot of the association between objectively measured PA and self-reported PA by level of adispoity

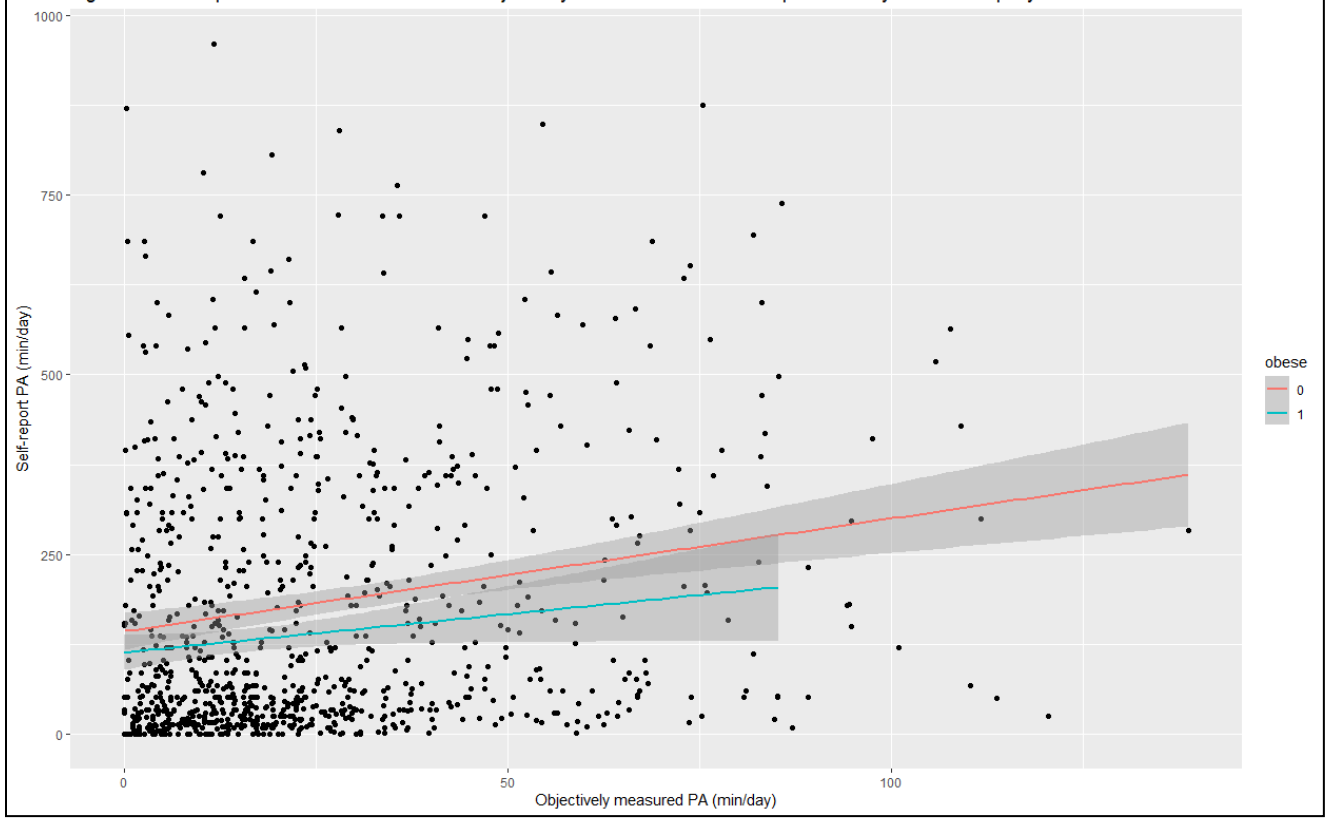
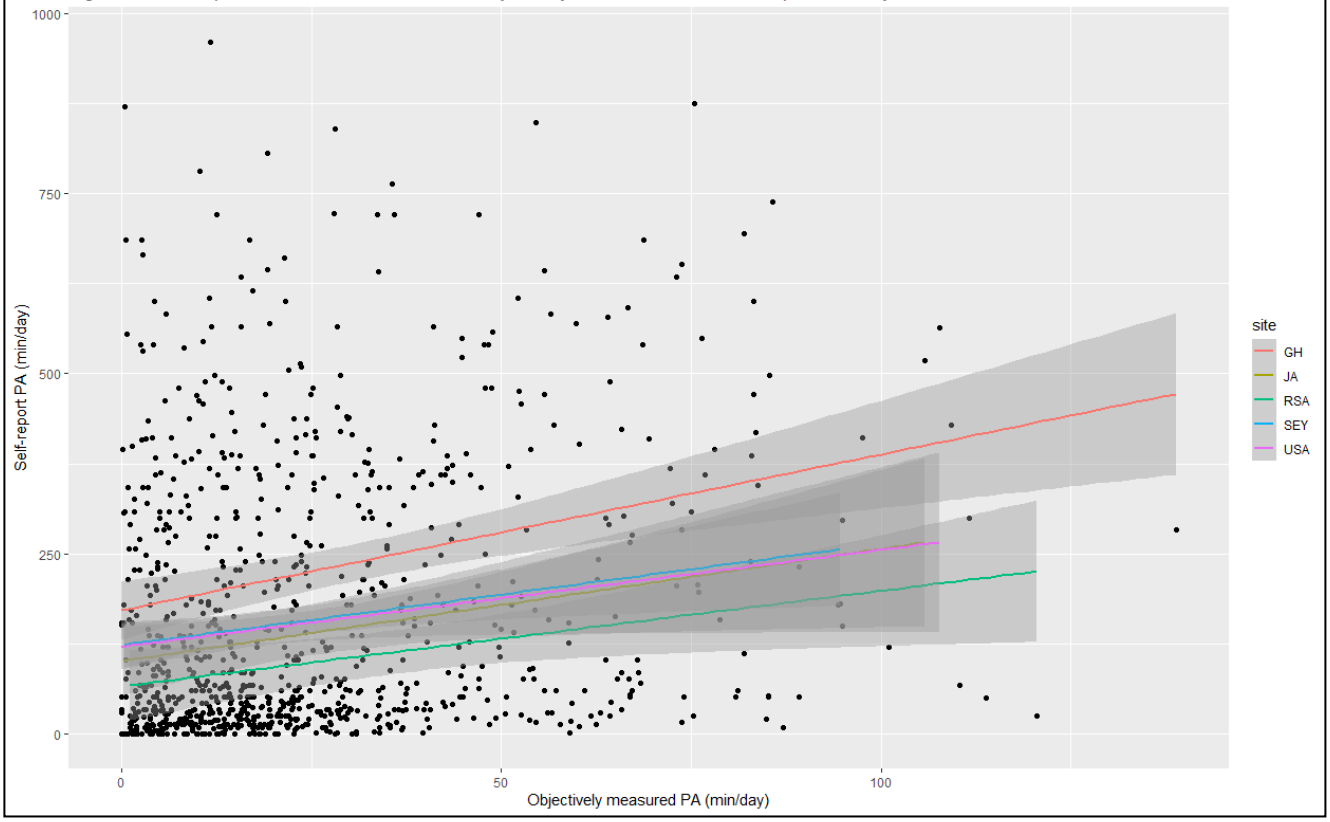


Figure 3: Scatter plot of the association between objectively measured PA and self-reported PA by site



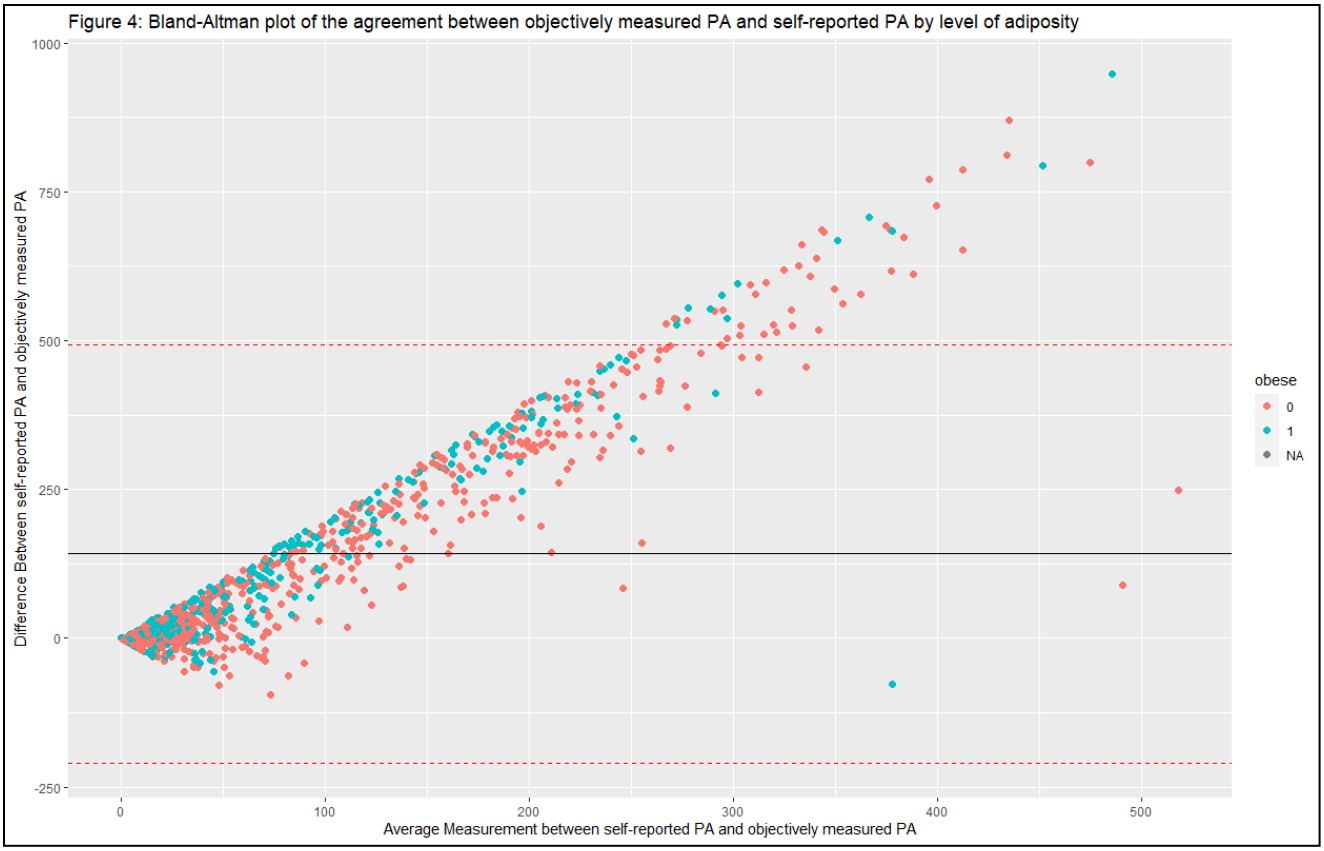


Figure 4: Bland-Altman plot of the agreement between objectively measured PA and self-reported PA by level of adiposity
Difference Between self-reported PA and objectively measured PA
Average Measurement between self-reported PA and objectively measured PA
obese
0
1
NA
1000
750
500
250
0
-250
0
100
200
300
400
500

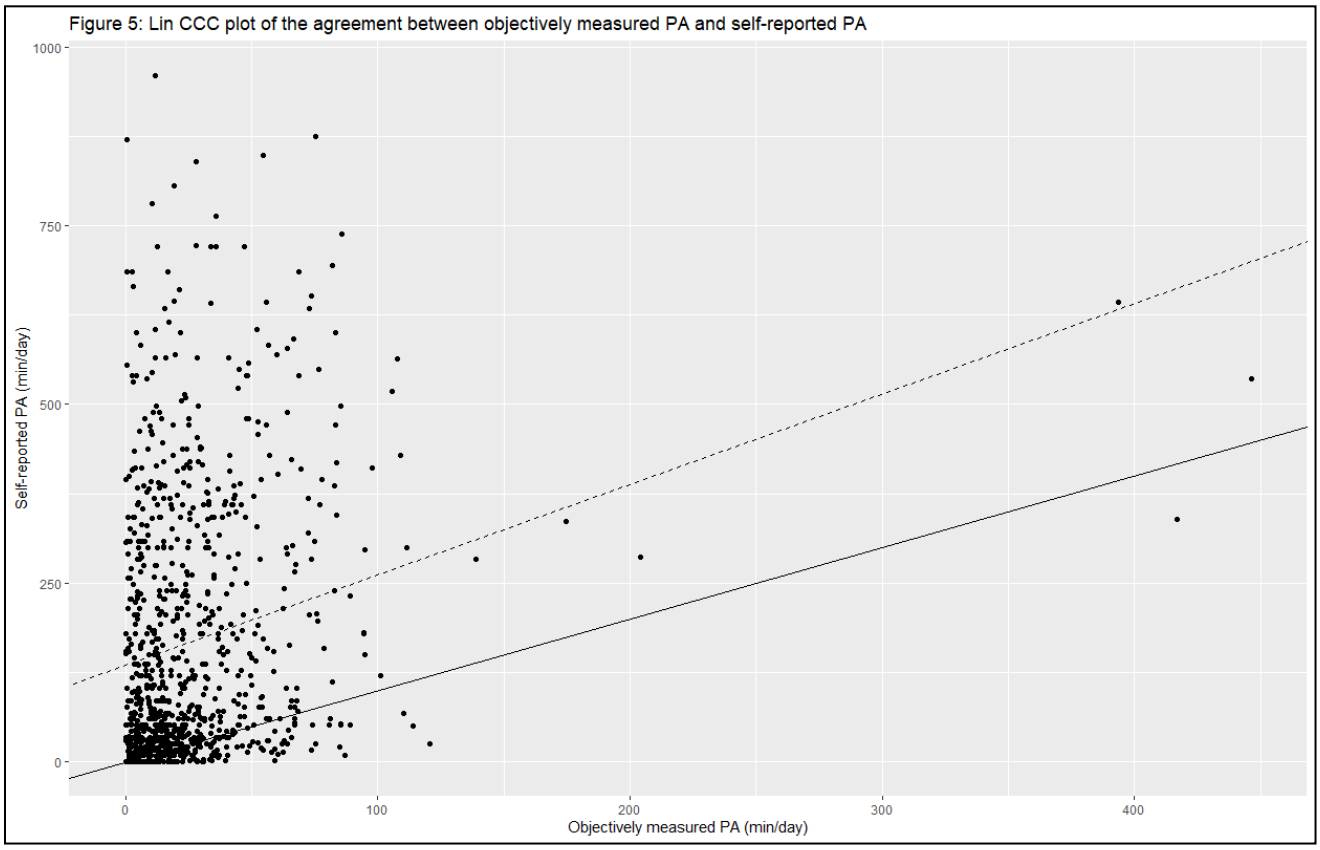


Figure 5: Lin CCC plot of the agreement between objectively measured PA and self-reported PA
Self-reported PA (min/day)
Objectively measured PA (min/day)
1000
750
500
250
0
0
100
200
300
400

.

Table 4: Proportions of participants by adiposity and whether they perform sufficient amounts of PA according to GPAQ classifications										
Men										
	Ghana		**Jamaica**		**South Africa**		**Seychelles**		**USA**	
	Meets GPAQ criteria >600 METmin/week	Does not meet GPAQ criteria >600 METmin/week	Meets GPAQ criteria >600 METmin/week	Does not meet GPAQ criteria >600 METmin/week	Meets GPAQ criteria >600 METmin/week	Does not meet GPAQ criteria >600 METmin/week	Meets GPAQ criteria >600 METmin/week	Does not meet GPAQ criteria >600 METmin/week	Meets GPAQ criteria >600 METmin/week	Does not meet GPAQ criteria >600 METmin/week
Overweight/obese	4 (3.96%)	3 (2.97%)	16 (11.59%)	5 (3.62%)	2 (4.17%)	1 (2.08%)	35 (30.97%)	4 (3.54%)	37 (35.58%)	7 (6.73%)
Healthy weight	92 (91.09%)	2 (1.98%)	92 (66.67%)	25 (18.12%)	39 (81.25%)	6 (1.25%)	69 (61.06%)	5 (4.42%)	54 (51.92%)	6 (5.77%)
Risk ratio	0.58		0.97		0.77		0.96		0.93	
95% CI	-1.18, 0.10		-0.29, 0.23		-1.07, 0.55		-0.16, 0.08		-0.22, 0.08	
Women										
	Ghana		**Jamaica**		**South Africa**		**Seychelles**		**USA**	
	Meets GPAQ criteria >600 METmin/week	Does not meet GPAQ criteria >600 METmin/week	Meets GPAQ criteria >600 METmin/week	Does not meet GPAQ criteria >600 METmin/week	Meets GPAQ criteria >600 METmin/week	Does not meet GPAQ criteria >600 METmin/week	Meets GPAQ criteria >600 METmin/week	Does not meet GPAQ criteria >600 METmin/week	Meets GPAQ criteria >600 METmin/week	Does not meet GPAQ criteria >600 METmin/week
Overweight/obese	54 (28.13%)	11 (5.73%)	81 (30.80%)	78 (29.66%)	26 (40.0%)	19 (29.23%)	63 (40.13%)	11 (7.01%)	102 (50.25%)	43 (21.18%)
Healthy weight	115 (59.90%)	12 (6.25%)	59 (22.43%)	45 (17.11%)	12 (18.46%)	8 (12.31%)	67 (42.68%)	16 (10.19%)	35 (17.24%)	23 (11.33%)
Risk ratio	0.92		0.90		0.96		1.05		1.17	
95% CI	-0.21, 0.04		-0.33, 0.12		-0.47, 0.40		-0.09, 0.20		-0.08, 0.39	

Discussion

Our study explored the relationship between objectively measured PA and self-reported PA and whether adiposity or site moderated the discrepancy between two PA measures in 5 African-origin populations. Overall, we found that the greatest discrepancy between the two measures of PA was surprisingly among the Ghanaians, who accumulated among the highest objectively measured PA. Secondly, we were unable to account for an adiposity interaction. Finally, we found that among all participants, except the females from Seychelles and US, indicate that meeting the GPAQ guidelines of performing sufficient amounts of PA is less likely in those participants who are overweight/obese.

We were surprised that the greatest discrepancy for reporting PA was not in fact among the US population, with the highest levels of adiposity, but rather among the Ghanaians, which is contrary to our hypothesis. It had been anticipated that the US participants would overestimate their self-reported PA the most compared to what was measured by the accelerometer because it has previously been shown that overweight/obese people may overestimate their PA by a greater margin compared to normal weight people, because of the social desirability and stigma associated with being overweight and obese. Indeed, we have previously shown in our data that US participants, previously overestimated their PA by the greatest margins compared to the other four countries. The Ghanaians are the leanest of the five of the included countries, 94.0% of Ghanaian men and 65.0% of Ghanaian women are a healthy weight (**Table 1a**), and Ghana's HDI ranking is the lowest (12, 18). Further research is warranted to understand why the Ghanaians overestimated PA by as much as they did.

The second finding, pertaining to the primary purpose of this study, is that there is no interaction between adiposity and the discrepancy between self-reported PA and objectively measured PA. These findings are statistically significant and therefore we cannot confidently reject our null hypothesis (**Table 5b**). Although no evidence of interaction was found, we did identify a small

additive adiposity effect, such that overweight/obese people do 31 min/day less PA than healthy weight people after adjusting for sex (-55.48, -6.69, p=0.01). Be that as it may, we were therefore unable to conclude that adiposity in indeed moderating the association between the two measures of PA. In addition to these findings, results pertaining to a sub-aim of this study indicate that there is no interaction of site on the association between self-reported PA and objectively measured PA (**Table 5c**). These findings are significant and therefore we cannot conclude that country of residence is moderating the association between the two measures PA.

The third finding is that all participants, except the females from the Seychelles and US, indicated that they met the GPAQ guidelines of performing sufficient amounts of PA, especially if those participants were not overweight/obese.

The utility of the GPAQ is that it allows for the exploration of self-reported PA in different domains. Among the men (**Table 2b**), the Ghanaians and the Seychellois self-reported that vigorous work contributed the greatest amount of PA to their overall PA, with the Ghanaians performing a median of 11,520.0 METmin/week and the Seychellois performing a median of 6,960.0 METmin/week. The Jamaicans and US self-reported that transport PA contributed the most, with the Jamaicans walking/bicycling for a median of 600.0 METmin/week and the US a median of 960.0 METmin/week. The South Africans self-reported that moderate work is the greatest contributor, with a median of 720.0 METmin/week spent in this domain. Notably, no significant amount of time was self-reported in the recreational domains for the Ghanaians, Jamaicans or South Africans. However, the smallest contributor for the Seychellois (median of 480.0 METmin/week) and US (median of 240.0 METmin/week) is moderate recreational PA. Among the women (**Table 2d**), the Ghanaians, Jamaicans and US self-reported that transport PA was the greatest contributor to their overall self-reported PA. The Ghanaians self-reported walking/bicycling a median of 1,920.0 METmin/week, while the Jamaicans self-reported a median of 310.0 METmin/week and the US a median of 340.0 METmin/week. The South Africans and Seychellois are similar as they both self-

reported moderate work as being the greatest contributor, with South Africans self-reporting a median of 720.0 METmin/week and the Seychellois a median of 3,600.0 METmin/week. Neither the Jamaicans, the South Africans, nor the US self-reported any time spent performing vigorous work. Notably, none of the sites self-reported any significant amount of time performing vigorous recreational PA, but the Seychellois (median of 480.0 METmin/week) and the US (median of 80.0 METmin/week) self-reported time spent performing moderate recreational PA.

Finally, we detected a weak, yet statistically significant correlation between self-reported PA and objectively measured PA ($p=0.223$, 95% CI 0.16, 0.28; p-value<0.05). This confirms previous studies (30). To account for the lack of correlation and agreement between the two measures of PA, a mixed methods approach is the most appropriate choice to use when feasible and possible. This approach will make it more likely that the differences in the measures are accounted for (13, 15).

Table 5: Coefficient estimates from the linear regression models for the association between objectively measured PA and self-reported PA with interactions

Model	Variable	Estimate	95% CI	p-value
A. SRPA~OMPA	Intercept	134.55	(119.73, 149.36)	<0.05
	Objectively measured PA (min/day)	1.27	(0.91, 1.62)	<0.05
B. SRPA~OMPA*obese	Intercept	151.82	(131.70, 171.94)	<0.05
	Objectively measured PA (min/day)	1.26	0.84, 1.68)	<0.05
	Overweight/obese	-32.38	(-62.04, -2.72)	0.03
	Objectively measured PA:obese interaction	-0.55	(-1.38, 0.27)	0.19
C. SRPA~OMPA*site	Intercept	124.07	(95.55, 152.59)	<0.05
	Objectively measured PA (min/day)	1.15	(0.10, 2.21)	0.03
	Ghana (GH)	47.63	(1.57, 93.70)	0.04
	Jamaica (JA)	-22.61	(-78.31, 33.09)	0.43
	South Africa (RSA)	-57.81	(-126.49, 10.88)	0.1
	Seychelles (SEY)	9.15	(-28.62, 46.93)	0.63
	Objectively measured PA:Ghana interaction	1.01	(-0.38, 2.40)	0.16
	Objectively measured PA:Jamaica interaction	0.4	(-1.36, 2.16)	0.65
	Objectively measured PA:South Africa interaction	0.17	(-1.57, 1.91)	0.85
	Objectively measured PA:Seychelles interaction	-0.18	(-1.33, 0.96)	0.75

Conclusion

Taken together, we can conclude that neither adiposity nor site moderates the association between self-reported PA and objectively measured PA. Instead, we identified that other factors including sex, may moderate the relationship between self-reported and objectively measured PA. The greatest contributor to self-reported PA, across all the sites for both men and women came from work (vigorous or moderate) and transport, but not recreational PA, as is expected in high income settings. Finally, we were unable to reject the null hypothesis. Further investigations are therefore warranted to explore the association between the two measures of PA, particularly in the context of adiposity, and for future public health PA recommendations.

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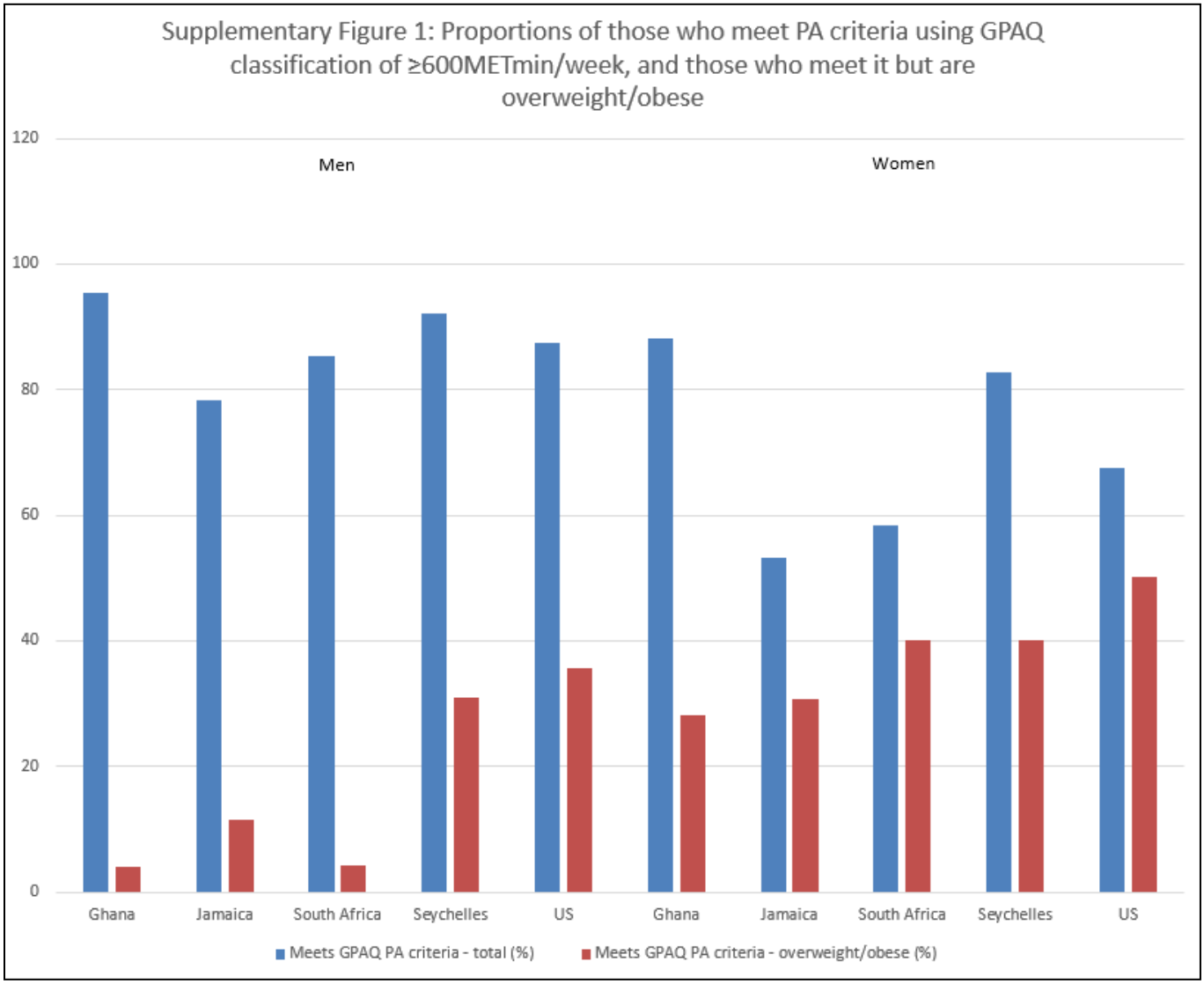
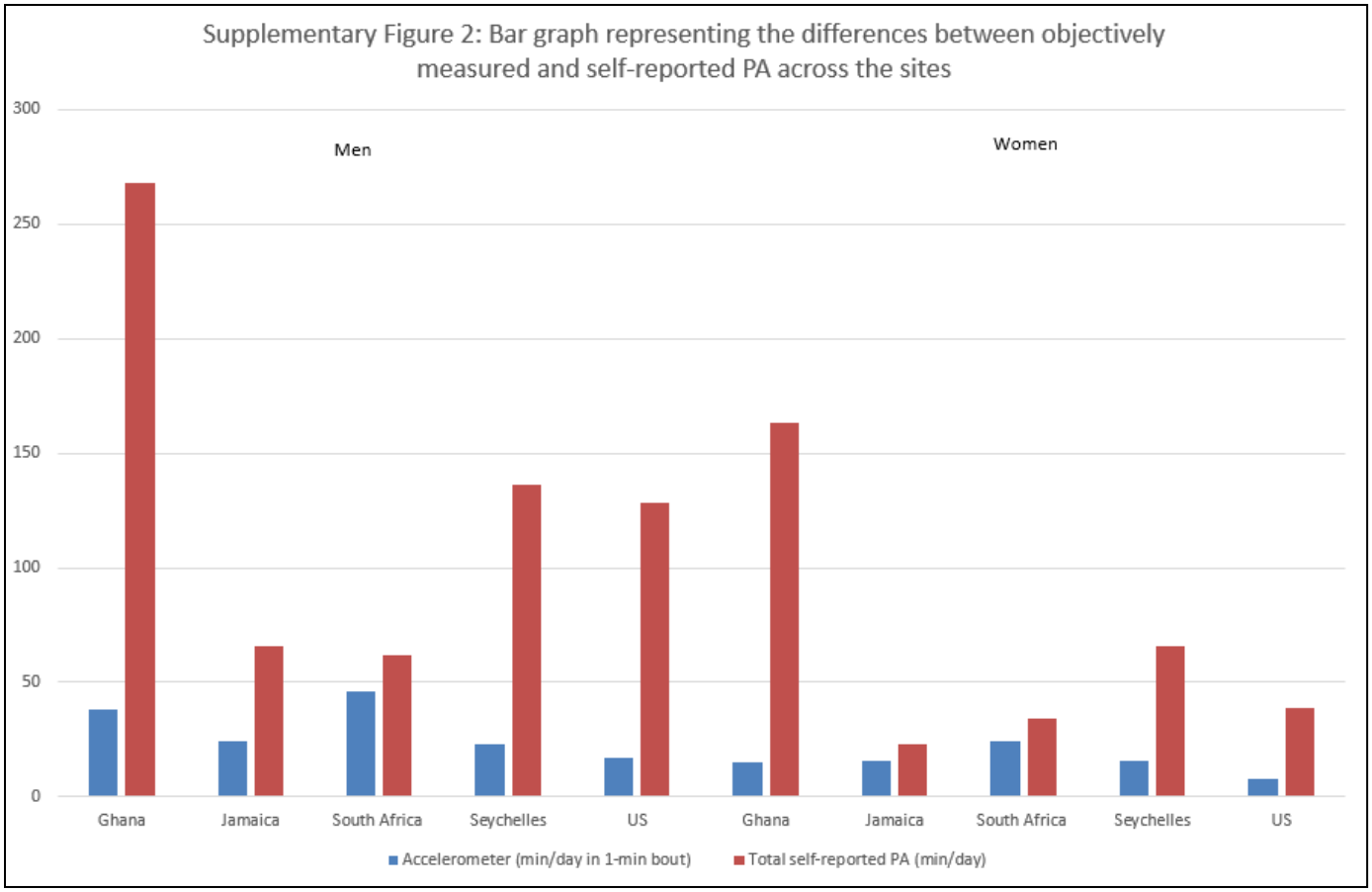
Appendices

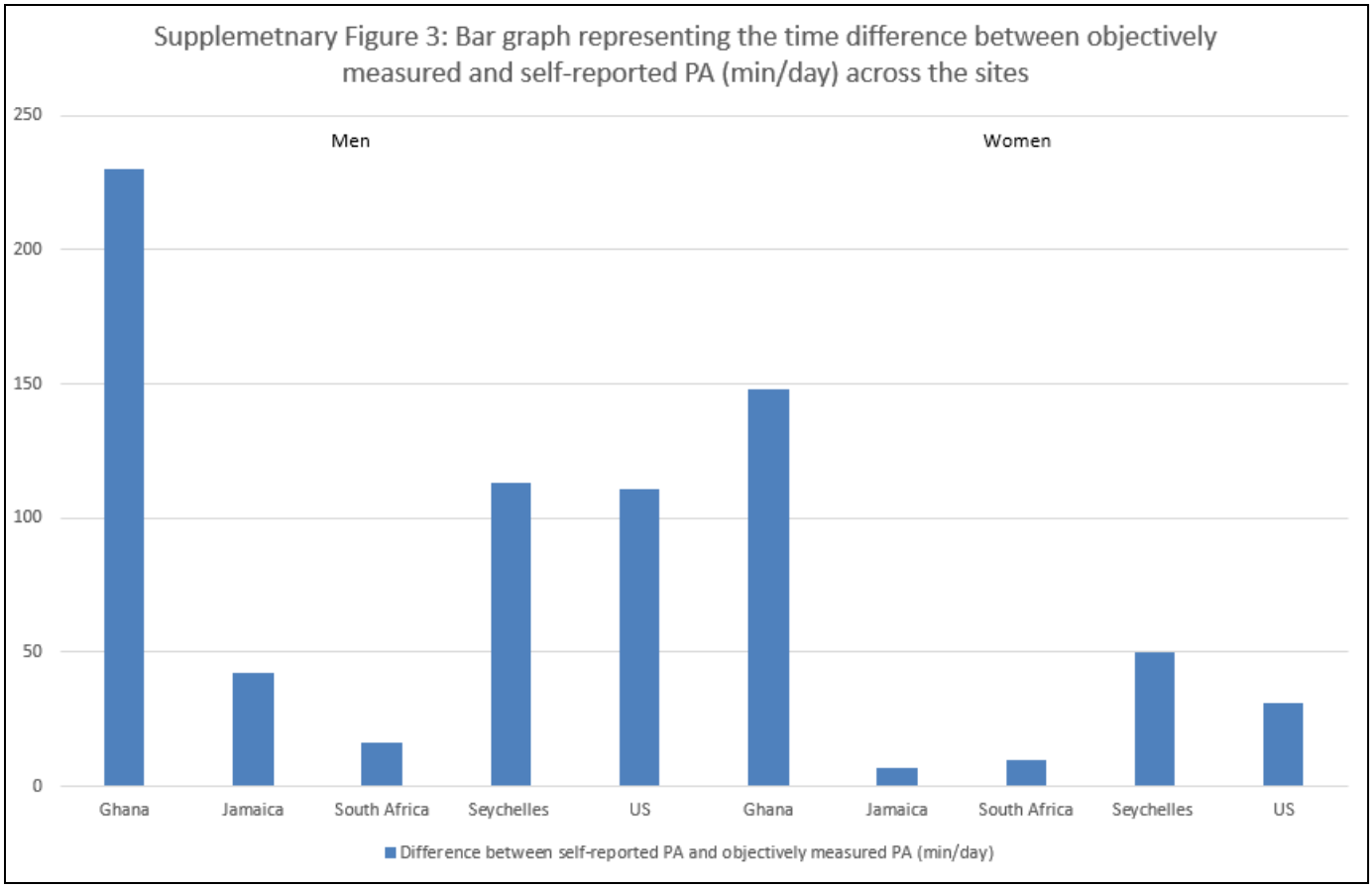
A. Supplementary Tables and Figures included in the manuscript

Supplementary Table 1: Coefficient estimates from the linear regression models for each site for the association between objectively measured and self-reported PA with interactions

Model	Variable	Estimate	95% CI	p-value
A. Ghana	Intercept	185.83	(138.72, 232.94)	<0.05
	Objectively measured PA (min/day)	2.03	(0.95, 3.11)	<0.05
	Overweight/obese	-25.77	(-124.29, 72.75)	0.61
	Objectively measured PA:obese interaction	-1.28	(-5.38, 2.83)	0.54
B. Jamaica	Intercept	98.94	(37.26, 160.63)	<0.05
	Objectively measured PA (min/day)	1.46	(-0.13, 3.05)	0.07
	Overweight/obese	-10.65	(-115.65, 94.35)	0.84
	Objectively measured PA:obese interaction	1.57	(-2.73, 5.87)	0.48
C. South Africa	Intercept	78.67	(2.90, 154.44)	0.05
	Objectively measured PA (min/day)	1.2	(-0.17, 2.57)	0.09
	Overweight/obese	-11.79	(-122.99, 99.41)	0.84
	Objectively measured PA:obese interaction	-0.34	(-3.88, 3.21)	0.85
D. Seychelles	Intercept	135.92	(105.51, 166.33)	<0.05
	Objectively measured PA (min/day)	1.15	(0.64, 1.66)	<0.05
	Overweight/obese	-3.84	(-50.20, 42.53)	0.87
	Objectively measured PA:obese interaction	-0.6	(-1.49, 0.30)	0.19
E. USA	Intercept	163.76	(115.80, 211.71)	<0.05
	Objectively measured PA (min/day)	0.78	(-0.52, 2.09)	0.24
	Overweight/obese	-55.94	(-119.00, 7.12)	0.08
	Objectively measured PA:obese interaction	0.04	(-2.59, 2.67)	0.98


Supplementary Figure 1: Proportions of those who meet PA criteria using GPAQ classification of ≥600METmin/week, and those who meet it but are overweight/obese
120
100
80
60
40
20
0
Men
Women
Ghana
Jamaica
South Africa
Seychelles
US
Ghana
Jamaica
South Africa
Seychelles
US
Meets GPAQ PA criteria - total (%)
Meets GPAQ PA criteria - overweight/obese (%)


Supplementary Figure 2: Bar graph representing the differences between objectively measured and self-reported PA across the sites
300
250
200
150
100
50
0
Men
Women
Ghana
Jamaica
South Africa
Seychelles
US
Ghana
Jamaica
South Africa
Seychelles
US
Accelerometer (min/day in 1-min bout)
Total self-reported PA (min/day)


Supplemetnary Figure 3: Bar graph representing the time difference between objectively measured and self-reported PA (min/day) across the sites
250
200
150
100
50
0
Men
Women
Ghana
Jamaica
South Africa
Seychelles
US
Ghana
Jamaica
South Africa
Seychelles
US
Difference between self-reported PA and objectively measured PA (min/day)

B. Data collection tools used in the parent study

METS-Microbiome Visit Checklist Baseline Visit:

Informed Consent _____

Form 1 – Demographics _____

Form 2 - Anthropometrics _____

Form 3 – Biochemical measures
- Urine _____
- Blood _____
- OGTT _____
- Accelerometer Placement _____

Form 4 – GPAQ _____

Form 5 – FFQ _____

Form 6 – SES _____

Form 7 – Microbiome _____

Form 8 – Discrimination _____

Return Appointment _____

Visit 2:

Was monitor returned? _____

Was stool collected? _____

Did participant receive reimbursement? _____

Did participant receive feedback forms? _____

Future appointments reminder _____

FORM 1 **METS-MICROBIOME** **DEMOGRAPHICS FORM**

Participant ID: _____ **Exam date:** _____/_____/_____ (MM/DD/YYYY)

☐ Clinic visit ☐Home visit **Interviewer Initials** _____

New participant ☐ Yes ☐ No

CONTACT INFORMATION **Email** _____

Last name _____ **First names** _____ **MI** _____

Address _____

City _____ **State** _____ **Zip**_____

Home phone _____ **Work phone** _____ **Alternate/cellular phone** _____

Nearest intersection: _____

BASIC DEMOGRAPHICS

Age: _____ **Birth date:** _____/_____/_____ (MM/DD/YYYY)

Birth place: _____

Country _____ **State** _____ **City** _____

1. **When did you move to your current residence?**
   - ☐ Less than 1 year ago
   - ☐ 1-2 years ago
   - ☐ 2-10 years ago
   - ☐ More than 10 years ago

2. **Have you travelled outside of the country in the past:**

Month ☐ Yes ☐ No
6 Months ☐ Yes ☐ No
1 year ☐ Yes ☐ No

☐ I have not travelled outside my country in the past year.

3. **What is your ethnic group?**
   - ☐ American Indian/Alaskan Native
   - ☐ Asian (Chinese)
   - ☐ Asian (Indian)
   - ☐ Black or African American
   - ☐ Native Hawaiian or Pacific Islander
   - ☐ White
   - ☐ White Hispanic (USA)
   - ☐ Mixed (i.e. not predominantly in an other groups, e.g. Creole)
   - ☐ Other ethnic group
   - ☐ Refused to answer
   - ☐ Don't know

BACKGROUND DEMOGRAPHICS

4. **Where were you born**
   ☐ At home ☐ In a hospital: Name of hospital _____ ☐ Don't know

5. **Were you born via caesarean section (C-section):**
   ☐ No ☐ Yes ☐ Don't know

6. **Gender** ☐ Male ☐Female

7. **Marital status:**
   - ☐ Married/living with a partner as married
   - ☐ Living without a partner
   - ☐ Refused to answer

Participant ID: _____ V2_05/24/2018

FORM 1 **METS-MICROBIOME** **DEMOGRAPHICS FORM**

8. **If you don't know the amount, can you give an estimate of the annual household income if I read some options to you? Is it** (READ OPTIONS)
   - ☐ ≤ $23 000
   - ☐ More than $23 000, ≤ $43 000
   - ☐ More than $43 000, ≤ $72 000
   - ☐ More than $72 000, ≤ $112 000
   - ☐ More than $112 000
   - ☐ Don't know
   - ☐ Refused

9. **On average, what is your gross personal income per year, including allowances, bonuses and other benefits?**
   - ☐ ≤ $15 000
   - ☐ More than $15 000, ≤ $30 000
   - ☐ More than $30 000, ≤ $46 000
   - ☐ More than $46 000, ≤ $75 000
   - ☐ More than $75 000
   - ☐ Don't know
   - ☐ Refused

For females only:

10. **Are you pregnant?**
    - ☐ No
    - ☐ Yes. **You are not eligible to participate in this study now. Please come back 6months after giving birth.**
    - ☐ Don't know

11. **Are you breastfeeding currently?**
    ☐ No ☐ Yes ☐ Refuse to answer

12. **Time since last pregnancy (years, if 6 months: 0.5)** _____

13. **Number of biological children** _____

14. **Are you currently menopausal?** ☐ No ☐ Yes

HEALTH HISTORY

15. **Have you seen a primary care physician in the last year?** ☐ No ☐ Yes

16. **If yes, what was the reason for the visit, select all that apply?**
    - ☐ Surgery/ accident
    - ☐ Simple short illness such as cold
    - ☐ Chronic condition such as diabetes or hypertension
    - ☐ Other situation (if yes, which one: _____)

17. **How do you pay for routine health care?**
    - ☐ Mostly cash/ out of pocket
    - ☐ Mostly covered by medical insurance
    - ☐ Medical insurance with some cash/out of pocket expenses
    - ☐ Public/government (Medicaid or universal health system with free or largely free provision of health care)

18. **Have you ever been told that you have:**
    - ☐ Heart attack or coronary heart disease, age _____
    - ☐ Rheumatic heart disease or other heart problem, age _____
    - ☐ Stroke, age _____
    - ☐ Cancer, age _____; type _____
    - ☐ High blood cholesterol, age _____
    - ☐ Diabetes/elevated blood sugar, age _____
      If yes to diabetes, do you take insulin now? ☐ Yes ☐ No

Participant ID: _____ V2_05/24/2018

FORM 1 **METS-MICROBIOME** **DEMOGRAPHICS FORM**

- ☐ Osteoarthritis, age _____
- ☐ Rheumatoid arthritis, age _____
- ☐ Kidney failure, age _____
- ☐ Mental health problems like depression, age _____
- ☐ Any other chronic disease? If so, what _____
- ☐ High blood pressure, age _____

19. If you were told you have high blood pressure:

Have you ever been told by a doctor or health care provider to:	Are you now:
☐ Take prescribed medicine for more than 1 month	☐ Taking prescribed medicine for >1 month
☐ Control your weight or lose weight	☐ Controlling or losing weight
☐ Cut down on salt	☐ Using less salt
☐ Exercise more	☐ Exercising more
☐ Reduce your alcohol intake	☐ Reducing your alcohol intake
☐ Stop smoking	☐ Trying to stop smoking

20. Medications

Did participant bring medications and supplements: ☐ No ☐ Yes

Is participant taking any of the following prescription medications

- ☐ Glucocorticoids/Corticosteroids (e.g. Entocort, Prednisone, Prednisolone, Decadron)
- ☐ Anticonvulsants (e.g. Depakote, Diazepam, Dilantin, Tegretol)
- ☐ Loop or Thiazide Diuretics (e.g. Furosemide, Bumatanide, Hydrocholorthiazide)
- ☐ Other medications for hypertension (ACEIs, ARB, BB, CCB, etc))
- ☐ Metformin or another oral antidiabetic medicine
- ☐ Other:

Other currently prescribed medications	Reason for Taking Medication

FOR FEMALES ONLY

- ☐ Estrogens (e.g. Premarin, Climara, Vivelle, Estraderm, Cenestin)
- ☐ Oral contraceptive
- ☐ Injectable contraceptive (Depo-Provera)

21. Are you taking any nutritional/ herbal supplement?

- ☐ No
- ☐ Yes _____

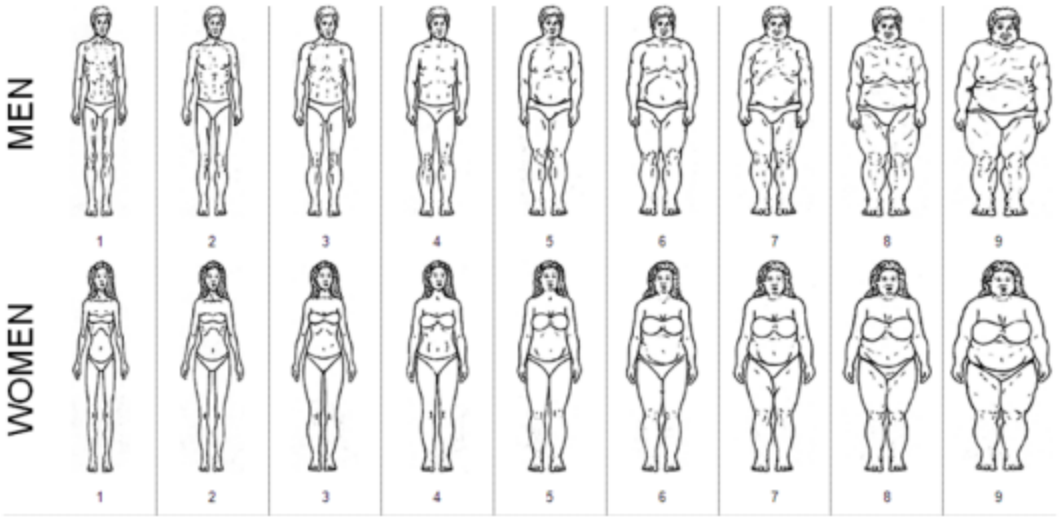
FORM 1 **METS-MICROBIOME** **DEMOGRAPHICS FORM**

RISK FACTORS

22. Approximately how many hours do you sleep each night? _____

23. Do you consider your current weight to be:

- ☐ Largely underweight
- ☐ Slightly underweight
- ☐ About right
- ☐ Slightly overweight
- ☐ Largely overweight
- ☐ Refused to answer



24. In the drawing, which figure best reflects how you think you look like with regards to your body shape?

Answer (1-9): ____

25. In the drawing, which figure best represents how you would like to look like with regards to your body shape, ideally?

Answer (1-9): ____

26. Have you been intentionally trying to lose weight over the last year? ☐ No ☐ Yes

If yes, what method? ☐ Exercise ☐ Diet ☐ Other _____

If diet, what diet? _____

Smoking

27. Smoking (any tobacco use excluding e-cigarettes)

- ☐ Smoker: is currently smoking cigarettes (at least 1 per day). How many per day on average? _____
- ☐ Occasional: Smokes, but not every day. How many per week on average? _____
- ☐ Ex-smoker: Stopped smoking for at least 1 month.
- ☐ Non-user: Never smoked regularly

28. E-cigarettes usage

Do you ever use e-cigarettes: ☐ No ☐ Yes, occasionally ☐ Yes, regularly?

During the past 5 days, including today, on how many days did you smoke an e-cigarette? _____

Participant ID: _____ V2_05/24/2018

FORM 1 **METS-MICROBIOME** **DEMOGRAPHICS FORM**

Recreational Drug Use

29. Smoking (marijuana, hashish, pot)

☐ No ☐ Yes, Occasionally ☐ Yes, regularly Times per week _____

30. Cocaine, heroin, methamphetamine, amphetamines, ecstasy

☐ No ☐ Yes, Occasionally ☐ Yes, regularly Times per week _____

Alcohol

Note: 1 standard drink= 12 oz (350ml) beer= 5 oz (150 ml) glass of wine= 1.5 oz (44ml) glass of spirit (whiskey, gin, vodka)

31. Have you ever consumed any alcohol such as beer, wine, spirits or home-made alcohol?
- ☐ Yes
- ☐ No

32. Have you consumed any alcohol within the past 12 months?
- ☐ Yes
- ☐ No

33. If yes, during the past 12 months, how frequently have you had at least one standard alcoholic drink, on average?
- ☐ Daily
- ☐ 5-6 days per week
- ☐ 3-4 days per week
- ☐ 1-2 days per week
- ☐ 1-3 days per month
- ☐ Less than once a month

34. Have you consumed any alcohol within the past 30 days?
- ☐ Yes
- ☐ No

35. If yes, during the past 30 days, on how many occasions, approximately, did you have at least one standard alcoholic drink (standard drink: 1 bottle beer or 1 shot whisky or 1 glass wine)? _____

36. During the past 30 days, when you drank alcohol, how many standard drinks on average did you have during one drinking occasion? _____

37. During the past 30 days, what was the largest number of standard drinks you had on a single occasion on one single day/night, counting all types of alcoholic drinks together? _____

38. During the past 30 days, on how many days did you have six or more standard drinks in a single drinking occasion? _____

39. During each of the past 7 days, how many standard drinks did you have each day, on average?

Monday	_____		
Tuesday	_____	Friday	_____
Wednesday	_____	Saturday	_____
Thursday	_____	Sunday	_____

Life events

40. In the past year, have you experienced any of the following major life events:
- ☐ Death of a spouse
- ☐ Death of a family member or friend
- ☐ Divorce or separation
- ☐ Major injury or illness
- ☐ Change in financial state
- ☐ Imprisonment
- ☐ Dismissal from work
- ☐ Marriage
- ☐ Birth of a child

Participant ID: _____ V2_05/24/2018

FORM 2 **METS-MICROBIOME** **ANTHROPOMETRICS FORM**

Interviewer Initials: _____ **Exam Date:** _____/_____/_____ (MM/DD/YYYY)

1. **Age:** _____
2. **Weight:** _____ . _____ kilograms **SCALE ID** _____
3. **Height:** _____. _____ m

Note: third measurements for all of the following are only required if first two differ by 0.5cm or more

4. **Waist circumference**	_____. ___ cm	5. **Hip circumference**	_____. ___ cm
	_____. ___ cm		_____. ___ cm
	_____. ___ cm		_____. ___ cm
6. **Upper mid-arm circumference**	_____. ___ cm		
	_____. ___ cm		
	_____. ___ cm		

BIOELECTRICAL IMPEDANCE ANALYSIS (BIA) **BIAID** _____

If participant has pacemaker or any other metal medical device, BIA cannot be done.
All piercings and jewelry must be removed before proceeding.

7. **During the BIA measurement, the participant was:** Lying down _____
8. **Resistance measure:** _____
9. **Reactance measure:** _____

BLOOD PRESSURE **OMRON ID** _____
Time of day ____: _____ (hh:mm, e.g. 14.23, 24 hour time)

10. **Have you had any food, alcohol, coffee or cigarettes within the last 30 minutes?**
    - ☐ Food
    - ☐ Alcohol
    - ☐ Coffee
    - ☐ Cigarette
    - ☐ Recreational drugs
11. **Arm Circumference** _____. ____**cm**
12. **Cuff size selected**

Adult Arm Circumference	Recommended Cuff Size
22-26cm	12x 22cm (small adult)
27- 34cm	16x 30cm (adult)
35-44cm	16x 36cm (large adult)
45- 52cm	16x 42cm (adult thigh)

13. **Arm selected** ☐ Right ☐ Left. Specify reason: _____

Participant ID: _____ V1_01/03/2018

FORM 2 **METS-MICROBIOME** **ANTHROPOMETRICS FORM**

14. **Blood Pressure measure refused?** ☐ No ☐ Yes

15. **First Blood Pressure Measurement**

SBP _____

DBP _____

60-second pulse rate _____

16. **Second Blood Pressure Measurement**

SBP _____

DBP _____

60-second pulse rate _____

17. **Third Blood Pressure Measurement**

SBP _____

DBP _____

60-second pulse rate _____

A second set of blood pressure measures follows the placement of the Actical.

18. **Repeat Blood Pressure measure refused?** ☐ No ☐ Yes

19. **First Repeat Blood Pressure Measurement**

SBP _____

DBP _____

60-second pulse rate _____

20. **Second Repeat Blood Pressure Measurement**

SBP _____

DBP _____

60-second pulse rate _____

21. **Third Repeat Blood Pressure Measurement**

SBP _____

DBP _____

60-second pulse rate _____

Participant ID: _____ V1_01/03/2018

FORM 3 **METS-MICROBIOME** **BIOCHEMICAL MEASURES FORM**

Interviewer Initials: _____ **Exam Date: _____/_____/_____** (MM/DD/YYYY)

FOR FEMALES ONLY:

1. **Date of Last Menstrual Period: _____ /_____/_____** (MM/DD/YYYY)
2. **If greater than four weeks, is participant on Depo provera? Or other device (IUD); which one; _____**

Phlebotomist Initials: _____

When was the last time you had something to eat or drink?

3. Date last ate **_____ /_____/_____** (MM/DD/YYYY)
4. Time last ate **_____ :_____** (hh:min, Record in 24-hour time)

Glucose Check (Accuchek)

5. ☐ No ☐ Yes 6. **Result _____ (mg/dL) or _____(mmol/l)**

If the glucose check is ≥ 125 mg/dL (7.0 mmol/L), participant may not participate in the oral glucose tolerance test.

Baseline blood draw (timepoint 0:00)

6. Time of blood draw **_____ :_____** (hh:min, Record in 24-hour time)

Baseline BLOOD COLLECTION TUBES

2 tubes of 6 ml with K2EDTA

☐ No
☐ Yes

3 tubes of 6ml with no EDTA

☐ No
☐ Yes

Glucose drink:

7. Time at which entire 75 gram glucose drink was completed **____ :____** (hh:min, Record in 24-hour time)

2nd blood draw (timepoint **30min** after drink was completed)

8. Time of blood draw **_____ :_____** (hh:min, Record in 24-hour time)

1 BLOOD COLLECTION TUBE

1 tube of 6 ml with no EDTA

☐ No
☐ Yes

3rd blood draw (timepoint **60min** after drink was completed)

9. Time of blood draw **_____ :_____** (hh:min, Record in 24-hour time)

1 BLOOD COLLECTION TUBE

1 tube of 6 ml with no EDTA

☐ No
☐ Yes

Worksheet for Phlebotomist	
Time of drink	
Time for 2nd blood draw (30min)	
Time for 3rd blood draw (60min)	
Time for 4th blood draw (120min)	

Participant ID: _____ v1_01/03/2018

FORM 3 **METS-MICROBIOME** **BIOCHEMICAL MEASURES FORM**

4th blood draw (timepoint **120min** after drink was completed)

10. Time of blood draw _____ :_____ (hh:min, Record in 24-hour time)

1 BLOOD COLLECTION TUBES
1 tube of 6 ml with no EDTA
☐ No
☐ Yes

URINE

11. **Spot urine**

☐ No ☐ Yes

ACCELEROMETER 12. **Serial Number** _____

13. **Was accelerometer placed on right hip?**

☐ Yes ☐ No Reason for using left hip: _____

14. **Start date** _____ /_____/_____ (MM/DD/YYYY)

15. **Start time** ___ ___ :___ ___ (hh:min, Record in 24-hour time)

16. **Epoch period** 60 seconds☐ No ☐ Yes

17. **Mode** Record steps ☐ No ☐ Yes

☐ *Retrieve Anthropometrics (Form 2) and record second set of blood pressure measures*

Check date ___ ___ /___ ___/_____ (MM/DD/YY)

Comments: _____

Participant ID: _____ v1_01/03/2018

FORM 3 **METS-MICROBIOME** **BIOCHEMICAL MEASURES FORM**

FOLLOW UP

Interviewer initials: _____

18. **Was monitor returned?** ☐ No ☐ Yes

19. **End date** ___ ___ /_____/_____ (MM/DD/YYYY)

20. **End time** ___ ___ :___ ___ (hh:min, Record in 24-hour time)

21. **Would you say this period represents your usual activity level?**

☐ No ☐ Yes

If no, what was different about this period? _____

_____

STOOL SAMPLE

22. **Date that stool was passed:** _____/ _____/_____ (MM/DD/YYYY)

23. **Approximate time that stool was passed:** ____: _____ (hh:mm, e.g. 14.23, 24 hour time)

24. **Date that stool was received:** _____/_____/_____ (MM/DD/YYYY)

25. **Approximate time that stool was received and stored at -80:** ____: _____ (hh:mm, e.g. 14:23, 24 hour time)

26. How has stool been stored since it was passed:

- ☐ Refrigerated
- ☐ On ice
- ☐ At room temperature
- ☐ Other _____

27. Occult blood test result:

- ☐ Positive
- ☐ Negative

Participant ID: _____ v1_01/03/2018

FORM 4 **METS-MICROBIOME** **GPAQ**

Interviewer Initials: _____

Physical Activity

Next I am going to ask you about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person.

Think first about the time you spend doing work. Think of work as the things that you have to do such as paid or unpaid work, study/training, household chores, harvesting food/crops, fishing or hunting for food, seeking employment. *[Insert other examples if needed].* In answering the following questions 'vigorous-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate, 'moderate-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate.

	Questions	Response	Code
Activity at work			
1	Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like *[carrying or lifting heavy loads, digging or construction work]* for at least 10 minutes continuously? *[INSERT EXAMPLES] (USE SHOWCARD)*	Yes 1 No 2 *If No, go to P4*	P1
2	In a typical week, on how many days do you do vigorous-intensity activities as part of your work?	Number of days ⌊__⌋	P2
3	How much time do you spend doing vigorous-intensity activities at work on a typical day?	Hours : minutes ⌊__⌋⌊__⌋ : ⌊__⌋⌊__⌋ hrs mins	P3 (a-b)
4	Does your work involve moderate-intensity activity that causes small increases in breathing or heart rate such as brisk walking *[or carrying light loads]* for at least 10 minutes continuously? *[INSERT EXAMPLES] (USE SHOWCARD)*	Yes 1 No 2 *If No, go to P7*	P4
5	In a typical week, on how many days do you do moderate-intensity activities as part of your work?	Number of days ⌊__⌋	P5
6	How much time do you spend doing moderate-intensity activities at work on a typical day?	Hours : minutes ⌊__⌋⌊__⌋ : ⌊__⌋⌊__⌋ hrs mins	P6 (a-b)
Travel to and from places			
The next questions exclude the physical activities at work that you have already mentioned. Now I would like to ask you about the usual way you travel to and from places. For example to work, for shopping, to market, to place of worship. [insert other examples if needed]			
7	Do you walk or use a bicycle (*pedal cycle*) for at least 10 minutes continuously to get to and from places?	Yes 1 No 2 *If No, go to P 10*	P7
8	In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?	Number of days ⌊__⌋	P8
9	How much time do you spend walking or bicycling for travel on a typical day?	Hours : minutes ⌊__⌋⌊__⌋ : ⌊__⌋⌊__⌋ hrs mins	P9 (a-b)
Recreational activities			
The next questions exclude the work and transport activities that you have already mentioned. Now I would like to ask you about sports, fitness and recreational activities (leisure), [insert relevant terms].			
10	Do you do any vigorous-intensity sports, fitness or recreational (*leisure*) activities that cause large increases in breathing or heart rate like [*running or football,*] for at least 10 minutes continuously? *[INSERT EXAMPLES] (USE SHOWCARD)*	Yes 1 No 2 *If No, go to P 13*	P10
11	In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational (*leisure*) activities?	Number of days ⌊__⌋	P11
12	How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?	Hours : minutes ⌊__⌋⌊__⌋ : ⌊__⌋⌊__⌋ hrs mins	P12 (a-b)

Participant ID: _____

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FORM 4 **METS-MICROBIOME** **GPAQ**

Physical Activity (recreational activities) contd.			
Questions		**Response**	**Code**
13	Do you do any moderate-intensity sports, fitness or recreational (*leisure*) activities that causes a small increase in breathing or heart rate such as brisk walking, (*cycling, swimming, volleyball*) for at least 10 minutes continuously? *[INSERT EXAMPLES] (USE SHOWCARD)*	Yes 1 No 2 *If No, go to P16*	P13
14	In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (*leisure*) activities?	Number of days ⌊__⌋	P14
15	How much time do you spend doing moderate-intensity sports, fitness or recreational (*leisure*) activities on a typical day?	Hours : minutes ⌊__⌋ : ⌊__⌋ hrs mins	P15 (a-b)
Sedentary behaviour			
The following question is about sitting or reclining at work, at home, getting to and from places, or with friends including time spent [sitting at a desk, sitting with friends, travelling in car, bus, train, reading, playing cards or watching television], but do not include time spent sleeping. *[INSERT EXAMPLES] (USE SHOWCARD)*			
16	How much time do you usually spend sitting or reclining on a typical day?	Hours : minutes ⌊__⌋ : ⌊__⌋ hrs min s	P16 (a-b)

Participant ID: _____

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FORM 5 METS-MICROBIOME Food Frequency Questionnaire

1. Food frequency questionnaire

	In a typical week, on how many days do you have the following on average:	**On these days, how many servings of the same do you take on average?**
Water (bottled, tap water)		(200-300ml glass)
Tea		(200ml cup) :
Coffee		(200ml cup):
Do you generally add milk in coffee or tea (powder or liquid)	Yes/No :	
Do you generally add sugar in coffee or tea (powder or liquid)	tea spoons/cup: 0,1,2, 3:	
Commercial soft drink (Cola, Fanta, etc) (3dl ~1 small bottle)		(300ml serving):
Commercial diet drink (Diet coke, etc) (3dl ~1 small bottle)		(300ml small bottle):
Fresh fruit juice (pressed, 1-2dl ~1 glass)		(200-300ml serving):
Fruit juice canned/packet (1 small packet ~2.5dl~1 serving)		(200-300ml serving):
Milk in glass (fresh, reconstituted, etc)		(200-300ml serving):
Soup (homemade, packet, etc)		(1,2,3 meals/day)
Beer		(300ml bottle or equivalent):
Wine or liquor (Porto, Irish coffee, etc)		(200ml glass):
Spirit (whisky, rum, gin, vodka, etc)		(20ml peg):
Locally made alcohol (moonshine)		(300-500ml glass):
Rice (white polished or brown unpolished)		Meals per day 1,2 3
Corn/maize (grits,hominy, crude, cooked, roasted, etc)		Meals per day 1,2 3
Potato (boiled, cooked, fries, hashbrown, fries)		Meals per day 1,2 3
Yam, taro, cassava, sweet potato (roots)		Meals per day 1,2 3
Bread (white or brown; buns, muffin, biscuit, bagel, sandwich, crackers, hamburger)		Slices or equivalent/d
Pasta (macaroni, spaghetti, ramen noodles)		Meals per day 1,2 3
Grains, beans and legumes		Meals per day 1,2 3
Raw vegetables (fresh, green, tomato, carrots, lettuce, avocado, guacamole, etc)		(1,2,3 meals/d)
Cooked Vegetables -canned, frozen, stirred e.g. cabbage, pumpkin, (but not salad, not roots):		(1,2,3 meals/d)
Cereals "for breakfast" (oatmeal, cornflakes, porridge)		(1,2,3 meals/d)
Local/commercial savory snacks (e.g. chips, peanuts, etc)		(servings per day)
Fruit (fresh, canned, frozen, etc, but not counting juice)		(portions/d)
Fast food (McDonalds, fried chicken, pizza, taco)		(1,2,3 meals/d)
Chicken (roasted, grilled, cooked, curry, etc)		(1,2,3 meals/day)

Participant ID: _____ V1_01/03/2018

FORM 5 METS-MICROBIOME Food Frequency Questionnaire

Meat (beef, pork, goat cooked, grilled, curry, etc but not processed)		(1,2,3 meals/day)
Meat processed (sausage, bacon, ham, bologna, burger, hot dog, etc)		(1,2,3 meals/day)
Fish (fresh, frozen, fried, cooked, grilled, can [tuna])		(1,2,3 meals/day)
Eggs (boiled, poached, omelet, etc)		(1,2,3 meals/day)
Cheese (processed, piece)		(1,2,3 meals/d)
Dessert, chocolate, cake, ice cream, shake, candy, cookie, donut		(1,2,3 meals/d)

General pattern of meals:

2. On a typical week day (Monday to Friday), do you usually eat for:
   Breakfast (Y/N) _____ Lunch (Y/N) _____ Dinner (Y/N) _____
3. On a typical week day (Monday to Friday), do you usually take a solid snack (not just a drink):
   Between breakfast & lunch Y/N) _____; between lunch & dinner Y/N) _____; after dinner Y/N) _____
4. In a typical week, how many times do you buy food, for lunch or for dinner, from a take away business, vendor or food truck? (1-5) _____
5. In a typical week, on how many days do you usually eat food from a workplace canteen? (1-5) _____
6. In a typical month, how many times do you eat in a restaurant/from a fast food vendor/ street food vendor? _____
7. In a typical week, how often do you buy a salty or sugary snack (not as main meal, not drink) from a vendor?
   1) Not every week
   2) 1-2 times /week
   3) 3-5 times per week
   4) Every day or almost every day
   5) More than once on most day of week
8. Do you substitute artificial sweetener for sugar (in your tea, coffee, etc) ?
   1) Never or nearly never
   2) Sometimes
   3) Regulary (every day)
9. How often do you drink water from the tap ?
   1) Never or virtually never
   2) Occasionally (not every week)
   3) Often, at least once every week
   4) Often, every day or nearly every day
10. In a typical week, do you usually use water from a water dispenser at home Y/N) ___ ; at work Y/N) ___

Participant ID: _____ V1_01/03/2018

FORM 6 **METS-MICROBIOME** **SES**

Interviewer Initials: _____

Section A: General household characteristics

1. How many people are part of this household, including yourself, and what gender are they? [The household is defined as people who normally live and eat together in the household, sleeping at least 4 nights per week in the household on a regular basis]

males _____ females _____

2. How many of the household members are in the following age ranges. Include yourself.

0-2 years old	_____	40-65	_____
3-15	_____	over 65	_____
16-40	_____		

3. How many of the household members contribute to the household income. Include yourself. _____

4. How many of the household members are currently enrolled in school, including up to university degree? _____

Section B: Subject's socioeconomic characteristics

5. Can you read and write? ☐ No ☐ Yes

6. What is the highest grade you completed, or how many years of formal education (including primary, secondary, tertiary/university but excluding pre-school/creche) do you have? _____

7. Do you have any of the following degrees? [Choose only the highest degree]

- ☐ No formal education or less than primary school
- ☐ Primary School (i.e. school between 3-5 and 15-16, often considered "obligatory school" in some countries)
- ☐ Some High School (i.e beyond age of 15-16, generally beyond what is considered "obligatory school"
- ☐ Completed High School
- ☐ Vocational degree or certification (e.g., electrician's license, auto repair certificate)
- ☐ Bachelor's degree (college or university undergraduate,BA, BS, BArch, BEng, etc.)
- ☐ Graduate or advanced professional degree (MBA, PhD, JD, MD, etc.)

8. How many days of work did you miss in the past 12 months due to sickness, illness, or injury?

- ☐ none, but did work last year
- ☐ 1 week or less
- ☐ 1-2 weeks
- ☐ more than 2 weeks
- ☐ did not work last year

9a. Did you do any type of work for pay in the last month? ☐ No ☐ Yes

9b. If you did not work in the last month, what was the main reason you did not work?

- ☐ No work available
- ☐ Seasonal inactivity
- ☐ Student
- ☐ Household/family duties
- ☐ Too old or too young to work
- ☐ Infirmity/sickness
- ☐ Other (Write in "Other" reason_____)

10. How were you paid for your work?

- ☐ Regular Wages or salary
- ☐ Payment in kind
- ☐ Casual labor (hourly/daily)
- ☐ Unpaid contributing worker
- ☐ Self-employed or own my own business

11. What is the main industry or activity at your primary job? (If currently unemployed, please use your last job)

- ☐ Agriculture
- ☐ Mining/quarrying
- ☐ Manufacturing/ processing

Participant ID: _____ V1_01/03/2018

FORM 6 **METS-MICROBIOME** **SES**

Interviewer Initials: _____

- ☐ Construction
- ☐ Transport
- ☐ Trade/selling
- ☐ Services (e.g.: restaurant, beauty salon, lodging)
- ☐ Education/health
- ☐ Administration
- ☐ Other (Write in "Other" industry_____)

12. What is the main occupation at your primary job? (If currently unemployed, please use your last job)

☐ Senior managers or administrators (finance manager - chief executive)
☐ Traditional professional occupations (accountant - solicitor/lawyer - physician - scientist/engineer)
☐ Modern professional occupations (teacher - nurse - social worker - artist - police officer sergeant+))
☐ Middle or junior managers (office manager - bank manager - restaurant manager)
☐ Clerical and intermediate occupations (secretary - clerical worker - call center agent - nursing aid)
☐ Technical and craft occupations (car mechanic - inspector - plumber - printer - electrician)
☐ Semi-routine manual and service occupations (postal worker - machine operator - security guard)
☐ Routine manual and service occupations (driver - cleaner - porter - laborer – waiter)
☐ Farming or agricultural occupations (farmer, herder)
☐ Fishing
☐ Other occupation (Write in occupation here: _____)

13. How many other people work in your workplace? (if currently unemployed, answer for your last job)

- ☐ 0 (I work alone or freelance)
- ☐ 1
- ☐ 2-9
- ☐ 10-24
- ☐ 25 or more

14. How many employees do you supervise? (if currently unemployed, answer for your last job)

- ☐ 0 (I do not supervise anyone)
- ☐ 1
- ☐ 2-9
- ☐ 10-24
- ☐ 25 or more

15. In the course of your work, do you make management decisions, such as how many people to hire? (if currently unemployed, answer for your last job) ☐ No ☐ Yes

16. Not counting the place where you currently stay (and whether you own it or rent it), do you own a house, an apartment or another building that you rent to others? ☐ No ☐ Yes

Section C: Significant other's information

17. Does your significant other have any of the following degrees? [Pick only one, the highest degree obtained]

- ☐ No formal education or less than primary school
- ☐ Primary School
- ☐ Some High School
- ☐ Completed High School
- ☐ Vocational degree or certification (e.g., electrician's license, auto repair certificate)
- ☐ Bachelor's (college or university undergraduate) degree (BA, BS, BArch, BEng, etc.)
- ☐ Graduate or advanced professional degree (MBA, PhD, JD, MD, etc.)
- ☐ Don't Know
- ☐ Not applicable. Not living with a significant other

Section D: Household assets and amenities

19. Does the household or a household member own the dwelling you live in?

- ☐ Owns the dwelling

Participant ID: _____ V1_01/03/2018

FORM 6 **METS-MICROBIOME** **SES**

Interviewer Initials: _____

☐ Rents the dwelling
☐ Uses without paying rent
☐ Nomadic or temporary dwelling

21. Does the household use land it does not own? ☐ No ☐ Yes

22. Does the household own any cattle or other livestock, like cows, horses, donkeys, pigs, goats, sheep, (even 1-2) ?

☐ No ☐ Yes

23. Does the household have electricity? ☐ No ☐ Yes

24. Does the household or any member of the household (including yourself) own or have any of the following? (Include only if they are in working condition)

☐ Electric iron
☐ Refrigerator
☐ Television
☐ Satellite Dish or Cable Television
☐ DVD player or VCR
☐ Computer (only include a computer purchased by you or a member of your household)
☐ Mattress or bed
☐ Sofa
☐ Sprayer (Jamaica, Ghana only)
☐ Radio or CD player
☐ Telephone (land line)
☐ Cell phone
☐ Fan
☐ Air conditioner
☐ Bicycle
☐ Motorcycle
☐ Car or truck

25. Do you personally own any of the following? (Include only if they are in working condition; include any items that were listed above)

☐ Cell phone
☐ Bicycle
☐ Motorcycle
☐ Car or truck

26. In the past year, did your household have problems satisfying the food needs of the household members?

☐ Never
☐ Seldom
☐ Sometimes
☐ Often
☐ Always

27. How do you compare the overall economic situation of your household compared with other households in your local area?

☐ Much worse now
☐ A little worse now
☐ Same
☐ A little better now
☐ Much better now
☐ Don't know

28. What is the material of the roof of the house?

☐ Mud
☐ Thatch
☐ Wood

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FORM 6 **METS-MICROBIOME** **SES**

Interviewer Initials: _____

- ☐ Iron/ Aluminum sheets
- ☐ Cement/ concrete
- ☐ Roofing tiles
- ☐ Asbestos
- ☐ Other (please name other roofing material:_____)

29. What is the material of the walls of the house?

- ☐ Mud/ mud brick
- ☐ Stone
- ☐ Burnt bricks
- ☐ Iron/ Aluminum sheets
- ☐ Cement/ sandcrete
- ☐ Wood/Bamboo
- ☐ Cardboard
- ☐ Dry Wall
- ☐ Other (please name other material :_____)

30. What is the main source of drinking water?

- ☐ Public piped into dwelling or compound
- ☐ Public outdoor tap or borehole
- ☐ Protected well
- ☐ Unprotected well or rain water
- ☐ River, lake, or pond
- ☐ Vendor, truck, or bottled
- ☐ Other (name other source :_____)

31. What type of toilet facility does your household have?

- ☐ None
- ☐ Flush
- ☐ Pan/bucket
- ☐ Covered pit latrine
- ☐ Uncovered pit latrine
- ☐ Ventilation improved pit latrine
- ☐ Other (please name other type:_____)

32. What is the main fuel used for cooking?

- ☐ Firewood
- ☐ Charcoal
- ☐ Kerosene/oil
- ☐ Gas
- ☐ Electricity
- ☐ Crop residue/ saw dust
- ☐ Animal waste
- ☐ Other (please name other fuel:_____)

33- 38. How many minutes does it take from your home to reach the nearest ...? (circle one)

	0-14	15-29	30-44	45-59	60+
33. Supply of drinking water:	1	2	3	4	5
34. Food market:	1	2	3	4	5
35. Public transportation:	1	2	3	4	5
36. Pharmacy:	1	2	3	4	5
37. Health clinic or hospital:	1	2	3	4	5
38. Primary School:	1	2	3	4	5

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FORM 7 **METS-MICROBIOME** **MICROBIOME FORM**

Interviewer Initials: _____ **Exam Date:** ____/_____/_____(MM/DD/YYYY)

General Lifestyle and Hygiene Information

1. Do you bite your fingernails? ☐ Yes ☐No

2. How often do you swim in a river/lake/swimming pool/hot tub?
   - ☐ Daily
   - ☐ Regularly (3-5 times/week)
   - ☐ Occasionally (1-2 times/week)
   - ☐ Rarely (few times/month)
   - ☐ Never

3. Do you have any animals inside your home?
   - ☐ Dog ☐ None
   - ☐ Cat ☐ Other _____

4. Do you have daily or weekly contact with some kind of animal that may be kept outside
   - ☐ Dog ☐ Chicken ☐ Sheep
   - ☐ Cat ☐ Goat ☐ Cow
   - ☐ Other _____

General Health Information

5. How many times do you have a bowel movement in an average day?
   - ☐ Less than one ☐ Two ☐ Four
   - ☐ One ☐ Three ☐ Five or more

6. Have you had diarrhea in the last 3 months? ☐ No ☐ Yes

7. Describe the quality of your bowel movements:
   - ☐ I tend to be constipated (have difficulty passing stool) – Type 1 and 2;
   - ☐ I tend to have diarrhea (watery stool) – Type 5, 6 and 7;
   - ☐ I tend to have normal formed stool – Type 3 and 4.

   Use the chart below as a reference:

8. I have taken antibiotics in the last _____.
   - ☐ Week (Name of antibiotic) _____
   - ☐ Month (Name of antibiotic) _____
   - ☐ 6 months
   - ☐ Year
   - ☐ I have not taken antibiotics in the past year.

9. I have received a flu vaccine in the last _____.
   - ☐ Week ☐ 6 months ☐ I have not gotten the flu vaccine in the past year.
   - ☐ Month ☐ Year

10. My weight has _____ within the last 6 months.

Participant ID: _____ V1_01/03/2018

FORM 7 **METS-MICROBIOME** **MICROBIOME FORM**

- ☐ Increased more than 10 pounds/6kg.
- ☐ Decreased more than 10 pounds/6kg.
- ☐ Remained stable

11. Have you had your tonsils removed?
    ☐ No ☐ Yes ☐ Not sure

12. Have you had you appendix removed?
    ☐ No ☐ Yes ☐ Not sure

13. Have you had chickenpox?
    ☐ No ☐ Yes ☐ Not sure

14. How were you fed as an infant?
    ☐ Primarily breast milk ☐ A mixture of breast milk and formula
    ☐ Primarily infant formula ☐ Not sure

15. Do you have seasonal allergies? ☐ No ☐Yes

16. Do you have any of the following non-food allergies? (check all that apply)
    ☐ Drug (e.g. Penicillin) ☐ Beestings ☐Sun
    ☐ Pet dander ☐ Poison ivy/oak

17. Are you intolerant to milk (lactose intolerant)? ☐ No ☐ Yes

18. Are you gluten intolerant?
    ☐ I was diagnosed with celiac disease
    ☐ I was diagnosed with gluten allergy (anti-gluten IgG), but not celiac disease
    ☐ I do not eat gluten because it makes me feel bad
    ☐ No

19. I am allergic to _____ (mark all that apply)
    ☐ Peanuts ☐ Shellfish
    ☐ Tree nuts ☐Other _____
    ☐ I have no food allergies that I know of.

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FORM 8 **METS-MICROBIOME** **DISCRIMINATION FORM**

Interviewer Initials: _____ **Exam Date: _____/_____/_____** (MM/DD/YYYY)

In your day-to-day life, how often do any of the following things happen to you?

1. You are treated with less courtesy than other people are.
   - ☐ Almost every day
   - ☐ At least once a week
   - ☐ A few times a month
   - ☐ A few times a year
   - ☐ Less than once a year
   - ☐ Never

2. You are treated with less respect than other people are.
   - ☐ Almost every day
   - ☐ At least once a week
   - ☐ A few times a month
   - ☐ A few times a year
   - ☐ Less than once a year
   - ☐ Never

3. You receive poorer service than other people at restaurants or stores.
   - ☐ Almost every day
   - ☐ At least once a week
   - ☐ A few times a month
   - ☐ A few times a year
   - ☐ Less than once a year
   - ☐ Never

4. People act as if they think you are not smart.
   - ☐ Almost every day
   - ☐ At least once a week
   - ☐ A few times a month
   - ☐ A few times a year
   - ☐ Less than once a year
   - ☐ Never

5. People act as if they are afraid of you.
   - ☐ Almost every day
   - ☐ At least once a week
   - ☐ A few times a month
   - ☐ A few times a year
   - ☐ Less than once a year
   - ☐ Never

6. People act as if they think you are dishonest.
   - ☐ Almost every day
   - ☐ At least once a week
   - ☐ A few times a month
   - ☐ A few times a year

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FORM 8 **METS-MICROBIOME** **DISCRIMINATION FORM**

- ☐ Less than once a year
- ☐ Never

7. People act as if they're better than you.
   - ☐ Almost every day
   - ☐ At least once a week
   - ☐ A few times a month
   - ☐ A few times a year
   - ☐ Less than once a year
   - ☐ Never

8. You are called names or insulted.
   - ☐ Almost every day
   - ☐ At least once a week
   - ☐ A few times a month
   - ☐ A few times a year
   - ☐ Less than once a year
   - ☐ Never

9. You are threatened or harassed.
   - ☐ Almost every day
   - ☐ At least once a week
   - ☐ A few times a month
   - ☐ A few times a year
   - ☐ Less than once a year
   - ☐ Never

Follow-up Question (Asked only of those answering, "A few times a year" or more frequently to at least one question): (Check more than one options if participant indicates)

What do you think is the main reason for these experiences?

- ☐ Your ancestry or national origins
- ☐ Your gender
- ☐ Your race
- ☐ Your religion
- ☐ Your height
- ☐ Your weight
- ☐ Some other aspect of your physical appearance
- ☐ Your education or income level

Participant ID: _____ v1_05/25/2018

Loyola University Chicago

METS – Microbiome Study

Results Form

Name: _____ **Date:** _____

Height: _____ft._____in._ **Weight:** _____lbs._

Age: _____

Body Mass Index (BMI): _____

Underweight	Below 18.5
Normal	18.5 – 24.9
Overweight	25.0 – 29.9
Obese	30.0 or Higher

National Heart, Lung, and Blood Institute (NHLBI), NIH

Blood Pressure #1: _____/_____ _____/_____ _____/_____

Blood Pressure #2: _____/_____ _____/_____ _____/_____

	Systolic (Top Number)		**Diastolic (Bottom Number)**
Normal	Below 120 mmHg	And	Below 80 mmHg
Pre - Hypertension	120 – 139 mmHg	Or	80 – 89 mmHg
Hypertension	140 or Higher	Or	90 or Higher

American Heart Association (AHA)

Blood Glucose Results: _____mg/dL_

Normal FASTING glucose	70 – 99 mg/dL
Normal glucose 2hrs after eating	70 – 145 mg/dL
Impaired fasting glucose (pre-diabetes)	100 – 125 mg/dL
Indicates diabetes	126 mg/dL & above on more than one occasion

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH

Fecal Occult Blood Test: _____

Negative	No blood was detected in your stool sample.
Positive	Blood was detected in your stool sample. You may need additional testing such as a colonoscopy to locate the source of the bleeding and rule out colon cancer, ulcers or hemorrhoids.

Mayo Clinic

C. Ethics Approval Documents

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room 45 E-52-E-Floor- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-submissions@uct.ac.za
Website: www.health.uct.ac.za/home/human-research-ethics

17 October 2022

HREC REF: 632/2022

Prof L Dugas
Division of Epidemiology & Biostatistics
Room 5.37 Falmouth Building-FHS
Email: Lara.dugas@uct.ac.za
Student: dvsjes009@myuct.ac.za

Dear Prof Dugas

PROJECT TITLE: A COMPARISON OF SELF-REPORT VERSUS OBJECTIVELY MEASURED PHYSICAL ACTIVITY IN AFRICAN-ORIGIN ADULTS AND THE ROLE OF ADIPOSITY: A PROSPECTIVE COHORT STUDY-SUB-STUDY LINKED TO 696/2014- (MASTERS CANDDIATE-MISS JESSICA DAVIES)

Thank you for your response letter, addressing the issues raised by the Faculty of Health Sciences Human Research Ethics Committee (HREC).

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

Approval is granted for one year until the 30 October 2023.

Please submit a progress form, using the standardised Annual Report Form (FHS016) if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Miss Jessica Davies will also be involved in this study.

Please quote the HREC REF 632/2022 in all your correspondence.

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

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

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE

HREC/ref 632.2022

Federal Wide Assurance Number: FWA00001637. Institutional Review Board (IRB) number: IRB00001938 NHREC-registration number: REC-210208-007
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2020), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC/ref 632.2022

D. Informed Consent Forms from the parent study

IRB NUMBER: 209537021517

LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES DIVISION
MAYWOOD, ILLINOIS
DEPARTMENT OF

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE: Gut microbiota, short chain fatty acids, and adiposity across the epidemiologic transition.

THE APPROVAL FOR THIS PROJECT EXPIRES ON 01/16/2020.

Participant Information

PRINCIPLES CONCERNING RESEARCH: You are being asked to take part in a research project. It is important that you read and understand the principles that apply to all individuals who agree to participate in the research project described below:

1. Taking part in the research is entirely voluntary.
2. We do not know if you will benefit from taking part in the research but the knowledge obtained may help others.
3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.
4. If during your participation in the research project new information becomes available which would affect your being in the research project, your doctor will discuss this new information with you and will help you make a decision about your continuing in the research.

The purpose of the research, how it is to be done, and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

PURPOSE OF RESEARCH: You are being asked to participate in this study because we are investigating the relationship between the bacteria in your gut, short chain fatty acids and the risk for the development of obesity, diabetes and cardiovascular disease.

Document ID#: 209537am20.070919
Version Date: 07/09/2019

This research is sponsored by the Department of Public Health Sciences, Loyola University Chicago. Components of this project are also being conducted by researchers at the University of West Indies, Kingston, Jamaica; Kwame Nkrumah University of Science and Technology, Ghana; Minstry of Heatlth, Victoria, Seychelles, and the University of Cape Town, Cape Town, South Africa

Approximately 500 people will participate in this research.

The goal of this research is not to diagnose or treat any problems you may have. Therefore, participation in this study is not a substitute for the care you are receiving from your doctor. During the time you are in this study you should continue to see your doctor or if you have a problem contact your doctor.

DESCRIPTION AND EXPLANATION OF PROCEDURES: If you agree to participate in this study, you will complete the following research procedures outlined below.

Your initial participation in the study will last 8 days; you will be contacted for a follow-up visit each for two years from your initial visit. Your participation in the last year will also last 8 days.

Procedures for initial visit:

Time involved:
Day 1 - you will be at the clinic for about 2.5 hrs
Day 8 - you will be at the clinic for about 45 minutes
1 year later - you will be at the clinic for about 45 minutes
2 years later - Day 1; you will be at the clinic for about 1.5 hrs
2 years later - Day 8; you will be at the clinic for about 45 minutes.
3 years later – you will be at the clinic for about 45 minutes.
4 years later – you will be at the clinic for about 45 minutes.

During the initial visit:
1. We ask that you arrive at the clinic after not eating anything from 10pm in the evening before your visit.

2. We will ask you about foods you have eaten in the last 24 hours. We will do this twice, separated by 7 days. This information will allow us to calculate your daily food calories, the time at which you eat 50% of your calories, and the types of foods that you eat.

We will also ask you about your activity patterns, your health and sleep habits, as well as your personal wellbeing.

3. We will take the following body measurements: height, weight, blood pressure, waist, hip, and percent body fat. Body fat will be measured by bioimpendance analysis. With this method, we will place 4 electrodes on your hands and feet, and apply a small amount of electricity to measure

the amount of water in the body. This test does not cause any pain or discomfort. If you have a pacemaker, you will be excluded from having your body fat measured and from the bone scan.

4. You will either have an IV catheter placed in your arm or you will undergo phlebotomy to provide blood samples. If you receive an IV catheter, it will be flushed with 0.9% normal saline following each blood draw.

5. Three tablespoons of blood will be drawn to measure substances in the blood that may be related to diabetes, nutritional status and cardiovascular disease.

6. You will be asked to provide a urine sample. We will use this urine sample to check your kidney function.

7. You will be given a stool collection kit and the clinic staff will detail the collection method. You will be instructed to provide the sample in the preceeding 24 hrs prior to your second clinic visit.

8. You will complete a standard oral glucose tolerance test. You will be given a sugar solution to drink and we will measure the sugar in your blood after 30, 60 and 120 mins. The total amount of blood is one table spoon.

9. An activity monitor will be strapped around your waist by a staff member. This monitor is the size of a watch and is attached to an elastic belt. The activity monitor measures physical activity patterns. You will be instructed to wear the monitor at all times during the next 7 days, including during the night unless you are unable to sleep with it on. You will be asked to remove the monitor for bathing and swimming and to avoid completely submerging the monitor in water.

10. You may have two skin sensitivity tests to evaluate your risk for nerve damage from having prediabetes or diabetes. These tests will be performed by a study physician. The first test uses tiny wire filaments, which will individually be gently pressed on your hand until you feel the pressure from the wire filaments. During the second test, the physician will use a safety pin, and gently press both the sharp and dull side onto your hand to evaluate your skin sensation.

11. You may be asked to wear a sleep monitor around your wrist. This measurement may coincide with either first, second or third year follow-up. The monitor is the size of a watch and is attached by a velcro band. The sleep monitor will record your sleep patterns. You will be instructed to wear the sleep monitor at all times during the next 7 days, including at night. You will be asked to remove the sleep monitor for bathing and swimming and to avoid completely submerging the monitor in water.

11. You will be given a light snack and may leave the clinic.

After the first visit:

After the first night, a staff member will call you at a phone number you provide to insure that you are comfortable with the monitor and to answer any questions you may have.

7 days later (Day 8): You will be asked to return to the clinic. You will bring the stool sample, collected in the preceding 24hrs with you. You will have the activity and sleep monitor removed, and you will be asked about the foods you have eaten the previous 24 hours.

1 year later (Day 1): You will be contacted and asked to return to the clinic. We will measure your weight, blood pressure, waist, hip and percent body fat and the bone mineral content as you had at the beginning of the study.

2 years later (Day 1): You will be contacted and asked to return to the clinic. We ask that you refrain from eating from 10pm in the evening before your clinic visit. We will measure your weight, blood pressure, waist, hip and percent body fat and bone mineral content. We wills strap a monitor to your waist, and a sleep monitor to your wrist and ask you some health, physical activity and dietary questions. You will have two tablespoons of blood drawn, and we will provide you with a stool collection kit. We will provide you with a snack, and you will be free to leave the clinic.

2 years later (Day 8): You will be asked to return to the clinic. You will bring the stool sample, collected in the preceding 24hrs with you. You will have the activity and sleep monitors removed, and you will be asked about the foods you have eaten the previous 24 hours.

3 years later (Day 1): You will be contacted and asked to return to the clinic. We will measure your weight, blood pressure, waist, hip and percent body fat as you had at the beginning of the study.

4 years later (Day 1): You will be contacted and asked to return to the clinic. We will measure your weight, blood pressure, waist, hip and percent body fat as you had at the beginning of the study.

RISKS/DISCOMFORTS: There are no risks with having your percent body fat measured. In addition, there are no risks from wearing an activity or sleep monitor. You may experience a minor and temporary discomfort and bruising at the site of the blood draw or IV catheter site. You may experience an infection at the site of the blood draw or IV catheter site. You may feel lightheaded during the OGTT test. If you participate in the skin sensitivity tests, you may experience some discomfort at the site where the wire filaments or safety pin is pressed onto your skin.

There is a small risk of loss of confidentiality.

REPRODUCTIVE AND SEXUAL ACTIVITY INFORMATION: The intervention in this study could affect a developing baby. Therefore, you cannot participate in this research project if you are pregnant at the time that you would start the study.

BENEFITS: Your participation will help us better understand the relationships between the composition of bacteria in your gut and your health, short chain fatty acids and the risk for obesity, diabetes and cardiovascular disease. It is unlikely that you will benefit directly from being in this research project. We will notify you if the blood test indicates high blood sugar or fat, or if your blood pressure is high. We will inform you if you have an increased risk of kidney disease based on results from your blood test and urine test. We will not provide any additional evaluations but would recommend that you see your doctor to discuss the results.

ALTERNATIVES: You do not have to participate in this project if you do not want to.

FINANCIAL INFORMATION: To compensate you for the time spent in the study, you will be given $75.00. Compensation will be provided at the clinic on Day 8. You will be compensated $20.00 for the time spent in the study for the 1-year follow-up study. You will be compensated $75.00 for the time spent in the study for the 2-year follow-up study. You will receive this payment at the clinic on Day 8. You will be compensated $20.00 for the visit during the 3rd year follow-up and $20.00 for the visit during the 4th year. If you participate in the skin sensitivity test, you will receive an additional $30.00. If you participate in the 7-day sleep monitoring activity, you will receive an additional $75.00. If you receive payment for participating in this research, personal information about you, including your name, address, and Social Security number, will be released to the Loyola University Chicago Accounting Office for the purpose of recording the payment and for tax reporting to the United States Internal Revenue Service (IRS). You will need to complete a W-9 form. This form will be provided to you. If you choose not to complete the W-9, you will not receive reimbursement.

You will not charged for any of the tests that are performed in this research project. In the event we recommend that you see your doctor for additional testing because of abnormal results obtained from the study tests, you will be financially responsible for the cost of care.

RESEARCH RELATED INJURY: In the event that you are injured or have side effects as a result of participating in this research project, there are no funds available from Loyola University Chicago to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems. By signing this form, you are not giving up any legal rights to seek to obtain compensation of injury. .

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, and your research test results. The information will be collected by Lara Dugas, Ph.D., MPH, and the research staff.

Information about you will be provided to Loyola University Chicago; The National Institutes of Health (the research sponsor); data collection and study verification agencies.

In this way, we will learn about the relationships between the gut microbiota, short chain fatty acids and the risk for obesity, diabetes and cardiovascular disease.

The information we will collect and send includes:

- X DEMOGRAPHIC AND QUESTIONNAIRE INFORMATION (e.g., name, address, phone number, physical activity patterns, health, sleep, wellbeing, and foods eaten)
- X PHYSICAL AND SLEEP ACTIVITY MEASUREMENTS
- X BODY MEASUREMENTS (e.g. blood pressure, weight, height, waist, hip, and percent body fat)
- X URINE AND BLOOD SAMPLES
- X SALIVA AND STOOL SAMPLES

We will collect and provide this information about you for as long as you are in the study which will be about 3 years.

It is possible that the sponsor, The National Institutes of Health, research nurses, data collection and/or study verification agencies, data administrators or staff. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUC to use and disclose your medical information is required in order for you to participate in the study.

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.[2]
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

WITHDRAWAL OF CONSENT: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent for LUMC to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at LUMC unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by LUMC and the sponsor.

If you withdraw from the study, we will ask that you sign the form attached to this consent and send it to Lara Dugas, Ph.D., MPH or give it to the study staff. Your withdrawal from the study will not have any effect on any actions by LUC taken before the attached form is received by LUC.

Your study doctor, the Institutional Review Board, the regulatory authorities, or the sponsor, The National Institutes of Health, may terminate the study at any time with or without your consent.

CONSENT

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-327-9029.

_____Date:____/_____/____
Signature

Lara Dugas, Ph.D., MPH, the principal investigator for this study, or her associates will be available to answer any questions you may have. Dr. Dugas can be reached at: 708-327-9029.

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Division, at 708-216-4608.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

Document ID#: 209537am20.070919
Version Date: 07/09/2019

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

Document ID#: 209537am20.070919
Version Date: 07/09/2019

IRB NUMBER: 209537021517

LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES DIVISION
MAYWOOD, ILLINOIS
DEPARTMENT OF

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE: Gut microbiota, short chain fatty acids, and adiposity across the epidemiologic transition.

THE APPROVAL FOR THIS PROJECT EXPIRES ON 01/16/2020.

Participant Information

PRINCIPLES CONCERNING RESEARCH: You are being asked to take part in a research project. It is important that you read and understand the principles that apply to all individuals who agree to participate in the research project described below:

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4. If during your participation in the research project new information becomes available which would affect your being in the research project, your doctor will discuss this new information with you and will help you make a decision about your continuing in the research.

The purpose of the research, how it is to be done, and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

PURPOSE OF RESEARCH: You are being asked to participate in this study because we are investigating the relationship between the bacteria in your gut, short chain fatty acids and the risk for the development of obesity, diabetes and cardiovascular disease.

Document ID#: 209537am20.070919
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This research is sponsored by the Department of Public Health Sciences, Loyola University Chicago. Components of this project are also being conducted by researchers at the University of West Indies, Kingston, Jamaica; Kwame Nkrumah University of Science and Technology, Ghana; Minstry of Heatlth, Victoria, Seychelles, and the University of Cape Town, Cape Town, South Africa

Approximately 500 people will participate in this research.

The goal of this research is not to diagnose or treat any problems you may have. Therefore, participation in this study is not a substitute for the care you are receiving from your doctor. During the time you are in this study you should continue to see your doctor or if you have a problem contact your doctor.

DESCRIPTION AND EXPLANATION OF PROCEDURES: If you agree to participate in this study, you will complete the following research procedures outlined below.

Your initial participation in the study will last 8 days; you will be contacted for a follow-up visit each for two years from your initial visit. Your participation in the last year will also last 8 days.

Procedures for initial visit:

Time involved:
Day 1 - you will be at the clinic for about 2.5 hrs
Day 8 - you will be at the clinic for about 45 minutes
1 year later - you will be at the clinic for about 45 minutes
2 years later - Day 1; you will be at the clinic for about 1.5 hrs
2 years later - Day 8; you will be at the clinic for about 45 minutes.
3 years later – you will be at the clinic for about 45 minutes.
4 years later – you will be at the clinic for about 45 minutes.

During the initial visit:
1. We ask that you arrive at the clinic after not eating anything from 10pm in the evening before your visit.

2. We will ask you about foods you have eaten in the last 24 hours. We will do this twice, separated by 7 days. This information will allow us to calculate your daily food calories, the time at which you eat 50% of your calories, and the types of foods that you eat.

We will also ask you about your activity patterns, your health and sleep habits, as well as your personal wellbeing.

3. We will take the following body measurements: height, weight, blood pressure, waist, hip, and percent body fat. Body fat will be measured by bioimpendance analysis. With this method, we will place 4 electrodes on your hands and feet, and apply a small amount of electricity to measure

the amount of water in the body. This test does not cause any pain or discomfort. If you have a pacemaker, you will be excluded from having your body fat measured and from the bone scan.

4. You will either have an IV catheter placed in your arm or you will undergo phlebotomy to provide blood samples. If you receive an IV catheter, it will be flushed with 0.9% normal saline following each blood draw.

5. Three tablespoons of blood will be drawn to measure substances in the blood that may be related to diabetes, nutritional status and cardiovascular disease.

6. You will be asked to provide a urine sample. We will use this urine sample to check your kidney function.

7. You will be given a stool collection kit and the clinic staff will detail the collection method. You will be instructed to provide the sample in the preceeding 24 hrs prior to your second clinic visit.

8. You will complete a standard oral glucose tolerance test. You will be given a sugar solution to drink and we will measure the sugar in your blood after 30, 60 and 120 mins. The total amount of blood is one table spoon.

9. An activity monitor will be strapped around your waist by a staff member. This monitor is the size of a watch and is attached to an elastic belt. The activity monitor measures physical activity patterns. You will be instructed to wear the monitor at all times during the next 7 days, including during the night unless you are unable to sleep with it on. You will be asked to remove the monitor for bathing and swimming and to avoid completely submerging the monitor in water.

10. You may have two skin sensitivity tests to evaluate your risk for nerve damage from having prediabetes or diabetes. These tests will be performed by a study physician. The first test uses tiny wire filaments, which will individually be gently pressed on your hand until you feel the pressure from the wire filaments. During the second test, the physician will use a safety pin, and gently press both the sharp and dull side onto your hand to evaluate your skin sensation.

11. You may be asked to wear a sleep monitor around your wrist. This measurement may coincide with either first, second or third year follow-up. The monitor is the size of a watch and is attached by a velcro band. The sleep monitor will record your sleep patterns. You will be instructed to wear the sleep monitor at all times during the next 7 days, including at night. You will be asked to remove the sleep monitor for bathing and swimming and to avoid completely submerging the monitor in water.

11. You will be given a light snack and may leave the clinic.

After the first visit:

After the first night, a staff member will call you at a phone number you provide to insure that you are comfortable with the monitor and to answer any questions you may have.

7 days later (Day 8): You will be asked to return to the clinic. You will bring the stool sample, collected in the preceding 24hrs with you. You will have the activity and sleep monitor removed, and you will be asked about the foods you have eaten the previous 24 hours.

1 year later (Day 1): You will be contacted and asked to return to the clinic. We will measure your weight, blood pressure, waist, hip and percent body fat and the bone mineral content as you had at the beginning of the study.

2 years later (Day 1): You will be contacted and asked to return to the clinic. We ask that you refrain from eating from 10pm in the evening before your clinic visit. We will measure your weight, blood pressure, waist, hip and percent body fat and bone mineral content. We wills strap a monitor to your waist, and a sleep monitor to your wrist and ask you some health, physical activity and dietary questions. You will have two tablespoons of blood drawn, and we will provide you with a stool collection kit. We will provide you with a snack, and you will be free to leave the clinic.

2 years later (Day 8): You will be asked to return to the clinic. You will bring the stool sample, collected in the preceding 24hrs with you. You will have the activity and sleep monitors removed, and you will be asked about the foods you have eaten the previous 24 hours.

3 years later (Day 1): You will be contacted and asked to return to the clinic. We will measure your weight, blood pressure, waist, hip and percent body fat as you had at the beginning of the study.

4 years later (Day 1): You will be contacted and asked to return to the clinic. We will measure your weight, blood pressure, waist, hip and percent body fat as you had at the beginning of the study.

RISKS/DISCOMFORTS: There are no risks with having your percent body fat measured. In addition, there are no risks from wearing an activity or sleep monitor. You may experience a minor and temporary discomfort and bruising at the site of the blood draw or IV catheter site. You may experience an infection at the site of the blood draw or IV catheter site. You may feel lightheaded during the OGTT test. If you participate in the skin sensitivity tests, you may experience some discomfort at the site where the wire filaments or safety pin is pressed onto your skin.

There is a small risk of loss of confidentiality.

REPRODUCTIVE AND SEXUAL ACTIVITY INFORMATION: The intervention in this study could affect a developing baby. Therefore, you cannot participate in this research project if you are pregnant at the time that you would start the study.

BENEFITS: Your participation will help us better understand the relationships between the composition of bacteria in your gut and your health, short chain fatty acids and the risk for obesity, diabetes and cardiovascular disease. It is unlikely that you will benefit directly from being in this research project. We will notify you if the blood test indicates high blood sugar or fat, or if your blood pressure is high. We will inform you if you have an increased risk of kidney disease based on results from your blood test and urine test. We will not provide any additional evaluations but would recommend that you see your doctor to discuss the results.

ALTERNATIVES: You do not have to participate in this project if you do not want to.

FINANCIAL INFORMATION: To compensate you for the time spent in the study, you will be given $75.00. Compensation will be provided at the clinic on Day 8. You will be compensated $20.00 for the time spent in the study for the 1-year follow-up study. You will be compensated $75.00 for the time spent in the study for the 2-year follow-up study. You will receive this payment at the clinic on Day 8. You will be compensated $20.00 for the visit during the 3rd year follow-up and $20.00 for the visit during the 4th year. If you participate in the skin sensitivity test, you will receive an additional $30.00. If you participate in the 7-day sleep monitoring activity, you will receive an additional $75.00. If you receive payment for participating in this research, personal information about you, including your name, address, and Social Security number, will be released to the Loyola University Chicago Accounting Office for the purpose of recording the payment and for tax reporting to the United States Internal Revenue Service (IRS). You will need to complete a W-9 form. This form will be provided to you. If you choose not to complete the W-9, you will not receive reimbursement.

You will not charged for any of the tests that are performed in this research project. In the event we recommend that you see your doctor for additional testing because of abnormal results obtained from the study tests, you will be financially responsible for the cost of care.

RESEARCH RELATED INJURY: In the event that you are injured or have side effects as a result of participating in this research project, there are no funds available from Loyola University Chicago to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems. By signing this form, you are not giving up any legal rights to seek to obtain compensation of injury. .

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, and your research test results. The information will be collected by Lara Dugas, Ph.D., MPH, and the research staff.

Information about you will be provided to Loyola University Chicago; The National Institutes of Health (the research sponsor); data collection and study verification agencies.

In this way, we will learn about the relationships between the gut microbiota, short chain fatty acids and the risk for obesity, diabetes and cardiovascular disease.

The information we will collect and send includes:

- X DEMOGRAPHIC AND QUESTIONNAIRE INFORMATION (e.g., name, address, phone number, physical activity patterns, health, sleep, wellbeing, and foods eaten)
- X PHYSICAL AND SLEEP ACTIVITY MEASUREMENTS
- X BODY MEASUREMENTS (e.g. blood pressure, weight, height, waist, hip, and percent body fat)
- X URINE AND BLOOD SAMPLES
- X SALIVA AND STOOL SAMPLES

We will collect and provide this information about you for as long as you are in the study which will be about 3 years.

It is possible that the sponsor, The National Institutes of Health, research nurses, data collection and/or study verification agencies, data administrators or staff. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUC to use and disclose your medical information is required in order for you to participate in the study.

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.[2]
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

WITHDRAWAL OF CONSENT: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent for LUMC to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at LUMC unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by LUMC and the sponsor.

If you withdraw from the study, we will ask that you sign the form attached to this consent and send it to Lara Dugas, Ph.D., MPH or give it to the study staff. Your withdrawal from the study will not have any effect on any actions by LUC taken before the attached form is received by LUC.

Your study doctor, the Institutional Review Board, the regulatory authorities, or the sponsor, The National Institutes of Health, may terminate the study at any time with or without your consent.

CONSENT

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-327-9029.

_____Date:____/_____/____
Signature

Lara Dugas, Ph.D., MPH, the principal investigator for this study, or her associates will be available to answer any questions you may have. Dr. Dugas can be reached at: 708-327-9029.

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Division, at 708-216-4608.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

Document ID#: 209537am20.070919
Version Date: 07/09/2019

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

Document ID#: 209537am20.070919
Version Date: 07/09/2019

PROJECT TITLE: Gut microbiota, short chain fatty acids, and adiposity across the epidemiologic transition.

REVOCATION OF AUTHORIZATION TO
RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the study titled, "Gut microbiota, short chain fatty acids, and adiposity across the epidemiologic transition.", at Loyola University Medical Center ("LUMC"). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information to The National Institutes of Health as outlined on the consent form, which I signed on ____/_____/____ (INSERT DATE CONSENT WAS SIGNED ORIGINALLY). I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

_____Date:____/_____/____
Signature: Participant

Please return this form to:

Dr Lara Dugas
Loyola University Chicago
2160 South First Avenue
Maywood, Illinois 60153

IRB NUMBER: 211585011819

LOYOLA UNIVERSITY MEDICAL CENTER
MAYWOOD, ILLINOIS
DEPARTMENT OF PUBLIC HEALTH SCIENCES

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE: Gut microbiota, short chain fatty acids, and adiposity across the epidemiologic transition Biospecimen Repository.

This project will undergo re-review on or before 01/18/2020.

General Repository Information

As part of your enrollment in the METS-Microbiome research study, you are being asked to give a biospecimen (or sample) to a repository for possible future research.

It is important that you understand that:

1. Taking part in the repository is research and is voluntary. You do not have to give a sample to the repository if you do not want to. Your decision about participation will not affect your care or treatment at Loyola University Medical Center (LUMC).

2. You will not benefit from giving a sample to the repository but the knowledge obtained may help others.

3. You may withdraw your sample from the repository at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

The purpose of the research and how it is to be done and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not you wish to participate. Please take your time to make your decision. You are urged to discuss any questions you have about this research with the staff members.

Document ID#: 211585r3.011819
Version Date: 01/18/2019

PURPOSE OF RESEARCH: You are being asked to allow us to store a biospecimen (or sample) for possible use in future research. How your specimen(s) will be collected and, the amount to be collected, are explained to you in a separate Informed Consent Document. This consent document only explains how the material will be stored and used. The laboratory freezer where we store the sample is called a repository. If you agree, these specimens will be kept and stored in the laboratory and may be used in future research projects to learn more about diseases. Many different kinds of studies use samples from patients for research.

Some research may develop new tests to find diseases. Other research may find out more about the causes of disease and/or develop new ways to treat or even cure diseases.

Some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your specimen may look at genetic causes and signs of disease. Even if your specimens are used for this kind of research, the results will not be put in your health record.

DESCRIPTION AND EXPLANATION OF PROCEDURES: We are asking your consent to store your left over samples for future tests. These additional tests may include a newly discovered plasma, serum or urine analyte, an analyte recently linked to the disease of interest, or newly identified genetic markers for that disease/condition. Retaining samples collected at great expense from well-defined populations is critical to advancing our understanding of chronic disease – physiologically, genetically and environmentally. The physiologic samples collected during research studies provide the basis for future research.

The use of genetic material collected during population-based research has the potential to greatly advance our understanding of determinants of chronic disease, however, there are additional risks to the research participant. These include inappropriate release of genetic information to outside sources, e.g., insurance companies. Every effort will be made to prevent such occurrences by de-identification of genetic material when used for exploratory analyses. No results of genetic testing will be released whether the samples are de-identified or not.

The repository will retain coded biospecimens with relevant accompanying coded medical record data. This means that individuals who are participating in a procedure involving the collection of a biological specimen may be asked to contribute some or all of that specimen to the repository.

All biospecimens are given to the repository by individuals through their clinicians who collect these specimens as part of an individual's participation in an IRB approved research study

Future research that may be done on your specimen may include "genetic testing". This is a test of a person's DNA (heredity). The results of any genetic testing that are done will not be given to you or your doctor. The results will not be placed in your medical record.

We will collect from your medical record information about you and your diagnosis, including your age, height, weight, race, ethnicity, sex, and related laboratory data for use in future research studies. However, this data will be coded such that it will not be possible to readily identify you. A unique identification (ID) number will be used to code your samples and information to protect your identity.

These studies are for research efforts only and will not influence the treatment of your disease. Because these are research studies, you and your doctor will not be notified of the results of any tests that are done. The results of research tests will not be placed in your medical record.

The samples will not be sold although we may charge other researchers that use your samples for the cost of storing the samples. The samples may be stored indefinitely or may be properly disposed of at a later date in accordance with state and federal law. Loyola University Chicago may continue to use your information from any research performed that used your sample indefinitely.

If a researcher wishes to use the sample in the repository for a research project, he or she will request permission from Loyola's research review board called the "Loyola University Chicago Health Science Division Institutional Review Board for the Protection of Human Subjects Institutional Review Board" (IRB). The IRB is a group of individuals whose responsibility is to review, approve, and monitor human subject research. They help to protect the rights and welfare of the research participants. The IRB may require the researcher to contact you to get your further permission.

The researchers who use your sample and the information about you may be local or part of a worldwide network of cooperative researchers. Any sample given to researchers outside Loyola will never have your name or any other identifying information on it.

The results of a research project using your sample and information from your medical record may be published in a journal to advance medical knowledge. You will not be identified by name or any other identifying information in any reports about this research.

METHODS

a) Blood, urine and stool samples from the METS-Microbiome research project are assigned a unique identifier when collected. The label contains only the assigned number. All tubes, both pre- and post-processing, are labeled only with this number.

b) After all study-approved tests are performed on the collected plasma, serum and buffy coat samples and urine and stool samples, the remainder will be transferred to the repository area in the Public Health Sciences lab freezer (-80°C).

Inclusion/exclusion criteria: All consented participants currently enrolled in METS-Microbiome (LU209537) will be invited to store their left over blood, urine, and stool samples in the METS-Microbiome repository. Only METS-Microbiome study participants will be asked whether they will be willing to participate in the repository.

DATA COLLECTION

METS-Microbiome is not affiliated with Loyola University Medical Center patient, instead this community-based projects recruits participants from the neighboring community. Research participant files linking identification number and confidential information are kept only by the department's data manager and project coordinator in a password-protected file. The password-protected key linking data to participants is kept separately to the data files. For the repository, samples will be identified by the unique, study assigned identification number, in order to be linked with the participant data.

RISKS and DISCOMFORTS: While every effort will be made to protect your identity and health information, there is a small risk of loss of confidentiality that information about your health might become known to individuals outside the repository. Genetic testing can create information about a person's and his/her families' personal health risks and can cause or increase anxiety, and/or interfere with your ability to get insurance or a job, and can even lead to discrimination.

To further protect privacy, the repository has obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). This Certificate means that the repository staff cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. The repository staff will use the Certificate to resist any demands for information that would identify you **UNLESS (1)** the United States Government is auditing or evaluating federally funded projects or information must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA), **(2)** you give written consent to release certain information or directly inform others that you are participating, and **(3)** repository staff are not prevented from taking steps, including reporting to appropriate authorities, to prevent serious harm to a you or others.

You may receive a copy of the Certificate of Confidentiality upon request. If you would like a copy of the Certificate of Confidentiality, please contact Dr. Lara Dugas via email at ldugas@luc.edu.

Document ID#: 211585r3.011819
Version Date: 01/18/2019

FINANCIAL INFORMATION: It will not cost you anything to participate in this research project. The specimens will be collected from procedures as described in a separate consent document. You will not receive any money for participating in this project or future research done with your sample. The research done with your specimens may lead to the development of new profitable products in the future. You will not share in any profits.

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: We will collect information on you, your test results, and how you do. The information will be collected by the biorepository with the help of Loyola data administrators and staff. Information about you will be provided to Loyola University Chicago and their data collection and study verification agencies and/or government regulatory agencies such as the Food and Drug Administration or the Loyola University Chicago Health Sciences Institutional Review Board or State of Illinois Auditors. They may also see and make copies of study information (such as the consent form) which identifies you.

The information we will collect and send includes:

1. Demographic information including, but not limited to, your name, address, phone number, etc.

2. Biospecimens

We will collect and provide this information about you indefinitely or for as long as you willing to participate. It is important to note that, once information is disclosed outside of LUMC, it may no longer be protected by federal privacy laws. Your consent for LUMC to use and disclose your medical information is required in order for you to give your sample to this repository.

WITHDRAWAL: This authorization does not expire, but you are free to withdraw your consent and discontinue participation in the repository at any time without affecting your care at LUMC. If you decide to withdraw your consent, we will destroy your specimens and your demographic and clinical information will also be destroyed from the research repository. We will continue to use the results of any tests that are already done. It may not be possible to retrieve specimens and clinical information that have already been given to other researchers. If you decide to withdraw your consent, please sign the form at the back of this consent.

The repository investigator, the Institutional Review Board, and/or regulatory authorities may terminate the repository at any time with or without your consent. This may happen, for example, if the repository loses funding.

CONSENT: I have fully explained to _____ the nature and purpose of the above- described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability.

_____Date:____/_____/____
Signature

Lara Dugas, Ph.D., MPH, the principal investigator for this repository, or her associates will be available to answer any questions you may have. Dr. Dugas can be reached at 708-327-9029. If you ever feel that you have been injured by participating in this repository or, if you have any questions concerning your rights as a research participant, you may contact either Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Division, at 708-216-4608 or Cynthia Tom-Klebba, MSN, Director of the Human Research Subjects Protection Program at 708-216-6198.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

_____Date:____/_____/_____
Signature: Witness

Document ID#: 211585r3.011819
Version Date: 01/18/2019

Gut microbiota, short chain fatty acids, and adiposity across the epidemiologic transition
Biospecimen Repository

REVOCATION OF AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the METS-Microbiome Biospecimen Repository at Loyola University Medical Center ("LUMC"). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information as outlined on the consent form, which I signed on _____. I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

_____ _____
Patient Name or Personal Representative Date

Please return this form to:

Dr. Lara Dugas
Loyola University Chicago
2160 South First Avenue
Maywood, Illinois 60153

Document ID#: 211585r3.011819
Version Date: 01/18/2019

IRB NUMBER: 211585011819

LOYOLA UNIVERSITY MEDICAL CENTER
MAYWOOD, ILLINOIS
DEPARTMENT OF PUBLIC HEALTH SCIENCES

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE: Gut microbiota, short chain fatty acids, and adiposity across the epidemiologic transition Biospecimen Repository.

This project will undergo re-review on or before 01/18/2020.

General Repository Information

As part of your enrollment in the METS-Microbiome research study, you are being asked to give a biospecimen (or sample) to a repository for possible future research.

It is important that you understand that:

1. Taking part in the repository is research and is voluntary. You do not have to give a sample to the repository if you do not want to. Your decision about participation will not affect your care or treatment at Loyola University Medical Center (LUMC).

2. You will not benefit from giving a sample to the repository but the knowledge obtained may help others.

3. You may withdraw your sample from the repository at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

The purpose of the research and how it is to be done and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not you wish to participate. Please take your time to make your decision. You are urged to discuss any questions you have about this research with the staff members.

Document ID#: 211585r3.011819
Version Date: 01/18/2019

PURPOSE OF RESEARCH: You are being asked to allow us to store a biospecimen (or sample) for possible use in future research. How your specimen(s) will be collected and, the amount to be collected, are explained to you in a separate Informed Consent Document. This consent document only explains how the material will be stored and used. The laboratory freezer where we store the sample is called a repository. If you agree, these specimens will be kept and stored in the laboratory and may be used in future research projects to learn more about diseases. Many different kinds of studies use samples from patients for research.

Some research may develop new tests to find diseases. Other research may find out more about the causes of disease and/or develop new ways to treat or even cure diseases.

Some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your specimen may look at genetic causes and signs of disease. Even if your specimens are used for this kind of research, the results will not be put in your health record.

DESCRIPTION AND EXPLANATION OF PROCEDURES: We are asking your consent to store your left over samples for future tests. These additional tests may include a newly discovered plasma, serum or urine analyte, an analyte recently linked to the disease of interest, or newly identified genetic markers for that disease/condition. Retaining samples collected at great expense from well-defined populations is critical to advancing our understanding of chronic disease – physiologically, genetically and environmentally. The physiologic samples collected during research studies provide the basis for future research.

The use of genetic material collected during population-based research has the potential to greatly advance our understanding of determinants of chronic disease, however, there are additional risks to the research participant. These include inappropriate release of genetic information to outside sources, e.g., insurance companies. Every effort will be made to prevent such occurrences by de-identification of genetic material when used for exploratory analyses. No results of genetic testing will be released whether the samples are de-identified or not.

The repository will retain coded biospecimens with relevant accompanying coded medical record data. This means that individuals who are participating in a procedure involving the collection of a biological specimen may be asked to contribute some or all of that specimen to the repository.

All biospecimens are given to the repository by individuals through their clinicians who collect these specimens as part of an individual's participation in an IRB approved research study

Document ID#: 211585r3.011819
Version Date: 01/18/2019

Future research that may be done on your specimen may include "genetic testing". This is a test of a person's DNA (heredity). The results of any genetic testing that are done will not be given to you or your doctor. The results will not be placed in your medical record.

We will collect from your medical record information about you and your diagnosis, including your age, height, weight, race, ethnicity, sex, and related laboratory data for use in future research studies. However, this data will be coded such that it will not be possible to readily identify you. A unique identification (ID) number will be used to code your samples and information to protect your identity.

These studies are for research efforts only and will not influence the treatment of your disease. Because these are research studies, you and your doctor will not be notified of the results of any tests that are done. The results of research tests will not be placed in your medical record.

The samples will not be sold although we may charge other researchers that use your samples for the cost of storing the samples. The samples may be stored indefinitely or may be properly disposed of at a later date in accordance with state and federal law. Loyola University Chicago may continue to use your information from any research performed that used your sample indefinitely.

If a researcher wishes to use the sample in the repository for a research project, he or she will request permission from Loyola's research review board called the "Loyola University Chicago Health Science Division Institutional Review Board for the Protection of Human Subjects Institutional Review Board" (IRB). The IRB is a group of individuals whose responsibility is to review, approve, and monitor human subject research. They help to protect the rights and welfare of the research participants. The IRB may require the researcher to contact you to get your further permission.

The researchers who use your sample and the information about you may be local or part of a worldwide network of cooperative researchers. Any sample given to researchers outside Loyola will never have your name or any other identifying information on it.

The results of a research project using your sample and information from your medical record may be published in a journal to advance medical knowledge. You will not be identified by name or any other identifying information in any reports about this research.

METHODS

a) Blood, urine and stool samples from the METS-Microbiome research project are assigned a unique identifier when collected. The label contains only the assigned number. All tubes, both pre- and post-processing, are labeled only with this number.

b) After all study-approved tests are performed on the collected plasma, serum and buffy coat samples and urine and stool samples, the remainder will be transferred to the repository area in the Public Health Sciences lab freezer (-80^{o}C).

Inclusion/exclusion criteria: All consented participants currently enrolled in METS-Microbiome (LU209537) will be invited to store their left over blood, urine, and stool samples in the METS-Microbiome repository. Only METS-Microbiome study participants will be asked whether they will be willing to participate in the repository.

DATA COLLECTION

METS-Microbiome is not affiliated with Loyola University Medical Center patient, instead this community-based projects recruits participants from the neighboring community. Research participant files linking identification number and confidential information are kept only by the department's data manager and project coordinator in a password-protected file. The password-protected key linking data to participants is kept separately to the data files. For the repository, samples will be identified by the unique, study assigned identification number, in order to be linked with the participant data.

RISKS and DISCOMFORTS: While every effort will be made to protect your identity and health information, there is a small risk of loss of confidentiality that information about your health might become known to individuals outside the repository. Genetic testing can create information about a person's and his/her families' personal health risks and can cause or increase anxiety, and/or interfere with your ability to get insurance or a job, and can even lead to discrimination.

To further protect privacy, the repository has obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). This Certificate means that the repository staff cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. The repository staff will use the Certificate to resist any demands for information that would identify you **UNLESS (1)** the United States Government is auditing or evaluating federally funded projects or information must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA), **(2)** you give written consent to release certain information or directly inform others that you are participating, and **(3)** repository staff are not prevented from taking steps, including reporting to appropriate authorities, to prevent serious harm to a you or others.

You may receive a copy of the Certificate of Confidentiality upon request. If you would like a copy of the Certificate of Confidentiality, please contact Dr. Lara Dugas via email at ldugas@luc.edu.

FINANCIAL INFORMATION: It will not cost you anything to participate in this research project. The specimens will be collected from procedures as described in a separate consent document. You will not receive any money for participating in this project or future research done with your sample. The research done with your specimens may lead to the development of new profitable products in the future. You will not share in any profits.

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: We will collect information on you, your test results, and how you do. The information will be collected by the biorepository with the help of Loyola data administrators and staff. Information about you will be provided to Loyola University Chicago and their data collection and study verification agencies and/or government regulatory agencies such as the Food and Drug Administration or the Loyola University Chicago Health Sciences Institutional Review Board or State of Illinois Auditors. They may also see and make copies of study information (such as the consent form) which identifies you.

The information we will collect and send includes:

1. Demographic information including, but not limited to, your name, address, phone number, etc.

2. Biospecimens

We will collect and provide this information about you indefinitely or for as long as you willing to participate. It is important to note that, once information is disclosed outside of LUMC, it may no longer be protected by federal privacy laws. Your consent for LUMC to use and disclose your medical information is required in order for you to give your sample to this repository.

WITHDRAWAL: This authorization does not expire, but you are free to withdraw your consent and discontinue participation in the repository at any time without affecting your care at LUMC. If you decide to withdraw your consent, we will destroy your specimens and your demographic and clinical information will also be destroyed from the research repository. We will continue to use the results of any tests that are already done. It may not be possible to retrieve specimens and clinical information that have already been given to other researchers. If you decide to withdraw your consent, please sign the form at the back of this consent.

The repository investigator, the Institutional Review Board, and/or regulatory authorities may terminate the repository at any time with or without your consent. This may happen, for example, if the repository loses funding.

CONSENT: I have fully explained to _____ the nature and purpose of the above- described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability.

_____Date:____/_____/____
Signature

Lara Dugas, Ph.D., MPH, the principal investigator for this repository, or her associates will be available to answer any questions you may have. Dr. Dugas can be reached at 708-327-9029. If you ever feel that you have been injured by participating in this repository or, if you have any questions concerning your rights as a research participant, you may contact either Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects- Loyola University Chicago Health Sciences Division, at 708-216-4608 or Cynthia Tom-Klebba, MSN, Director of the Human Research Subjects Protection Program at 708-216-6198.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

_____Date:____/_____/_____
Signature: Witness

Document ID#: 211585r3.011819
Version Date: 01/18/2019

Gut microbiota, short chain fatty acids, and adiposity across the epidemiologic transition
Biospecimen Repository

REVOCATION OF AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the METS-Microbiome Biospecimen Repository at Loyola University Medical Center ("LUMC"). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information as outlined on the consent form, which I signed on _____. I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

_____ _____
Patient Name or Personal Representative Date

Please return this form to:

Dr. Lara Dugas
Loyola University Chicago
2160 South First Avenue
Maywood, Illinois 60153

Document ID#: 211585r3.011819
Version Date: 01/18/2019

E. Manuscript preparation for the Journal of Physical Activity and Health

Authorship Guidelines

The Journals Division at Human Kinetics adheres to the criteria for authorship as outlined by the International Committee of Medical Journal Editors*:

Each author should have participated sufficiently in the work to take public responsibility for the content. Authorship credit should be based only on substantial contributions to:

a. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
b. Drafting the work or revising it critically for important intellectual content; AND
c. Final approval of the version to be published; AND
d. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conditions a, b, c, and d must all be met. Individuals who do not meet the above criteria may be listed in the acknowledgments section of the manuscript.
*http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

Open Access

Human Kinetics is pleased to allow our authors the option of having their articles published Open Access. In order for an article to be published Open Access, authors must complete and return the Request for Open Access form and provide payment for this option. To learn more and request Open Access, click here.

Manuscript Guidelines

JPAH is a peer-reviewed journal. Manuscripts reporting Original Research, Public Health Practice, Technical Notes, Brief Reports, or Reviews will be reviewed by at least two reviewers with expertise in the topical field, and the review process usually takes 6 to 8 weeks. A double-

blind method is used for the review process, meaning authors and reviewers remain unknown to each other.

All types of manuscripts submitted to *JPAH* are judged on the following primary criteria: adherence to accepted scientific principles and methods, the significant or novel contribution to research or practice in the field of physical activity, clarity and conciseness of writing, and interest to the readership. There are no page charges to contributors.

Manuscripts generally should not exceed 25 pages (~5,000 words including everything except title and abstract pages, tables, figure legends, and online-only supplementary materials; the word limit includes the reference section). Reviews should not exceed a total of 30 pages and Brief Reports should not exceed 15 pages. Major exceptions to these criteria must be approved through the Editorial Office before submission. Submissions should not include more than 10 tables/graphics, and should follow the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (visit ICMJE for more detail). *JPAH* welcomes and encourages the submission of supplementary materials to be included with the article. These files are placed online and can be accessed from the *JPAH* website. Supplemental material can include relevant appendices, tables, details of the methods (e.g., survey instruments), or images. Contact the Editorial Office for approval of any supplemental materials.

Is My Manuscript a Good Fit for *JPAH*?

JPAH welcomes physical activity research from all cultures, countries, and climates and encourages our editorial leadership, reviewers, authors, and readers to help reduce publication bias based on where we live, work, and play. Read our position statement on publication bias related to research from Majority World (i.e., Global South, low-to-middle income) countries.

Standardized Publication Reporting Guides

JPAH highly recommends that authors refer to relevant published reporting guidelines for different types of research studies. Examples of reporting guidelines include:

- Consolidated Standards of Reporting Trials (CONSORT)
- Meta-analysis of Observational Studies in Epidemiology (MOOSE)
- Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)
- STrengthening the Reporting of OBservational studies in Epidemiology (STROBE)
- Improving the Quality of Web Surveys: The Checklist for Reporting Results of Internet E-Surveys (CHERRIES)
- Template for Intervention Description and Replication (TIDieR) checklist. Authors are required to submit separate TIDieR Checklists for all intervention components that are delivered within a study, including interventions targeted at actors involved in implementation (e.g. parents, partners, teachers, colleagues, peers).

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Acknowledgments

Provide the names, affiliations, and the nature of the contribution for all persons not included as an author who played a critical role in the study.

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Details of all funding sources for the work should be provided (including agency name, grant numbers, etc.). Provide the registry name and registration number for all clinical trials (see *JPAH* Ethics Policies below).

Example: “This work was supported by a grant (grant #) from the National Cancer Institute, National Institutes of Health. This study is registered at www.clinicaltrials.gov (No. xxxxx).”

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Melby CL, Osterberg K, Resch A, Davy B, Johnson S, Davy K. Effect of carbohydrate ingestion during exercise on post-exercise substrate oxidation and energy intake. *Int J Sport Nutr Exerc Metab*. 2002;12:294–309.

Book references: Author(s) as above, title of book (italicized and all major words capitalized), city and state/province of publication, publisher, and year.

Pearl AJ. *The Female Athlete*. Champaign, Ill: Human Kinetics; 1993.

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Perrin DH. *The evaluation process in rehabilitation*. In: Prentice WE, ed. *Rehabilitation Techniques in Sports Medicine*. 2nd ed. St Louis, Mo: Mosby Year Book; 1994:253–276.

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