Principal Investigator: Kathryn Sandberg
Study Number: 2016-0793
Title: "Effect of continuous ecological assessment of physical activity on body weight and blood pressure in the greater Washington DC black population"

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GHUCCTS

Informed Consent for Clinical Research
Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS)

INSTITUTIONS: **Howard University, Georgetown University**

INTRODUCTION

You are invited to consider participating in this study, entitled "Effect of continuous ecological assessment of physical activity on body weight and blood pressure in the greater Washington DC Black population." Please take your time in making your decision and include your family and friends in the discussion. It is important that you read and understand several general principles that will apply to all study participants:

(a) Your decision to participate in the study is entirely voluntary;

(b) Personal benefit to you may or may not result from taking part in the study, but knowledge may be gained from your participation that may benefit others;

(c) You may decline to participate or you may withdraw from the study at any time without loss of any benefits to which you are entitled and without jeopardizing your access to care, treatment, and health services unrelated to the research.

The purpose and nature of the study, possible benefits, risks or discomforts, your rights as a participant, and other information about the study are discussed below. Any new information discovered, at any time during the study, which might affect your decision to participate or remain in the study will be provided to you. You are urged to ask any questions you have about this study with the staff members who explain it to you. You are urged to take whatever time you need to discuss the study with your physician, hospital personnel, and your family and friends. The decision to participate or not is yours. If you decide to participate, please sign and date where indicated at the end of this form. You may not participate in this study if you are under 18 years old.

The study is being sponsored by the Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS). GHUCCTS is called the sponsor because it is providing funding for the study. Medical research scientists are in charge of this study, including principal investigators Dr. Teletia Taylor, Dr. Carla Williams, and Dr. Veronica Clarke-Tasker from Howard University, and principal investigators Dr. Kathryn Sandberg and Dr. Stephen Wright from Georgetown University. The other principal investigator in the study is Dr. Jason Umans from MedStar Health Research Institute.

WHY IS THE STUDY BEING DONE?

You are being asked to participate in this study because you are of Black African descent (African American, Black African immigrant, or of Caribbean Black ancestry) residing in the greater Washington, DC area. Because these populations are at particularly high risk for high blood pressure and its consequences (like heart attack and stroke), we want to find out how much physical activity helps reduce your risk, and what are the best ways to really know about the factors involved.

We also want to learn about what affects physical activity and its impact on high blood pressure in high-risk populations like yours. Our goal is to figure out how to help people like yourself who have this higher risk of future problems like heart attack and stroke.

This research is being done because current methods of intervention haven't solved the problem yet.

Please check yes or no to the questions below:

Yes: ___ No: ___ Are you taking medication for high blood pressure?

You may not participate in this study if you are under 18 years old.

Yes: ___ No: ___ Do you have a chronic disease, medical, or muscle-joint problem that might limit your physical activity, for example, peripheral arterial disease (poor circulation to your legs), effort angina (heart pain), heart failure, rheumatologic disorder (like arthritis), or lung disease (including asthma or COPD) severe enough to interfere with low-impact exercise?

Yes: ___ No: ___ Do you have a condition that might limit your use of the Withings devices (i.e., you can't read a smartphone display even with corrected vision, you can't use a smartphone because of a lack of dexterity (problems with your fingers)?

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 80 participants will take part in this study. (All participants will be recruited from the greater Washington, DC area.)

WHAT IS INVOLVED IN THE STUDY?

Study participation is expected to last for six months.

If you agree to participate in this study, you will be provided with 3 wireless devices made by Withings. The 3 devices used by study participants are:

1. An activity monitor watch (called "Activité," that counts steps and other movements, and sends the information to your personal smartphone) to measure physical activity,

2. A scale (that sends your weight, heart rate, and other readings to your personal smartphone) to measure your body weight, heart rate, artery health, and other factors, and

3. A blood pressure cuff (that sends your blood pressure to your smartphone) to measure your blood pressure.

If you become a study participant, we will show you how to use the activity tracker watch. We will also give you instructions on how to use the blood pressure cuff and the scale so you can measure your own blood pressure, weight, heart rate, and artery health at home. You will also have the opportunity to ask questions.

The 3 devices will provide a steady stream of measurements from you in a natural setting instead of asking you to come in to a clinic.

You'll be asked to fill out a few short surveys (total of 20-30 minutes). We will also measure your blood pressure, height, and body weight. We will help you set up the equipment with your smartphone. This first appointment when you join the study will take about 60 to 90 minutes. There will be one more appointment at the end of the study (six months later) that will take 30 minutes or less that will involve a repeat of the blood pressure and body weight measurements and about 10 minutes of questionnaires.

Optional: You will have the opportunity to do some cognitive exercises that are like games on a computer screen. They try to measure things like reaction time, pattern matching, memory and processing over short periods of time, etc.

The Watch:
Participants are asked to wear the Activité tracker watch as much as possible, preferably all the time. It is waterproof.

The Scale:
Use the scale to weigh yourself and measure your heart rate every morning and evening the first week of every month. If you wish, you can use the scale every morning and evening throughout the study. We ask for this study, however, that you do this at least the first week of every month.

So **at least on the first week of every month–every morning and evening**–please step on the scale in your bare feet until all four cycles show on the display (including your heart rate). This takes a few seconds. Please make sure you do this **at least 5 of the 7 days**.

The main thing we are interested in that this high-tech scale provides is your heart rate and your "pulse wave velocity," a measure of the health of your arteries.

The Blood Pressure Cuff:
Also **on the first week of every month–every morning and evening**–please use the wireless blood pressure cuff to measure your blood pressure. Please make sure you do this **at least 5 of the 7 days**.

Please advise the researchers of any medications you are taking. Also, if you are taking any over-the-counter drugs or herbal supplements which you have obtained from the drug store, grocery store, via the internet, etc., you should advise the researchers.

Focus Group: When the study is finished, you may be asked to participate in a focus group to give the researchers feedback on various aspects of the study, including how to make it work better.

HOW LONG WILL I BE IN THE STUDY?

We plan to have you participating in the study for six months.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first.

WHAT ARE THE RISKS OF THE STUDY?

Risks and side effects of participation in this study are those related to the devices we are using, which are minimal. We think that they are the same as the risks of wearing a watch, using a scale, and using a blood pressure cuff (i.e., scratching yourself, bumping your toe on the scale, etc.).

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you.

We cannot promise that you will experience medical benefits from participating in this study. We hope the information learned from this study will benefit others in the future, especially those at higher risk of heart attack and stroke.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law; however, we cannot guarantee absolute confidentiality. Medical records of research study participants are stored and kept according to legal requirements. You will not be identified in any reports or publications resulting from this study.

In addition to the researchers and research institutions conducting this study, organizations that may request to inspect and/or copy your research and medical records for quality assurance, data analysis and other research related and operational or administrative purposes, include groups such as:

The Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS), the Food and Drug Administration, GHUCCTS Institutional Review Board (IRB), MedStar Health Research Institute, Inc, MHRI IRB, Georgetown University, Georgetown University IRB, Howard University, Howard University IRB, Veteran's Affairs Medical Center, Veteran's Affairs Medical Center IRB, federal research oversight agencies.

Withings, the manufacturer of devices including a tracker watch, blood pressure cuff, and scale, will collect data from the devices used in this study and send it to the researchers—This will be done with a code for each participant rather than using participants' names. Withings asks all users of their devices to provide first and last name and email address when they download the app. Withings may send email reminders to participants to wear the watch if no data is received for 24 hours, to turn Bluetooth on, and to use the other equipment; the researchers will be cc'd on those emails, and these may contain participants' names. Appendix I is the Withings consent form that allows them to share data they receive from the Withings devices you are using with the researchers.

DATA SECURITY

Information about your participation in this study is stored in a computer, and we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage:

Data will be kept on a computer that will have a code for each participant in the study. Names associated with these codes will be kept in a separate file, with backup files on paper. We carefully protect this information by keeping the files with personal information on a computer in a lab room which is always locked when researchers are not in the room, and the backup files in a small office which is always locked when researchers are not in that office. The computer with personal information is not connected to the Internet, and is only accessible to a small number of researchers in our lab. The office is only accessible to these same researchers. The computer has a pass code that must be used any time it is started up or goes to sleep.

WHAT ARE THE COSTS?

Participation in this study will not involve any costs to you.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

The Policy and Procedure for Georgetown University Medical Center and MedStar Health Research Institute are as follows:

We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive necessary medical care. The costs of this care will be charged to you or your third-party payer (e.g., your health insurer) in the usual manner and consistent with applicable laws. No funds have been set aside by Georgetown University, Georgetown University Hospital, or their affiliates, to repay you or compensate you for a study related injury or illness.

NO PAYMENT FOR PARTICIPATION

We are not able to offer any payment for your participation in this study. We hope that you will be willing to contribute some of your time for the advancement of science. We hope that what we discover will help people in the future.

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part in or leave the study at any time. If you choose to not take part in or to leave the study, your regular care will not be affected nor will your relations with your physicians, other personnel and the hospital or university. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

You have the right to receive all significant information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant, and to have them answered to your satisfaction before you make any decision. You also have the right to ask questions and to receive answers throughout this study.

By signing this form, you do not lose any of your legal rights.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions about this study you may contact one of the principal investigators, Dr. Stephen Wright at (202) 687-9846 or at swright@georgetown.edu; or Dr. Teletia Taylor, at (202) 806-4199 or at t_r_taylor@howard.edu; or Dr. Kathryn Sandberg at (202) 687-3010 or at sandberg@georgetown.edu. Please do not disclose any sensitive information over email, however, as it is not a secure form of communication.

The MedStar Health Research Institute-Georgetown University Institutional Review Board has reviewed this study. For questions about your rights as a research participant, contact the MedStar Health Research Institute-Georgetown University Institutional Review Board at:

Address: Georgetown University Medical Center
3900 Reservoir Road, N.W.
SW104 Med-Dent
Washington, D.C. 20057

Telephone: (202) 687-1506

Withdrawal by investigator, physician, or sponsor

The investigators, physicians, or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

OPTIONAL PARTICIPATION IN THE FUTURE

Yes: ___ No: ___ I'm willing to be contacted in the future about the possibility of participating in other studies.

RESEARCHER'S STATEMENT

I have fully explained this study to the participant. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____	_____	_____
Signature of person **obtaining** the consent	Print Name of Person	Date

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I am otherwise entitled. I agree to cooperate with Dr. Kathryn Sandberg and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____	_____	_____
Signature of **Participant**	Print Name of Participant	Date

Appendix I

Withings
Inspire health

Consent for the processing of personal data

I (print name), _____

the undersigned (sign here): _____,
agree to participate to the study entitled "The Relationship Between Physical Activity and Blood Pressure,"* and grant my freely given agreement to the transfer of my personal data gathered by Withings to the following recipient: this study's research team, in accordance with the following purpose of personal data processing:

1. Receive weekly reports of measurements taken by the Activité Steel watch, blood pressure cuff, and Body Cardio scale

2. Be cc'd on email reminders to turn Bluetooth on, wear the watch, and use the other equipment

Purpose of the Study:

Examine relationships among variables including survey instruments and measurements taken by the Withings equipment

Duration of the Study:

Data collection will be done for at least 6 months for each participant, from the date of that participant's data being first included on the weekly report, until 6 months later.

Data transfer will cease at the end of the study, 6 months after the last participant to enroll has been added to the weekly report.

Transferred data should be limited to:

- Email
- Identifying data of Withings products
- Personal data collected when using Withings products and services.

In compliance with the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, any collection and proceeding of personal data must be carried out with my prior and freely given consent.

Withings grants me the right of access to and the right to rectify any data concerning me:

By Mail: Withings – 2 rue Maurice Hartmann, 92130 Issy-les-Moulineaux, France

By email: privacy@withings.com

I can also object at any time on compelling legitimate grounds relating to my particular situation to the processing of data related to me.

I have read carefully the above and agree to all provisions and data processing described. A copy of this document has been given to me.

Signed in two original copies on the _____ day of _____, _____
day month year

*The official, full title of the study is the "Effect of continuous ecological assessment of physical activity on body weight and blood pressure in the greater Washington DC Black population"