Addressing African American Health through Mobile App Education and Community Engagement Focus Group Study
Morehouse School of Medicine
Consent to Participate in the Pilot Group

Principal Investigator:

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Sponsor: National Heart, Blood and Lung Institute (NHLBI)
Bethesda, MD

Invitation to Participate:

You are asked to take part in the Addressing African American Health through Mobile App Education and Community Engagement Pilot Group. This study was created to improve heart disease outcomes among African Americans. We will empower volunteers to embrace behaviors that can improve their heart health through using creative, digital health strategies. You are being asked to join so that we can explore the use of the project's smartphone app. We are looking for any changes in heart health-related behaviors, including physical activity, sleep quality, food choices and mental/emotional health. We expect about 175 people in the metro-Atlanta area to be in the pilot group. In addition, we are inviting up to 20 persons to beta test the app for approximately one month. This form will help you to decide whether you want to take part. Please read carefully all parts of this consent form. Ask us about any parts or words that are not clear to you.

Information on the Research Project:

The purpose of this pilot group is to assess the long-term success of a community-based mobile health research project. This project will evaluate a novel approach to observe and improve healthy behaviors in young African American adults through an app on their smart phones. The project involves the combination of three existing mobile apps into one "Project smartphone app." We seek full input of pilot group participants. As a participant, you will co-create the Project smartphone app on a cellular device. In addition, you will wear the Jawbone UP3 to record both clinical and emotional

measurements. The measurements include blood pressure, BMI, waist circumference, fat/blood sugar levels, physical activity levels, food choices, levels of perceived discrimination and levels of depression, anxiety and stress. In addition, we will access your Electronic Health Records (EHR) to understand your engagement with your healthcare provider.

What we will ask you to do if you decide to take part in the study

If you choose to be a part of the beta testing, you will test the app and wearable device for approximately one month. If you choose to take part in the pilot group, you will co-create the smartphone app on a cellular device and wear a Jawbone UP3 during the project period (24 weeks). At the start of the project we will record your blood pressure, body mass index (BMI), waist circumference, fat/blood sugar levels, and physical activity levels. We will also record data about your internal and external stress and food choices. We will collect this data every 8 weeks during the project period and a final time 3 months after the project period. In addition, we will have access to your text messages as part of the study. We will access text messages to assess key word frequency, the number of people engaged, and your relative location. Each clinical visit is expected to be around 59 minutes in length. Lastly, we will ask you to complete a survey to assess your opinion of the Project's smartphone app.

Possible Risks or Discomforts:

There are few risks and discomforts involved in this project. However, during the clinical visit, we will prick your finger or use a needle to take blood from your vein. You may get a bruise from the needle. There is a small chance of getting an infection from giving blood. Some people feel faint when they give a blood sample. Please tell the study staff if this has ever happened to you. We urge you to tell us about any unusual effects. Tell us even if you feel these effects are mild or do not bother you.

Potential Benefits: What you can expect from being a part of the study.

There may be no health benefit to you from being in this pilot group. However, observing your diet and increasing physical activity may lead to some weight loss.

Alternatives to Involvement: Other choices you may have.

Your alternative is not to take part in the pilot group.

Financial Commitment: What you are responsible to pay.

Participation in the pilot group and the beta testing group will be free of charge.

Compensation for Involvement: What you will receive for being in the study.

Each person will receive a coupon for $20 for participating in the pilot group. In addition, each person will receive $20 if they join in the beta testing of the app. Each coupon is valid at one of several commercial outlets.

Assurance of Privacy: How research records and data about you are kept.

Absolute confidentiality of data about you cannot be assured. We will not give out data about you to anyone without your written consent unless the law says that we must. We respect your privacy. We will not tell anyone facts about you that might reveal you are in this study. Your recorded responses and your measured values will not be linked to your name. Your data will be kept in locked files. The Morehouse School of Medicine's Institutional Review Board -- the group that approved this research project -- may have access to these research records. "In addition your unnamed data will be made available to other researchers and partners beyond Morehouse School of Medicine. However your privacy will be maintained." You will not be acknowledged in any way as being in this research in any papers in scientific or other journals. You will not be known in any reports made on this research at scientific meetings.

Emergency Care and Compensation for Injury: What happens if you should be hurt or become ill from being in the study.

Although it is unlikely, we will provide care for you at once, if you are hurt as a direct result of taking part in this study. Morehouse School of Medicine and/or sponsors of the study will pay for the cost of this care, if your health insurance doesn't cover it. Care for research-related injuries may include reasonable costs for hospital care and treatment. We will not bill public programs like Medicaid for treating a research injury, unless the law allows it. No funds have been set aside to pay for lost wages, pain or distress that might result from research injuries. You do not give up any of your legal rights by being in this study. You must instantly contact all persons listed in this form if you believe you have an injury caused by this study.

Persons to contact:

If you have any questions about this project you may contact the following:

Dr. Herman Taylor 404-752-1545
Dr. Gari Clifford 404-712-0163

If you have any questions about your rights as a volunteer in any part of this study, you may contact - without sharing your name - Dr. Brenda Klement, Chairman of the Morehouse School of Medicine's Institutional Review Board at (404) 752-1973 or (404) 752-1637.

You may also contact the Morehouse School of Medicine's Research Subject Advocate, at (404) 752-1140.

Voluntary Involvement and Right to Withdraw from the Research Study:

You are free to join the study or not. You are also free to join the study and later decide to leave for any reason. If you decide not to take part in the research, we will still give you any info that may be important to your health. If you decide to leave the study, we ask that you notify the study staff as soon as possible.

VOLUNTEER CONSENT STATEMENT

I know that taking part in this research study is my choice. I may choose to leave this study at any time, for any reason, or for no reason. If I decide not to stay in the study, I shall tell the doctor of this decision. I freely consent to take part in this research study, under the direction of Dr. Herman Taylor and Dr. Gari Clifford. I know there may be some risks or discomforts to me. I have read about these risks in this form and they have been carefully explained to me. My role in this research has been clearly explained to me. I have had the chance to ask questions about the study and have had time to decide to join. My questions have been answered to my liking. I know I am free to ask further questions about the study at any time. I have been told about the materials and methods used in this study. I know what I am supposed to do in this research study. I understand I will receive a copy of this consent form.

In my judgment the volunteer, having been fully informed of the research project described herein, has enough ability. They are also knowingly and willingly giving informed consent to join in this research project.

PLEASE KEEP THIS FORM IN A HANDY PLACE AND REFER TO IT FROM TIME TO TIME WHILE YOU ARE IN THE STUDY.

(Optional)
I hereby consent for all purposes to the lawful use, copy and sharing of voice, likeness and/or pictures of me. This includes content with or without use of my name, bio or work-related description. This also includes photographs of any personal or real property belonging to me by Morehouse School of Medicine, Inc. This applies to all forms of media (to include education, promotion, trade, editing, art and display).

In giving this consent, I release Morehouse School of Medicine and Morehouse Healthcare, Inc. d/b/a Morehouse Medical Associates, Inc., all of their affiliates, trustees, directors, employees, agents from liability for any violation. This includes all personal, privacy, publicity or patented rights I may have in connection with such reproduction and use.