INSTITUTE: National Heart, Lung and Blood Institute

STUDY NUMBER: 13-H-0183 PRINCIPAL INVESTIGATOR: Tiffany M. Powell-Wiley, M.D., MPH

STUDY TITLE: Cardiovascular Health and Needs Assessment in Washington D.C. – Development of a Community-Based Behavioral Weight Loss Intervention

Initial Review Approved by the IRB on 7/16/13
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Standard

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

NIH research studies are voluntary, and you may drop out or leave the study at any time without losing any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be a taking part in a study or be under evaluation to take part in a study.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Anyone with personal, religious or ethical beliefs that will not allow them to take part in certain medical or research projects (such as blood transfusions) should tell the NIH doctors or research team before agreeing to join the study.

Before choosing to join the project, please take as much time as needed to read all the information and talk it over with your family, friends, and/or your medical doctor. If you have any questions or concerns regarding the study or the NIH, please feel free to contact us here at the NIH. We are here to help you.

1. Why is this research being done?

The purpose of this research is to conduct a community health and needs assessment for individuals in predominantly African-American (Black) churches in Washington D.C. Past studies suggest that community-based programs are needed to improve cardiovascular (heart) health in the African-American community. This assessment is being conducted in partnership with DC community leaders. In this assessment, we will study the levels of heart health factors in the church population, such as levels of diabetes (blood sugar), high blood pressure, high cholesterol, and obesity. We will also study the use of technology to measure exercise and food intake, and we will study the use of web-based tools for keeping track of one's own heart health factors. We plan to use the information collected in this study to evaluate the health needs of this church-based community. With this information, we plan to work in partnership with community leaders to create an intervention for future programs to improve heart health in African-American churches in the District of Columbia.

2. Why are you being invited to participate?

You are being asked to participate in this research study because you attend a church in the District of Columbia.

3. How many people will take part in this research study?
Up to 100 participants will take part in this study.

4. How long will you take part in this research study?
You will be a part of this study for one (1) month, only.

5. How can one be eligible to join this study?
For this study, you must be:

- Between 19 to 85 years old
- Attend one of the churches in this study

6. What procedures are involved in this research study?
You will be asked to come to your church for a health examination. You should not eat anything after midnight the day before the exam, except for water for taking medications. After signing the consent, you will have blood testing for blood sugar and blood cholesterol and get your body weight measurements. You will get a snack during the exam after blood testing and body weight measurements. You will also complete a survey after measurements and receive a physical activity monitor to use. The exam will take approximately 4 hours to complete. The following are steps for testing, which are described below:

Procedure	Visit 1	1 month
Blood pressure measurements	X	
Fingerstick blood sample for blood sugar, cholesterol levels	X	
Body weight measurements	X	
Questionnaire (survey)	X	
Instructions for use of Fitbit® Flex	X	
Monitoring use of Fitbit® Flex Physical Activity Monitor and Fitbit® website		X
Instructions for use of Actigraph GT3X accelerometer (optional)	X	
For those using Actigraph GT3X accelerometer: - Return device to study team		X
Instructions for use of digital camera for three-day digital food record (optional)	X	
For those using Digital camera: - Return device to study team		X
For those with untreated high blood pressure, diabetes, or high cholesterol - Call from study team about follow-up with primary care		X

a) Blood Pressure Measurements: We will measure your blood pressure during the screening and let you know your results.

b) Fingerstick blood draw for Blood Sugar and Blood Cholesterol Levels: We will take a small drop of blood from your finger using a fingerstick. The amount of blood drawn in the fingerstick will be less than one-fourth of a teaspoon of blood. All of the blood tests will be taken during the screening exam only. None of the blood sample will be kept. We will provide you with the results of the blood tests.

c) Body weight measurements: We will measure height, weight, waist size, and distance around your hips during the exam. We ask that you wear lightweight, loose-fitting clothing with empty pockets to the event so it is easier to take these exact measurements.

d) Questionnaire (Survey): You will be asked to complete a survey about your medical history, physical activity (exercise) and dietary (eating) habits. You will also be asked about psychological/emotional factors, like stress, that might affect your exercise and eating habits. Finally, you will be asked questions that can help us create a church-based program to increase physical activity and improve diet for better heart health.

e) Instructions for use of Fitbit® Flex/Monitoring of Use of Fitbit® Flex and Fitbit® website: At the screening, you will be given a physical activity monitor called a "Fitbit® Flex" with instructions on how to use the device. The device will be worn as a wristband, and it will record your levels of physical activity during the day and will record the number of hours you sleep each night. You will be asked to use this device for one (1) month and will be taught how to follow your physical activity levels on the Fitbit® website. The website will also let you keep track of your dietary intake (types and amounts of food you eat), types of physical activity (exercise) that you do, and heart health factors such as weight, heart rate, blood pressure, and blood sugar. During the one month, we will check your use of the Fitbit® Flex and the Fitbit® website. After one month, we will no longer check the use of the Fitbit® Flex or the Fitbit® website, and the device will be yours to keep.

f) Instructions for use of Actigraph GT3X accelerometer (OPTIONAL): At the screening, you will have the choice to receive another type of physical activity device called the "Actigraph GT3X accelerometer". This device will be worn each day around the waist. The device will record your physical activity each day. You will be asked to wear this activity device each day for one month. If you are willing to be in this part of the study, we will ask that you wear both the Actigraph GT3X accelerometer and the Fitbit® Flex for one month. After one month, we will collect the Actigraph GT3X accelerometer back from you to read the physical activity data.

g) Instructions for use of digital camera for three-day food record (OPTIONAL): At the screening, you will also have the choice to get a digital camera to count your food intake over a three-day period. If you are willing to be in this part of the study, you will be given directions on how to take pictures of each meal for three days in a row (2 weekdays and 1 weekend day). You will be asked to take pictures before and after eating a meal. After taking pictures for the three-day food record, the digital camera will be collected back from you to review the food intake pictures.

h) Referral for untreated high blood pressure, diabetes, and high cholesterol: If you are found to have high blood pressure, high blood sugar or high cholesterol that is not being treated, we will provide you with some information on a primary care doctor to follow-up for further evaluation and possible treatment. We will contact you one month after screening to determine if a follow-up appointment has been made with a primary care doctor.

7. What are the risks and discomforts of this research study?

a) Fingerstick blood draw: You may feel a slight pinch of pain from the small needle when collecting your blood sample. There is a small chance that you will feel lightheaded or faint with the needlestick.

b) Questionnaire: You may be a little frustrated with answering the questions.

c) Measurement of blood pressure, blood sugar, cholesterol levels: We may find signs of high blood pressure, high blood sugar, and/or high cholesterol during the medical exam, which may cause you to be a little anxious. As a study participant, you will experience a heart health examination with the principal investigator, Dr. Powell-Wiley. Based on the results, she will talk to you about the status of your blood pressure, blood sugar, cholesterol, or body weight.

d) Use of the Fitbit® Flex: The Fitbit Flex activity monitor is an item you can buy in a store, and it is not painful to wear this plastic monitor around the wrist. You may feel a little skin irritation or itching if the monitor is worn too tightly around the wrist.

8. Are there any benefits to you if you take part in this research study?

It is possible that you will benefit from participating in this study by getting an evaluation of your heart health. This may assist in managing your blood pressure, blood sugar, cholesterol and body weight.

9. What other choices do you have?

You do not have to participate in this study if you do not want to. You may stop participating in this study at any time.

10. Will your clinical and test results be shared with you?

We will provide you with the blood pressure, blood sugar, cholesterol, and body weight results that we obtain. We will also provide you with a cardiovascular risk assessment during the screening.

11. Will the results of this research study be shared with you?

We will tell you about our research results. However, it may not be ready for several months in order to compare all the results from the participants in the study as a whole. We will also announce the research results at each of the participating churches; however, no one would be able to identify you when the research results are presented. We will share the published information of this study with you.

By agreeing to participate in this study, you do not give up any rights that you may have regarding access to and disclosure of your records. For further information on those rights, please contact Dr. Powell-Wiley.

12. Will any of your blood, tissue, other samples, or data be stored and used for research in the future?

In this protocol, we will obtain heart-related health factor data and questionnaire data that will be stored. We will also include certain information in your medical record. Other information will be for scientific research, publication, and teaching. Your name and other personal information will not be revealed and it would be private. When we do so, your information will identified by a code to link your test samples with your name and other personal information. The code will be stored in a secret password-protected database under the control of Dr. Powell-Wiley. If we share or publish these data, your name or personal information will not be told to ensure your identity will be protected. We may contact you in the future about taking part in the intervention to improve heart health in the community. **JUST TO NOTE:** You are under no contract to participate in any future studies with NIH.

13. Will you receive any compensation (money or other) for taking part in this research study?

The following table describes the compensation for this study:

Description of tests or procedures	Compensation
Completion of all Testing at Screening Event, including blood draw and survey	$25 Visa gift card
Completion of 1 month of data collection with physical activity (exercise) monitor	$25 Visa gift card
Return of accelerometer to research team (up to 15 participants)	$25 Visa gift card
Return of digital camera to research team (up to 15 participants)	$25 Visa gift card

14. Do any of the researchers or the NIH have a financial interest related to this research study?

No, the researchers or the NIH do not have a financial interest related to this research study.

The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process: http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf. You may ask your research team for additional information or a copy of the "Protocol Review Guide."

15. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator: Tiffany M. Powell-Wiley, MD, Building 10, Room 5-3340, Telephone 301-594-3735.

You may also call the Clinical Center Patient Representative at (301) 496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Adult Patient/Legal Representative _____ Date _____

Print Name _____

B. Parent's Permission for Minor Patient.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.
(Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/Guardian _____ Date _____

Print Name _____

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian _____ Date _____ Print Name _____

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM JULY 16, 2013 THROUGH JULY 15, 2014.

Signature of Investigator _____ Date _____

Print Name _____

Signature of Witness _____ Date _____

Print Name _____