TOSS Feasibility + Fitbit Community = Reduced Obesity in Older Black Women

Informed Consent

NCT: IRB-300004159

Date of Last Protocol Approval: 12 November 2019

Pamela G. Bowen, PhD, CRNP, FNP-BC, Principal Investigator
University of Alabama at Birmingham
Birmingham, AL 35294

CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: TOSS Feasibility + Fitbit Community = Reduced Obesity in Older Black Women

UAB IRB Protocol #: **IRB- 300004159**

Principal Investigator: Pamela G Bowen, PhD, FNP-BC

Sponsor: The Division of Preventive Medicine

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to test whether text messages and the use of a Fitbit device will help to promote a healthier lifestyle among community- dwelling older overweight or obese Black women.
Duration & Visits	You will be in this study for only 12 weeks however you will only come to UAB twice for a baseline visit and a post-intervention visit.
Overview of Procedures	This study will include will receive tailored text messages at different frequencies for 12 weeks. You will also wear a Fitbit device to measure your daily steps and physical activity behavior. We will also obtain information about your overall health and physical activity behavior. We hope that a healthier lifestyle will lead to better overall physical and mental health outcomes.
Risks	The most common risks include negative emotions such as embarrassment or anxiety during the baseline and post-intervention session.
Benefits	You may or may not benefit from this study. However, the information you provide may help us learn how to assist older Black women who are overweight or obese increase their participation in healthier lifestyle behaviors, which may improve their overall health.
Alternatives	If you do not want to take part in the study, you do not have to.

Purpose of the Research Study

We are asking you to take part in a research study. The purpose of this research study is to test whether text messages and the use of a Fitbit device will help to promote a healthier lifestyle among community- dwelling older overweight or obese Black women. This research study will examine whether tailored text messages and Fitbit technologies will help to promote a healthier lifestyle in older Black women who are classified as overweight or obese. There will be 30 participants enrolled.

Study Participation & Procedures

If you agree to participate in this study: There will be a baseline and a post-intervention session, which will last 90-120 minutes.

- You will answer some general questions about yourself, such as your age, gender, educational level, current physical activity level and questionnaires about your overall physical and mental health (baseline and post-intervention).
- You will wear a Fitbit device to measure your physical activity behaviors such as number of steps, distance, and minutes of activity for- 12 weeks.
- You will receive text messages at different frequencies for 12 weeks
- You will permit us to obtain your weight, body mass index, waist circumference, blood sugar via finger stick at baseline and post-intervention.
- You will be asked to authorize the research staff to access and download your historical Fitbit data. This authorization will not require you to give your password or other personal information to the research staff. You will be directed to a secure system (Fitabase) that will allow you to sign in with your Fitbit login and authorize the research staff to download your data. After you complete the study described the research staff will delete your authorization so that any data you collect after you complete the study will not be collected. Research staff will access and download the following data gathered from your Fitbit account:
    a. Daily steps total
    b. measured steps per minutes
    c. minutes of light, moderate or vigorous activity
    d. minutes of sedentary time
    e. sleep length, quality, and movement

Once you agree to participate in the study, we will use a computer program (like the flip of a coin) to determine which group you will be in.

Risks and Discomforts

There are minimal discomforts in participating in this study. However, you may experience negative emotions such as embarrassment or anxiety during the baseline and post-intervention sessions. Remember, you can stop the sessions for any reason. Here are the numbers for the Crisis Center (205) 323-777 for further emotional support if needed. As with all research, there is a risk for breach of confidentiality. We try to minimize this risk by keeping your information private and secured, available to those involved with this study trained to keep information confidential, assigning a unique identifiers to your study records instead of using your name or other identifiers on the research data we collect, and password-protecting any electronic research data. You will be assigned to a group by chance, which may prove to be less effective than the other study group or alternatives.

Benefits

You may not benefit directly from taking part in this study. However, information you provide may help us learn how to assist older Black women who are overweight or obese increase their participation in healthier lifestyle behaviors that may improve their overall health.

Alternatives

Your alternative to this study is not to participate

<u>Confidentiality and Authorization to Use and Disclose Information for Research Purposes</u>

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

What protected health information may be used and/or given to others?
All medical information related to your participation in this study. This may include your name, medical record number, date of birth, dates of service, etc.; any past, present, and future history related to this research study, examinations, laboratory results, imaging studies and reports and treatments; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used.

Who may use and give out this information?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).
Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- The UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of
- The National Institute on Minority Health and Health Disparities, National Institutes of Health
- The Division of Preventive Medicine: Obesity Health Disparities Research Center.
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, Children’s of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the UAB IRB and its staff

- the billing offices of UAB and UAB Health Systems affiliates and/or Children's of Alabama and its billing agents

The information from the research may be published for scientific purposes; however, your identity will not be given out. We do this to keep your personal information private. Only a unique identifier, not your name, will be used to identify your information on study materials. This will be maintained in a password-protected computer database on a secure server within UAB School of Nursing.

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time.
You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal
You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. However, you should return to see the study doctor for safety reasons so you can be taken off the study drug and referred for follow-up care. Contact the study doctor if you want to withdraw from the study.

Cost of Participation
There will be no cost to you for taking part in this study.

Payment for Participation
You will be paid up to $55.00 ($25.00 for participating in a baseline and a post-intervention session, which includes wearing an accelerometer for five (5) days. You will be paid $30.00 for returning the accelerometer). You will be paid $110 in all for the completion of the study. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Our research team conducts many research studies. We would like the opportunity to contact you for future studies you may be eligible to participate in. You may change your mind at any time. You may contact Dr. Pamela Bowen at (205) 934-2778 if you have questions.

Initial your choice below:

_____ I agree to be contacted for future research studies.
_____ I do NOT agree to be contacted for future research studies.

Questions

If you have any questions, concerns, or complaints about this study, please contact Dr. Pamela Bowen. She will be more than happy to answer any of your questions or concerns. Dr. Bowen's number is 205-934-2778. After hours, you may email her at pbowen@uab.edu.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

_____

Signature of Person Obtaining Consent Date