Official study title: Preventing Weight Gain Among Those Who Decline Behavioral Weight Loss Treatment

NCT #: NCT04751656

Date: 10/20/2020

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent: _____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study (this "Research Study")?
Understanding health behaviors and interest in interventions

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Megan McVay, PhD: (352) 294-7029

Other research staff: Melinda Rajoria, MPH: (352) 294-1815

4. Who is paying for this Research Study?

The National Heart, Lung and Blood Institute (NHLBI), part of the National Institutes of Health (NIH)

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of this study is to test an approach to helping patients avoid weight gain. We are mainly interested in participants opinions of the program and how easy this study is to conduct.

If you join the study, you will be actively involved for about 12 months. Additionally, we will review your medical records and obtain any recorded body weight from your records for 3 years.

b) What is involved with your participation, and what are the procedures to be followed in the research?

If you join the study today, you will be mailed a scale that uses the cellular network to send your weight to our study team. You will be sent instructions on how to use this scale. You will also be sent text messages from this study every-other week. These messages will provide you with information about your progress with self-weighing and weight changes. These text messages may also give you an option to learn more about resources that can help you with weight management, such as online apps like MyFitnessPal and programs such as Noom. These text messages may have links to surveys, which rely on internet access to use. Standard rates may apply for text messages or for data usage.

You will also do the following:

- Complete online surveys about your experience with the program at 3 and 12 months.
- You may be invited to do an interview at the end of the study (that will last about 30-45 minutes). The decision on who to invite will be based on the goal of interviewing people who have had a variety of different responses to the program.

We will also look at the following data

- The study staff will look in your medical records to record your weight measurements and dates of weight measurements over a period of one year prior to the start of this study and three years after this study started. We will not review other material in your records.

c) What are the likely risks or discomforts to you?

A potential area of risk of this study is loss of privacy through data collected and stored by the study team at University of Florida. We cannot guarantee that data will not be unlawfully obtained.

Weights taken on the BodyTrace scale will be received and stored by the BodyTrace corporation. This data shared with BodyTrace is not protected by the University and is subject to the terms outlined in the privacy policy of BodyTrace.

Your name and address will be provided to BodyTrace, Inc. for scale shipping purposes.

As part of this study, you may be recommended to use a weight management resource such as a dietary tracking app or online weight loss program. Please note that the use of these programs is voluntary. Any information you provide in the app or to the program may be stored by the app developer or its third parties. This data shared is not protected by the University and is subject to the terms outlined in the privacy policy of the app or program you are using. Information shared in the app is your decision and may identify you individually. If you decide to use the resources, you do not have to provide personal identifying information when you use them. If you use the resources, you are encouraged to use safeguards to protect your device, such as maintaining physical control of your device and password protecting your device.

d) What are the likely benefits to you or to others from the research?

This research may help you improve your health by maintaining your weight or losing weight.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

You can choose to do nothing, or to address weight by talking to your doctor or using commercially available tools or programs.

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.

Our study results will be available at this website. Additionally, the study team may contact you with results when the study is completed.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

Regardless of if you participate, your normal clinical care will continue as usual. If you chose to participate, you may discuss some of the weight management tools with your primary care provider.

7. What will be done only because you are in this Research Study?

If you join the study today, you will receive three things:

- First, you will mail you a cellular-connected “smart” scale
- Second, you will receive study instructions and recommendations on how to weigh yourself.
- Third, you will receive text messages from the Research Team every other week that include feedback and suggestions for weight management. Standard text messaging rates apply.

In addition to the text messages mentioned above, you will interact with the study team at additional time points.

- After 3 months of participation, we will send you an email with an online survey to complete. It will ask about your weight management behaviors, physical activity, eating habits, mood, and your thoughts about the intervention. These will take about 15-20 minutes to complete.
- After 12 months of participation, we will ask that you complete the same questionnaires mentioned at month 3.
- After the 12-month survey is complete, we will ask some participants to do a phone interview (that will last about 30-45 minutes). If you do the phone interview, it will be audio- or video-recorded.

We will also look at the following data:

The study staff will look in your medical records to record your body weight measurements from 1 year prior to enrollment until 3 years after the study.

Once this research study is completed, information that could identify you (such as your name and specific age and location) will be removed. After such removal, the study data could be shared on a publically available archive. This allows other researchers to use the data to make new findings and to confirm the findings presented, which may increase the value of your contribution to this research.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect information about you such as your age, gender, your weight, and information about your diagnosis of weight-related health conditions (diabetes, heart disease).

The Research Team may collect this information from you and/or your medical record. Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

Your last contact with the study team will be about 12 months after the study started. The study team will examine your medical records 3 years after the study started; after that point, you will have no other involvement in the study.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

We plan to enroll 40 patients in this portion of the research study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

A potential area of risk of this study is loss of privacy through data collected and stored by the study team at University of Florida. We cannot guarantee that data will not be unlawfully obtained.

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As part of this study, you may be recommended to use a weight management resource such as a dietary tracking app or online weight loss program. Please note that the use of these programs is voluntary. Any information you provide in the app or to the program may be stored by the app developer or its third parties. This data shared is not protected by the University and is subject to the terms outlined in the privacy policy of the app or program you are using. Information shared in the app is your decision and may identify you individually. If you decide to use the resources, you do not have to provide personal identifying information when you use them. If you use the resources, you are encouraged to use safeguards to protect your device, such as maintaining physical control of your device and password protecting your device.

13a. What are the potential benefits to you for taking part in this Research Study?

This research may help you to meet your goals for improving your health via weight management.

13b. How could others possibly benefit from this Research Study?

This study may help identify ways to help others achieve their weight management goals.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

14. What other choices do you have if you do not want to be in this study?

You can choose to talk to your doctor about other approaches to weight management. You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive outside of this study.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation. No further data will be collected, but data that is already collected may still be used.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let

them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- You become pregnant during the study. Please inform us if you become pregnant during the study.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

No.

17. Will you be paid for taking part in this Research Study?

You will be paid for completing study assessments. You will be paid $10 for each of two assessments. You will be paid an additional $20 for completing an interview at the end of the study (if you are invited).

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.

18. What if you are injured while in this Research Study?

Please contact one of the Research Team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study.

Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photographed ☒ video recorded ☒ audio recorded

You will have a choice if you want to do video recording or only audio recording.

This will be done at the end of this study, during an interview when we ask you about your opinion of the study.

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, Megan McVay, PhD, or her successor, will keep the photograph(s), video and/or audio recordings in a password protected computer server drive or as an encrypted electronic file.

These recordings will be destroyed no later than 12 months after they are collected.

SIGNATURES

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Person Consenting and Authorizing Date