



Proof-of-Concept Study of an Integrated Mobile and Social Network Weight Loss Intervention

NCT 05295849

12-7-22



Consent for Participation in Research

Protocol Title: Building Habits Together Online Weight Loss Program: Pilot Trial

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Study Sponsor: The National Institutes of Health

Disclosures: Dr. Pagoto is a paid consultant for Fitbit, Inc.

Key Information

You are being asked to volunteer for research. Below is some key information to keep in mind when thinking about why you may or may not want to be in the research. Additional details will follow in later sections.

Introduction

The purpose of this form is to provide you information that will help you decide whether to participate in this research study. The person performing the research will answer any of your questions. Take your time, read the information below, and ask any questions you might have before deciding whether to take part. If you decide to be involved in this study, this form will be used to record your consent.

Purpose of the Study

You have been asked to participate in a research study that is evaluating an online weight loss program that is paired with either of two mobile apps.

The purpose of this study is to evaluate the practicality of an app when combined with an online weight loss program.

Why am I being asked to take part in this research study?



You are being asked to take part in this study because you are interested in losing weight. Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without penalty or loss of benefits to you.

How many people will take part in this study and how long will it take?

This study will take approximately 54 hours from the screening phase to follow-up assessments at 6 months. See the table below for the expected time commitment for participating in the study. This study will include approximately 70 study participants from across the United States.

Study Phase	Time
<u>Screening</u> Initial Screening Survey (~15 min)	15
<u>Baseline</u> Orientation webinar (60 min) E-consent (~10 min) Baseline survey (~20 min) Scale and app set-up (~10 min)	100
<u>Weight Loss Program</u> Online weight loss group and mobile app use 15 min/day for 6 months (~2,730 minutes) Weekly video chat sessions (45 min/week for 6 months) (210 minutes)	3,000
<u>Follow-up:</u> Weigh-in (~5 min) Online survey (~30 min) Focus group (~60 min)	95
Total	3,210 minutes (approx. 54 hours)

What will I be asked to do?

You can participate in this study from home; there are no study visits at our research site. If you agree to participate in this study, you will be asked to complete a screening and baseline phase, the weight loss program, and follow-up assessments.

The screening and baseline phase will include:

- An initial screening survey to determine eligibility (*you have already completed this*).
- A 60-minute live orientation webinar that goes over all the details of this study and what it means to be a participant in a research study (*you have already completed this*).
- Informed electronic consent. Reading this form and deciding if you want to volunteer to participate in this research.
- A baseline survey that will ask you questions about demographic information, mental health, and problem solving.



- We will ask you to weigh-in on a Fitbit Wi-Fi/Bluetooth scale that we will send to your home after completing the screening survey, webinar, consent, and baseline survey.

The weight loss program will include:

- A 6-month weight loss program carried out in a private Facebook group led by a professional weight loss counselor and either the MyFitnessPal app or an app we developed called Habit app. You will be randomized to one of the two apps. Everyone in the study will receive the weight loss program in a private Facebook group.
- Weekly weigh-ins with the scale we send to your home.

Detailed information of each feature is below.

Randomization:

Randomization will take place once you complete all the screening and baseline tasks, and we confirm you are eligible to participate. You will be randomly assigned to one of two weight loss apps. One is the commercial app MyFitnessPal and the other is a novel app we developed called Habit app. Both groups will receive the same weight loss program led by a professional counselor in a Facebook group. The only difference is the app that you will use during the program. You have a 50/50 (equal) chance, like the flip of a coin, of being in one group or the other.

Weight loss program:

Facebook Group. The 6-month weight loss program will be carried out in a private Facebook group. Each week the professional counselor in the group will cover different topics relating to healthy weight management and all the content in the group is based on an evidence-based weight loss program called the Diabetes Prevention Program. Every Monday the group is given diet and exercise goals and every Friday the group is asked to report weight change for the week. A weight loss counselor will run the group and be available to you daily in the group to answer questions and give you feedback on your progress. The counselor will post twice a day to start conversations about behavioral weight loss strategies and pose questions to the group to find out what is working and what isn't working for you. You will be encouraged to interact with other participants in the Facebook group by providing each other support and helping each other brainstorm challenges. The weight loss goal is 1-2 pounds per week and the exercise goal is to work toward 150-300 minutes of moderate intensity exercise per week or 75-150 minutes of vigorous intensity exercise per week if you prefer that. For those who are randomized into the Habit app group, researchers from WPI will be in the Facebook group to provide tech support.

The counselor will host monthly 45-minute video chats through the Facebook group. You will be able to join these from the "events" tab in the Facebook group. These video chats will focus on a different topic each week. The counselor will lead the discussion on topics relating to weight management (e.g., emotional eating), lead group brainstorming, and provide guidance. Each session will be recorded and then posted in the Facebook group so that any members who missed it may watch the recording. If you do not want to be recorded, you can turn your video off when attending the chats.



Facebook's group privacy settings allow us to restrict the group's access to only those who have been invited and make the group invisible to all others on Facebook. This means content from the group including your posts and comments will NOT show up in your Facebook friends' newsfeeds. This also means that your friends will not know you have joined this private Facebook group. In spite of every effort we make to protect privacy, it is always the case with online activity that other group members could take screenshots and share them or discuss what is happening in the group with people outside of the group; however, we will ask all participants to refrain from sharing any content in the group with anyone.

We will download all posts, comments, replies, and reactions participants make in the Facebook group so that we can study how much participants engaged in the program and what they shared. This will help us make improvements to the program.

Mobile Apps. In addition to the weight loss program in the Facebook group, you will be asked to use an app, and which app depends on which group you are randomized to. One group will be asked to use MyFitnessPal. This app gives you a daily calorie goal that will help you lose weight. Then, throughout the 6-months, you will track your dietary intake and exercise daily in an effort to hit your calorie goal. The other group will be asked to use the Habit app, which our team has developed. Habit app helps users understand why they overeat and what gets in the way of their developing an active lifestyle. First, it will ask you to track when you feel tempted to overeat and for each temptation, whether you ended up overeating or resisting that temptation. This feature will help you understand the circumstances in which you overeat and how often you overcome temptations. Next, the app asks you to plan your workouts for the week to help you keep your exercise on track and to understand the circumstances in which you miss workouts. Then, the Habit app has a problem-solving feature that helps users solve diet and exercise problems they encounter as they are trying to lose weight. Finally, Habit app provides each users "insights" or summaries of information the user puts in to help them understand their eating and exercise patterns.

Weekly Weigh-ins. You will receive a Fitbit wifi/Bluetooth scale so we can keep track of your weight throughout the study. Your weight will be uploaded directly from the scale to your Fitbit account via wifi/Bluetooth. We will ask you to weigh yourself at several points in time: when you set your scale up, on the first day of the program, weekly during the program, and at the end of the study so that we can assess how much you lost in the 6-month program. Each time you weigh yourself it is important that you do so in the morning with no clothing and before eating or drinking so that we can get an accurate measure of weight. We will ask you to set up a Fitbit account for the study and share your login information (i.e., your username and password) with study staff during the study so that we can access your weight data. We will not add or change any information in your Fitbit account; we will log in only to record your weights during the study. If you already have a Fitbit account and choose not to create a second account to use in this study, you may choose to share that login with the study staff. If you prefer to not let staff access your Fitbit account, you may upload a screenshot of the weight entry directly from the Fitbit screen to a secure survey link provided to you by the study team. At the end of



the study, the scale is yours to keep and at that point you will be advised to change the password on your Fitbit account.

Follow-up:

After the 6-month program is over, we will ask you to complete follow-up assessments. The follow-up assessments will include:

- A final weigh-in on the Fitbit wifi/Bluetooth scale.
- A final survey which includes some of the same questions you were asked in the baseline survey plus questions about your opinion of various aspects of the program.
- A 60-minute focus group (described below)

Focus group. We will audio-record the focus group call and then transcribe it without the use of your name or other identifying information so it will be anonymized. If you wish that your name is not used during the focus group, let the study team know and we can provide you with an alias. We also delete the recordings once all the transcripts are finished. You will not need to turn on your video and you can ask for an individual interview if you'd like. Additionally, we will use a transcription service that takes the audio recorded from the focus groups and turns it into a written transcript to allow us to analyze the data. The transcription service site will not retain the recordings or information derived from the recordings and they will not use these recordings to improve their software. The information we learn from the recordings will help us learn how to improve our program.

Data Collection:

During this study we will collect your study data in these ways: 1) the surveys you complete throughout the study, 2) the mobile apps (Habit or MyFitnessPal), 3) your posts, comments, reactions, and video chat attendance in the Facebook group, 4) your feedback from the focus group call, and 5) your weight from the study scale. This information is very important to our study and necessary to answer our study questions. If you are uncomfortable with the study team accessing this data, you may choose not to participate in the study.

We use a software program called Grytics to collect data (posts, comments, replies, reactions) from the Facebook group. When you join the Facebook group, you'll be asked to click a link to "opt in" to the Grytics software so we can collect your engagement (posts, comment, reactions) from the group; this process is voluntary and not required for participation in the study. The study team Grytics account is password protected and only members of the study team will be able to view and download the engagement data collected by Grytics. If you forget to opt in with Grytics, your engagement data will be extracted from the group manually.

What are the risks involved in this study?

The risks involved with participation in this study are low and may include injury during exercise, accidental exposure of personal information, and discomfort with study procedures (e.g., feeling uncomfortable with questions asked on a survey or focus group).



If you feel discomfort during any part of the study procedures, you may withdraw at any time.

What are the possible benefits of this study?

The possible benefits of participation are weight loss, improved health, fitness, or mood, and feeling supported in your weight loss efforts. We cannot promise these benefits.

Is there an alternative to participation?

There are various methods for losing weight. If you are interested in exploring other options outside of this study, please see your primary care provider to discuss these options.

Do I have to participate?

No, your participation is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will not affect your relationship with the University of Connecticut in any way.

If you would like to participate, please sign this form, and fill out the subsequent questions when you are done reading through this document. You will receive a copy of this form.

Will participating in the study cost me anything?

No. There are no direct costs for taking part in this research study. However, depending on your smartphone data usage plan, additional charges may incur due to use of mobile apps.

Will there be any travel or other study-associated costs (for example, childcare) and will researchers provide any money to cover those costs?

No. There will be no travel or study-associated costs during this study, and you will not be reimbursed for costs you incur e.g., childcare, meals etc., while participating in this study.

Will I be paid for taking part in this research?

Yes. You will receive a \$100 Amazon gift card to thank you for your time and effort. You will receive the payment by email after all the follow-up assessments (weigh-in, survey, and focus group) have been completed. Additionally, you may keep the Fitbit scale we sent to you for weight collection.

Additional Information about your Participation



How will my information be protected?

We will make every effort to protect the confidentiality of study records that identify you, but we cannot guarantee total confidentiality. The data will be maintained on UConn servers which are secured through UConn's networks. Staff members who are approved to work on the study and have completed the necessary approvals will be given access to such data. The files will be managed by the project coordinators and data manager, who controls user access. All computers that have access to study are password protected. Certain databases for study participants also require a username and password to access. UConn research staff will be the ones to transcribe your focus group. Data that will be shared with others outside of approved study personnel will be coded by removing any identifying information to help protect your identity. After data analysis, we will remove identifying information and replace it with a number.

Your information will be viewed by the research team and other people within UConn who help administer and oversee research, including the UConn Institutional Review Board, and Research Compliance Services. People outside of UConn may also need to see or receive your information for this study. For example, researchers from WPI may access data from this study as they are collaborating with UConn on this project. Other examples include the study sponsor, and government agencies (e.g., Office of Human Research Protections (OHRP), etc.), safety monitors, other sites in the study and organizations that sponsor or help conduct the study. If information from this study is published or presented at scientific meetings, your name and other identifiable information will not be used.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

To use Facebook, MyFitnessPal, or Fitbit for this study, you will be asked to carefully read and separately agree and sign an end user or terms of service agreement. You should know that there is an increased risk to the security of your information if you are asked to use your personal device to download an app, transmit data, provide an electronic signature, or if your personal device is used to collect or store study data that identifies you. Using your personal device may lack sufficient protections for your data, also resulting in an increased risk of a breach of confidentiality. For any app or website, we encourage you to choose a password that includes a mix of lowercase letters, uppercase letters, numbers, and symbols, and does not include your username, the app/website name, or other easily guessable information about you. We also encourage you to not use the same password across different accounts.

Study staff will also use Google Voice to communicate with you via phone calls and text messages. Google Voice utilizes the staff member's Wi-Fi or data plan to send text messages and make phone calls. Researchers will retain the call history and text message exchanges for the duration of the study. Call history and text messages will be deleted once the study is over. If something sensitive is shared by you, we will delete it right away and save it in our secured files if it is relevant to the study. Anonymized copies



of call record information, with no personally identifiable information will be retained on Google systems to meet reporting and auditing requirements. This is no different than any standard phone plan.

During the focus group videoconference call at the end of the study we ask that everyone on the call keeps the conversation confidential.

Certificate of Confidentiality. This research is covered by a Certificate of Confidentiality. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know.

- The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
- The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA).
- The Certificate also DOES NOT prevent your information from being used for other research studies if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What will happen if I decide to withdraw from the study?

If you decide to leave the study, contact the researchers so they know. The researchers may ask you the reason, but you are not required to provide it. You will be given the option to partially end your participation in this study. This means you could still complete the follow-up assessments (weigh-in, survey, and focus group), but you would not have to keep doing the study program (Facebook group and using the app). This way the researchers can continue to ask about your health and any changes in your health. The follow-up assessments would occur at the end of the 6-month program.

After you leave the study, no new information will be collected from you unless you decide to complete the follow-up assessments. Information that has already been collected will remain in the study database and be used to determine the results of the study.



In addition, the researchers could end your participation in this study if they don't feel that it is in your best interest, or if the study is stopped early. Other examples ending participating are, but not limited to, pregnancy or inappropriate posts on Facebook.

Who can I contact with questions about the study?

Prior to, during or after your participation you can contact the Principal Investigator (using the contact information on page one) or the research team at mhealthstudy@uconn.edu for any questions or concerns or if you feel that you have been harmed or injured as a result of being in the research.

Who can I contact with questions concerning my rights as a research participant?

Prior to, during, or after your participation you can contact the IRB Office at irb@uconn.edu to:

- Discuss problems, concerns, and questions, including questions about your rights as a person in a research study
- Obtain information
- Offer input.

The IRB Office is not affiliated with any specific research study. You can contact anonymously if you wish.

Voluntary Participation

Your participation in this research study is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will not affect your relationship with the University of Connecticut in any way.

If you would like to participate, please sign this form, and fill out the subsequent questions when you are done reading through this document. You will receive a copy of this form.

Consenting to be in this Study:

You have been informed about this study's purpose, procedures, possible benefits, and risks, and you will receive 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 other questions at any time. You voluntarily agree to participate in this study.

If you sign below, it means you have read this consent form and agree to be a participant in this study. By signing this form, you are not waiving any of your legal rights.

First Name:

Last Name:

Sign Here:

Date: