Randomized Trial of Diet Tracking Prescriptions for Weight Loss

NCT not yet assigned

9-14-23

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Consent for Participation in Research

Protocol Title: Mentoring in mHealth and Social Networking Interventions for CVD Risk Reduction: Intervention Phase
Principal Investigators: Sherry Pagoto, Ph.D. (sherry.pagoto@uconn.edu)
Study Sponsor: The National Institutes of Health

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 with 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 different approaches to dietary tracking when paired with an online weight loss program.

The purpose of this study is to evaluate the practicality and sustainability of dietary tracking in an online weight loss program.

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

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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 16 hours from the screening phase to follow-up assessments that occur after the program ends. See the table below for the expected time commitment for participating in the study. This study will include approximately 108 study participants from across the United States.

Study Phase	**Approximate Time (min)**
Screening Initial Screening Survey (15 min)	15
Baseline Orientation Webinar (60 min) E-consent (10 min) Baseline survey (15 min) Scale and app set-up (10 min)	95
Weight Loss Program Online weight loss group and mobile app use (8-weeks)/15 min/day (840 min)	840
Study follow-up #1 (week 9) Weigh-in (5 min) Online survey (15 min) Study follow-up #2 (week 12) Weigh-in (5 min)	25
Total	960 minutes (approx. 16 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 study 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 and various aspects of your health.

- We will ask you to weigh-in on a 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:

- An 8-week weight loss program carried out in a private Facebook group led by a professional weight loss counselor and use of MyFitnessPal.
- 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 the three groups of this program. All groups will receive the same weight loss program led by a professional counselor. The only difference between these three groups is the schedule by which we will ask you to track your diet and exercise in MyFitnessPal. You will be asked to track every day, daily every other week, or two weeks on and one week off. You have an equal chance of being in one group or the other. If you are not interested in being randomized into one or more of the groups, this study is not the right fit for you.

Private Facebook Group Weight Loss Program.

In this group, the 8-week weight loss program will be carried out in a private Facebook group. Each week the professional counselor in the group will guide you through an evidence-based weight loss program called the Diabetes Prevention Program. A weight loss counselor will lead 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 share the goals, behavioral weight loss strategies, and pose questions to the group to find out what is working and what isn't working for you. Each week the group will be assigned a diet and exercise goal that will help you reach the weight loss goal and gradually shape your diet to be consistent with the American Heart Association diet. You will be encouraged to interact with other participants in the Facebook group by providing 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.

Facebook's group privacy settings allow us to restrict the group's access to only those who have been invited. The group is 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 Facebook friends will not know you have joined the 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 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.

MyFitnessPal. You will be asked to use MyFitnessPal, a free mobile app, to track your dietary intake and exercise to help you stay within your calorie goal. This app gives you a daily calorie goal that will help you lose weight. The group you are randomized into for this study will determine how much you will track in MyFitnessPal. Group one will be asked to track their diet and exercise every day in MyFitnessPal for the entirety of the program. Group two will be asked to track every other week. Group three will be asked to track for 2 weeks and then get a 1-week break and repeat that cycle throughout the program. You have an equal chance of being in one group or the other. After 8 weeks you will be encouraged to continue diet tracking as much as you can for the subsequent month.

Weekly Weigh-ins. You will receive a Wi-Fi scale so we can keep track of your weight throughout the study. Your weight will be uploaded directly from the scale to its app on your phone (free on the Apple App Store or Google Play Store). We will ask you to weigh yourself at several points during the program: when you set your scale up, on the first day of the program, weekly during the program, and twice after the program is over (in week 9 and week 12). Each time you weigh yourself it is important that you do so in the morning with no clothing, after voiding, and before eating or drinking so that we can get an accurate measure of weight. We will ask you to set up an account for the study and share your login information (i.e., your username and password) with study staff so that we can access your weight data. We will not add or change any information in your account; we will log in only to record your weights during the study. If you prefer to not let staff access your account, you may upload a screenshot of the weight entry directly from the scale 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 account.

Follow-up:

We will ask you to complete two assessments after the weight loss program is over. They will occur at the 9 and 12-week mark after the start of the weight loss program. The follow-up assessments will include:

- A weigh-in on the scale (both time points)
- A survey which includes questions about your opinion of various aspects of the program (9-week assessment only)
- We will collect your MyFitnessPal entries; no work is required on your end for this (12-week assessment only)

Data Collection:

During the study, we will collect data in these ways: 1) surveys, 2) your weight from the study scale, 3) your posts, comments, reactions in the Facebook group, and 4) what you enter in MyFitnessPal. 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 and/or cardiovascular event, accidental exposure of personal information, and discomfort with study procedures (e.g., feeling uncomfortable with questions asked on a survey or something said in Facebook.

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 $50 for the 9-week assessment and $25 for the 12-week assessment. The procedures for each assessment will need to be completed before providing compensation. Additionally, you may keep the scale we will send 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. 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, the study sponsor, 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.

It is possible that the data from this study could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. Your name of any other identifiable information would be removed before being distributed.

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 any technology for this study (Facebook, MyFitnessPal, and the app for the scale) 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.

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 and survey), but you would not have to keep doing the study program. This way the researchers can continue to ask about your health and any changes in your health. The assessments would occur at the 9-week and 12-week mark from the start of the program.

After you leave the study, no new information will be collected from you unless you decide to complete the 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, inappropriate posts on Facebook, acting inappropriate/making people feel repeatedly uncomfortable during group meetings.

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:

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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: