8/31/2019

Informed Consent Form

Grant Title: RELAX: A mobile application suite targeting obesity and stress

NCT02615171

Information Sheet for Participation in a Research Study

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UNIVERSITY OF CONNECTICUT

Principal Investigator: Sherry Pagoto, Ph.D. and Bengisu Tulu, Ph.D.

Study Title: A technology based weight loss program using mobile apps and Facebook

Sponsor: The National Institutes of Health

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

Overview of the Research

You are being asked to provide consent to participate in a research study. Participation is voluntary. You can say yes or no. If you say yes now you can still change your mind later. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision.

- This research is being done is to evaluate the practicality and acceptability of two different technology-based weight loss programs.
- Participation will involve approximately 11.5 hours of your time over the next 14 weeks.
- The screening process includes a phone call with study staff to give you more details about the study, two screening surveys and a webinar.
- The possible risks of this study include injury during exercise, exposure of personal information, or discomfort with study procedures. If you feel discomfort during any part of the study procedures, you may withdraw at any time. Risks are described in more detail later in this form.
- There may also be benefits from participation. It is possible you may lose weight by participating in this study, but we cannot promise that. This research may also result in information that leads a societal benefit to deliver weight loss programs in settings such as worksites, in health plans, and clinics that have limited resources.
- Before making a decision about whether to participate in this research you should know that there are other options available to you. You may choose not to participate in the study or you may wish to talk to you doctor to review other weight loss options available to you.
- A more detailed description of this research follows.

Introduction

You are being asked to participate because you are interested in losing weight and managing your stress.

Why is this study being done?

The purpose of this research is to evaluate the feasibility and acceptability of two different technology-based weight loss programs. Both will include a mobile app for dietary management and a Facebook group. Each group will be asked to use a different diet mobile app, otherwise the programs are identical. This will help us determine which diet mobile app is most helpful. .

What are the study procedures? What will I be asked to do?

This is an online-only study. If you would like to take part in this research, your participation will include a screening phone call and online survey, 1-hour orientation webinar, a 12-week weight loss program on Facebook and using your assigned app, and a 60-minute focus group conference call after the program. Your participation will last approximately 14 weeks. We will also ask you to complete an online survey before the orientation webinar and after the 12-week program.

Screening surveys and phone call:
Screening involves an online survey (starting on the next page), a telephone interview with study staff, and a webinar, followed by another online survey.

Orientation webinar:
The webinar will last 1 hour and will include: an explanation about what it means to participate in research like this; a description of study procedures; the importance of completing study procedures; and an explanation of how to use the app your group is assigned to.

Weight Loss Program:
During the 12-week Facebook weight loss program, you will join a private Facebook group where you will receive weight loss counseling based on an evidence-based behavioral weight loss program. You will be asked to use a diet mobile app regularly for the 12 weeks. . You will be encouraged to interact with other study participants and the coaches in the private Facebook group. The program weight loss goal is 1-2 pounds per week and the physical activity goal is 150 minutes per week.

Diet App:
You will be assigned to one of two mobile apps. Both apps help you to track your diet but in slightly different ways. In one app, you will be asked to track your calorie intake, exercise, and meet a calorie goal. In the other app, you will be asked to track your overeating episodes, hunger, exercise, sleep, and mood. We ask that you only use the study app you are assigned to during the study and forego using other commercial diet apps until the study is over.

The private Facebook group:
Groups can be created on Facebook, and with the use of privacy settings, we can 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. As is the case with any online activity, it is always possible that other group members could screenshot content and share the screenshots or to discuss what is happening in the group with other people; however, we will ask all participants to in no way share any content in the group with anyone.

We will download data from the Facebook group including posts, comments, and reactions from the weight loss counselor, you, and other people in your group so that we can study this data to better understand how people participated. We will not download any data from your Facebook profile. Facebook may ask you to indicate (for example, by clicking on a button) that you are OK with us collecting these data from Facebook.

Weekly Weigh-ins:
You will receive a Fitbit Aria scale so we can keep track of your weight throughout the study. We ask for participants' weights at the beginning of the study, weekly, and at the end of the study so that we have a measure of how people are doing. It is important that you weigh yourself at these time points in the morning with no clothing and before eating or drinking so that we can get an accurate measure of weight for everyone. Weight is uploaded directly from the Fitbit scale to your Fitbit account. 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 email a screenshot of the weight entry directly from the Fitbit screen, or download a spreadsheet (CSV) file from Fitbit and email it to study staff. At the end of the study, the Fitbit Aria scale is yours to keep. You may change the password on your Fitbit account.

Follow-up:
At the end of the weight loss program, you will complete a 60-minute webinar focus group to discuss your feedback related to the program, and a 15-minute online survey. We will audio-record the focus group webinar. We will transcribe the group recording, during which time we will remove any names of participants to make the transcript de-identified. The information we learn from the recordings will help us learn how to improve our program.

Data Collection:
During this study we will collect data in 4 ways: 1) the surveys you complete at the beginning and end of the study, 2) the mobile apps, 3) the Facebook group, and 4) the Fitbit Aria 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.

Time Commitment:
See the table below for the expected time commitment for participating in the study.

Visit	Time
Initial Screening Survey (10 min)	10
Telephone Screening (20 min)	20
Baseline (60 min total)	60

Scale set-up (10 min) Online survey (50 min)	
Webinar (60 min)	60
Intervention (12 wks): Participants: ~35 min/week	420
Follow-up (120 min total) Focus group (60 min) Online survey (60 min)	120
Total	690 minutes (approx. 11.5 hrs)

What other options are there?

You may choose not to participate in the study or you may wish to talk to you doctor to review other weight loss options available to you.

What are the risks or inconveniences of the study?

Possible risks related to this research study include: injury during exercise. We try to avoid injuries by avoiding exercise that could result in discomfort, pain, or injury. Another possible risk of being in this study is that your personal information could be lost or exposed. To minimize this risk, we will do everything we can to make sure that your information is protected. Confidentiality will be maintained by the use of network secured database and locked file cabinets only accessible to study staff.

Information you share in the Facebook group is subject to Facebook's terms of use and privacy policy, for their website and mobile application. You should review these terms and the privacy policy carefully before participating. Facebook may be able to collect, store and use information about you, such as personal information, location data, shared information, photographs, and more. During the study, if the research team becomes aware of any changes made to Facebook's privacy policy, we will notify you and will encourage you to review your Facebook privacy settings. The Facebook group will be set to "secret" and posts are only available to group members. However, we cannot guarantee confidentiality. To help protect yourself, please do not share your location or contact information in the group. Additionally, please do not to share information from the Facebook group with people who are not in the group. The research team will not download any photographs you share in the Facebook group when we download engagement data. Online social interactions will be monitored by study staff to ensure the protection of privacy. We will delete the private (secret) Facebook group 6 months after the last post or comment.

Similarly, information you enter into the apps used in this study (including weights uploaded from the study scale), is subject to the terms of use and privacy policy. You should review these terms and the privacy policy carefully before choosing to download and use the app or the website. They may be able to collect, store and use information about you, such as personal information, location data, shared information, photographs, and more. During the study, if the research team becomes aware of any changes made to their privacy policies, we will notify you that this has occurred and will encourage you to review your privacy settings.

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.

During the focus group call at the end of the study, to protect your information we ask that everyone on the call keeps the conversation confidential and if you prefer to use an alias during the call, we can assign one to you so that only the study team knows who you are, but the others on the call do not.

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

What are the benefits of the study?

It is hoped that you will receive a benefit (weight loss) by participating in this study, however we cannot promise a benefit. Benefits to society include providing evidence to support a technology based weight loss program that is easily delivered in settings like worksites, health plans, and clinics that serve large populations but have limited space, staffing, and resources for traditional in person interventions.

Will I receive payment for participation? Are there costs to participate?

We will provide $20 compensation for completing the screening procedures (telephone screening, webinar, and survey) and $50 for completing the end-of-study focus group, follow-up survey, and your weight data. Compensation will be in the form of an online Amazon gift card e-mailed to you after you complete the follow-up assessment at the end of the study. You can also keep the Fitbit Aria scale ($120 value).

How will my personal information be protected?

The following procedures will be used to protect the confidentiality of your data. The researchers will keep all study records (including any codes to your data) locked in a secure location. At the end of the study, we will remove your name and contact information from the research records and replace with a code. The code will be a three digit number that reflects how many people have contacted the study team to express interest in the study. Audio recordings will be destroyed after 3 years. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. Data that will be shared with others will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. Future analysis of the de-identified data may be conducted as well and will not require additional consent. If you would like a copy of the results, please email the study team at mhealthstudy@uconn.edu.

We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee 100% confidentiality. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

You should also know that the UConn Institutional Review Board (IRB) and Research Compliance Services may inspect study records as part of its auditing program, but these reviews will only focus

on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

Can I stop being in the study and what are my rights?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.

Whom do I contact if I have questions about the study?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the principal investigator, Dr. Sherry Pagoto (sherry.pagoto@uconn.edu, 860-486-2313) or the program director, Jessica Bibeau (jessica.bibeau@uconn.edu, 860-486-8979). If you have any questions concerning your rights as a research subject, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.

NEXT STEPS

If you are interested in learning more about this research and participating, proceed to the next page and begin the initial screening survey. In this survey, the only personal contact information we will collect is your e-mail address. If you are eligible to proceed with the study, we will collect your name and contact information. The questions in this survey will ask questions to determine your eligibility. Some of these questions are related to your health. We will retain this information for our data analysis.

This study is registered on https://clinicaltrials.gov/ct2/show/NCT02615171