9/1/2019

Informed Consent Form

**Study Title:** “Facebook and Friends” Developing an Effective Online Social Network for Weight Loss

NCT02656680

# Information Sheet for Participation in a Research Study

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UNIVERSITY OF CONNECTICUT

**Principal Investigator:** Sherry Pagoto, Ph.D.

**Study Title:** Developing an Effective Online Social Network for Weight Loss

**Sponsor:** The National Institutes of Health

Disclosures: Dr. Pagoto is a paid consultant for Fitbit, Inc and provides them with advice about weight loss technology.

## 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.

- The purpose of this research is to test the effectiveness of using Facebook as a format to deliver weight loss counseling.
- Participation will include a screening phase, a webinar to learn more about the study, 16-week weight loss intervention on Facebook, and a focus group call to gather your opinions about the intervention after it ends. We will also ask you to complete an online survey before the orientation webinar and after the intervention ends about your health, social media use, and your opinions on this intervention.
- Participation will involve around 14 hours of your time during the 5 months of this intervention. Compensation will include a $40 Amazon gift card and a Fitbit scale.
- Possible risks related to this study includes injury during exercise, psychological discomfort while participating in the group, and release of confidential information. Some of the questions on the surveys may also cause you to feel upset. Risks are described in more detail later in this form.
- There may also be benefits from participation. It is hoped that you will receive a benefit of losing weight by participating in this intervention, but we cannot promise that will happen.
- Before making a decision about whether to participate in this research you should know that other options to improve your physical activity may be available to you. Please talk to you primary care doctor about possible options. A more detailed description of the study is below.

## Introduction:

Online social networking has the power to connect people overcoming geographical and financial barriers, and give us the ability to enhance social support for weight loss.

## Why is this study being done?

The purpose of this study is to test the effectiveness of weight loss counseling via Facebook.

## 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 phase, 1-hour orientation webinar, 16-week weight loss intervention on Facebook, and a 60-minute audiotaped focus group conference call after the intervention. Your participation will last approximately 5 months. We will also ask you to complete an online survey before the orientation webinar and after the intervention.

Screening Phase:
The screening phase includes an initial survey (beginning on the next page), a 10-minute telephone screening to discuss the study and allow for any questions, and a 2nd online survey.

Orientation webinar:
The webinar will last 1 hour and will include: an explanation about what research is; description of study procedures; and to express the importance of completing study procedures.

Weight Loss Intervention:
You will receive a Fitbit scale to take your weight weekly and at the end of the study follow-up. Weight is logged directly from the Fitbit scale to your Fitbit account. We will ask you to set up a Fitbit account for the study and share login with the study staff so that the staff can record the weight taken. At the end of the study, you will be allowed to keep your scale and instructed to change your password. If you already have a Fitbit account and choose not to create a 2nd one for the study, they may choose to share that login with the study staff. This method will allow for a standard weight measure for each participant. If you prefer to limit staff access to your Fitbit account, you may email a screenshot of the weight entry directly from the Fitbit screen.

During the 16-week Facebook weight loss intervention, you will join a private study group (secret Facebook group) in which you will receive dietary and exercise advice and tips to help you meet your goals. You will be encouraged to interact with other study participants and the coaches using the Facebook social network. We will encourage you to use MyFitnessPal to track your diet and exercise daily, which will help you stay on goal. Your weight loss goal will be 1-2 pounds per week and physical activity goal will be 175 minutes per week. You will also get an individualized calorie goal from MyFitnessPal to help you reach your weekly weight loss goal from MyFitnessPal to help you reach your weekly weight loss goal.

All Facebook posts, comments, replies, and reactions made in the study group will be downloaded from the group. This information is used to look at engagement in our intervention.

Follow-up:

The follow-up will take place the week after the intervention ends (in week 17). This will include a 60-minute phone call focus group to discuss your feedback related to the intervention, and a final online survey. This group is recorded. The group recording is transcribed after the group, during which time any names of participants are removed to make the transcript de-identified.

The information collected in the recordings will be analyzed to modify our intervention based on the feedback given by participants.

**Time Commitment:** This table shows time commitment for participated in this study.

| Visit | Study Participants |
|---|---|
| Initial Screening Survey (10 min) | 10 |
| Telephone Screening (20 min) | 20 |
| Baseline (35 min total)<br>Scale set-up (10 min)<br>Online survey (25 min) | 35 |
| Webinar (60 min) | 60 |
| Intervention<br>Approx. 35 min/week for 16 weeks (approx. 10 hrs) | 600 |
| Follow-up (85 min total)<br>Focus group (60 min)<br>Online survey (25 min) | 85 |
| Total | 810 minutes<br>(approx. 14 hrs) |

## What other options are there?

You may choose not to participate in the study or you may wish to talk to your primary care 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 and psychological discomfort while participating in the group. 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. If you feel discomfort during any part of the study procedures, you may withdraw at any time. If you wish, we will also provide you with an alias to use during the focus group call at the end of the study to remain anonymous to the others on the call.

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 use locations or contact information, when talking to other study participants. Additionally, please do not disclose that you are in a research study to protect confidentiality of other participants and do not to share links of the Facebook group with people not in the group. Online social interactions will be monitored by study staff to ensure the protection of privacy.

## What are the benefits of the study?

It is hoped that you will receive a benefit (losing weight) by participating in this study and taking part in the intervention, however we cannot promise a benefit.

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

We will provide $40 compensation in the form of an online gift card e-mailed to you after you complete the focus group and surveys at the end of the study. We will also send you a Fitbit scale for you to use during the study, which you can keep (value $120).

## 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, Sherry Pagoto (sherry.pagoto@uconn.edu, 860-486-2313) or the program director, Jessica Oleski (jessica.oleski@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.

This study is posted on Clinical Trials https://clinicaltrials.gov/ct2/show/NCT02656680