Consent Form for Participation in a Research Study

UCONN
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Principal Investigator: Sherry Pagoto, Ph.D.
Study Title: Get Social: Randomized Trial of a Social Network Delivered Lifestyle Intervention
Sponsor: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Introduction

You are being asked to participate because you are between the ages of 18-65 and are interested in losing weight.

Why is this study being done?

The purpose of the study is to compare two different approaches in delivering a standard behavioral weight loss intervention. We are testing to see how delivering the weight loss counseling through an online (Twitter) social network compares to the traditional approach of group meetings.

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

If you would like to take part in this research, your participation will include a baseline visit, a webinar, an orientation, participation in a 12-month weight loss intervention, and 2 follow-up visits occurring at 6- and 12-months.

Baseline Visit: This visit will last 90 minutes and will include the consent process, a description of the study, weight/height measurements, blood pressure reading, three 24-hour diet recall interviews, and completion of surveys assessing your eligibility and personality characteristics. We will also ask for medical approval from your primary care doctor to participate.

24-hour diet recalls: Recalls will be completed using a web-based program called Automated Self-Administered 24-hour (ASA24®) Dietary Recall System. Three recalls will be completed at each assessment (baseline, 6 months, and 12 months). At the end of the baseline appointment, a staff member will walk you through your first recall, then two days will be chosen randomly for you to enter over the next week. You may enter these two days on your home computer (you will be given log in instructions) or you may come into our office to complete them.

During the baseline procedures, you'll be scheduled to attend a 60-minute webinar, which will include: an explanation about what research is; description of study procedures; and to express the importance of attending study visits. Attendance at the webinar is required before we can randomize you.

Once you've complete all baseline measures, we will determine your eligibility. This includes physical measurements collected at the baseline visit, all baseline surveys (including current health and medications), your medical clearance from your primary care doctor, the 3 dietary recalls, and the webinar.

Randomization: This will take place after the webinar once we've determined if you are eligible for the study. You will be randomly assigned to one of two weight loss interventions. One is online (Get Social) and one is in-person (Traditional), both include the same lifestyle intervention content. You have a 50/50 (equal) chance, like the flip of a coin, of being in one group or the other.

Intervention Phase (Lasting 12 months):

If you are assigned to the **Traditional** intervention, your participation will include:

- Intervention: During the 12-month intervention you will receive dietary and exercise counseling and tips to help you meet your healthy lifestyle goals. In-person groupswill be held weekly for 8 weeks, then biweekly for 16 weeks, then monthly between 6- and 12-months. The first group will be two hours long to review My Fitness Pal and the study. My Fitness Pal is a freely accessible mobile app that you can use on your phone or computer and is used to track your diet and physical activity. You will also receive study goals for weight loss, diet, and physical activity. The rest of the groups will last 1.5 hours each. You will receive calorie and physical activity goals to help you achieve a healthy weight loss of 1-2 pounds per week. We will take your weight on a weekly basis. We will encourage you to track your diet and exercise daily using My Fitness Pal, which will help you stay on goal. Groups will be audiotaped for quality control of the intervention.

If you are assigned to the **Get Social** intervention, your participation will include:

- Orientation Visit: This will be an in-person individual visit lasting 1 hour and will include setting up your Twitter account, receiving training on Twitter, and downloading an app called App Usage Tracker. This app will track the time you spend on Twitter so that we can measure the time participants are spending on the intervention as it compares to an in-person intervention. You will be asked to follow the study staff and the other study participants. We will have you set your account to "protected" and we will review suggestions on how to engage in the Twitter group. We will ask you to tweet daily to get experience with the way Twitter works and to bring any questions or concerns to the group orientation.

- We will also schedule you for a 2-hour in-person group orientation visit with your smartphone or laptop to receive additional training/practice on Twitter, an introduction to My Fitness Pal, and an overview of your participation and the study goals. You will receive your study goals for weight loss (1-2 lbs. per week), diet, and physical activity.

- Intervention: During the 6-month intervention phase you will receive dietary and exercise counseling and tips in a "protected" group on Twitter, to help you meet your healthy lifestyle goals. You may also ask the interventionists who are experts in weight loss counseling, questions via "tweets" or direct messages on Twitter. You will be encouraged to interact with

other study participants on Twitter and to participate in the group every day. You will receive calorie and physical activity goals to help you achieve a healthy weight loss of 1-2 pounds per week. We will encourage you to track your diet and exercise daily using My Fitness Pal, which will help you stay on goal. You will engage with other participants and coaches via tweets and direct messages.

- We will email you regularly to ask you for your current weight so that we can help you stay on track with your weight loss goals. Also, in the same e-mail we will ask you how much time you spent on Twitter in the group for that week. If you use an iPhone staff will show you how you can find that information in your battery setting. If you have an Android phone, you will access that information from the App Usage Tracker. Additionally, we will include some questions that will ask you how much time it took to read some of the materials. This survey will only take a couple of minutes to complete each time.

  By protecting your tweets, you can approve/decline other twitter users following you. Participants and counselors will have the privacy setting activated so that tweets are only viewable to each other. Please visit this link if you wish to read more about Twitter protected tweets: https://support.twitter.com/articles/20169886.

Follow Up: In-person follow-up visits will be scheduled at 6- and 12-months. These visits will last 1 hour and will include a weight measurement, blood pressure reading, three 24-hour diet recall interviews, and a repeat of the baseline measures. We will e-mail you the survey link to complete the surveys online 1 week prior to the scheduled follow-up visits.

Time Commitment: This table summarizes the time commitment for participating in this study:

Visit	Get Social (online) (in minutes)	Traditional (in-person) (in minutes)
Telephone Screening (20 min)	20	20
Baseline: Visit (90 min) 2 at-home dietary recalls (60 min) Online survey (60 min)	210	210
Webinar (60 min)	60	60
Orientations	180	
Intervention GS: approx. 35 min/week 8 weeks, 14 min/week for 16 weeks, 8 min/week for 28 weeks (12.5 hrs) T: 22 1.5 hr groups (33 hrs)	750	1980
6-month (150 min total) Visit (30 min) 2 at-home dietary recalls (60 min) Online survey (60 min)	150	150
12-month (150 min total) Visit (30 min) 2 at-home dietary recalls (60 min) Online survey (60 min)	150	150
Total	1520 minutes (approx. 25 hrs)	2570 minutes (approx. 43 hrs)

What other options are there?

You do not have to be in this study to receive weight loss counseling. If you wish you receive weight loss counseling without participating in this study please contact your primary care doctor for more information about weight loss.

What are the risks or inconveniences of the study?

Possible risks related to this research study include: injury during exercise, psychological discomfort while completing measures or groups, and breach of confidential information. We try to avoid injuries by avoiding exercise that could result in discomfort, pain, or injury.
If you report that you are a safety concern to yourself or someone else we will need to release your confidential information for emergency care purposes. If we determine it is necessary, we will bring you to the emergency room, call emergency services for you, and/or we will consult with your treatment provider if you are currently seeking psychiatric treatment. Additionally, if you present with a high blood pressure reading of 220/120 or higher we will call an ambulance for you to receive immediate care in an emergency room.

Confidentiality will maintained by the use of first names during groups, network secured database, and locked file cabinets and password protected computers only accessible to study staff. If you feel discomfort during any part of the study procedures you may withdraw from the study at any time. You do not need to complete measures during study visits, attend groups, or participate in the Twitter feed if you do not want to.

Get Social Participants: In an effort to protect confidentiality on Twitter, we ask that you not use real names, locations, or contact information, and to only use usernames, not real names, when communicating with other study participants on Twitter. We will also ask that you do not disclose that you are in a research study to protect confidentiality of other participants. 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 lose weight by participating in this study, however we cannot promise this will happen. If you experience weekly episodes of excessive overeating (i.e., eating significantly more than what most people would eat in a similar period of time), of which you have difficulty controlling and it causes you distress, you will likely not benefit from this intervention and you may want to consider other options.

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

We will provide $30 compensation for completing all baseline procedures including: the baseline visit, the online surveys, and 3 24hr recalls. If you complete the 6 month assessment within the 2-week target window, we'll provide $40 compensation; otherwise we'll provide $30. If you complete the 12 month assessment within the 2-week target window, we'll provide $60 compensation; otherwise we'll provide $45. Assessment visit compensation will be provided after completing the follow-up visit, follow-up surveys, and 3 24hr recalls. Payment will be in the form of an online Amazon gift card paid upon completion of each assessment. Please note

that in order to provide you with compensation at each assessment, we will ask that you complete all measures for each assessment.

The Twitter, MyFitnessPal app, and App Usage Tracker will not cost any money to use. They are freely accessible. We do encourage you to check your data usage plan to ensure you are using the appropriate settings on your phone to minimize the use of your data so you don't incur any charges due to the increased use of apps during participation in the study.

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 four digit number that reflects how many people have contacted the study team to express interest in the study. Audio recording 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.

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.

You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.

Data that we have already used will stay in the study database and cannot be removed in order to maintain the integrity of the research. However, you can ask us to destroy any information that identifies you so that no one can tell the data belonged to you. Our contact information is below.

If you only want to withdraw from the intervention portion of the study, we will ask if you would like to complete the follow-up assessments.

The person in charge of the research study or the sponsor can take you out of the study even if you do not want to leave. This may happen if you do not complete the webinar or baseline procedures, disrupt in-person groups, or post inappropriate content on Twitter.

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 study 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 on the research study Jessica Oleski (Jessica.oleski@uconn.edu, 860-486-8979). If you have any questions concerning your rights as a research participant, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.
This study is registered on https://clinicaltrials.gov/ct2/show/NCT02646618

Documentation of Consent:

I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

_____	_____	_____
Participant Signature:	Print Name:	Date:
_____	_____	_____
Signature of Person Obtaining Consent	Print Name:	Date: