Project Title: Peer Support for Weight Loss Maintenance

Informed Consent

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Consent Form for Participation in a Research Study

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UNIVERSITY OF CONNECTICUT

Principal Investigator: Tricia M. Leahey, Ph.D.
Study Title: Peer Support for Weight Loss Maintenance
Sponsor: National Institutes of Health

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 to examine effective strategies for long-term weight management. Participation will involve approximately 2 hours of your time per/week over the next 2.5 years. You will be asked to participate in an online weight loss program followed by an 18-month weight maintenance intervention, which would require attendance at group sessions. In the event of a national emergency (like COVID-19), these sessions will be held online via videoconference. You may also be asked to exchange emails with another participant on a weekly basis. In addition, you will be asked to complete online surveys every 3 months and have your weight and blood pressure taken every 6 months.

The principal risks of weight loss are hunger associated with eating less and injuries from physical activity. Because this is an investigational study there may also be risks that are not yet known. Some of the survey questions may also cause discomfort and you do not have to answer questions that are uncomfortable for you. Risks are described in more detail later in this form. There may also be benefits from participation. You will receive important information about weight loss and physical activity and you may lose weight, eat healthier, and become more physically active, though this is not guaranteed. In terms of societal benefits, this research will advance knowledge regarding effective programs for weight loss maintenance and may help others lose weight and maintain their weight loss.

Before making a decision about whether to participate in this research you should know that there are other options available to you. Alternative treatments include very low calorie diets, medications, or bariatric surgery. A more detailed description of this research follows.

Introduction

You are invited to participate in a research study to examine effective strategies for long-term weight management. You are being asked to participate because you are an adult between the ages of 18 and 75; have a body mass index (which is a measure of weight relative to height) between 25 and 50 kg/m^2; have access to the Internet; are not involved in any other weight loss programs; have

no history of bariatric surgery or recent, substantial weight loss; do not plan to become pregnant within the next year; do not plan to relocate outside of the greater Hartford area; can read and write in English; and have no medical conditions that prevent you from being involved in a weight management research study.

This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences or discomforts that you may have while participating. We encourage you to take some time to think this over and to discuss it with your family, friends and doctor. We also encourage you to ask questions during the orientation session and anytime in the future. If you decide to participate and your orientation occurs in-person, you will be asked to sign this form. If you decide to participate and your orientation session occurs via videoconference, you will be asked to agree to participate during our virtual videoconference. Research staff will keep a record of your agreement to participate. You will be given a copy of this form.

Why is this study being done?

Overweight and obesity are common and associated with serious health risks. Behavioral weight loss programs have been shown to produce significant weight loss and prevent the onset of medical problems linked to excess body weight. However, one of the major challenges following initial weight loss is weight loss maintenance. That is, most individuals regain the weight that they lost. Thus, effective interventions that prevent weight regain are needed.

This study aims to test two strategies for weight loss maintenance. It involves two phases, a weight loss phase and a maintenance phase. If you agree to participate, during Phase I (the weight loss phase), you will receive a 16-week, Web-based behavioral weight loss program that involves access to weekly weight loss information and weekly personalized feedback on diet, activity, and weight loss goals. If you lose at least 5% of your initial body weight during this program, you will be invited to participate in Phase II. During Phase II, we will test two 18-month treatments for weight loss maintenance. At the beginning of Phase II, you will be randomly assigned to one of the two maintenance programs: (1) a standard maintenance program that involves group meetings delivered by study staff or (2) a new maintenance program that involves group meetings delivered by a successful weight loser (someone who has lost weight and kept it off) and weekly social support from a fellow participant. Throughout the study, you will complete assessments that examine the effects of the interventions on weight and other important health and psychosocial outcomes.

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

As mentioned, there are two parts to this research study. At the beginning of Phase I we will ask you to complete surveys assessing basic demographic information (e.g., sex, age, race, ethnicity) and feelings of social support, hope, inspiration, etc. These measures will take approximately 60-minutes to complete. After you complete these measures, you will be invited to attend a one-time meeting. In the event of national emergency (COVID-19), this meeting will occur via videoconference. During normal times, this meeting will occur in-person. This meeting will be approximately 1 ½ hours in duration. During the meeting, your weight and height will be measured and you will be oriented to the 16-week, Web-based behavioral weight loss program.

This program involves weekly lessons that include behavioral strategies to help you meet your weight loss goals. You will be asked to reduce your caloric intake and increase your physical activity. You will also be given weight, calorie, and physical activity goals and taught how to self-monitor these behaviors. You will be asked to submit your diet, activity, and weight self-monitoring information via a secure Website on a weekly basis. After the information is submitted, you will receive an individualized feedback message with suggestions for meeting weight loss goals. At the end of the 16-week Web-based weight loss program we will ask you to complete surveys including measures of social support, emotions, and perceptions along with diet and weight management behaviors. This measures will take approximately 60-minutes to complete. You will be asked to attend a post treatment assessment visit, either virtually or in-person, during which we will measure your weight and determine your eligibility for Phase II.

If you lose at least 5% of your initial body weight during Phase I, and are available to attend group sessions (virtually in the event of COVID-19, or in-person under normal circumstances), you will be eligible to participate in Phase II, the weight loss maintenance phase. During this phase, we will evaluate two different approaches to weight loss maintenance. Phase II will be approximately 24-months in duration. It will include an 18-month maintenance intervention and a 24 month follow-up visit. If eligible at your post-treatment assessment visit, we will then continue to take additional measures to mark the beginning of the maintenance phase. These measures will take approximately 30-minutes to complete. We will first measure your blood pressure. If blood pressure is elevated, research staff will inform you at the assessment visit and ask you to contact your doctor for follow-up care. Finally, we will measure your current level of physical activity by asking you to wear a physical activity monitor at your waist for one week. After this visit, you will be randomized to one of two maintenance interventions. Randomization means that you are put into a group by chance. Which group you are put in is done by a computer. Neither you nor the researcher will choose the group you are in. You will have an equal chance of being placed in each group. Below is a description of each maintenance group:

- **Standard Weight Loss Maintenance Treatment**. Standard weight loss maintenance treatment will involve 18-months of group meetings focused on healthy eating and physical activity. In the event of national emergency (e.g., COVID-19), these group meetings will occur virtually via videoconference. In normal times, these meetings will occur in-person. Meetings will be weekly for one month, every other week for three months, and monthly for 10 months. Meetings will be approximately one hour in duration. Meetings will be led by a masters-level interventionist trained in behavioral weight management. Group content will cover evidence-based weight management strategies focused on diet, exercise, and behavioral skills. You will also be encouraged to continue to monitor your diet, activity, and weight. We will ask you to send us your weight progress via email, and the group leader will provide feedback on your progress.

- **Patient-Provided Weight Loss Maintenance Treatment.** Science suggests that patients who are going through or have gone through similar treatment experiences provide a unique sense of empathy, compassion and support to one another that is not duplicated by professionals, family, or friends. Thus, in the Patient-Provided intervention, patients trained by the investigators (in the exact fashion in which we train professionals) will deliver the entire treatment. Specifically, if you are assigned to this group, you will attend seven treatment sessions that are up to two hours in duration and led by two successful

weight losers, defined as individuals who lost at least 7% of their body weight and kept it off for at least one year and who are trained to deliver treatment. In the event of national emergency (e.g., COVID-19), these group meetings will occur virtually via videoconference. In normal times, these meetings will occur in-person. You will also engage in weekly email and/or text-based communication with another participant in the group. You will be asked to use your personal email account / phone for this communication. Your group leaders (successful weight losers) will teach you and your partner how to provide one another with social support and help in meeting weight loss goals. You will be expected to exchange emails or texts with your partner every week and share your weight management progress (diet, activity, weight) and provide each other with feedback and support. Your successful weight loser interventionist will also email you lessons that include important weight management strategies every week. You will also be given access to a "secret," or private, Facebook page where you can interact with your interventionist and other group members; interacting on this page is optional. Being involved in a "secret" Facebook group means that the public is unable to "see" the group and only the study team can invite users, which will include you, your group leaders, and participants from your group. The study team and your group leaders will monitor posts in the "secret" group to ensure that posts are appropriate and safe. If there are concerns regarding a post that you published, you will be contacted and counseled on appropriate posts. Study staff may remove participants from the "secret" group who do not adhere to group standards, despite counseling. This entire intervention is 18-months in duration.

Researchers will record treatment meetings for treatment standardization purposes and to provide group leaders with supervision and feedback. All information will be kept confidential. Recordings will be destroyed after all standardization and supervision procedures are complete, or three years after the study ends, whichever comes first.

Throughout the 18-month maintenance program and six months after the program ends, you will be asked to complete assessments. Specifically, every three months during the program, you will be asked to complete surveys assessing various aspects of social support, quality of life, and behavioral and psychological factors related to weight management. These assessments will take approximately 30-minutes to 1-hour to complete. Every six months during the program, you will also be asked to provide measures of weight and blood pressure. You will be asked to provide measures of physical activity a total of four times throughout the program (procedures will be identical to those noted above – e.g., activity monitor, etc.). These assessments will be approximately 1-hour in duration. In the event of national emergency (e.g., COVID-19), assessments will occur virtually via videoconference. We will send you assessment equipment in the mail, you will complete your videoconfernce assessment with research staff, and you will send the equipment back to us. In normal times, assessments will occur in-person.

To best determine which of our weight loss maintenance programs is most effective, you will be asked not to join any other weight management programs during the study. Similarly, to best determine which program is most effective, you will be expected to complete all assessment visits. During normal times, all assessment and intervention sessions will occur at 1 Constitution Plaza in Hartford, Connecticut. In the event of a national emergency (e.g., COVID-19), assessment and intervention sessions will be conducted remotely via options like video conference, online surveys, phone, and/or email.

Once the study is over, we may contact you to see if you are interested in participating in a research study. Under these circumstances, your name and contact information would be stored separately from your personal health information (e.g., weight, survey data, etc.) and we would call you to describe the new study. At that time, you can decide whether you want to attend an orientation session to learn more about the new study. At the orientation session, you would officially decide whether you want to participate.

What other options are there?

A wide variety of other weight control and activity programs are available from commercial entities and, in some cases, physician offices. Alternative treatments include very low calorie diets, medications, or bariatric surgery. These alternative treatments are considered to have greater risks than the lifestyle interventions to be tested herein.

You have the option not to participate in this study. The potential risks associated with this option are missing out on important weight management information and an opportunity to potentially lose weight, improve physical fitness, and experience health benefits associated with weight loss and physical activity. However, because many aspects of the interventions being tested are new, there is no guarantee that these changes would happen for you. The benefits associated with not participating in this study are that you could try a variety of weight management strategies (commercial programs, medications, etc.) and would not have to commit to just one. In addition, this study involves a serious commitment of time and energy to the research procedures; thus, if you chose not to participate, you would not have the time and effort commitments associated with attending treatment sessions, engaging in all Web-based treatment activities, and attending and completing assessment visits.

What are the risks or inconveniences of the study?

There are minimal risks associated with participating in this study. These risks are consistent with those of routine daily activities and routine doctor's appointments. These risks are detailed below. The order in which they are listed (first to last) is indicative of the likelihood that you will experience the risk:

- **Hunger associated with eating less**. You may experience some initial hunger associated with eating fewer calories. However, the dietary approach prescribed is balanced and you will only be asked to reduce your caloric intake by approximately 1,000 calories per day, thereby minimizing this risk.
- **Injuries related to physical activity.** Although increasing your physical activity can have great benefits, you may feel tired or develop sore muscles or joints from being active. It is also possible that you could fall or be injured during physical activity. Being physically active at very high intensity has been known to cause heart attack and sudden death related to heart problems in 1 in 20,000 adults. Performing moderate intensity physical activity such as walking reduces the risk of these complications. Thus, to reduce risk, we will encourage moderate intensity physical activity and recommendations will start slow (exercise 10 minutes five days per week) and increase/decrease at your own pace.

- **Discomfort completing questionnaires.** You may experience discomfort while completing questionnaires. If this occurs, you will not have to answer questions that are uncomfortable for you.
- **Time commitment.** As noted above, this study involves a significant commitment of both time and energy. Your time and commitment to the study will be required for assessment visits and treatment engagement (both in person visits [when allowable] and Web-based intervention activities). To optimize your time during the study, research staff will help to ensure that all procedures and visits are conducted as efficiently as possible.
- **Unforeseen risks.** If there are any risks that arise during the course of the study that are not mentioned here, you will be informed of the new risk(s) and asked to provide your permission to continue participation.

What are the benefits of the study?

There are potential personal and societal benefits to participating in this research study. With regards to personal benefits, you will receive important information about weight loss and physical activity. Participation may also help you lose weight, eat healthier, and become more physically active. The benefits of participating in this program could include improvement in physical health and fitness associated with weight loss and increased physical activity, however, there is no guarantee that these changes will happen. In terms of societal benefits, the information you provide during the study will advance knowledge regarding effective programs for weight loss maintenance and may help others lose weight and maintain their weight loss.

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

If you qualify for and participate in Phase II, you will be given $25 for completing the 6- and 12-month assessment visits, $50 for completing the 18-month assessment visit, and $75 for completing the 24-month assessment visit. These monies will be paid to you in cash, check, money order, e-gift card or electronic payment (e.g. Paypal). No monies will be paid for completing Phase I assessment visits. General transportation expenses (gas, bus, etc.) will not be reimbursed by the study. However, the research study will pay for you to park in downtown Hartford during all of your in-person study visits (Phase I and Phase II).

How will my personal information be protected?

The following procedures will be used to protect the confidentiality of your data. Only researchers and study staff involved in this project will have access to your study data. The researchers will keep all study records (including any codes to your data) in locked filing cabinets in locked rooms. Research records will be labeled with a code. The code will be derived from a number (a sequential three digit code plus your cohort number – e.g., 1001) that reflects how many people have enrolled in the study. A master key that links names and codes will be maintained in a separate and secure location. Research data will be kept indefinitely; however, the master key linking participants to their data will be destroyed 3 years after the study ends. Similarly, the study team will have access to recordings; such recordings will be reviewed by research study staff including the principle investigator. All recordings will be destroyed 3 years after the study ends. Electronic files (e.g., databases, spreadsheets, etc.) containing identifiable information will be password protected. Any

computer hosting such files will also have password protection to prevent access by unauthorized users. All study data collected electronically by our staff will be encrypted and stored in a password protected database and/or on a secure Web hosting site. All data will be stored on secure servers. While protections are in place, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

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 and identifying information will be removed 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. If you choose to use an app to monitor your diet, activity, or weight (e.g., MyFitnessPal), data entered into the app is only secure to the extent offered by the app. If you are randomly assigned to the patient-provided weight loss treatment, you will be asked to use your personal email account and/or your personal phone to communicate with fellow patients. In the case of a national emergency (e.g. COVID-19) you will be expected to attend group intervention sessions and individual assessment sessions via a video conference platform, such as WebEx. Information shared in virtual groups is only secure to the extent offered by the platform itself. You will also have the option of engaging in a "secret," or private, Facebook group to interact with your interventionist and fellow group members. Being involved in a "secret" Facebook group means that the public is unable to "see" the group and only the study team can invite users, which will include you, group leaders, and participants from your group. Participation in this private Facebook group is voluntary; it is your choice as to whether you want to be involved in the private Facebook group. Choosing not to participate in the private Facebook group will not affect your experience with any other aspects of the weight management intervention. Any information transmitted via email, phone, video conference or Facebook is only secure to the extent offered by the providers' privacy / security policy; we encourage you to familiarize yourself with these policies. It is also important to keep in mind that anything you post on Facebook is technically governed by and can be used by Facebook; therefore, the study team cannot ensure complete confidentiality of all of your Facebook posts and information. Similarly, you may receive other notifications from Facebook or suggestions and requests about people you may know – this is controlled by Facebook and not the research team. Facebook terms and conditions may be updated periodically; therefore, we highly recommend that you go to https://www.Facebook.com/legal/terms to check the latest statement of your rights and responsibilities related to Facebook use. The study team may also examine your Facebook group posts throughout the program for the frequency and nature of the posts. These results may be presented, but if any data are presented the data will not be identifiable by name or other personal information; instead, the results will be presented anonymously and in aggregate (grouped) format. Given the limitations of technological security and privacy, we recommend that you be mindful of these limitations while sharing information and only share to the extent that you are comfortable.

This study is funded by the National Institutes of Health (NIH). Because of this, progress reports will be provided to the NIH. Such reports will include your data but will not be connected to you personally. Specifically, data shared will "de-identified," meaning that it will not contain any identifying information (names, addresses, phone numbers, etc. will not be included). Data that we collect from you may also be shared with other researchers and linked together with other information such as your age, gender and ethnicity. However, again, before data are shared, your name and all identifying information will be removed. De-identified data will be retained indefinitely.

All study participants will be encouraged to maintain strict confidentiality. However, confidentiality of your identity or information discussed during group sessions or in any communication outside of group sessions (email, text, face-to-face) with other participants cannot be guaranteed by research staff.

Research staff will maintain your confidentiality to the extent the law allows. If, during the course of this research study, a UConn employee suspects that a minor (under the age of 18) has been abused, neglected, or placed at imminent risk of serious harm, it will be reported directly to the Department of Children and Families (DCF) or a law enforcement agency.

If you choose to withdraw from the study, information collected from you prior to your withdrawal will be used for research purposes.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this web site at any time.

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.

What happens if I am injured or sick because I took part in the study?

In the event you become sick or injured during the course of the research study, immediately notify the principal investigator or a member of the research team. If you require medical care for such sickness or injury, your care will be billed to you or to your insurance company in the same manner as your other medical needs are addressed.

However, if you believe that your illness or injury directly resulted from the research procedures of this study, you may be eligible to file a claim with the State of Connecticut Office of Claims Commissioner. For a description of this process, contact Research Compliance Services at the University of Connecticut at 860-486-8802.

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. If there are survey questions that make you feel uncomfortable to complete, you do not have to complete them. You will be notified of all significant new findings during the course of the study that may affect your willingness to continue. Research staff may also inform you that you need to be removed from the study at any time. That is, if you join the study, but later the researcher or your doctor feels that being in the study is no longer appropriate for you due to safety / medical reasons, they may choose to take you out of the study before it is over. Also, if you miss an appointment or are disruptive during any study procedures, you may be removed from the study.

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, Dr. Tricia Leahey at 860-380-2987. 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.

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: