Project Title: PACE (Physical Activity Choices Everyday)

Informed Consent

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Consent Form for Participation in a Research Study

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Study Title: Decisions about exercise during weight management
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 conducted to explore effective strategies for long-term weight loss maintenance. Participation will involve approximately 3-4 hours per week over the next 8-months. There are two phases in this study. Phase I is a 16-week, web-based behavioral weight loss program which includes reporting your weekly weight, physical activity, and caloric intake and receiving weekly personalized feedback. If you lose 5% of your starting weight by the end of Phase I, you may be eligible for Phase II. Phase II tests two 4-month treatments for weight loss maintenance. Requirements for Phase II involve in-person group meetings, occasional meetings with a case-manager, plus daily exercises on your personal mobile device. You will also be asked to complete web-based surveys and attend in-person assessments. In the event of a national emergency (e.g., COVID-19), these in-person meetings will be held online via videoconference on a platform like WebEx.

The risks associated with participating in this study are consistent with those of routine daily activities and routine doctor's appointments. These risks include hunger associated with eating less and potential injury from physical activity. Because these long-term weight management strategies are investigational there may also be risks that are not yet known. Some of the questions on the surveys or interview may also cause you to feel upset. Risks are described in more detail later in this form. There may also be benefits from participation. Benefits 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.

Before making a decision about whether to participate in this research you should know that there are other options available to you. A wide variety of other weight control and activity programs are available from commercial entities. Other options include very strict diets and bariatric surgery. You should review any alternative options with your doctor.

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 70; have a body mass index (which is a measure of weight relative to height) between 30 and 50 kg/m^2; have access to the Internet and a smartphone; 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; are willing to use videoconference during the program; 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 now and at any time. If you decide to participate, you will be asked to sign this form and it will be a record of your agreement to participate. 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 4-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 in-person meetings plus daily exercises where you review information about physical activity and healthy eating or (2) a new maintenance program that involves in-person meetings plus daily exercises where we ask you to think about your future and your health goals. Throughout the study, you will complete assessments that examine the effects of the interventions on weight, physical activity 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, your weight and height will be measured and we will ask you to complete measures assessing basic demographic information (e.g., sex, age, race, ethnicity) and psychosocial variables. These measures will take approximately 45-minutes to complete.

After you complete these measures, you will be invited to attend a meeting. During normal times, these meetings will occur in-person. In the event of national emergency (e.g., COVID-19), this meeting will happen via videoconference. This meeting will be approximately 1 ½ hours in duration. During the meeting, 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, 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, you may 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 4-months in duration. At the beginning of the maintenance phase, you will be asked to complete an assessment. In the event of national emergency, assessments will take place via videoconference. The assessment will take approximately 1.5 hours to complete. We will also ask you to complete self-report measures that assess aspects of your environment, social support, emotions, and perceptions along with diet and weight management behaviors. We will measure your current level of physical activity by asking you to wear a physical activity monitor on your waist for one week. After your assessment, we will ask you to complete brief surveys (1-3 minutes each) every day for one week through a smart-phone application that include questions about your environment, mood, sleep, exercise behavior, and a brief decision-making task. You will be asked to use your personal smartphone to complete the daily brief surveys. After the assessment period, 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:

- **Weight Loss Maintenance Treatment + Healthy Thinking.** This weight loss maintenance treatment will involve 4-months of group meetings focused on healthy eating and physical activity. Meetings will be weekly for two weeks, every other week for six weeks, and monthly for 2 months (7 sessions total). Meetings will be about 60 minutes in duration. Meetings will be led by a clinician trained in behavioral weight management. During the meetings, you may be privately weighed and 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 and the group leader will provide feedback on your progress. In normal times,

these meetings will occur in person. In the event of national emergency (e.g., COVID-19), these meetings will occur via videoconference.

In this treatment you will read information through our study website twice a day for the duration of treatment. Your personal healthy living cues will only be available to you and will be password protected. You will receive twice daily text or email prompts to read your passages. These prompts may include picture messages. You will be asked to use your personal email account/phone to receive these daily messages. You will have a case-manager that will meet with you in-person or, in the event of national emergency (e.g., COVID-19), via videoconference and check-in with you regularly over the phone throughout the four-month treatment about your progress in the program.

- **Weight Loss Maintenance Treatment + Future Thinking.**
  This weight loss maintenance treatment will involve 4-months of group meetings focused on healthy eating and physical activity. Meetings will be weekly for two weeks, every other week for six weeks, and monthly for 2 months (7 sessions total). Meetings will be about 60 minutes in duration. Meetings will be led by a clinician trained in behavioral weight management. During the meetings, you may be privately weighed and 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 and the group leader will provide feedback on your progress. In normal times, these meetings will occur in-person. In the event of national emergency, these meetings will occur via videoconference.

  Research suggests that thinking about personal, positive future events for which a health goal is important (e.g., weight loss for a wedding) may lead to better health decisions in the moment. In this treatment you will record detailed descriptions of a future event and be asked to read short passages at least twice a day for the duration of treatment. Your personal cues will only be available to you and will be password protected. You will receive twice daily text or email prompts to read your passages. These prompts may include picture messages. You will be asked to use your personal email account/phone to receive the daily messages. You will have a case-manager that will meet with you in-person or, in the event of national emergency (e.g., COVID-19), via videoconference and check-in with you regularly over the phone throughout the four-month treatment about your progress in the program.

Researchers will audio- or video-record treatment meetings for treatment standardization purposes and to provide group leaders with supervision and feedback. You will not be identified in any way on the recordings, and 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 phase II maintenance program, you will be asked to complete assessments. Specifically, 1, 2, and 4 months into the program you will be asked to complete an assessment similar to the first phase II assessment, including online surveys, cognitive tasks, and one week of physical activity monitor. At the 2 and 4 month assessments you will also complete daily brief surveys completed on your own smart phone.

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. 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, Qualtrics, phone, and/or email. We will send you assessment equipment in the mail, you will complete your videoconference assessment with research staff, and you will send the equipment back to us. In normal times, assessments will occur in-person.

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 in-person treatment sessions, engaging in all Web-based treatment activities, and attending and completing assessment visits.

What are the risks or inconveniences of the study?

The risks associated with participating in this study 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.
- **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.
- **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.

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 $20 each for completing the 1 and 2-month assessment visits, and $40 for completing the 4-month assessment visit. This money may be provided to you via cash, money order, or electronic gift card. No monies will be paid for completing Phase I assessment visits or the Phase II baseline assessment. 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). Also, since the study requires the use of your personal mobile phone, standard data and message rates will apply when interacting with the study application and receiving text/ image messages.

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 – e.g., 001) 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 audio / video recordings; such recordings will be reviewed by research study staff including the principle investigator. All files 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. The smartphone app and website that we use during assessments and treatment have security measures in place to keep your information private. Your name and other identifiable information will not be transmitted using this data collection app. 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. In the case of a national emergency (e.g. COVID-19) group sessions will occur via a video conference platform, such as WebEx. Information shared in virtual groups is only secure to the extent offered by the platform itself. Any information transmitted via email, phone or video conference is only secure to the extent offered by your personal providers' privacy / security policy; we encourage you to familiarize yourself with these policies. 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.

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. 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.

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. Results of this study will be summarized on this website once the study is complete. 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 or incompliant 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. Amy Gorin at 860-486-5670. 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: