Project Title: Peer Support for Weight Loss Maintenance

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Purpose / Introduction.

Obesity is a public health crisis.[1, 2] Lifestyle interventions for the treatment of obesity produce excellent initial weight losses and improvements in cardiovascular disease (CVD) risk factors.[3, 4] However, within 2-3 years most individuals regain all the weight that they lost and CVD risks return.[5, 6] Given these findings, NIH has identified weight loss maintenance as the next major challenge in obesity treatment.[8]

Continuous care (ongoing patient-professional contact) promotes excellent maintenance outcomes;[9, 10] however, the traditional approach to providing continuous care (professional staff) is costly and thus unsustainable.[11] Further, when professional contact inevitably ends or becomes less frequent, weight regain occurs.[9-11] Thus, a new method for providing continuous care that is sustainable and cost-effective could hold substantial promise for long-term obesity management.

Patient-delivered interventions may be a unique solution to providing continuous care at low cost and with organic sustainability. There are 2 types of patient providers: Mentors (patients who *previously* and *successfully* modified their health behavior coach incoming patients) and Peers (two patients *initiating* behavior change coach one another). Patient-to-patient interventions can occur via phone, email, text, or in-person. Both types of patient providers (mentors, peers) have shown short-term efficacy at reducing HbA1c.[12, 13] Moreover, our preliminary studies demonstrate that our team: 1) achieves high levels of treatment adherence among peer and mentor providers and 2) that both peers and mentors yield excellent weight maintenance outcomes through 6 months of maintenance, with mentors yielding sustained maintenance and peers producing additional weight *loss*.

Patient-delivered treatment holds great promise; however, there is still much to learn. To date, all patient-delivered interventions have used a hybrid approach in which targeted patients receive care from fellow patients *and* professionals. No study has ever trained patient providers to execute all treatment components. Moreover, a recent Cochrane review calls for 1) studies that investigate whether patient-provided care is naturally sustained once formal treatment ends, 2) more evidence-based patient training, and 3) rigorous efficacy trials.[14] Lastly, qualitative data suggest that, given their shared experience, patients provide one another with a unique sense of empathy and inspiration, not duplicated by professionals;[15] however, the unique mechanisms by which patients may promote health behavior change have never been examined. The proposed project will fill these gaps. We will 1) eliminate professional providers from our patient-delivered intervention, 2) examine the extent to which patient-provided treatment is naturally sustained once formal treatment ends, 3) provide patients with evidence-based training in weight management and autonomy support (a type of support consistently linked to maintenance success[16]), and 4) examine the mechanisms (e.g., empathy, inspiration) by which patient providers impact outcomes. Regarding the latter, these 2 types of patient providers have potentially unique strengths (due to their success, mentors may provide inspiration; given they are actively changing behavior, peers may provide empathy), thus, we will also capitalize on the unique strengths of each and involve both types of patient providers in one treatment, which has not been done.

Consistent with contemporary weight loss maintenance trial designs,[17] this study involves two phases: a weight loss induction phase and a maintenance phase. During Phase I (weight loss) individuals will complete a 16-week Internet weight loss program. Those who achieve a ≥5%[1] weight loss will be invited

to participate in Phase II, the actual maintenance trial. The maintenance trial will be a head-to-head comparison of current best practice for maintenance vs. patient-delivered treatment. Specifically, Phase II participants will be randomized to either best practice (Standard) or a novel patient-to-patient intervention (P2P). Both treatments will be 18 months. Standard will include 24 group sessions delivered by a professional that taper over time (consistent with current best practice[4]). P2P will involve 7 group sessions, all delivered by a trained mentor (successful weight loser), followed by peer patient-to-patient coaching via email or text. Because peers are uniquely capable of providing *ongoing* contact at *low cost*, peer coaching will be weekly. We hypothesize that P2P will yield significantly better maintenance because it involves (a) weekly (instead of tapered) contact (b) potentially powerful components unique to patient-provided treatment (empathy, hope, inspiration[15]), and (c) autonomy support (evidence-based support associated with maintenance success[16]). Detailed hypotheses are below.

Primary hypothesis: P2P will yield significantly less weight regain compared to Standard at 18-months.
Secondary hypothesis: P2P will have better CVD risk profiles (blood pressure) compared to Standard at 18-months.

Exploratory aims:
1. Examine whether components unique to patient-to-patient care (empathy, inspiration, hope, autonomy support) mediate P2P vs. Standard weight outcomes at month 18.
2. Explore the cost-effectiveness of P2P vs. Standard at 18-months.
3. Investigate the sustainability of patient coaching during the no treatment follow-up period (18-24 months) by examining (a) the extent to which patients continue to coach one another and (b) differences in P2P vs. Standard on the following outcomes: weight, CVD, empathy, hope, inspiration, and autonomy support.

Design, Procedures, Materials, and Methods.

Overview. This project consists of two phases. The purpose of **Phase I** is to induce weight loss efficiently. Thus, all participants recruited in Phase I (N=860) will be given a Web-based behavioral weight loss intervention derived from the Diabetes Prevention Program (DPP).[30] Dr. Leahey (PI) is one of the co-developers of the Web-based intervention and has published several trials demonstrating its efficacy.[24, 25, 31] Weight will be objectively assessed before and after the 16-week weight loss treatment, which is the same treatment length as the DPP.[30] Consistent with designs used in several other large-scale maintenance trials,[17, 32-34] those who achieve a clinically meaningful weight loss during Phase I (lose ≥5% of initial body weight) will be eligible for Phase II, the maintenance trial and the primary focus of this application. Given our previous experience with the weight loss intervention,[23-25, 31] we anticipate that 54% of participants who enter Phase I will reach the ≥5% goal and be eligible for Phase II (N=269). While we have substantial data to support this estimate from 4 large trials, if necessary, given the relatively low cost of this intervention, we can adjust the Phase I N to ensure that we reach the Phase II target N for which the trial is powered (N=269). **Phase II** will involve a randomized controlled trial that tests the efficacy of patient-provided treatment for weight loss maintenance. Participants (N=269) will be randomized to either (1) Patient-to-Patient treatment (P2P; mentor patients deliver treatment and peer patient dyads provide one another with ongoing care and support) or (2) Standard (a traditional, continuous care maintenance intervention that is consistent with current best practice[4]). Both maintenance interventions will be 18 months in length. Standard will involve 24 in-person group sessions that taper over time and are delivered by a professional. In contrast, P2P will be delivered entirely by trained patients and will involve only 7 in-person sessions (delivered by mentors) followed by weekly evidence-based e-coaching (delivered by peers and overseen by mentors). The primary outcome is weight change from the beginning of Phase II (baseline) through the end of the maintenance program (month 18). To assess sustainability of patient-provided care, a 6-month no treatment follow-up assessment at month

24 will also be included. All study-related visits will take place at either UConn's Weight Management Research Lab, in Hartford Connecticut at 1 Constitution Plaza, or at UConn's Institute for Collaboration on Health, Intervention and Policy (InCHIP) in Storrs Connecticut at 2006 Hillside Rd. During the entire study (Phase I and Phase II), participants assigned to the Standard maintenance program will complete a total of 32 visits (7 assessment visits and 25 treatment visits). In contrast, given that P2P involves fewer treatment sessions, participants assigned to this arm will complete a total of 12 (7 assessment and 8 treatment). Presented below is the detailed approach for Phase I and Phase II. [Note, this two-phase design represents current best practice in weight loss maintenance research. While some early maintenance trials (e.g., STOP Regain) recruited individuals from the community who had already lost weight, more recent studies (e.g., Weight Loss Maintenance Trial) have included a weight loss induction phase. This new approach facilitates recruitment and ensures that the sample is at similar stages of the weight management cycle, thereby optimizing methodological rigor and reducing variability in treatment response.[17, 23, 32-34]]

Timeline. Participants will be recruited in 5 Cohorts. For each Cohort, we will recruit N=172 into Phase I. We expect that ~34% (N=54) who enter Phase I will achieve a 5% weight loss and be eligible for Phase II. Eligible participants (N=269) will be randomized in Phase II and complete intervention / assessments.

PHASE I APPROACH

Phase I Participants. At entry into Phase I, all participants (N=860) will be adults 18-75 years of age, have a BMI between 25-50kg/m^2, and 30% will be racial/ethnic minority. We have chosen an upper age of 75 as individuals older than 75 may have increased medical comorbidities and risks associated with unsupervised exercise. We chose a BMI limit of 50kg/m^2 as individuals with a higher BMI may require increased medical supervision or more intensive treatment (e.g., bariatric surgery). Individuals will be excluded from enrolling in Phase I if they: report being unable to walk 2 blocks without stopping; are currently participating in weight loss treatment, have a history of bariatric surgery, or lost ≥5% in the past 6-months; are pregnant or plan to become pregnant within 1 year; report chest pain or loss of consciousness on the Physical Activity Readiness Questionnaire[35] (joint problems, hypertension, high cholesterol, medication use, or diabetes will require physician consent to participate); report a medical condition that could jeopardize their safety in a weight control program with diet and exercise guidelines (e.g., cancer); report conditions that, in the judgment of the PI, would render them unlikely to follow the protocol (e.g., relocation, dementia, unable to read and write in English); have no Internet access. Given that Internet use is similar among racial/ethnic groups (Hispanic: 83%; African American: 81%; White: 85%),[36] we do not anticipate that requiring Internet use will disproportionately impact enrollment of minorities.

Phase I Recruitment and Screening. Participants will be recruited for Phase I (weight loss) via mass mailings, local newspapers, Facebook and Instagram, Internet and local listserv postings (e.g., UConn Daily Digest), letters to area businesses and community organizations, direct email and mail campaigns, as well as postings in physician offices, google ads, and public spaces. "Snowball" recruitment procedures may also be used in which current participants inform friends and family about the study. Individuals who respond to the advertisements will be screened for eligibility via Website or phone. Eligible individuals will attend an orientation where informed consent will be obtained. In the event of a national emergency (e.g., COVID-19), the session will be conducted remotely via a video conferencing platform like WebEx. Before consent, individuals whose BMI was assessed as being close to the cut-off for eligibility (24.7-24.9, or 50.1-50.3) will be weighed and measured to assess BMI. Those not meeting criteria will be provided a referral. As done in our previous Phase I/Phase II maintenance trial, during the consent process, participants will learn about both phases, including the Phase I Web program and the Phase II maintenance interventions. They will also be informed that they are only eligible for Phase II if they achieve a 5% weight loss during Phase I. [Note: After Phase I, those who do not achieve a 5% weight loss but want additional treatment will be referred to appropriate community programs.] During

consent, participants will also be asked if they can be contacted to see if they are interested in participating in future studies. Those meeting criteria will complete a pre-treatment assessment and then begin Phase I.

Phase I Weight Loss Program. During Phase I (the weight loss phase), all individuals will receive a 16-week Web-based behavioral weight loss intervention based on the DPP.[30] Dr. Leahey (PI) is a co-developer of this intervention and has shown that it consistently produces clinically meaningful weight losses of ≥5%.[23-25, 31]

Web-based behavioral weight loss intervention based on the DPP. Prior to beginning the Web-based program, participants will complete a one-time, in-person, group-based "Weight Loss 101" session. In the event of a national emergency (e.g., COVID-19), the session will be conducted remotely via a video conferencing platform like WebEx. This session will be approximately 1 ½ hr in duration. During the session, participants will be given their weight loss goals (lose 1-2 pounds/week; achieve a ≥5% weight loss), calorie and fat goals (weight<200lbs: 1200-1500kcals/day, 40-50g fat/day; weight≥200lbs: 1500-1800kcal/day, 50-60g fat/day), and exercise goals (gradually increase to 250mins MVPA/week[37]). In addition, they will be taught how to monitor their intake using either paper/pencil diaries and a calorie reference book (provided by the study) or a smart phone app (MyFitnessPal) (participant preference). The importance of weekly self-weighing and how to accurately interpret weight changes will be explained. Finally, at the end of the one-time, one-hour group "Weight Loss 101" session, participants will be oriented to the 16-week Web-based behavioral weight loss program Website. The Web-based behavioral weight loss program involves weekly multimedia videos based on the DPP, a self-monitoring platform, and automated feedback.[23-25, 30, 31] Weekly multimedia videos are ~10 minutes in length and include topics such as stimulus control, goal setting, and problem solving. During each of the 16 weeks, participants will submit their daily weight, calorie, and activity information into the self-monitoring platform and receive weekly automated feedback. After the 16-week program, participants will no longer have access to the Web-based weight loss intervention and will return to the Center for their post-treatment assessment.

It is certainly possible for a participant to become concerned if they are not losing weight or are gaining weight. To mitigate this concern, all weight loss strategies suggested in Phase I are evidence-based and have been shown to yield clinically meaningful weight loss[23-25, 31]; thus, participants are given excellent behavioral tools for weight loss success. In addition, all participants will be given weekly feedback that includes suggestions to help with weight loss. Finally, participants will be provided contact information of intervention staff should they have any concerns or questions about weight management. These intervention staff will be trained in how to help participants problem-solve their weight management difficulties.

[Information on the MyFitnessPal application (app): The MyFitnessPal app can be downloaded to any personal smartphone or iPad device. Any participant interested in using the app and needing instruction on how to download the app will receive assistance from research staff. The MyFitnessPal app allows users to track their calorie intake, weight, and activity minutes on their device. For this project, data will not be directly accessed from MyFitnessPal for research purposes. Instead, if a participant chooses to use the app to monitor their diet, activity, and weight and wants feedback on their progress (suggestions to improve diet, increase exercise, etc.) they will have to enter that information into the weight loss website (Phase I) or print out their data from the app and share it with intervention staff during intervention meetings (Phase II), who will then provide feedback. Individuals who use the MyFitnessPal app create a username and password. Thus, app data are password protected. For participants concerned about privacy issues, personal data (name, etc.) do not have to be entered into the app to use the app. MyFitnessPal indicates that data are stored for as long as the individual maintains an account and, as necessary, to comply with legal obligations and agreements. According to the MyFitnessPal privacy policy (https://account.underarmour.com/privacy), technical and organizational security features protect individual data against unauthorized access, theft, and loss. The MyFitnessPal app is capable of accessing location and contacts and delivering notifications. However, the user must authorize access for this to occur. Participants will be informed that they can discontinue app use at any time and delete the app from their mobile device; if they need help deleting the app, research staff will offer assistance. The PI of this

study has used this app in many previous studies, and no privacy concerns have been raised. Participants in this study will be informed that, if they choose to use the app (as opposed to paper/pencil monitoring), their data will only be secure to the extent afforded by the MyFitnessPal privacy statement. As noted above, participants do not have to use the app to participate in the study; they could instead record their diet, weight, and activity using a paper/pencil diary.]

Phase I Assessments. Given that the primary purpose of Phase I is to efficiently induce weight loss for Phase II, assessments will be minimal. Pre- and post-treatment assessments will be relatively minimal, taking approximately 45-minutes to complete. The following will be collected:

Demographics. Demographics (e.g., sex [male, female, non-binary], age, income) will be collected at pre-treatment only. We will also collect data on type of device and operating system participants are using to complete assessment measures (e.g., PC, tablet, phone).

Weight and height. At both pre- and post-treatment, weight will be measured to the nearest 0.1kg using a digital scale. Height will be measured to the nearest millimeter using a stadiometer (baseline only). Participants will be measured wearing light, indoor clothing without shoes.

Maintenance treatment mechanisms. While we are most interested in how mechanisms unique to patient-provided care (empathy, compassion, hope) impact weight loss maintenance, we will also include these measures at the start of weight loss to capture how these constructs change throughout the weight management cycle. Perceived empathy and compassion for weight management will be assessed with the Patient Perception of Empathy and Compassion Scales[38, 39] Hope and inspiration will also be assessed with validated measures of these constructs.[40, 41] We will assess autonomy support using Williams' et al. (2007) validated Important Other Climate Questionnaire.[42]

PHASE II APPROACH

Participants. Those who lose at least 5% of initial body weight during Phase I (N=269) will be eligible to participate in Phase II, the weight loss maintenance trial (i.e. the primary focus of the application). Given our previous findings,[23-25, 31] we anticipate that the demographic characteristics of participants entering Phase II will be similar to those of participants in Phase I. In addition, in a previous trial in which we used the proposed two-phase maintenance design with Phase I as the Web program, we found that 99% of participants who met the 5% weight loss criterion in Phase I elected to continue into Phase II.[23]

Randomization. Individuals who lose ≥5% initial body weight during Phase I (i.e., achieve a clinically meaningful weight loss[1]), agree to participate in Phase II, are available for group sessions, and complete Phase II baseline measures will be randomized to P2P or Standard. The statistician will conduct the randomization and will use a permuted block randomization scheme for each cohort. Given evidence that greater initial weight loss is associated with better long-term weight outcomes,[43] randomization will be stratified by initial weight loss (5-10% vs. ≥10%). To account for the intraclass correlation (ICC) among peer patient dyads, a 9:8 randomization scheme will be used (P2P : Standard; see Section C.13.b.). In the P2P condition, we will also randomly pair participants to coach one another (i.e., engage in 1:1 peer patient e-coaching via email or text). Gender, age, and baseline BMI similarity may be important for the facilitation of supportive relationships / helping to ensure similar life experiences,[15, 26] thus, P2P participants will be randomly paired within gender, age range (18-30, 30-40, etc.), and baseline BMI range (e.g., 25-30, etc.) to provide care to / coach one another. In addition, prior to randomization, participants will be asked whether they know anyone in the trial and, if so, if they would be uncomfortable being paired with that individual. If they are uncomfortable, they will not be paired with the person and, instead, will be randomly paired with another participant. We have used these procedures in three previous trials and no peers needed to be reassigned due to discomfort with their initial pairing.

Overview of the two weight loss maintenance interventions. Both Standard and P2P participants will receive an 18-month weight loss maintenance program and evidence-based weight loss maintenance strategies. The Standard arm will be consistent with current best practice for long-term weight control; it will involve 24 in-person sessions delivered by a professional. In contrast, P2P will be a new treatment approach in which intervention providers are patients (mentors and peers), there are substantially fewer sessions compared to traditional care (7 vs. 24), and peer patient dyads engage in weekly e-coaching. The number of sessions in P2P will be reduced for the following reasons: (1) there is strong evidence that regular in-person weight control sessions are not well attended long-term (i.e., 15-36% attendance at month 24),[5, 44] thus, transitioning from in-person treatment to peer e-coaching may reduce in-person treatment barriers (time, transportation, childcare) and enhance engagement relative to traditional approaches; (2) minimal in-person contact with patient e-coaching has demonstrated high engagement and excellent weight loss outcomes in our previous trials, and (3) the reduced contact schedule enhances dissemination potential by minimizing costs (no need for rooms, rent, utilities, etc.). Thus, we believe the schedule is reasonable / appropriately justified. Mentor patients (i.e., successful weight losers) will deliver the 7 in-person sessions. During these sessions, peer patient dyads (participant pairs) will engage in relationship building activities with one another and be trained in how to provide evidence-based e-coaching, including weight management strategies and autonomy support. Then, from months 4-18, P2P participants will have no in person treatment; instead, during this time, peer patient dyads will engage in weekly evidence-based e-coaching. Mentor patients will monitor e-coaching and provide corrective suggestions, if necessary. In addition, mentors will e-mail maintenance intervention materials to participants. These materials will involve evidence-based weight control strategies plus relevant patient-to-patient peer activities that promote autonomy support. P2P participants will also have the option of participating in a secret Facebook group that includes their mentors and other group members. Being involved in a secret group means that the public is unable to "see" the group and only the study team can invite users (mentors and participants). Please see below for Standard and P2P intervention details and the appendix for additional intervention information.

Standard intervention. Participants in Standard will receive a weight loss maintenance program that is consistent with current best practice and well-accepted in the field.[4, 11] The intervention will be group-based. Evidence-based weight maintenance strategies will be taught. Each session will be approximately 1-hour in duration and will occur either at the Weight Management Research Group in Hartford, CT, or at UConn's Institute for Collaboration on Health, Intervention and Policy (InCHIP) in Storrs Connecticut. In the event of a national emergency (e.g., COVID-19), sessions will be conducted remotely via a video conferencing platform like WebEx. Sessions will taper over time; 1 month of weekly group sessions, 3 months of bimonthly group sessions, and 14 months of monthly sessions (24 sessions total).

Interventionists. Standard interventionists will be masters-level and will be trained by the PI. Two interventionists will co-deliver treatment.

In-person treatment sessions. Participants will be weighed privately by interventionists at each session. Given evidence that most individuals do not recover from even small amounts of weight regain,[45] participants will be given the goal to keep their weight at or below their Phase II baseline weight (i.e., maintain their initial weight loss in full). Participants will be provided evidence-based weight loss maintenance strategies to meet this goal, including calorie guidelines, a physical activity plan, and behavior change skills associated with optimal weight maintenance. These components are detailed below.

Diet. Participants will receive a personalized calorie goal based on their reduced body weight designed to promote weight maintenance or continued weight loss (if desired). For example, if a participant wants to maintain their current weight at 150 pounds, a calorie reference guide (www.calorieking.com/interactive-tools/weight- maintenance-calories-calculator/) will be used to prescribe a new calorie goal for weight maintenance. This reference guide has been used in our

previous trials[23] and takes into account sex, age, weight, height, and activity level; activity level will be obtained from accelerometry data collected at the Phase II baseline assessment. Alternatively, if a participant wants to continue to lose weight, they will be encouraged to adhere to the dietary recommendations provided during Phase I (the active weight loss phase; Section C.6.). Consistent with AHA guidelines, all participants will be instructed to limit calories from fat to 30% of total daily caloric intake. Given evidence that self-monitoring is critical for long-term weight control,[46] monitoring caloric intake will be encouraged. Participants will be provided self-monitoring diaries and a *Calorie King* reference book or will be able to self-monitor their intake with the MyFitnessPal smartphone app (participant preference).

Exercise. Current physical activity guidelines recommend 300 minutes or more of weekly moderate-to-vigorous physical activity (MVPA) for weight loss maintenance.[37] Given that the Phase I weight loss intervention involves gradually increasing activity to 250 minutes per week, participants are expected to be engaging in some physical activity before entering maintenance. However, we will assess each participant's activity level at the beginning of the maintenance intervention and regularly engage in goal setting and problem solving activities to further increase activity to the recommended level. Participants will be encouraged to monitor their physical activity in the paper/pencil logs provided or with the smartphone app, MyFitnessPal.

Behavior therapy to promote maintenance. During group sessions, self-regulation skills for weight loss maintenance will be taught. Participants will be encouraged to weigh themselves daily and use that information to make changes to their eating and activity behaviors (e.g., if their weight is trending up, they will be instructed to decrease intake and increase activity until they are at or below their maintenance start weight).[47] When necessary, evidence-based strategies to reduce caloric intake (e.g., meal plans) will be encouraged.[48] Problem solving will be used to address barriers to diet and activity.[49] Strategies to maintain motivation, increase lifestyle activity, reduce sedentary behavior, decrease calorie intake (volumetrics, mindful eating), and manage stress / emotions will also be covered. Finally, at each group meeting, participants will set goals to be accomplished between meetings (e.g., maintain weight, eat an average of 2100kcals, and engage in 280 minutes of physical activity per week). All strategies are consistent with current best practices for weight loss maintenance.[4, 11, 46, 47, 49]

P2P intervention. Participants assigned to the P2P arm will receive a total of 7 in-person group sessions delivered by mentor patients (i.e., previous patients who lost ≥7% of initial body weight and kept it off for at least 1 year) and evidence-based e-coaching delivered by peer patients (i.e., paired participants who coach one another). Mentors will be trained by the PI to deliver the 7 group sessions. Sessions will be weekly for 1 month then bimonthly for 1 month and monthly for 1 month. This treatment dose is based our experience with patient-provided interventions involving reduced intensity in-person treatment; the 7 weekly sessions will be 2-hours in length in order to cover core maintenance strategies plus peer patient training in evidence-based weight management and autonomy support strategies. The sessions will also allow for peer patient dyads to engage in relationship development activities. The subsequent 3 meetings (i.e., alternating in-person treatment with peer patient e-coaching), will be one hour each. These meetings will allow mentors to supervise between session e-coaching and give in-person corrective feedback during group prior to the "e-coaching only phase" (months 4 to 18), during which there will be no in-person sessions. During the e-coaching only phase, mentors will be cc'd on coaching correspondence and provide corrective feedback via email / phone, if necessary. Mentors will also email all PTP participants PDF files of evidence-based treatment materials, which will include weight management suggestions and activities for providing autonomy support. All intervention sessions will occur at either our Weight Management Research Group in Hartford, CT, or at our Institute for Collaboration on Health, Intervention and Policy (InCHIP) in Storrs Connecticut. In the event of a national emergency (e.g., COVID-19), sessions will be conducted remotely via a video conferencing platform like WebEx. Details are below.

Interventionists: P2P interventionists will be mentors. Mentors will be former patients from our weight management trials who lost ≥7% of initial body weight and kept it off for ≥1 year. Mentor exclusion criteria include history of weight reduction surgery; hospitalization for a psychiatric condition within the past year; current diagnosis of schizophrenia, bipolar disorder, or eating disorder; current alcohol or substance abuse; planned relocation within the next 18 months; lack of availability during group times; and current diagnosis of dementia or Alzheimer's disease. Mentors who report being out of town for more than 2 weeks in a row during treatment or training periods will also be ineligible. During 2 half-day workshops, PI Leahey and Co-I Gorin will train mentors in how to deliver core weight management strategies, facilitate relationship development activities among peer patient dyads, and train peers to provide evidence-based e-coaching. Specifically, we will recruit and train a total of N=3 mentors for each cohort; 2 mentors to co-lead group and 1 "substitute" in the event that a mentor must be absent (e.g., illness). Two mentors will co-deliver the 7 in-person manualized intervention sessions. Sessions will include evidence-based maintenance strategies, peer dyad training in evidence-based weight control strategies and autonomy support, and peer dyad relationship development activities. During the e-coaching only phase (month 4 to month 18), mentors will monitor peer patient e-coaching every week for the first 3 months and then monthly thereafter. If necessary, mentors will provide corrective feedback by email or phone. Mentors will also be responsible for sending intervention materials to P2P participants via email (PDF). Intervention materials will be sent at the same schedule used in Standard. Staff will track mentors hours, who will be compensated at $25/hour for their time. Our group has significant experience recruiting, training, and engaging mentors. A benefit of this model is that it is self-sustaining; incoming participants who lose ≥7% and keep it off for ≥1 year can become mentors for future cohorts.

In-person treatment sessions. P2P will involve a total of 7 in-person treatment sessions, which will occur during the first 12 weeks. P2P participants will be weighed privately by mentors at in-person sessions. During these sessions, mentors will announce peer dyad pairings and will have manualized treatment materials to 1) deliver core maintenance strategies, 2) facilitate peer patient dyad relationship development activities, and 3) train peer patients in how to provide one another with evidence-based e-coaching. Details are below.

Announce peer patient pairings. Prior to treatment, P2P participants will be randomly paired within gender, age and BMI range to coach and be coached by another member of their group. This approach has been used in all of our previous peer provider studies and is well-received by peers. It also eliminates selection bias. Mentors will announce peer dyad pairings at session 1.

Core maintenance strategies. Similar to Standard, at the initial treatment sessions, mentors will instruct participants to keep their weight at or below their Phase II baseline weight and will provide participants with evidence-based diet and activity strategies to meet this goal (see Section C.10.a, Diet and Exercise).

Peer dyad training. During sessions 1-4, mentors will train peer patient dyads in how to provide evidence-based e-coaching to one another. Peer patient dyads will: (1) be given the goal of e-coaching (i.e., help their partner maintain or lose additional weight depending on their goal), (3) be provided evidence-based maintenance strategies to recommend to their partner (which will also be covered in group); (3) be provided the rationale for autonomy support, and (4) engage in interactive training in autonomy supportive e-coaching strategies. Specifically, emphasis will be placed on how to create an autonomy supportive context. Peers will be taught how to support each other's personal choices and goals for making sustained behavior change.[50, 51] The ABC model of autonomy support that we developed will be taught during the 7 in-person group sessions (i.e., **A**sk your peer partner what they find helpful [rather than assume], **B**e empathic to your peer's weight management efforts, and **C**urtail Criticism and Control when offering suggestions). Peer patient dyads will be encouraged to keep these principles in mind during all interactions. During training, peers will also be encouraged

to use the "sandwich technique" if their partner requests weight management suggestions. The "sandwich technique" involves structuring feedback by starting with a supportive statement, followed by suggesting helpful weight management strategies that allow for personal choice, and finishing with a supportive statement.[52] Peers will practice the ABC model and the "sandwich technique" by completing worksheets where different participant progress scenarios are presented and coaches provide written feedback with evidence-based suggestions. Peers will also engage in brief role plays in which they provide feedback to one another. After these role plays, mentors and fellow participants will provide dyads with feedback.

The likelihood of a peer becoming anxious or depressed during the trial is low. However, it may occur and it is important that peers know how to manage such a situation. Training peers to manage mental health issues is beyond the scope of their abilities and this project. Thus, during their training, peers will be informed that if they have concerns about their partner's mental health or weight management behaviors to immediately contact study intervention staff and contact information will be provided. In addition, study staff will be monitoring email correspondence to address any such issues. If such issues arise, study staff will contact the individual of concern to get information regarding the situation. (S)he will then discuss the situation with the PI, who is a clinical psychologist. If deemed necessary by the PI, intervention staff will provide the participant with an appropriate referrals.

Relationship building activities. Initial relationship development is necessary for effective patient-to-patient intervention delivery.[15, 26] Thus, during the 7 group sessions, peer dyads will sit with one another and engage in brief relationship building activities. We have used these activities in all of our peer patient trials and found that they facilitate familiarity, perceived similarity, and cohesion, all of which are important for relationship development.[27-29] For example, to facilitate familiarity, peer dyads will engage in activities to promote self-disclosure; they will share personal information including background, family, hobbies, major stressors, and primary reasons for weight control. To facilitate similarity, peer dyads will be asked to explicitly identify commonalities in background (children, pets, occupations, interests, eating habits) and similarities in weight and health history and share them with the group. At the 2nd group session (the session before coaching begins), all peer dyads will choose weight, calorie, and activity goals to be achieved between sessions, share them with their peer partner, and explain to their peer how they can help them achieve these goals. All of these procedures have been used in our trials and have resulted in excellent engagement (see Section C.1.).

Peer patient e-coaching. From weeks 13-66, peer patient dyads will engage in weekly e-coaching that involves evidence-based autonomy support and weight management strategies. Specifically, peer dyads will exchange information on core weight management treatment targets and provide one another with feedback. Peers will report weight loss or maintenance (depending on goal), number of self-monitoring days (out of 7), average daily calorie intake, total minutes of activity for the week, weekly challenges/triumphs, and type of desired support (advice, information, pep talk) to each another and respond to each other with autonomy supportive feedback. [Note: peers will be able to have different weight goals (weight loss vs. maintenance) given that similar coaching strategies will be used regardless.] To be as natural as possible, peers will be allowed to use email or text, whichever they prefer. To objectively track adherence, provide corrective feedback if necessary, and oversee communication, all peer dyads will "cc" the trained mentor on all email/text communication. At minimum, peer dyads are expected to exchange progress towards goals and provide feedback once per week. However, it is common in our trials for peers to text/email more often. Mentors will also be included on all extra communication. Other types of correspondence (e.g., in person, phone) will be tracked through the use of a brief questionnaire distributed every 3-months.

To help ensure that peer patient dyads are adherent to the email/text coaching protocol, an automated email reminder will be sent from a mentor on the typical day of group asking peer dyads to exchange their week's information. Peers will also receive an automated email reminding them to deliver

feedback. If a peer does not respond, their partner will be trained to "check-in" and provide any necessary support. This strategy was used in our prior peer patient provider studies and was successful at promoting compliance (see Section C. 1.).

Intervention materials. Mentors will email PDF files of evidence-based maintenance strategies to peer patient dyads (participants) at the same frequency as Standard (bimonthly to monthly). Content will be the same as Standard (see Section C.10.a., Behavior Therapy) with one exception: each lesson will also include a peer dyad autonomy support activity suggestion. For example, in the problem solving lesson, peer patient dyads will be encouraged to ask their partner how (s)he is feeling about the problem, how (s)he sees the problem, what could be helpful, what (s)he would like from his/her peer coach, and which choices (s)he wants to make regarding their problem, rather than just offering solutions.

Optional Secret Facebook Group. Given that participants are recruited in cohorts (groups) but that in-person group sessions taper over time, we want to offer P2P participants the opportunity to interact with one another and receive social support via a group setting when there are no in-person group sessions. As such, we plan to create a "secret" group for the P2P intervention arm and participants will have the option to join if they so choose. That is, joining is completely voluntary. Participants interested in this platform will be encouraged by mentors to post positive weight management information and progress (e.g., healthy eating tips, completion of a 5k race, etc.). Participants' decision whether or not to join the closed Facebook group will not impact any other aspects of the intervention they will receive and is completely voluntary. The groups are "secret" and thus not searchable or viewable by anyone on Facebook unless they have received an invitation from our intervention team. These invitations will be limited to randomized participants who have already consented to participate in the trial and been randomly assigned to the P2P treatment arm. Study staff and mentors will monitor posts to ensure appropriateness and safety. If there are concerns re: a post, the participant posting the material will be contacted and counseled on appropriate posts. If concerns remain, the individual will no longer have access to the secret Facebook page.

[**Note regarding use of mentor and peer personal email and phone accounts.** Part of the scientific impact of the proposed study is to examine whether patients are able to organically provide sustainable support to one another by communicating with each other indefinitely / long after treatment ends (Exploratory Aim 3). Thus, to test this aim, it is important that artificial research infrastructure (research study email servers and phones) not be used in the study, as such an approach would limit the examination of the organic sustainability of patient-provided support once treatment ends (18 months – 24 months). Further, requiring mentors and peers to log into and manage an additional email account raises concerns about non-compliance and adherence to the e-coaching protocol. Given these two issues (aim to examine organic sustainability and adherence concerns) we are not aware of any reasonable alternatives to having participants use their own email / phone accounts. To provide some context to this approach, it may be important to note that three of the PI's previous NIH-funded randomized trials (R01DK095771, R18DK083248, F32DK082128) have used this email approach in which peers and mentors use their personal email and phone numbers for email / text communication. All three of these trials were approved by three different IRBs, and there have been no privacy or confidentiality concerns.]

Sub-study 1: Student (Emily Wyckoff) dissertation:
Dietary disinhibition, the degree to which one overeats in response to external (i.e. the presence of food) and internal (i.e. emotional) cues, is a domain specific aspect of self-control. Behavioral weight loss interventions target dietary disinhibition and decreases in dietary disinhibition are associated with more weight loss and better weight loss maintenance (Teixeira et al., 2010; Niemeier et al., 2007). Further, research suggests a link between more general measures of self-control (i.e. executive functioning) and weight outcomes (Gettens & Gorin, 2017), however there has been little research examining general self-

control in a long-term weight loss maintenance trial. This sub-study aims to examine 1) changes in self-control and dietary disinhibition throughout weight loss and weight loss maintenance and 2) the association between self-control and weight outcomes. Hypotheses are detailed below:

Hypothesis 1: Self-control skills taught in behavioral weight loss (i.e. dietary inhibition) will generalize to increases in general self-control
Hypothesis 2: Improvements in self-control and dietary disinhibition that occur during Phase 1 will be maintained during Phase II.
Hypothesis 3: Change in self-control and dietary disinhibition during Phase II will be associated with weight change.

References:
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Sub-study 2: Student (Carnisha Gilder) dissertation:
The World Health Organization has identified social connectedness (i.e., perception of meaningful connections with others) as a significant determinant of health.[1,2] Being socially connected, in general, is associated with an increase in exercise levels, better adherence to medical recommendations, and a 50% reduced risk of mortality.[3,4,5,6] However social connectedness has never been examined within the context of obesity treatment. The primary aim of this study is to examine whether social connectedness impacts obesity treatment outcomes in this ongoing trial. Data from this study may uncover new social processes that are important for intervention. They may also provide new information for the development of more effective social / interpersonal interventions for obesity treatment.

Phase I hypotheses (weight loss phase):

Hypothesis 1: Social connectedness (structural, functional, and relationship quality) at the beginning of Phase I will predict weight loss, with higher levels of social connectedness associated with greater weight loss.

Exploratory hypothesis: Given findings that higher structural connectedness (more social network members) and higher relationship quality and functional connectedness predict better health outcomes, [15] we will explore whether the association between structural connectedness (number of social network members) and weight loss outcomes is *mediated* by relationship quality and perceived social support.

Phase II hypotheses (maintenance phase):

Hypothesis 1: Social connectedness (structural, functional, and relationship quality) at the beginning of Phase II will predict weight loss maintenance, with higher levels of social connectedness (structural, functional, relationship quality) associated with less weight regain.

Hypothesis 2: Given that the P2P arm involves patients getting to know one another and helping each other with weight management, we hypothesize that P2P participants will have higher levels of perceived social connectedness (structural, functional, relationship quality) compared to Standard participants.

Hypothesis 3: Within the P2P arm, we will also examine perceived social connectedness among patient partners and explore which aspects of social connectedness (social support, relationship quality) among patient partners are associated with better weight loss maintenance outcomes.

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Sub-study 3: Student (Shane Sacco) dissertation:

Research has explored the associations between perceived stress, physical activity and weight management outcomes (Elfhag & Rössner, 2004; Katterman et al., 2014); however, few studies have focused on whether individuals perceive weight management as a challenge (weight management will make me a stronger person) versus a threat (weight management makes me anxious) impacts activity and obesity treatment outcomes. Better understanding perceptions of weight management (challenging / threatening) may inform obesity treatment interventions. In the present study, we hypothesize that cognitive appraisals of challenge will moderate the relationship between physical activity and weight outcomes (Bak-Sosnowska et al., 2013; Curioni & Lourenco, 2005). We will also explore whether the relationship between social support and weight change is moderated by threat perceptions (Elfhag & Rössner, 2004; Lazarus & Folkman, 1984).

References

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Sub-Study 4: Postdoctoral fellow (Mary Himmelstein) research

Weight stigma involves stereotyping and mistreatment related to body weight. [1]. Independent of body mass index (BMI) and sociodemographic characteristics, over a decade of research has established links between weight stigma and weight gain,[2] overeating,[3] physical inactivity,[4] stress,[5] and depression.[6]. Correlational evidence suggests a link between weight bias internalization and difficulty in

maintaining weight loss among individuals enrolled in popular diet programs [7] but studies have yet to examine the role of stigma in clinical trials focused on behavioral weight loss and weight loss maintenance. This sub-study will examine associations between reported experiences with weight stigma and weight bias internalization on outcomes in both Phase 1 and Phase 2 of CHAMPS.

Phase I Hypotheses (Weight Loss Phase)

Hypothesis 1: I expect previous experiences with weight stigma to predict treatment completion versus treatment dropout, pounds lost during the behavioral weight loss phase, engagement with the program, less hope for weight management, higher sugar sweetened beverage consumption, more uncontrolled eating, more emotional eating, and less cognitive restraint.

Hypothesis 2: I expect weight bias internalization to predict treatment completion versus treatment dropout, pounds lost during the behavioral weight loss phase, less hope for weight management, more uncontrolled eating, more emotional eating, and less cognitive restraint.

Phase II Hypotheses (Maintenance Phase)

Hypothesis 1: I expect previous experiences with weight stigma to predict weight regain, drop-off in physical activity, uncontrolled eating, emotional eating, and cognitive restraint during the maintenance phase.

Hypothesis 2: I expect weight bias internalization to predict uncontrolled eating, emotional eating, and cognitive restraint during the maintenance phase. Given these challenges, and the self-blame aspects of weight bias internalization, I expect weight bias internalization to predict less communication with coaches, and less attendance in meetings in the weight loss maintenance phase.

References

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	Phase II: Maintenance Trial Assessment Schedule							
	BL	3-mo	6-mo	9-mo	12-mo	15-mo	18-mo	24-mo
Weight	x		x		x		x	x
Cardiovascular	x		x		x		x	x
Mediators[1]	x	x	x	x	x	x	x	x
Cost, diet,	x		x		x		x	x
Activity	x		x				x	x

[1] To appropriately test for mediation (i.e. demonstrate change in mediator prior to change in outcome),[7] mediators will be examined at 3-month intervals and at time points in which weight is not assessed.

Assessments. Blinded staff will conduct assessments. The primary outcome is weight change during the maintenance trial (baseline to month 18). A 6 month no treatment follow-up is also included (months 18-24) to assess sustainability of peer patient e-coaching. Baseline, 6-, 12-, 18-, and 24-month assessment visits will be approximately 1-hour in duration. Intermediate assessments (month 3, 9, and 15) will take approximately 30 minutes to complete. All visits will occur either at our Weight Management Group in Hartford, CT, or at our Institute for Collaboration on Health, Intervention and Policy (InCHIP) in Storrs Connecticut.

Demographics/height. Collected at Phase I.

Outcome measures.

Weight (primary outcome). Weight will be measured to the nearest 0.1kg with a digital scale. Participants will be measured wearing one layer of clothing without shoes. Mentors will also have their weight measured at BL, 6-, 12-, 18-, and 24-months.

CVD risk factors. Blood pressure will be measured by trained staff using the Dinamap Carescape V100 using standardized procedures.

Mediators.

Empathy, Compassion, Hope, and Inspiration. For the first time, mediators thought to be specific to patient-provided care will be assessed. Validated measures will be used. Empathy will be assessed with Jefferson's Patient Perception of Empathy Scale.[38] Compassion will be assessed with the Compassion Scale.[39] Hope and inspiration will be assessed with two measures of these constructs validated for use with patients.[40, 41] All participants will complete these measures keeping in mind important others in their life (partner, family, friends). P2P participants will also answer these questions keeping in mind their relationship with their peer partner. Standard participants will answer these questions keeping in mind their relationship with their group leader.

Autonomy support. Autonomy support for weight control will be assessed with the validated Important Other Climate Questionnaire.[42]

Other possible mediators. Adherence will be assessed by examining frequency of self-weighing using a validated measure.[55] General weight-related social support will be assessed using the validated Social Support for Healthy Behaviors Questionnaire.[56] Finally, we will assess "non-specific" factors (task and bond alliance) between participants and providers with the validated Working Alliance Inventory.[54]

Cost-effectiveness, diet, activity, session attendance, and peer patient e-coaching.

Cost-effectiveness. We will assess costs from the payer, participant, and societal perspective (i.e., sum of payer and participant costs). Costs will be assessed with measures and procedures developed by our group and used in DPP, SHARE (Co-I's: Leahey, Subak), and PRIDE (PI: Subak, Co-I: Gorin).[24, 25, 57, 58] Consistent with standard cost analysis procedures, research-related costs (e.g., costs associated with assessments) will not be included in cost analyses. Instead, cost analysis will reflect costs associated with real-world intervention delivery and implementation. Payer costs will be the sum of labor, intervention materials, and rent. Labor costs associated with intervention preparation and delivery will be estimated by using market values for staff time.[59] Cost of rental space will be determined by using local costs in Hartford, CT. Participant direct and indirect costs will be assessed with questionnaires used in PRIDE and SHARE and consistent with published protocols.[57] Specifically, participant indirect costs will be determined for time spent on the intervention (e.g., attending sessions, coaching) and intervention-related travel time by using age and gender specific wage rates of US adults.[60] The EuroQOL 5D (EQ-5D) will be used to assess quality of life (utilities) for cost utility analyses. The EQ-5D is reliable and scores are associated with weight status.[61-65]

Activity. The validated[69, 70] Actigraph GT9X will be worn on the waist for 1 week at the 6-, 18-, and 24-month assessment time points. Data will be processed with the ActiLife software, ensuring wear time requirements and validated algorithms. Time spent in MVPA and bout-related MVPA (≥10 min in duration) will be specifically examined.

Session attendance and peer patient e-coaching. Attendance will be monitored in both arms. (Note: because the 2 arms now systematically and substantially differ in total sessions [4 vs. 24], attendance will not be examined as a mediator.) To assess peer patient e-coaching (P2P arm), all peer patient dyads will "cc" a mentor on all email/text correspondence. Peer dyads will record all "other" communication (in-person, phone) on their "contact log;" logs will be collected at each assessment visit.

Additional measures. Measures will be added to this project for the three aforementioned sub-studies (student dissertations) and to further elucidate the association between weight management (weight loss and maintenance) and relevant behavioral and psychological processes. The added measures fall into three main categories: stress/resilience, dietary behavior, and social processes. Student questionnaires

added to the study include a measure of eating behavior (TFEQ), the household environment (food and household chaos), a measure of self-control (BRIEF-A), measures of social influence (MOS, Social Connectedness, Lubben Social Network Scale), a measure of stress appraisal (Stress Appraisal Measure), and measures of weight stigma (History of Experienced Weight Stigma, Interpersonal Sources of Weight Stigma, WBIS-M, WSSQ). The inclusion of these measures may elucidate new treatment targets for the development of novel, more effective interventions for obesity. Medical events will also be assessed via interview. Survey measures are detailed below.

Stress / resilience. Measures of stressors (perceived stress, chaotic environments, "costs" of weight loss) and resilience factors (self-control, stress appraisal, healthy habits, sleep, perceived "benefits" of weight loss) will be assessed. These measures are well-used in the field and have been shown to have excellent psychometric properties (Cohen, et al., 1983; Matheny et al, 1995; Jeffery et al., 2004; Roth et al., 1996; Gardner et al., 2012; Galla et al., 2015; Home & Osteberg, 1976; Evans et al., 2017; Sheeran, 2003).

Diet behaviors. Measures that assess dietary behavior (eating frequency, restaurant eating, disinhibition, beverage intake), weight management practices, and the household food environment will be added. These measures have been included in large, NIH trials focused on weight management (e.g. SNAP) and are recommended by the ADOPT NIH working group to be included in new trials (https://www.nhlbi.nih.gov/research/reports/accumulating-data-optimally-predict-obesity-treatment-adopt-core-measures-working-group-meetings). Where possible, these measures have demonstrated appropriate levels of reliability and excellent validity (Megson, 2017; Karlsson et al., 2000; Wing et al., 2016; Gorin et al., 2013).

Social processes. Measures of social connectedness (network size, norms, social support, relationship quality, and relationship satisfaction) will be added. These measures are validated and reliable measures and are well accepted in our field (Lubben et al., 2006; Leahey et al, 2015; Sherbourne et al, 1991; van Bel et al, 2009;).

Contingency plan for assessment procedures during national emergencies such as COVID-19.
Because primary outcome assessments take place in person, alternative remote procedures will be implemented in the case that in-person contact poses a health risk to participants. In these cases, data will be collected using the following methods:

Weight (primary outcome). Weights may be collected using a digital scale that will securely transmit participant weights back to study staff via cell tower. Given that these e-scales are expensive and could be cost-prohibitive, weights may also be collected by sending a bathroom scale to participants and having participants complete a remote assessment visit via videoconference. During the videoconference, research staff will guide participants through a remote assessment to ensure that they follow all gold-standard weigh-in assessment procedures (e.g., one layer of clothing, no shoes, empty pockets, etc.). Calibration weights will also be included with the scale, and participants will be asked to validate the scale's accuracy before weighing themselves Participants will show the scale's read-out to research staff via the videoconference function. Participants will return the scale to the lab (the scale is not an incentive/honorarium). Weight may also be collected via participant self-report. In these instances, participants will be asked to step on their home scale and to take a picture of their current weight. They will then email this picture to the study staff as a record of their assessment weight.

Adverse Event Interviews. The occurrence of adverse events will be assessed via Qualtrics, email or phone instead of in person.

Compensation. In case of national emergency, participants will receive e-gift cards, checks, money orders, or other electronic payment (e.g., Paypal) with a value based on the assessment time period ($25 for 6 and 12 months, $50 for 18 months, $75 for 24 months). That is, they will not receive any extra compensation for these procedures. Instead, they will receive their typical compensation, just via electronic or mail delivery method (as opposed to receiving cash in-person) to help ensure safety during COVID-19.

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Quality control.

Data management. The Project Director (to be hired) will be trained by the PI and responsible for providing immediate supervision of all assessment sessions. The PI will have the ultimate responsibility for ensuring that all staff are trained and appropriately completing assessment procedures. Survey data will be collected using Qualtrics (please see Human Subjects for security details). One to two weeks prior to their visit, participants will receive a link to complete their measures. On the day of the visit, the (blinded) assessor will log on and review participant responses for completion; missing data will be addressed during the visit. The assessor will record all physical measurements on a standardized form. These data will be entered into a password protected data entry and storage system, which provides programmatic protection against invalid data entries, and provides second-party, blinded double-entry data verification to validate accuracy of data entry. Dr. Heudo-Medina (biostatistician) will be responsible for data cleaning, error checks and preliminary analyses of all data to ensure accuracy.

Treatment fidelity. The Phase I Internet behavioral weight loss program is largely automated, ensuring fidelity. During Phase II (maintenance), all interventionists (professionals and mentors) will receive training in all skills and concepts being delivered and detailed interventionist and participant manuals will be available for each session. In addition, for the P2P arm, patient training procedures developed by Drs. Leahey and Gorin will be executed in this trial. Trained mentor patient interventionists will then train all peer patient dyads in how to provide evidence-based weight management strategies and autonomy support using a training manual. In addition, all peer patients will be given coaching manuals for reference. To ensure competency, after each training session, peers will complete a questionnaire to determine whether they have acquired knowledge in the core skills that were presented. Missed items will be reviewed by mentors. In addition, the first 2 peer support email exchanges (week 3 and 5) will be closely monitored by mentors. Peer patients will be given corrective feedback at the subsequent group meeting (week 4 or 6). Mentors will continue to monitor peer correspondence throughout the 18-months of the intervention.. Necessary corrective feedback will be provided via email or phone. All Phase I and Phase II intervention and peer training sessions will be audiotaped; Drs. Leahey and Gorin, who are clinical health psychologists, will review each tape and provide weekly supervision. Finally, two master's level interventionists, trained by the PI in the skills and concepts being delivered, will review 20% of all audiotapes to formally assess adherence, competence, and the presence of any cross-contamination between treatment arms using a treatment fidelity checklist. Any issues with fidelity will be addressed immediately.

Missed visits and drop outs. Participants who miss a maintenance session will be sent handouts via (e)mail by their interventionists. . If a P2P participant misses a visit, they will also connect with their peer partner via phone or in-person prior to the next group session to complete the relationship building activity. If a P2P participant stops treatment, his/her partner will be reassigned to work with another peer patient dyad. This occurred once in our pilot study and this approach was well tolerated by the participant who lost her partner and the twosome who incorporated the solo participant. Peer patients will receive weekly automated reminders for e-coaching. Evidence-based retention efforts will be used to minimize dropouts. Finally, participants will receive escalating compensation of $25 for initial assessment visits to $75 for the final visit.[30, 71]

Justification of Sample Size / Data Analysis.

Power. The trial is powered for the primary aim: efficacy of P2P vs. Standard at month 18. We aim to detect a clinically meaningful difference of 2.5 kg between arms.[79] Based on previous maintenance trials with similar designs and our own trials, we expect a common within-group standard deviation of 6kg and a 15% attrition rate.[17, 23] Hypothesis testing will be based on linear mixed effects models for longitudinal data, which increase power by fully exploiting the strong correlation in weight measures across time. The cluster effect of peer patient dyads in the P2P arm has been considered in the power calculations. Based

on results from our peer patient trials, we anticipate peer dyad weight change to be positively correlated at the pair level with an ICC of 0.20. Since power is maximized by equalizing effect sample sizes rather than nominal sample sizes across study groups,[80] we will enroll 110 participants into Standard and 124 (62 peer dyads) into P2P. Given these assumptions, the study will have 85% power to yield a statistically significant result that will increase in one unit per number of individual covariate(s) included in the models. Accounting for 15% attrition, 35 more participants will be added, so a total of 269 participants will be enrolled in Phase II.

Analyses.

Primary hypothesis. The primary outcome for which the trial is powered is weight change from Phase II baseline to month 18. Differences in baseline characteristics in P2P vs. Standard will be examined using either t-test, Chi-Square tests or analysis of variance when appropriate. If baseline differences exist, they will be controlled for in outcome analyses. Distributional properties of continuously scaled variables will be examined to determine if normalizing transformations should be applied or if distributions other than normal should be used in the models. Given that P2P participants interact with one another (peer e-coaching) in a pairwise fashion we will use specialized versions of dyadic longitudinal growth models that allow for such pairwise relations, originally developed for the analysis of family level data (marital discord, sibling relations).[72-74] Pairwise contrasts among study groups using linear mixed effects models will be fitted by restricted maximum likelihood using REML as implemented in the PROC MIXED procedure or PROC GLIMMIX SAS 9.3 if residuals do not meet normality. Unconditional models will be fitted to assess for variability in participant intercepts and slopes, and determine whether these factors should be treated as random effects in conditional models. Unconditional models will also be used to evaluate whether the trajectory of the outcome is best characterized as linear / non-linear (quadratic and cubic). Estimated mean differences will be developed using linear contrasts and assessed with Wald statistics. These analyses will result in a detailed model of weight change across the 18-month maintenance trial. However, given that our primary interest is in long-term weight change, our analyses will focus on the 18-month time point. Within the linear mixed effects model, an a priori test of the difference between least squared means for treatment arms at the 18-month time point, adjusted for covariates, will test for between-arm differences at the 18-month assessment. In the linear mixed models described above, we will add as covariates both the main effects of potential moderators and their interactions with treatment arm. Significant interaction effects will be plotted to illustrate the moderating effects, further assisting the interpretation for whom and under what circumstances the intervention has different effects.

Secondary hypotheses. Analyses will test differences in P2P vs Standard on cardiovascular outcomes (blood pressure) at 18 months using linear mixed models identical to the primary analysis.

Exploratory hypothesis 1. We will explore mediation effects for each of our proposed mediators (e.g., empathy, compassion, hope, inspiration) on weight change from baseline to month 18 using the Mediation package in R.[75, 76] General or generalized mixed effects models will be created for the indirect and total effects to determine the proportion of the mediation effect. A causal inference approach was selected over multiple regression because of the dyadic and multilevel nature of our models, the possible feedback between dependent and mediating variables, and its ability to relax identification assumptions when needed.[77, 78]

Exploratory hypothesis 2. Cost-effectiveness of the two interventions will be examined. Data from our cost measures, utility measure, and trial results (kg of weight change from baseline to month 18) will be used. Multi-way sensitivity analyses will be conducted to show how different variables interact. P2P participants will be sampled in pairs, so as to maintain their within-pair correlation structure. Univariate sensitivity analyses will be performed on all variables and assumptions used in the analyses. A Monte Carlo simulation will be used to vary all of the input parameters over their relevant ranges simultaneously

and to estimate the 95% confidence intervals for incremental cost-effectiveness analyses. The cost-utility analysis will use similar methods to estimate the incremental cost-utility of Standard and P2P at 18-months.

Exploratory hypothesis 3. To explore the sustainability of peer patient e-coaching, we will compare the number of completed coaching weeks, number of overall exchanges, and frequency of exchanges per week from months 18-24 vs. months 12-18 using dyadic analysis similar to Aim 1. Also, to examine if P2P and Standard differ in 24 month weight, CVD, and process outcomes (e.g., empathy, hope, inspiration, autonomy support), analyses similar to the primary aim will be conducted.

Missing data. Although concerted effort will be made to minimize missing data, we anticipate missing data due to refuted responses or lost to follow-up. Type of missingness will be evaluated and missing values will be imputed using full information or restricted maximum likelihood estimation[81] depending on type of missing data, completely at random or just random missing data. All variables in our models will be used to impute missing data. Sensitivity analyses will be used to compare results with and without imputed values.

Inclusion/Exclusion Criteria.

Participants in this study will be 860 healthy overweight or obese men and women ages 18-75 recruited from the greater Hartford, Connecticut area. Participants will have a body mass index between 25 and 50 kg/m^2. This weight criterion was chosen because of the high prevalence of overweight and obesity in the United States and because of the health implications associated with obesity. We have chosen a BMI upper limit of 50 kg/m^2, as individuals with a BMI greater than 50 have more medical co-morbidities and require greater medical supervision and eligibility screening.

Participants will be excluded if they report being unwilling to actively participate in a weight loss intervention that involves patient-provided treatment; are unable to walk 2 blocks without stopping; are currently participating in a weight loss program, taking a weight loss medication, have a history of bariatric surgery, or lost ≥ 5% of body weight during the past 6-months; are pregnant, lactating, less than 6 months post-partum, or plan to become pregnant during the time frame of the investigation; report a medical condition that would affect the safety and/or efficacy of a weight management program involving diet and physical activity (e.g., uncontrolled heart problem); or report conditions that in the judgment of the Principal Investigator (PI) would render them potentially unlikely to be able to follow the protocol for 12 months, including terminal illness, plans to relocate, substance abuse, dementia, bulimia nervosa, or other significant psychiatric problems. These exclusions are for the safety of participants and to reduce the likelihood of dropouts due to concurrent medical or psychological problems. During times of national emergency (e.g., COVID-19), participants unable or unwilling to engage in videoconference meetings will be excluded. Participants taking prescription medications, reporting joint problems, or other medical conditions that are affected by weight loss or may limit their ability to exercise will be required to obtain written approval to participate in a weight loss program from their physician.

Risks and Inconveniences.

The risks associated with this study are considered to be minimal and detailed below.

Intervention risks. The intervention involves a reduced calorie diet. The prescribed diet is balanced, with approximately only 1000 kcal per day deficit from the participant's usual intake, thereby minimizing risk. The physical activity recommendation is for moderate-intense activities. A potential risk is that

participants become injured while doing physical activity; to minimize this risk, participants will be instructed to engage in brisk walking and gradually increase their activity over time. Participants may try unhealthy dietary or physical activity practices to lose weight. However, this is not common in adult behavioral weight loss programs; yet, to be cautious, participants' weight and self-monitoring information will be monitored by intervention staff and, if participants are losing weight too quickly or there is suspicion of unhealthy practices, an interventionist will call and speak with the participant and make a referral, if necessary.

Assessment risks. Participants may also become uncomfortable when completing questionnaires, including measures asking about weight stigma which may cause participants to experience negative emotions related to past experiences of being stigmatized. If this occurs, participants will be informed that they do not have to answer any questions that they are not comfortable answering. Another potential risk is that participants may not lose weight in the program. However, this is a potential risk in any weight loss program. Alternative treatments for overweight and obesity include diets with lower daily calorie recommendations, pharmacological interventions, and surgical procedures. These treatments are considered to have greater risks than the diet and activity program prescribed in this intervention. We do not anticipate any risks associated with the waist-worn activity monitor.

Benefits.

The risks of participating in a behavioral weight control intervention that involves patient-provided care are minimal and outlined above. In comparison to the risks, the potential health benefits associated with this study are significant. Weight loss and maintenance of lost weight, as well as healthful dietary changes and increases in physical activity, have the potential to substantially improve the health of all participants in this study. Findings from this study will have important implications for the treatment of obesity and could inform clinical practice and public policy.

Risk/Benefit Analysis.

There are minimal risks associated with study participation. We will minimize the modest risk of this study by having highly qualified investigators and well-trained staff administer all assessments and carefully explain the study prior to study entry. If a participant is uncomfortable completing these measures, s/he does not have to complete them. We are using standardized questionnaires and assessments protocols that have been used extensively in the literature and in many cases by the study investigators in prior research protocols. We believe this project is significant because it deals with obesity, a major health problem, and aims to improve long-term weight loss outcome, the principal problem of obesity treatment. Findings from this study will have important implications not only for the treatment of obesity but for other health problems, such as drug and alcohol abuse, that may respond well to interventions targeting autonomy support and using patient providers. Our surveys, such as those addressing weight stigma, may further our understanding of the impact of psychosocial barriers to weight loss success. The anticipated benefits are considered to be much greater than the minimal risk.

Economic Considerations.

For in-person visits (treatment and assessments) participants will receive free parking near 1 Constitution Plaza in Hartford, CT. Or, if recruited to the InCHIP (Storrs, CT) location, free parking with be provided at the University of Connecticut. Participants will not be compensated

for Phase I visits. During Phase II, participants will receive $25 for their 6- and 12-month assessment visit, $50 for their 18-month assessment visit, and $75 for their 24-month assessment visit. Assessment visits will be approximately one hour in duration. Intervention-related payouts will be provided at in-person intervention visits, or in the case of COVID-19 via electronic gift cards or money order.

Data Safety Monitoring.

The PI of this study will be responsible for immediate oversight of data and safety monitoring. During the study, the Project Coordinator, intervention staff, and Research Assistants will be trained by the PI and will be required to demonstrate competence on all study procedures prior to data collection. As indicted in the protocol, to ensure that interventions are delivered as intended, detailed counselor, participant, and peer patient coaching manuals will be used. All Phase I and Phase II intervention and training sessions will be audiotaped and reviewed for treatment standardization purposes and to provide group leaders with supervision and feedback. A digital recorder will be used to record intervention sessions. At the end of the session, the interventionist will download the audio file from the digital recorder to the study drive (located on a secure server) and delete the file from the recorder. Drs. Leahey and Gorin will access the audiotapes to provide supervision and suggestions to intervention staff at weekly supervision meetings. Participants will not be identified in any way on the audiotapes, and all information will be kept confidential. A treatment fidelity checklist will be completed on 20% of all intervention and training sessions. Any issues with treatment fidelity will be immediately addressed. Tapes will be destroyed after all standardization and supervision procedures are complete, or three years after the study ends, whichever comes first.

All study data will be kept secure. Hard data will be stored in locked file cabinets. Electronic data files will be de-identified, password protected, and stored on secure servers. Back-up copies of electronic data files will be updated immediately following the entry of new data. The backed-up version of the file will be kept in a separate location to protect against loss or damage. Furthermore, the network server upon which the main data file will be stored is backed up nightly to provide additional protection against loss.

As noted above, there are few risks expected from this project. However, the occurrence of adverse events will be assessed at Phase I post-treatment and Phase II 6, 12, 18, and 24 month assessment visits via our standard adverse event structured interview form. If an adverse event is reported, Dr. Leahey will make a detailed record of the event indicating the date study personnel became aware of the event; a description of the event; date of event onset / offset; whether the event was study related (0=definitely unrelated, 1=unlikely, 2=possibly related, 3=probably related, 4=definitely related) and, if so, whether the event was expected (yes/no); event severity (1=mild, 2=moderate, 3=severe, 4=life threatening); and event resolution (1=resolved, 2=recovered with minor changes to daily activities, 3=recovered with major changes to daily activities, 4=condition still present and under treatment, 5=condition continues to worsen, 6=patient died), including medical care and whether any study related modifications are necessary (0=none, 1=diet/exercise modification, 2=minor counteractive medical treatment, 3=major medical intervention, 4=hospitalization). Adverse events will also be assessed to determine whether they qualify as serious adverse events, defined as inpatient hospitalization, significant and persistent life-changing disability that lasted at least 1 month, or a life-threatening event. All adverse events will be logged by the project coordinator. Serious adverse events that are related to the study will be reported immediately to the IRB. Summaries of data and safety monitoring reports (no identifying information) will be provided to the NIH and to our Data and Safety Monitoring Officer, Dr. Jessica LaRose at Virginia Commonwealth University.

Study staff conducting the Phase II baseline, 6-, 12-, 18-, and 24-month assessments will monitor blood pressure data. Based on NHLBI guidelines, the following actions will be taken for elevated values: **Privacy/Confidentiality.**

ELEVATED VALUE	ACTION
Blood pressure: SBP≥140, DBP ≥ 90 mmHg	Study staff will inform the participant at time of measurement. Participant will be advised to see their primary healthcare provider within 1 month for an assessment.
Blood pressure: SBP≥160, DBP≥100 mmHg	Study staff will inform the participant at time of measurement. Participant will be advised to see their primary healthcare provider within 1 week for an assessment.
Blood pressure: SBP≥180, DBP≥110 mmHg	Study staff will inform the participant at time of measurement. Participant will be advised to see their primary healthcare provider within 1-2 days or be evaluated immediately if other symptoms are present (e.g., headache, shortness of breath, chest pain should be evaluated immediately).
Hypotension SBP <90	Clinic staff will inform participant at time of measurement and ask "are you feeling dizzy or lightheaded?" If yes, participant should be advised to see their primary healthcare provider within 1 month, or sooner depending on the clinical situation or presence of other symptoms (e.g., passing out [syncope]).

All participant data will be treated as confidential. Records will be safeguarded according to the policies of the University of Connecticut and Connecticut law. Data confidentiality will be protected through a multi-tiered approach including data collection, data transmission, data handling, and data distribution processes to help ensure anonymity both during and after the study. Participants will be assigned a three-digit identification code (in addition to the cohort number, i.e 1001) that reflects the number of participants in the study. Only these identification numbers will appear on the questionnaires and data collection documents. A master key matching participant names to identification numbers will be maintained in a locked secure location at UConn's Weight Management Research Group. Only research staff will have access to the information or be able to associate identification codes with individuals. All raw data collected in paper form will be stored in locked filing cabinets. All data will be reported in aggregate form only, in order to protect individuals' identities. Individual participants will not be identified in any reports, papers, presentations or other media. During the consent process, participants will also be asked if they can be contacted for future studies. Under these circumstances, their name and contact information would be stored separately from all personal health information (e.g., weight, survey data, etc.) in a password protected computer, in a password protected file, on a secure server. Participants who agree to be contacted for future studies would be contacted and, at that time, decide whether they

wish to learn more about the new study. The study's project coordinator will work closely with the PI and study personnel to ensure the secure storage of all project databases and questionnaires. If necessary, data will be transmitted to study staff using password protected and de-identified files.

Participants may have the option of completing surveys online. Online surveys will be administered using Qualtrics, a well-established service that is committed to keeping all participant data secure and confidential. All data is stored in a password protected database at a web hosting site that provides top of the line virtual and physical security. The web hosting facilities make use of firewalls, real-time security alerting using intrusion detection scanners, and 24-hour monitoring from their network operations center. The website itself is safeguarded against common hacker tricks. Physical security of database servers includes perimeter fencing, green field space, card access, biometric entries, and mantraps, 24-hour security guards and continuous camera surveillance inside and outside the facility's buildings. To prevent the possibility that data will be intercepted as it travels the internet, all data is encrypted in transmission, both when survey participants fill out surveys and when survey creators download their data. All electronic files will be password protected to protect the information from unauthorized access.

The risk to using the MyFitnessPal app is loss of confidentiality. Data recorded in the app are stored for as long as the individual maintains an account and, when necessary, to comply with legal obligations and agreements. Thus, even if data are deleted, MyFitnessPal may have access to the data for legal and regulatory purposes. This risk is minimized in the following ways. First, individuals who use MyFitnessPal create a username and password. Thus, app data are password protected. Second, participants can use the app without having to provide personal information (e.g., name). Third, per the MyFitnessPal privacy statement, technical and organizational security features are used to protect individual data against unauthorized access, theft, and loss. Participants will be informed of the risk to confidentiality associated with MyFitnessPal app use and told that their data are only protected to the extent allowed by MyFitnessPal. It is also important to note that participants do not have to use this app to participate in the study. That is, those concerned with the privacy of MyFitnessPal data are able to record their diet, exercise, and weight using paper/pencil diaries, which will be provided by the study. Finally, it is worth noting that, the PI of this study has used MyFitnessPal in many previous studies, and no privacy concerns have been raised.

Participants in both arms will be interacting with one another during both group treatment and via email / text on their personal accounts. Given this participant-to-participant interaction, participants will be instructed to maintain each other's confidentiality. Like any treatment that involves participant interaction (e.g., groups), we will not be able to completely ensure that participants maintain each other's confidentiality. Similarly, while email accounts and phone accounts are largely password protected and have stringent security settings, confidentiality of these communication avenues is also limited to the extent of server privacy and security settings. Thus, all participants will be informed of these (group treatment, email, phone) limitations to privacy and confidentiality during the consent process prior to agreeing to participate. In addition, they will be informed during the intervention of these limitations and to only share with other group members / patients to the extent that they feel comfortable. This has been the approach used in all of our trials.

As noted above, participants in the P2P intervention arm will have the option of participating in a "secret" (i.e. private) Facebook group that includes their mentor interventionist and other members of their group and is monitored by study staff. Being involved in a secret group means that the public is unable to "see" the group and only the study team can invite users (i.e. mentors and participants). During the consent process all participants and mentors will be informed that the study team does not guarantee privacy / confidentiality

of any information shared on Facebook, and that any information transmitted via Facebook is only secure to the extent offered by Facebook's privacy / security policy. We will also encourage participants and mentors to familiarize themselves with Facebook's privacy policy and provide them the web address to do so. Moreover, we will inform them that it is important to keep in mind that anything posted on Facebook is technically governed by and can be used by Facebook; therefore, the study team cannot ensure complete confidentiality of all Facebook posts and information. Facebook terms and conditions may be updated periodically; therefore, we will highly recommend to our participants and mentors to visit https://www.Facebook.com/legal/terms to check the latest statement of their rights and responsibilities. The study team may examine 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 only be presented in aggregate (grouped) format.

Of note, if COVID-19 remains a public health threat but UConn allows in-person appointments with research participants, our lab will, of course, comply with all OVPR safety guidelines and trainings. Further, participants coming to the lab will be screened for COVID-19 symptoms and exposure. Within 24 hours of any scheduled visit, the participant will complete a COVID-19 screener via email, phone, text, or web-based assessment (Qualtrics). If the participant does not respond to this screener, s/he will be screened immediately upon arrival to their appointment. Screening questions listed below are recommended by UConn's OVPR / UConn Health.

- Have you been diagnosed with COVID-19?
    - Per UConn Health guidelines, participants who respond affirmative to this question will need to wait 21 days from time of diagnosis for an in-person appointment. If 21 days has elapsed since the test and the participant passes all other screening questions (see below), they will be allowed to complete their appointment. If not, they will need to wait the 21 days and then be reassessed for COVID risk.
- Have you been tested for COVID-19 with a negative result?
    - Out of abundance of caution and the possibility of a false negative, participants who respond affirmative to this question will also need to wait 21 days from time of diagnosis for an in-person appointment. If 21 days has elapsed since the test and the participant passes all other screening questions (see below), they will be allowed to complete their appointment. If not, they will need to wait the 21 days and then be reassessed for COVID risk.
- Are you having any of these new or worsening symptoms without an obvious cause: cough, shortness of breath or trouble breathing, fever, chills, muscle pain, headache, sore throat, loss of taste or smell? (Please note that screening items may evolve over time requiring investigators to update this list.)
    - Participants who respond affirmative to this question will have their appointment cancelled and a COVID-19 test will be recommended. Then, procedures noted above regarding positive / negative test results will be followed.
- Have you had contact with someone who has been tested for or diagnosed with COVID-19?
    - Per CDC guidelines, participants who respond affirmative to this question will be asked to self-quarantine for 14 days, upon which they will be reassessed for symptoms before being rescheduled.

Informed consent.

Consent setting. Participants will be screened via phone or through a secure portal on our lab website. All data on the website will be encrypted and accessed only by project research staff. If

an individual is interested in participating, (s)he will be invited to the lab in Hartford for a face-to-face orientation visit where (s)he will be provided with detailed information about the study's purpose, risks/benefits, design, and requirements and be given an opportunity to ask questions. If the individual remains interested in participating after any/all of his/her questions have been answered, (s)he will sign a consent form (provide written consent) at the end of this orientation visit and be enrolled in the study. In the event of national emergency (e.g., COVID-19), virtual orientation sessions will be conducted via WebEx. In the event of a virtual orientation sessions, all orientation documents will be sent to interested individuals prior to the session (including the consent form) and they will be encouraged to review these documents before the virtual session. During this session (whether in-person or virtual), interested individuals will receive all detailed information and have their questions answered, just like an in-person session. If the individual agrees to participate, s/he will provide oral/virtual consent via the audio, chat, or video functions of WebEx. Study staff will record all consented participants; these data will be stored on the UConn research drive in a locked file. After consent is provided, the participant will be officially enrolled.

Capacity to Consent. N/A

Parent/Guardian Permission and Assent. N/A

Documentation of Consent.
For the in-person consent process, an adult consent form will be used. For the virtual consent process, participants will be sent the adult consent form prior to their WebEx / virtual consent meeting. During the virtual consent / orientation session, they will be asked to provide consent via hand raise, oral indication, or by sending a message to study staff using the chat function in WebEx. Study staff will record who provides consent. This information will be saved in a password protected file on the UConn research drive.

Waiver or Alteration of Consent.

We are asking for 2 waivers of consent. One for the initial screener and the other to conduct virtual orientation sessions via WebEx. Please see below for details.

Waiver #1: Screener (already approved).

We will be conducting an initial telephone or Web screen only to determine an individual's initial eligibility status for participation. This task requires participants to provide basic information about their health and weight status. Identifying information is not collected until the participant agrees to provide such information. Once an item identifies a participant as ineligible, no further information is collected. We need to retain the following information on ineligible participants: name and phone number, to determine whether candidates for future cohorts have been screened before, and reasons for ineligibility in order to accurately report on the demographics of those individuals who were not eligible for our study, and to report why these individuals were excluded. All screening data collected from ineligible participants will be de-identified after recruitment for this study has officially concluded.

We are asking for a waiver of signed consent for the initial telephone / Web screen in order to establish whether an individual is eligible to participate in the study over the phone / via Web rather than in person. Participants will likely be responding to advertisements in the community within a 30 mile radius of our laboratory, thus, it would create a significant burden for respondents

to come to the laboratory to sign a consent form and then complete a screening questionnaire that is easily administered over the phone/Web and can identify initial eligibility status within minutes.

If on the telephone/Web screening, an individual is deemed eligible to participate, and agrees to provide their contact information, this information will be maintained in a locked secure location (if obtained via phone) at UConn's Weight Management Research Laboratory or on our secure, encrypted Website (if obtained via Web screen). Should an individual choose to continue in the study, they will come to our lab, provide informed consent and then be assigned a 3-digit code (plus cohort number). Only these codes will appear on questionnaires and data collection documents. A master key matching participant names to identification numbers will be maintained in a locked secure location at UConn's Weight Management Laboratory. Only research staff will have access data and be able to associate identification codes with individuals. All raw data collected in paper form will be stored in locked filing cabinets. All data will be reported in aggregate form only, in order to protect individuals' identities.

Waiver #2: Virtual orientations & waiver of signed consent.

In the event of a national emergency (e.g., COVID-19), we will conduct virtual orientation sessions via WebEx. Prior to the virtual orientation session, participants will be sent study documents and encouraged to review them before the meeting. They will also be sent instructions for how to log into WebEx using de-identifiable information. During the virtual orientation meeting, research staff will conduct a typical orientation, describing the study in detail, answering any questions individuals may have, and providing an opportunity to opt-out. Once all questions have been answered, in lieu of written consent, we will ask participants to indicate whether they consent by hand raise, messaging study staff via the chat function, or orally. Research staff will record who consents in a database, which will be saved in a password protected file on our secure UConn research drive. Individuals who do not consent will leave the virtual meeting. This waiver is being requested to allow participants to safely engage in research via virtual means in the era of COVID and social distancing. It will also allow this trial to move forward without any additional delay.

- Why is the study considered to be minimal risk?

  The waiver of consent for this study applies only to the eligibility screening process, which is considered minimal risk in the context of research study recruitment. That is, information obtained during the screening asks questions about health, which is commonplace in daily life and occurs regularly outside of the research setting. Once a participant is determined to be eligible, written informed consent will be obtained before the beginning of study procedures.

- How will the waiver affect the participants' rights and welfare? The IRB must find that participants' rights are not adversely affected. For example, participants may choose not to answer any questions they do not want to answer and they may stop their participation in the research at any time.

  This waiver will not affect participants' rights and welfare. Any person interested in this study will have to complete the screening questions and orientation session in order to participate. However, they can choose to stop answering these questions or not agree to participate at any time.

- Explain why the research could not be practicably carried out without the waiver. For studies that involve deception, explain how the research could not be done if participants know the full purpose of the study.

  Due to the high volume of interested candidates in this trial, it is not feasible or necessary to require every potential participant to arrive in person to be consented before determining their eligibility. It would create an unreasonable burden on study staff, as well as a significant barrier to participation for participants, when the screening can be completed over the web or phone with minimal burden or risk. Due to COVID-19, it is not possible to have in-person orientation sessions. Thus, online orientation sessions will allow us to continue this trial without further delay.

- Explain why the research could not be practicably carried out without using identifiable private information and/or identifiable biospecimens.

  In order to contact, schedule, and track individuals who has either expressed interest in the study, or completed the web screener, identifiable private information such as name, phone number and email address must be obtained by study staff.

- How will important information be returned to the participants, if appropriate? For studies that involve deception, indicate that participants will be debriefed and that the researchers will be available in case participants have questions.

  This question is not applicable to the waiver of consent requested, as the waiver only applies to screening for eligibility.

- Indicate if the waiver/alteration as noted above is applicable to the entire study or to a portion of the study.

  The waiver of consent applies to the screener (which was already approved) and the new online orientation procedures.

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