Project Title: PACE (Physical Activity Choices Everyday)

Protocol & SAP

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IRB-1 Study Protocol
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Study Protocol Title: Decisions about exercise during weight management
Protocol Number: H18-153

Clinical Trial/GCP Training
Is this a research study in which one or more human subjects are prospectively assigned to one or more biomedical or behavioral interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (i.e a clinical trial)? **yes** Is the study fully or partially funded by the NIH? **yes**
Have the required key personnel completed Good Clinical Practice (GCP) Training? **yes**

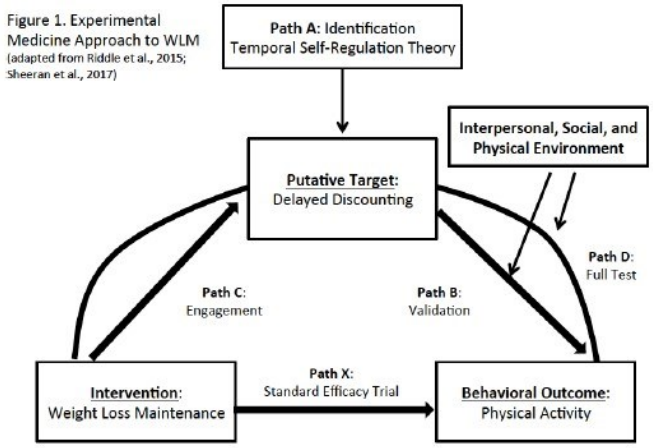
Research Plan
Purpose / Introduction.

Weight loss maintenance is the major challenge in obesity treatment. Over 70% of American adults are overweight or obese resulting in staggering healthcare costs[1-3]. Weight loss can be achieved through several methods [4][34, 35]; however, treatment response is variable, particularly during weight loss maintenance (WLM). Despite strong intentions to maintain healthy lifestyle behaviors, decay in adherence to behavioral recommendations is common [4,5], leading to weight regain. Recognizing this challenge, an expert panel recently convened by NIH has called for research to understand cognitive, behavioral, and environmental factors impacting WLM [6].

Physical activity (PA) is a robust predictor of WLM success but adherence to PA is highly variable. Jakicic[5] found that weight management over a 2-year period directly corresponded to PA minutes/week, with the best long-term weight loss in those exercising $\geq$300 min/week. Only 26% of participants, however, were able to achieve this level of PA. Our own work suggests variability in response to PA recommendations is seen within months of starting treatment (245.8$\pm$174.6 PA mins at 6 months, range=0-1064 mins, unpublished data). There is often a gap between intention and PA behavior; only about 50% of people who have intentions to exercise actually engage in PA[7-9]. Elucidating the mechanisms by which WLM interventions bridge the intention-behavior gap and lead to sustained change is necessary to build more efficacious treatment.

An experimental medicine approach to WLM could establish modifiable mechanisms of sustained behavior change. An experimental medicine approach[10-12] (Fig. 1) requires evidence that a putative target of behavior change is in fact engaged by a given intervention and that engagement of the putative target mediates behavior change outcomes. These paths are rarely measured in behavioral interventions[12] including WLM treatment. Also missing from the intervention literature are explorations of how mediational pathways may be context specific. This is a critical omission in WLM as some environments are more conducive to maintenance and some more conducive to weight gain[13,14] – simply put, putative targets may not work the same under different environmental pressures. To advance the science of behavior change, mediational tests of putative targets are needed that are sensitive to the context in which weight management is occurring.

Temporal Self-Regulation Theory (TST) provides a useful framework for identifying putative targets of PA adherence in WLM interventions. TST[15,16] posits that the association between intention and behavior is influenced by self-regulatory capacity (i.e., executive function; EF) and the environment (i.e., factors that slant responses toward or away from a behavior). EF refers to high-order processes that enable self-directed behavior[17,18] such as mental flexibility, self-control, and the ability to delay gratification. EF is linked to health behaviors including PA and weight loss outcomes[19-21]. For example, changes in EF during an exercise intervention predicted PA adherence at 1-year[22]. The environment, however, can deplete these self-regulatory resources and influence perceptions of the costs/benefits of engaging in a behavior at a particular point in time[15]. When the costs of engaging in a behavior are more proximal than the benefits (e.g., cost of leaving a warm house to go exercise vs. long-term benefit of WLM), more self-regulatory capacity is needed to overcome behavioral inertia and produce behavior change. When the benefits of engaging in the behavior are more proximal (e.g., seeing a friend while walking), self-regulatory capacity is a weaker determinant of behavior[23,24]. In brief, TST provides a rich framework for understanding the interplay between behavioral, neurocognitive, and environmental underpinnings of behavior. Further, a growing literature supports the major tenets of TST[23]. Interventions are now needed that translate TST concepts into behavior change strategies[25].



Delayed discounting (DD) is a self-regulatory capacity that is consistently associated with obesity treatment outcomes. One aspect of self-regulatory capacity that is particularly relevant to WLM is delayed discounting (DD), or the rate at which individuals devalue future rewards in favor of immediate rewards as a function of temporal distance[26]. DD has been framed as a dual-system model of decision making[27]; an appetitive, impulsive system that seeks immediate rewards and an inhibitory, executive system that inhibits impulses in order to maximize long-term gains. WLM requires individuals to value a long-term reward and engage in daily behaviors that are consistent with this future state. If one cannot inhibit behaviors that provide immediate gratification (i.e., pleasurable sedentary activity) in favor of behaviors that have longer-term benefits, but perhaps even some short-term costs or discomfort (i.e., exercising on a cold day), successful WLM is unlikely. The tendency to discount future rewards in favor of immediate rewards is associated overeating[28], obesity[28,29] weight loss outcomes[30], and other poor health behaviors (e.g., substance use).

Interventions that explicitly shift the value of rewards from immediate gratification to delayed rewards influence health behaviors. Episodic Future Thinking (EFT) is a trainable cognitive skill that reduces DD[31]. EFT involves asking participants to identify upcoming personal events (e.g., wedding) for which the behavioral goal (e.g., WLM) is important. Participants then regularly practice imagining the event, having reached their behavioral goal. Experimental studies suggest that EFT reduces bias for the present, increases activation of brain regions involved in long-term prospective thinking, and increases valuation of future rewards[32,33]. Given these promising findings, EFT is now being evaluated in substance abuse and obesity[34-37]. In obesity, EFT has been shown to reduce DD and energy intake in an ad libitum eating task in children and adults[38,39]. Novel work by Sze et al.[31] suggests that EFT can be used in a clinical weight management trial for parent-child dyads. Adherence to EFT was high and cues were perceived to be helpful, particularly by parents. EFT produced greater weight losses in parents and children compared to the control. While intriguing, the study was limited in duration (4-weeks) and did not assess delayed discounting as a potential putative factor.

The goal of the present study is to establish whether delayed discounting is engaged in a WLM intervention that involves EFT, whether this engagement mediates adherence to PA recommendations, and whether environmental factors moderate this relationship. We will do this by testing TST-based mediational pathways in both a standard WLM intervention (Weight Loss Maintenance- Healthy Thinking: WLM-HT) and a

WLM intervention that explicitly seeks to engage DD through EFT (Weight Loss Maintenance+ Future Thinking: WLM+FT). Given that the stated focus of many WLM interventions is on selfregulation[14,18] and the data linking DD to eating and exercise behaviors[29,40], it is reasonable to propose that this putative target is engaged in standard WLM interventions, although this hypothesis has not yet been empirically tested. At the same time, we recognize that there is tremendous variability in response to WLM interventions[6], which suggests the need to more systematically engage putative targets such as DD to improve behavioral adherence and long-term outcomes. EFT is a promising strategy but has yet to be explored in WLM. Thus, testing of the DD mediational pathway within these two interventions will allow for both within- group examinations of the hypothesized mechanism of action as well as between-group comparisons of whether explicit engagement of DD results in greater behavioral adherence and improved WLM outcomes. It is hypothesized that 1) Compared to WLM-HT, WLM+FT will produce more engagement of DD and PA adherence as measured by EMA and accelerometry. 2) In both WLM-HT and WLM+FT, within-person mediational pathways will be found between participation in the intervention and PA and changes in delayed discounting on 2a) a daily basis (EMA) and 2b) over longer-time periods (1- and 3-month change predicting PA outcomes at 6 months). 3) Environmental context will moderate the mediational pathways in both interventions such that DD will be a stronger determinant of behavior in environments with more proximal costs than in environments with more proximal benefits.

Design, Procedures, Materials, and Methods.

Overview. Consistent with contemporary WLM trial designs[41],[57] this study involves two phases: a weight loss induction phase and a maintenance phase. While early maintenance trials recruited individuals from the community who had already lost weight[42], more recent studies (e.g., Weight Loss Maintenance Trial[41]) have included a weight loss induction phase. This approach facilitates recruitment and ensures that the sample is at similar stages of the weight management cycle, thereby optimizing methodological rigor[41,43-46]. During **Phase I**, 160individuals will enroll in our existing 16-week Internet weight loss program. Those who achieve a ≥5%[47] weight loss will be invited to participate in Phase II, the actual maintenance trial. Given our previous experience with the weight loss intervention[44,48,49], we anticipate that 54% of participants who enter Phase I will reach the ≥5% goal and be eligible for Phase II. While we have substantial data to support this estimate from 4 large trials, if necessary, given the 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. In **Phase II,** participants (N=70) will be randomized to (1) Healthy ThinkingWLM (WLM-HT)[42,50] or (2) WLM with Episodic Future Thinking cues[51] to reduce delayed discounting (WLM+FT). Both interventions will be 4- months long and involve 7 in-person group sessions. Our team is known for high retention rates (90-98%)[44,49,52] and we have demonstrated our ability to meet our Phase I recruitment goal (N=160). In recent trials,[44,52,53] we enrolled an average of 200 participants/year. UConn's Institute for Collaboration on Health, Intervention, and Policy, an exceptional environment in terms of physical resources and research collaboration. Thus, we are confident we have the resources and experience to meet recruitment goals. Participants will be recruited in 2 cohorts. For each cohort, we will recruit N=70 into Phase 1, with the expectation that at least N=35 from each cohort will be randomized in phase II.

PHASE I APPROACH

Phase I Participants. At entry into Phase I, all participants (N=160) will be adults 18-70 years of age, have a BMI between 30-50kg/m^2, have a smartphone, and use text or email on a daily basis. 30% will be racial/ethnic minority. We have chosen an upper age of 70 as individuals older than 70 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[54] (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); have a history of Multiple Sclerosis, traumatic brain injury or other neurological disorders; 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 and smartphone use is similar among racial/ethnic groups we do not anticipate that requiring Internet and smartphone use will disproportionately impact enrollment of minorities[55].

Phase I Recruitment and Screening. Participants will be recruited for Phase I (weight loss) via mass mailings, local newspapers, Facebook and other social media (i.e. Instagram and Twitter), 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 (at our office in 1 Constitution Plaza Hartford) where informed consent will be obtained. In the event of a national emergency (e.g., COVID-19), the orientation session will be conducted remotely via a video conferencing platform like WebEx. 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.] 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 (CI) is a co-developer of this intervention and has shown that it consistently produces clinically meaningful weight losses of ≥5%[44,56,57].This web-based intervention is currently in use in another ongoing trial of Dr. Gorin and Leahey's (IRB# H17 099). There are 3 in-person visits during this phase: Baseline assessment (approximately 45min), Weight Loss 101 (approximately 90 min), post stage-1 assessment (approximately 45min). All study visits will be conducted at our office on the 6th floor of 1 Constitution Plaza Hartford.

<u>Web-based behavioral weight loss intervention based on the DPP.</u>
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[58]). 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, 1-1.5 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[44,52,53,59]. Weekly multimedia videos are 3-4 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[44,48,52,59]; 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 pretreatment only.

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 Phase I processes of change are not the focus of the study, we will include pre-post tests of delayed discounting[60,61] (see phase II measures) and PA. Accelerometry will be used in Phase II (focus of study) but not in Phase I for cost and efficiency reasons. Instead, the **Paffenbarger Activity Questionnaire (PAQ)**[62,63], will assess the hours/day an individual spends doing various levels of physical activity in a typical weekday and weekend day. The PAQ is frequently used in the field and has been found to have good validity and reliability among adults.

Financial literacy will also be assessed at baseline to clarify any role that financial literacy may play in Delay Discounting scores[96].

We will also ask participants to tell us their mobile phone service provider. Our Phase II treatment website will need to be adapted slightly for rare service providers that we have not yet come across, so we need to determine if we need to make these adaptions during Phase I of the program.

PHASE II APPROACH

Participants. Those who lose at least 5% of initial body weight during Phase I (N=70) 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[44,52,53,59], 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[44].

Randomization. Participants who lose ≥5% during Phase I, agree to participate in Phase II, and complete Phase II baseline measures will be randomized to WLM-HT or WLM+FT. The statistician will use a permuted block randomization scheme for each cohort, stratified by initial weight loss (5-10% vs. ≥10%) and age (18.0-34.9, 35.0-59.9 and 60.0 years old and above).

Treatment Components Common to Both Conditions. Both WLM-HT and WLM+FT will involve a 4- month group-based WLM program consistent with current best practice[50,65]. Sessions will taper over time; weekly for two weeks, every other week for six weeks, and once a month for two months (7 sessions total). Intervention contact time will be matched across groups to approximately 60-90 minutes per session. All treatment groups will be conducted at our office on the 6th floor of 1 Constitution Plaza Hartford.

Interventionists. Two interventionists will co-deliver treatment. Interventionists will be trained by the P.I. At least one of the two interventionists will be master's level in a related field.

In-person treatment sessions. Note: In the event of a national emergency (e.g., COVID-19), sessions will be conducted remotely via a video conferencing platform like WebEx. 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[66], 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[44] 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). 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[67], 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[58]. 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.

ehavior 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)[42]. When necessary, evidence-based strategies to reduce caloric intake (e.g., meal plans) will be encouraged[68]. Problem solving will be used to address barriers to diet and activity. 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[50,65].

Treatment Components Specific to the WLM+FT intervention. In WLM+FT, participants will receive training in Episodic Future Thinking (EFT). Using Sze et al.'s[51] paradigm, at each session, participants will generate a list of positive events they are looking forward to and for which they can describe vividly (e.g., reunion). Participants will be encouraged to think about events for which being physical active, fit, or at a reduced weight would be particularly salient[69]; however, we will not restrict cues to these types of events as general cues have also been associated with reduced DD[70]. Multiple cues have been shown to be more effective than using a single cue[70] so participants will generate new cues with their case manager at their in-person sessions (2, 30-60 minutes at the start and mid-way through treatment), or over the phone if the participant wishes to change their cues at other times during Phase II treatmentParticipants will be prompted to talk about what they are doing in this future event, who they are with, where they are, how they are feeling, and what they are seeing/hearing/tasting/smelling[71]. These brief cues (about 4 sentences) will be stored in a password protected format on our study website and participants will only have access to the cues they generate. Between sessions, participants will be instructed to read a cue at least twice a day, preferably when decisions are being made about PA. To increase adherence, participants will receive two reminders per day via text and/or email to log onto the website to listen to read their individualized EFT cues. These reminders may include image messages. After the cue, they will be asked brief questions to enhance the vividness of the visualization (e.g., How are you keeping in mind your cue during the day). Case-managers will speak on the phone with participants weekly (for about 10-20 minutes) to briefly check-in about cue-use and to change/replace any cues that have not been helpful.

Treatment Components Specific to the WLM-HT intervention. Similar to participants in WLM+FT, participants in WLM-HT will be accessing daily cues on our study website. The difference will be that, rather than EFT cues, these cues will focus on healthy living tips (e.g., Greek yogurt is a great source of protein and calcium). To increase adherence, participants will receive two reminders per day via text and/or email to log onto the website to read their physical activity cues. These reminders may include image messages. After the cue, they will be asked brief questions to enhance the affect of the cue (e.g., How are you keeping in mind your cue during the day). Participants will choose their healthy living tips from a list provided to them with their case manager at their in-person sessions (2, 30-60 minutes at the start and mid-way through treatment), or over the phone if the participant wishes to change their tips at other times during Phase II treatment. Case-managers will speak on the phone with participants weekly (for approximately 10 minutes) to briefly check-in about cue-use and to change/replace any cues if the participant wishes to.

Phase II Assessments. Assessments will occur at baseline (start of Phase II) and 1, 2, and 4 months later. EMA allows for a fine-grained analysis of how putative factors operate in the real-world environment in which behavioral decisions are made. The intensive within-participant assessment of DD and environmental factors will provide a rich test of how EFT engages DD and how engagement of DD impacts PA over the course of the day or week, precisely the type of data that is needed to inform our theories and interventions. All study visits will be conducted at our office on the 6th floor of 1 Constitution Plaza Hartford.

Ecological Momentary Assessment Procedure: EMA data will be collected through smartphones using the HIPAA compliant LifeData system (www.lifedatacorp.com) at Phase II 0, 2, and 4-month assessments. Consistent with protocols employed by Drs. Dunton and Leahey[72-76], each wave of EMA data collection will last 7 days with 4 prompts per day between the hours of 6:30 am and 10:00 pm. If participant schedule does not allow for data collection during this time window (e.g. night shift worker), the timing of the prompts will be adjusted. EMA prompts will be within 4 preprogrammed windows to ensure adequate spacing throughout the day. When prompted, participants will be instructed to stop what they are doing and complete a short electronic EMA sequence (3-5

minutes total). If signaled during an incompatible activity (e.g., driving), participants will be instructed to ignore the prompt. If no entry is made, the participant will receive up to 3 reminders. We anticipate that participants will answer between 80-85% of prompts based on prior research[75,77].

Executive function: Four aspects of executive function will be assessed at Phase II assessment clinic visits– working memory, inhibitory control, sensitivity to reward, and delayed discounting.

Working Memory: A N-back task will ask individuals to rapidly discern targets from foils by identifying whether the stimulus on the screen is the same as n trials previously. Stimuli will be presented for 1500ms or until the participant responds (25% targets). N-back tasks are sensitive to obesity-related cognitive dysfunction [78]. Dependent variables include both discrimination rate and reaction time for correct trials.

Response Inhibition: Established go/no-go tasks will ask individuals to quickly respond to target stimuli when presented on the screen (75% go stimuli) and inhibit to other stimuli [79]. Stimuli are presented for 500ms at varying 2000-4000ms inter-trial intervals. Such tasks are associated with eating behavior in overweight persons in other studies [80,81]. Discrimination and reaction time will serve as dependent variables.

Risk taking: The well validated measure Iowa Gambling Task [103] will be used to assess risk taking. In this task participants select from card decks (on a computer screen) with different probabilities of gaining/losing different amounts of hypothetical money.

Attentional Bias: measured by Dot Probe tasks will be used to assess attentional bias towards food[80]. On these tasks, participants are asked to watch the screen while 2 images are briefly presented. A dot then appears and participants are asked to identify which side of the screen it was presented (i.e. left vs right) as quickly and accurately as they can. Both food and non-food pictures will be used and both discrimination and reaction time will be assessed.

Given that depression can negatively affect cognitive functioning[97], the Center for Epidemiologic Studies Depression Scale (CES-D)[98] will be used to account for contribution of mood symptoms to cognitive functioning scores. Given that this is a screening tool, participants will be given referrals for mental health treatment if they score in the clinical range (16 or above).

To clarify the independent contribution of DD and executive functioning on PA, the **Spot-the-Word test** will be used to estimate full-scale intelligence. It will be utilized as a covariate in analyses to clarify the relative contribution of global vs. specific cognitive abilities on outcomes. Spot-the-Word is a well validated test based on lexical decision making which is highly correlated with verbal intelligence. This test was normalized on a sample stratified by age and socio-economic status and is relatively resistant to the effects of age, brain damage, and stress (*N*=224). [64]

Delayed Discounting. We will administer a clinic-based, adaptive computerized assessment of delayed discounting[60,61], at the start of weight loss maintenance and 1, 2, and 4 months later. This task asks participants to choose between less value now and greater value in the future (e.g. "would you rather have $50 now or $100 in two weeks"). A brief version of this task will be used for EMA assessment to capture the immediate effects of EFT on DD. The steepness of the DD curve will be examined across indifference points (i.e. when one opts for less sooner vs. now later across different time delays) to calculate a k discounting function.

Physical Activity (Primary Outcome). The validated [83,84] Actigraph GT9X will be worn on the waist for 7-days at Phase II 0,1, 2, and 4 months. 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 examined. In addition, following Dunton et al.'s protocol that has been validated against accelerometry[75,77], each EMA prompt will include questions about activity type and purpose that cannot be captured by accelerometers. To allow for future direct comparisons of Phase I processes, we will also administer the Paffenbarger (PAQ)[62,63].

Weight (Secondary 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. Weight will also be measured objectively at each WLM session and reported over the phone to case-managers on a weekly basis.

Environmental Context (Moderators). EMA measures of the environment focus on factors that may alter the cost/benefits of PA. On each EMA prompt, participants will be asked to indicate their current physical and social context. Following Elliston et al.[24], participants will be asked whether they can see others in their environment being physically active (**norms**), whether a TV or computer can be seen from where they are sitting/standing (**sedentary options**), and whether exercise equipment is available or if they are within a 5- minute walk to a place they can be physically active (**accessibility**). We will then ask, consistent with Booker & Mullan[85], about 5 potential PA triggers (physical, sensory, social, internal, and external drives; e.g., "Right now, are there any social triggers in the environment which are influencing your physical activity"). The mean of the 5 items will be used to create an **environmental responsiveness** score. Consistent with other EMA protocols[86], **stress** will be assessed with 3-items of the Perceived Stress Scale[87] adapted for momentary use (e.g., "How stressed do you feel right now") and **social support** will be measured with 1-item[88]. Local **weather** indices will be obtained for the EMA dates from a national weather service, as we have done in a prior study[89].

Additional Temporal Self-Regulation Theory Measures. To test the full TST model, we will supplement EMA with clinic-based assessments of intentions[72], habits[90], and temporal contingency[15,91], The following validated environment measures will also be administered: Weight Related Social Norms[92] adapted for PA, Exercise Environment Questionnaire[13] and a survey on sedentary activity options[14] (accessibility; sedentary options), Environmental responsiveness[23], Perceived Stress Scale[87], and the Social Support and Exercise Survey[93], Physical Activity Enjoyment Scale[99], Behavioral Regulation of Exercise Questionnaire[100], Self-efficacy for exercise [101] , CHAOS[101], and theThree Factor Eating Questionnaire- 18[102]. These measures are reliable and sensitive to obesity or eating behaviors, and for EF.

Additionally, frequency of self-weighing will be assessed in phase II assessments as it has been found to be a predictor of weight maintenance[104].

Treatment acceptability will be measured using a questionnaire adapted from prior weight control and EFT studies[51].

Phase II Summary of Time Commitment

9 in-person treatment sessions (7 groups, 2 case-management) over the course of 4 months, each 30-90 minutes in duration

Approximately 14 phone calls (about 15 minutes each) with a case manager, on weeks when there is not an in-person case management session.

4 assessments are completed in our office at 0 (90 min),1 (30 min), 2 (60 min) and 4 months (60 min).

Accelerometry data is collected for 7 days at 0, 1, 2, and 4 months.

EMA will be conducted for 7 days at 0, 2, and 4 months.

Phase I & II contingency plan for assessment procedures during national emergencies such as COVID-19.

Because 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. 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 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.

Quality control.

Data management.

The Project Coordinator, Ms. Wyckoff 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). Forty-eight hours prior to their visit, participants will receive a link to complete their measures. On the day of the visit, the 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 will receive training in all skills and concepts being delivered and detailed interventionist and participant manuals will be available for each session. Intervention sessions will be audio or video recorded; Drs. Leahey and Gorin, who are clinical health psychologists, will review recordings 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 recordings 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 called to schedule a make-up visit before the next meeting. If that is not possible, the interventionist will provide brief counseling via phone and send handouts via email. Evidence-based retention efforts will be used to minimize dropouts. Finally, participants will receive escalating compensation of 20 for initial assessment visits to 40 for the final visit.

Justification of Sample Size / Data Analysis.

Power. Based on prior DD and EFT work[31,34,39], power is computed for an effect size (d) of 0.50. The computations assume an intraclass correlation (ICC) of 0.250 for the 4 time points clustered within each participant. The standard deviation is assumed to be the same in the two conditions. The criterion for significance (alpha) has been set at 0.05. The test is 2-tailed, which means that an effect in either direction will be interpreted. Given these assumptions, the study will have 82.1% 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, 15 more participants will be added, so a total of 160 participants will be enrolled in Phase I.

Analyses.

Primary hypothesis 1: WLM+FT will produce more engagement of DD and PA adherence. Descriptive statistics will be generated on all the demographic variables as well as mediators (DD), moderators

(environmental variables), covariates (WAIS-II) and outcomes (PA and weight). Differences between WLM-HT and WLM+FT will be assessed through chi-square tests (proportions) or Student's t-test (means) at each time point; if differences on any of the demographics are found at baseline, the variable will be used as a covariate in the main model. The main outcome, PA distribution data will be examined and if variables violate distributional assumptions of normality, will be analyzed using generalized linear model (GLM) procedures, which enable the use of non-Gaussian error models. Using a mixed-effects model in Mplus we will be able to estimate the main effect of the intervention considering the four time points nested within individuals allowing for time-varying effects of covariates to vary with time for the daily data collected.

Primary hypothesis 2: Within-person mediational pathways will be found between participation in the intervention and PA and changes in DD on 2a) a daily basis (EMA) and 2b) over longer-time periods (1- and 2month change predicting PA outcomes at 4 months). Using mixed-effects mediation modeling assuming time points clustered within individuals with Mplus and mediation package from R[104-107], we will test how the relationship between intervention condition and PA is mediated by change in DD over time by using daily data and also running prediction models by the four time points. DD will be evaluated for normality and linearity assumptions and if assumptions are violated, GLM models will be established to determine the indirect effect.

Exploratory hypothesis: Environmental context will moderate the mediational pathways such that DD will be a stronger determinant of behavior in environments with more proximal costs. A moderated mediation mixedeffects model will test the strength or weakness of the indirect effect and/or the direct effect of the intervention condition on PA by the different environmental factors measured. The mixed-effects will considering effects by the daily data collected within the four general time points nested within individuals.

Missing data. We will run a systematic analysis of missing EMA data to determine whether the likelihood of response at any given prompt is time-varying (e.g., time of day/week, activity level). We anticipate approximately ~80% of prompts will be answered[75]. If needed, we will use multilevel data imputation strategies [94]. For clinicbased data, type of missingness will be evaluated and values will be imputed using full information or restricted maximum likelihood estimation [95]. 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 160 healthy overweight or obese men and women ages 18-70 recruited from the greater Hartford, Connecticut area. Participants will have a body mass index between 30 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. Additionally, as the EMA protocol will require answering questions on a smartphone app several times a day, participants must have a smartphone and use text and/or email on a daily basis to be eligible.

Participants will be excluded if they report being unwilling to complete accelerometry or EMA protocols, 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); have a history of Multiple Sclerosis, traumatic brain injury or other neurological disorders; 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 9 months, including terminal illness, plans to relocate, substance abuse, dementia, bulimia nervosa, or other significant psychiatric problems. Participants taking prescription medications, reporting joint problems, heart disease, 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. During times of national emergency (e.g., COVID-19), participants unable or unwilling to engage in videoconference meetings will be excluded. Participants may be removed from the study by the PI if they are consistently (i.e. across several group

meetings) disruptive or inappropriate during group interventions and have not changed their behavior after verbal and written feedback from study personnel. Participants may also be removed from the study if one of the conditions above (or other serious medical condition) emerges during the program and the participant's physician advises against continued participation.

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 (i.e. more than 10 pounds in a week) or there is suspicion of unhealthy practices (i.e. reporting under 800 calories per day average or over 1200 minutes physical activity a week), 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; 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 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 no significant 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. 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 longterm 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. 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. Participants will not be compensated for Phase I visits. During Phase II, participants will receive $20 for their month 1, and month 2 assessments and $40 for their 4-month assessment. Clinic assessment visits will be approximately one hour in duration.

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 and participant manuals will be used. All intervention sessions will be audio-/video-recorded 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 recordings to provide supervision and suggestions to intervention staff at weekly supervision meetings. Participants will not be identified in any way on the recordings, and all information will be kept confidential. A treatment fidelity checklist will be completed on 20% of all intervention sessions. Any issues with treatment fidelity will be immediately addressed. Recordings 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 deidentified, 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 2 and 4-month assessment visits via our standard adverse event structured interview form. If an adverse event is reported, Dr. Gorin will write a detailed report 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 and reported to the IRB by the project coordinator within 2 business days. Severe adverse events 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 Jessica Unick Ph.D., Assistant Research Professor, Brown University.

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.

Privacy/Confidentiality.

All participant data will be treated as confidential. Records will be safeguarded according to the policies of the University of Connecticut and Connecticut law. Participants will be assigned a three-digit identification code 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. The master key will be kept for 3 years after data collection has ended. 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. Electronic de-identified data will be retained in a database indefinitely. Audio recordings will be destroyed 3 years after data collection has ended 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.

EMA data will be collected using the HIPPA compliant LifeData System. Participants will not be asked to report any identifiable health information into the EMA system, and as with other data, all collected data will be linked to an identification code. As per the LifeData System privacy policy (https://www.lifedatacorp.com/lifedataprivacy-policy/) web servers keep log files that record data each time a device accesses those servers. The log files contain data about the nature of each access and error logs to assist in

servicing the applications. LifeData does not gather originating IP addresses from the mobile device. This site also collects data from the device and application one uses to access our services, such as device type and app version. The site may gather geographic location if participants opt in when they download the mobile application.

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.

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 or similar videoconference platform. 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. Adult consent forms have been developed (please see attached). 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.

There will be 2 waivers of consent. One for the initial screener (already approved) 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 it is determined that the participant is likely eligible for the study, and agrees to provide such information. Once an item identifies a participant as ineligible, no further information is collected. We do not collect any identifying information on ineligible participants; however, we need to retain some information regarding reasons for ineligibility in order to accurately report on the demographics of those individuals who were not eligible for our study, and to assess why these individuals were excluded.
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 of our laboratory, thus, it would create a significant burden for respondents to come to the university to sign a consent form to 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 (phone) at UConn's Weight Management Research Laboratory or on our secure, encrypted Website. 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. 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.

Waiver #3: Agreement forms.

In the event of a national emergency (e.g., COVID-19), EMA and Actigraph Agreement forms will be explained to the participant via videoconference and "signed" virtually. That is, staff will review each form with each participant during videoconference and ask if they agree. Agreement will be recorded by study staff in Qualtrics. The file will be downloaded and saved in a password protected file on our secure UConn research drive. Participants will not provide written consent. This waiver is being requested to allow participants and research staff 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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