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Episodic future thinking, delay discounting, and exercise during weight loss maintenance: The PACE Trial

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Abstract

Objectives: Weight loss maintenance is the next major challenge in obesity treatment. While most individuals who lose weight intend to keep their weight off, weight regain is common. Temporal Self-Regulation Theory posits that whether intentions lead to behavior depends on self-regulatory capacity, including delay discounting (DD; the tendency to discount a larger future reward in favor of a smaller immediate reward). Episodic Future Thinking (EFT; mental imagery of a future event for which a health goal is important) may improve DD and promote behavior change. Described herein is a trial protocol designed to examine whether EFT improves DD within the context of weight loss maintenance.

Methods: Participants who lose ≥5% of initial body weight in an online behavioral weight loss intervention will be randomly assigned to a standard weight loss maintenance program (WLM −STD) or a weight loss maintenance program plus EFT (WLM+EFT). Both interventions involve periodic phone and in-person treatment sessions. Participants in WLM+EFT will engage in daily

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EFT training via smartphone. To control for contact, participants in WLM−STD will engage in daily Healthy Thinking (reviewing strategies for weight management) on their smartphone. Our primary hypothesis is that WLM+EFT will yield better improvements in DD compared to WLM −STD. We will also explore whether DD mediates the relationship between intervention allocation and physical activity (secondary outcome). Weight, and contextual variables will be explored.

Conclusions: This study is the first to test whether EFT improves DD within the context of weight loss maintenance; results from this experimental medicine approach could have important implications for understanding the impact of both EFT and DD on sustained behavior change.

Keywords

Weight loss maintenance; delay discounting; episodic future thinking; physical activity; temporal self-regulation theory

Weight loss maintenance is the next major challenge in obesity treatment. Over 70% of American adults are overweight or obese resulting in staggering healthcare costs (Finkelstein et al., 2012; Ogden, Carroll, Kit, & Flegal, 2014). Weight loss can be achieved through several methods (Gudzune et al., 2015; Jensen et al., 2014); 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 (Jakicic, Marcus, Lang, & Janney, 2008), 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 (MacLean et al., 2015).

Physical activity (PA) is a robust predictor of WLM success, but adherence to PA is highly variable. Jakicic and colleagues 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 >300 min/week (Jakicic et al., 2008). Only 26% of participants, however, were able to achieve this level of PA. Similar findings have been reported from the Look AHEAD trial; successful weight loss maintainers (lost 10% of initial body weight and kept it off for four years) engaged in significantly more minutes of moderate / vigorous intensity PA compared to non-maintainers, yet only a minority of participants were able to achieve physical activity goals (Unick et al., 2017). There is often a gap between intention and PA behavior; only about 50% of people who have intentions to exercise actually engage in PA (Rhodes & Dickau, 2012). 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 (Riddle et al., 2015) 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 (Nielsen et al., 2018) 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 (Gorin, Phelan, Raynor, & Wing, 2011) – 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. Such information will lead to a better understanding of cognitive and environmental factors that promote physical activity during the maintenance process and, thus, more effective treatments for long-term weight management.

Temporal Self-Regulation Theory (TST) provides a useful framework for identifying putative targets of PA adherence in WLM interventions. TST (Hall & Fong, 2015) 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 (Gettens & Gorin, 2017; Miyake & Friedman, 2012) such as mental flexibility, self-control, and the ability to delay gratification. EF is linked to health behaviors including PA and weight loss outcomes (Gettens & Gorin, 2017; Hall, Fong, Epp, & Elias, 2008; Hayes, Eichen, Barch, & Wilfley, 2018). For example, changes in EF during an exercise intervention predicted PA adherence at 1-year (Best, Nagamatsu, & Liu-Ambrose, 2014). 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 (Hall, 2007). 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 (Booker & Mullan, 2013; Evans, Norman, & Webb, 2017). 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 (Booker & Mullan, 2013). Interventions are now needed that translate TST concepts into behavior change strategies (Hall, 2010).

Delay discounting (DD; rate at which individuals devalue future rewards in favor of immediate rewards as a function of temporal distance (Lin & Epstein, 2014)) is a self-regulatory capacity that is consistently associated with obesity treatment outcomes. DD is framed as a dual-system model of decision making (Bickel et al., 2007); an appetitive, impulsive system that seeks immediate rewards and an inhibitory, executive system that inhibits impulses in service of 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 (e.g., pleasurable sedentary activity) in favor of behaviors that have longer-term benefits, but perhaps short-term costs or discomfort (e.g., exercising on a cold day), successful WLM is unlikely. The tendency to discount future rewards in favor of immediate rewards is associated with overeating (Epstein, Salvy, Carr, Dearing, & Bickel, 2010), obesity (Amlung, Petker, Jackson, Balodis, & MacKillop, 2016), and weight loss outcomes (Manasse et al., 2017).

Interventions that explicitly shift the value of rewards from immediate gratification to delayed rewards may be especially effective at promoting weight loss maintenance. Episodic Future Thinking (EFT) is a cognitive technique that reduces DD (Sze, Stein, Bickel, Paluch, & Epstein, 2017). EFT involves asking participants to identify upcoming personal events (e.g., wedding) for which the behavioral goal (e.g., weight loss) is important. Participants then regularly practice imagining the event, having reached their behavioral goal. This strategy draws on several domains represented in the Behavior Change Taxonomy delineated by Michie and colleagues (2013) including strategies related to goals and planning and comparison of goals to current behavior. 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 (Schacter, Benoit, & Szpunar, 2017; Ward, 2016). Given these promising findings, EFT is now being evaluated in substance abuse and obesity. In obesity, EFT has been shown to reduce DD (Cohen's d=1.08) and energy intake (Cohen's d=0.27) in an ad libitum eating task in children and adults (Daniel, Said, Stanton, & Epstein, 2015; Sze et al., 2017). Novel work by Sze and colleagues (Sze, Daniel, Kilanowski, Collins, & Epstein, 2015) in a parent-child weight management trial suggests that EFT produces greater weight losses in parents and children compared to the control (Cohen's d 1.60 to 0.36). While intriguing, the pilot study was limited in duration (4-weeks) and did not assess DD as a potential putative factor.

Herein describes the protocol for the Physical Activity Choices Everyday (PACE) trial. The primary aim of the PACE trial is to examine whether a weight loss maintenance program involving EFT (WLM+EFT) yields greater improvement in DD compared to a standard program (WLM−STD). It will also examine DD mediates the relationship between intervention and physical activity outcomes, and whether contextual factors moderate these effects (Figure 1). This study is the first to (a) test EFT for sustained behavior change, (b) assess the impact of a longer-term EFT intervention (vs. experiments or short-term treatment) on DD in free-living adults, and (c) explore whether contextual factors (e.g., social cues, weather) moderate these effects. Our primary hypothesis is that, compared to WLM−STD, WLM+EFT will produce more engagement of DD as measured via Ecological Momentary Assessment (EMA). Our secondary hypothesis is that in both WLM−STD and WLM+EFT, within-person mediation pathways will be found between intervention participation and physical activity and changes in DD on both a daily basis (EMA; e.g., within day changes in DD predict physical activity later in the day) and over longer periods of time (e.g., clinic measured changes in DD during treatment predict physical activity outcomes at 4 months). We will also explore whether environmental context moderates the mediational pathways in both interventions such that DD will be a stronger determinant of behavior in environments with more proximal costs (e.g., bad weather) than in environments with more proximal benefits (Figure 1). Finally, the impact of the two interventions on the clinical outcome of weight will be explored, as will the feasibility and acceptability of the interventions.

Methods

Design overview.

Consistent with contemporary WLM trial designs (Svetkey et al., 2008), this study will involve two phases: a weight loss induction phase and a maintenance phase (Figure 2). During Phase I (weight loss), participants will receive a four month online weight loss program based on the Diabetes Prevention Program (DPP) (DPP Research Group, 2002). Those who lose at least 5% of initial body weight will be invited to participate in Phase II, the actual maintenance trial. In Phase II, participants will be randomized (parallel design; 1:1 allocation) to either a weight loss maintenance intervention that includes training in episodic future thinking (WLM+EFT) or a standard weight loss maintenance intervention (WLM−STD) that includes healthy thinking control materials. Both interventions will be four months in duration and will include in-person sessions, phone sessions, and mobile intervention. Assessments will occur at Phase I (pre and post) and during Phase II at baseline, month 1, month 2, and month 4. Ecological Momentary Assessment (EMA) and clinic-based assessment procedures will be used. Measures of DD, physical activity, contextual / environmental factors, and weight will be included, along with measures of other constructs (Table 1). This study was approved by the University of Connecticut's Institutional Review Board and is registered at clinicaltrials.gov. Confidentiality will be maintained consistent with IRB requirements (secure, locked files; encrypted data; sharing only of deidentified data). The Data and Safety Monitoring Committee is composed of two individuals with expertise in behavioral weight loss; these individuals will monitor overall study conduct and safety issues quarterly. All study procedures will take place at an academic research center in Hartford, CT, USA.

Participant eligibility & recruitment strategies.

Participants will be adults 18–70 years of age, with a BMI between 30–50kg/m^2. Individuals will be excluded from Phase I if they: lost ≥5% of body weight in the past 6-months or have a history of bariatric surgery; are pregnant or plan to become pregnant; report issues on the Physical Activity Readiness Questionnaire that are unsafe for physical activity (Thomas, 1992); report a medical condition that could jeopardize their safety in a weight program (e.g., cancer); report conditions that, in the judgment of the PI, would render them unlikely to follow the protocol (e.g., relocation, dementia); and do not own a smartphone.

Participants will be recruited via mass mailings, local newspapers, and electronic media. We aim to recruit at least 30% of our sample from racial or ethnic minority backgrounds. Individuals who respond to advertisements will be given a brief study description of both phases and screened to determine eligibility. Interested and eligible individuals will attend an orientation where informed consent will be obtained by study staff. Participants will then complete a pre-treatment assessment and then begin Phase I.

Phase I weight loss program.

Phase I involves a four month online DPP-based weight loss intervention (DPP Research Group, 2002). We have established the efficacy of the intervention in prior studies (e.g., Leahey et al., 2014). Prior to receiving access to the Web-based program, participants will

complete a one-time, in-person, group “Weight Loss 101” session. During this session, they will be given weight loss goals (1–2 pounds/week; overall ≥5% weight loss), dietary goals (weight<250lbs: 1200–1500kcals/day; weight≥250lbs: 1500–1800kcal/day), and exercise goals (increase to 250mins/week (Donnelly et al., 2009)). They will also be taught to monitor diet, exercise, and weight. Participants will then be oriented to the Web-based weight loss program. The Web-based program involves weekly multimedia videos based on the DPP, a self-monitoring platform, and automated feedback. Videos are ~3–4 minutes long on topics such as stimulus control, goal setting, and problem solving. Each week, participants will submit their daily weight, calorie, and activity information into the platform and receive weekly, tailored automated feedback. After the four month program, participants will no longer have access to the Web-based weight loss program and will complete their post-treatment assessment (see below).

Randomization.

Participants who lose ≥5% of initial body weight during Phase I and agree to participate in Phase II treatment and assessment sessions (see below) will be randomized to WLM−STD or WLM+EFT. The statistician will use a permuted block randomization scheme for each cohort, stratified by initial weight loss (5–10% vs. ≥10%) and sex. Participants will be informed of intervention assignment at the first treatment session.

Phase II weight loss maintenance interventions.

Treatment components common to both WLM+EFT and WLM−STD.—Both WLM+EFT and WLM−STD will include a four-month group-based WLM program consistent with current best practice (Wing, 2008). WLM+EF and WLM−STD groups will differ in content (please see below) and, thus, delivered separately. The same master’s level interventionists will deliver both groups. Sessions will taper over time (two months of weekly to bimonthly treatment, followed by 2 months of monthly treatment [7 sessions total]). Each session will include a private weigh-in. Participants will be given a goal to keep their weight at or below their Phase II baseline weight using the following evidence-based strategies:

Diet.: At the beginning of Phase II, participants will be asked their weight goal (maintenance vs. additional weight loss) and calorie goals will be adjusted accordingly. Consistent with American Heart Association guidelines (Jensen et al., 2014), participants will be instructed to limit calories from fat to 30% of total daily caloric intake. Participants will be encouraged to monitor calories and fat grams.

Exercise.: Current PA guidelines recommend >300 minutes/week of moderate-to-vigorous physical activity (MVPA) for weight loss maintenance (Donnelly et al., 2009). We will assess each participant’s activity level at the beginning of Phase II and engage in goal setting and problem-solving to further increase activity to the recommended level. That is, if participants are not at 300 minutes of MVPA per week, they will set goals to gradually increase their activity to 300 minutes per week. Participants will be encouraged to monitor PA.

Behavior therapy.: Self-regulation skills will be taught. Participants will be encouraged to weigh daily and use the information to make behavioral changes (e.g., if weight is trending up, decrease intake) (Wing, Tate, Gorin, Raynor, & Fava, 2006). When necessary, evidence-based strategies to reduce caloric intake will be encouraged (Wing et al., 1996). Strategies to maintain motivation, increase lifestyle activity, reduce sedentary behavior, and manage stress/emotions will also be covered (Wing et al., 2006).

Treatment components specific to WLM+EFT.—In WLM+EFT, participants will receive training in Episodic Future Thinking (EFT) (Sze et al., 2015). Between group sessions 1 and 2, participants will meet in-person with a case manager (trained intervention staff) and generate a list of positive events they are looking forward to (e.g., family reunion). Participants will be encouraged to think about events for which being active, fit, or at a reduced weight would be particularly salient (e.g., dancing at a nephew's wedding in a favorite dress) (O'Donnell, Oluyomi Daniel, & Epstein, 2017). These events are referred to as "cues." Multiple cues have been shown to be more effective than using a single cue (Stein et al., 2017), so participants will generate three cues at this initial session and three more cues after one month of treatment. During these cue generation appointments, participants will be instructed by their case manager to vividly describe their events in a few sentences (Snider, LaConte, & Bickel, 2016). These brief cues (approximately 3 sentences each) will be stored on a study website and participants will receive prompts via text to read and vividly imagine their cues at least twice a day, preferably when decisions are being made about physical activity and eating. In addition to the two in-person sessions for cue generation, participants will have four phone case management sessions (weeks 3, 7, 11, and 14) focused explicitly on cue use, cue utility (ineffective cues will be modified), and using cues to help make choices consistent with being active and eating healthy. During group sessions, leaders will also check-in on cue use, reiterate the rationale for future thinking, and encourage participants to use their cues throughout the day to inform choices around that week's lesson topic. For example, if the in-person lesson is focused on stimulus control, standard stimulus control strategies will be discussed (e.g., remove cues for unhealthy foods/sedentary behavior, increase cues for healthy foods and PA); in addition, participants will be encouraged to put "reminders" of their cues in their environment (e.g., put the invitation to their nephew's wedding on the refrigerator) to facilitate healthy choices.

Treatment components specific to WLM−STD.—To control for contact and daily EFT cue use, participants in WLM−STD will receive training in Healthy Thinking; such an approach has served as a successful control in a previous EFT study (Sze et al., 2015). WLM−STD participants will meet twice with a case manager to choose Healthy Thinking cues (e.g., recording intake helps with weight management), which they will then receive twice daily via text. Consistent with the WLM+EFT contact schedule, these two in-person meetings will be between sessions 1 and 2 and at month 1. Similarly, WLM−STD participants will have 4 case management calls to discuss healthy thinking cue use.

Measures (Table 1).

Phase I measures.—Given that the primary purpose of Phase I is to efficiently induce weight loss for Phase II, and that not all participants will lose 5% and be eligible to

participate in Phase II (the actual trial), Phase I assessments will be minimal and low cost / burden. All measures will be obtained at the beginning and end of Phase I unless otherwise noted.

Demographics.: Basic demographic information will be collected (pre-treatment only).

Physical activity.: The Paffenbarger will be used to measure physical activity (Paffenbarger, Wing, & Hyde, 1978).

Delay discounting.: The five-trial adjusting delay task will be used (Stein et al., 2017).

Weight / height.: Weight will be measured to the nearest 0.1kg with a digital scale. Height will be assessed with a stadiometer at the beginning of Phase I only.

Phase II measures.—Assessments will occur at Phase II baseline and at 1, 2, and 4 months and include EMA, accelerometry, clinic-based procedures, and online surveys (Table 1). Assessment staff will be masked to intervention allocation. Adverse events will be assessed at baseline, 2 months, and 4 months and when spontaneously reported.

Ecological momentary assessment procedure (EMA).: EMA allows for a fine-grained analysis of how putative factors operate in the real-world environment in which behavioral decisions are made (Shiffman, Stone, & Hufford, 2008). EMA data will be collected through smartphones. Each wave of EMA data collection will last 7 days with 4 prompts per day between the hours of 7:30 am and 9:00 pm. EMA prompts will occur randomly 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 survey (1–2 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 at 10-minute intervals. Specific content of the prompts is detailed below.

Delay discounting.—During EMA, participants will complete the Five-Trial Adjusting DD Task, which is a reliable measure of DD that is well-suited for EMA (less than 35 seconds) (Koffarnus & Bickel, 2014; Stein et al., 2017). This task asks participants to choose between smaller amounts of hypothetical money now vs. larger amounts later and produces discounting rates. Of note, given the state of the science, EMA measured DD is our primary outcome of interest. That is, no previous intervention trials have examined the effect of EFT on DD; instead, only brief laboratory studies have demonstrated that EFT immediately impacts DD. Thus, EMA measured DD (immediately following EFT tasks) may best capture any existing effects. That said, we will also include clinic-based DD measures to explore whether the effect is durable over time (please see below). Given that standard behavioral weight management intervention strategies may facilitate future thinking (e.g., goal setting, planning), DD will be assessed in both arms, which will allow us to determine whether EFT leads to any DD improvements above and beyond that of standard treatment.

Environmental context.—EMA measures of the environment focus on factors that may alter the cost/benefits of engaging in PA. On each EMA prompt, participants will be asked to

indicate their current physical, social, and internal state. Participants will be asked whether they can see others in their environment being physically active or eating healthy/unhealthy foods (norms), whether a TV or computer can be seen from where they are sitting/standing (sedentary options), and whether exercise equipment is available (accessibility) (Elliston, Ferguson, & Schuz, 2017). We will also ask about other potential PA triggers/barriers (physical [energy/sleep], physical [where they are], social [who they are with], and internal [mood/stress], and external drives [availability of food]; e.g., "Right now, do you have unhealthy food with you or near you that you could eat?") (Booker & Mullan, 2013). Intention to engage in physical activity and eat healthy foods will also be assessed. Local weather will be obtained for the EMA dates from a national weather service, as we have done in a prior study (Gorin et al., 1999).

Physical activity.: The Actigraph GT9X will be worn on the waist for 7 days, concurrent with our EMA protocol. Accelerometers will be worn during waking ours and removed only for water-related activities (e.g., showering). Four days of at least 10 hours of wear time per day will be required, calculated as total possible minutes per day [1440 minutes] less periods of time that the devise was not worn, defined as >=30 minutes of no activity counts. If a participant does not achieve this wear time, s/he will be required to continue accelerometry until the wear time criteria are met. Minutes of moderate to vigorous physical activity (>=3 METs) will be examined, as will MVPA bouts of >=10 minutes in duration. Accelerometry data will be processed using ActiLife software.

Clinic-based measures and online surveys.

Cognitive tasks.: To examine the durability of any EFT effects beyond immediate exposure to cues, DD will be assessed in the lab using the adjusting amount task and the Kirby DD questionnaire (Kirby & Marakovic, 1996). Further, to assess whether the intervention has any spillover effects, other executive functions will be measured. Established go/no-go protocols will measure response inhibition (Loeber et al., 2012). Attentional bias towards food will be measured with the validated food dot probe task (Teslovich et al., 2014). Working memory will be assessed using verbal N-back tasks (Gonzales et al., 2014). Risk taking will be assessed using the validated Iowa Gambling Task (Bechara, Damasio, Tranel, & Damasio, 2005). To clarify the independent contribution of DD and other executive functions on physical activity, the Spot-the-Word test will be used to estimate full-scale intelligence at Phase II baseline only. Spot-the-Word is a well validated test based on lexical decision making which is highly correlated with verbal intelligence (Baddeley, Emslie, & Nimmo-Smith, 1993).

Weight.: Weight will be measured in the lab to the nearest 0.1kg with a digital scale.

Online surveys.: To test the full TST model, we will supplement EMA with online surveys of TST constructs including perceived environmental context (physical, social, internal), activity and eating intentions (Maher et al., 2017), habits (Verplanken, 2003), temporal contingency (Gonzales et al., 2014), and executive functions. That is, while EMA will allow us to examine whether effects of DD on physical activity are moderated by immediate circumstances (e.g., weather), clinic-based measures of DD and survey measures of more

persistent environmental forces (e.g., social norms) will afford an examination of the effects of enduring moderators on overall changes in DD and PA, thereby allowing for a more complete test of the TST model. The following validated measures will be administered to assess the physical, social, and internal context: Neighborhood Environment Walkability Scale (Cerin, Saelens, Sallis, & Frank, 2006), Confusion, Hubbub, and Order Scale (Matheny, 1995), Weight-related Social Norms (Leahey, Doyle, Xu, Bihuniak, & Wing, 2015) adapted for PA, Social Support and Exercise Survey (Sallis, Grossman, Pinski, Patterson, & Nader, 1987), Perceived Stress Scale (Cohen, 1988), Center for Epidemiological Studies Depression Scale (Lewinsohn, Seeley, Roberts, & Allen, 1997), Difficulty in Emotion Regulation Scale (Gratz, 2004), Physical Activity Enjoyment Scale (Mullen et al., 2011), Self-Efficacy for Exercise (Resnick & Jenkins, 2000) and Power of Food Scale (Lowe et al., 2009). The following scales will assess intentions and habits associated with weight management behaviors: Intentions for Physical Activity and Healthy Eating (Sheeran & Abraham, 2003), Self-Report Habit Index (Verplanken, 2003), Behavioral Regulation of Exercise Questionnaire (Murcia, Gimeno, & Camacho, 2007), Self-weighing (Butryn, Phelan, Hill, & Wing, 2007), and the Paffenbarger physical activity questionnaire (Paffenbarger et al., 1978). Finally, the following surveys will measure temporal contingency and perceived executive functions: Connected Valence Timing (Evans et al., 2017), Consideration of Future Consequences Scale (Strathman, 1994), and the Behavior Rating Inventory of Executive Function (Roth, Lance, Isquith, Fischer, & Giancola, 2013).

Feasibility and acceptability.: Feasibility will be assessed by tracking treatment adherence (sessions, calls, and daily trianings). Adherence to EMA and accelerometry will also be measured. Acceptability will be measured via participant report of satisfaction, whether they would recommend the program, program utility, and enjoyment on a 5-point Likert scale.

Treatment fidelity.

The PIs will train intervention staff on all intervention procedures. Standardized participant and interventionist treatment manuals will be developed for both arms. All sessions (in-person and phone) will be audiotaped and reviewed and weekly supervision will be provided to staff by the PIs. Fidelity to session content will also be rated (core components, contamination) along with ‘non-specific’ interventionist skills (e.g., warmth, rapport) using a treatment fidelity rating scale.

Statistics.

Analytic plan.—Baseline differences in participant characteristics between WLM+EFT and WLM−STD will be assessed; significant differences will be considered as covariates in the main model. For each variable, data distribution will be examined; if variables violate distributional assumptions of normality, they will be analyzed using generalized linear model (GLM) procedures, which enable the use of non-Gaussian error models. To test the primary hypothesis (compared to WLM−STD, WLM+EFT will produce more engagement of DD as measured by EMA) a mixed-effects model will be used. The model will estimate the effect of the intervention on DD at all time points nested within individuals, allowing for time-varying effects of covariates to vary with time for daily data collected. To test the

secondary hypothesis (within-person mediational pathways will be found between participation in the intervention and PA (behavioral outcome) and changes in DD on a daily basis [using EMA] and over longer-time periods) a mixed-effects mediation model (Mplus) assuming time points cluster within individuals and mediation package from R (Tingley, 2014; R Development Core Team, 2014) will be used. To test the exploratory hypothesis, that 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 mixed-effects model (Preacher, 2007) will be used. Further, the impact of the two interventions on the clinical outcome of weight will also be explored using similar statistical procedures as indicated for the primary hypothesis above. Feasibility and acceptability data will be examined using descriptive statistics. As noted above, impact of the interventions on non-EMA measured DD (i.e. clinic-based assessments of DD) will be explored to determine whether the intervention has durable effects. Effects of the interventions on other types of executive functions (e.g., working memory) will also be examined as alternative mediators. Finally, given that this is a pilot study, we will conduct an exploratory dose-response analysis to examine whether frequency and duration of EFT cue use is associated with improvements in DD and secondary outcomes (e.g., PA, weight).

Power estimation.—This trial is powered to test the primary hypothesis, that the two arms will differ on EMA measured DD. Based on prior DD and EFT work (Daniel et al., 2015; Sze et al., 2015), power is computed for an effect size (d) of 0.50 (e.g., a delta of 0.15 between the two groups with a SD of 0.30). The computations assume an intraclass correlation (ICC) of 0.25 for the 4 time points clustered within participant and within each intervention arm. The standard deviation is assumed to be the same in the two conditions. Alpha has been set at 0.05 and 2-tailed. Given these assumptions, the study will have 82.1% power to yield a statistically significant result that will change by one unit per number of covariate(s) included in the models. Accounting for 15% attrition, 15 more participants will be added per arm, so a total of 130 participants will be enrolled.

Data quality / missing data.—Data quality procedures include double entry and addressing missingness, fixed responding, etc. with participants immediately when it occurs. Further, standard strategies will be employed to facilitate retention (monetary compensation, holiday cards, reminder calls/emails). Despite all efforts, missing data will likely occur. A systematic analysis of missing EMA data will be run 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 (Liao, Intille, & Dunton, 2015). If needed, we will use multilevel data imputation strategies (Little, 2002). For clinic-based data, type of missingness will be evaluated and values will be imputed using full information or restricted maximum likelihood estimation (Little, 2002). All variables in our models will be used to impute missing data. Sensitivity analyses will be conducted.

Discussion

The next major challenge in obesity treatment is developing more effective interventions to promote sustained weight loss maintenance (MacLean et al., 2015), and the experimental medicine approach may be particularly relevant for developing such interventions (Riddle et

al., 2015). The PACE Trial is utilizing an experimental medicine approach (Figure 1) to manipulate a putative mechanism of behavior change – delay discounting – that is hypothesized to impact physical activity and subsequent weight outcomes. Identifying active mediators of behavior change and interventions that affect such mechanisms may lead to new, more effective treatments for weight loss maintenance.

A unique element of the PACE Trial is the use of episodic future thinking (EFT) during weight loss maintenance to engage DD. EFT, while showing some promise in pediatric studies (Sze et al., 2015), has not been tested within the context of adult weight management. The PACE Trial will establish whether EFT improves DD, physical activity, and weight within the context of weight loss maintenance. The use of ecological momentary assessment will allow the PACE Trial to understand the impact of the episodic future thinking intervention on DD in real-time and to explore whether contextual factors (physical, social, and internal environments) moderate these effects. Couched in a Temporal Self-Regulation Framework (Hall, 2007), which has traditionally focused more heavily on the initiation of behavior change, the PACE Trial will extend TST into sustained behavior change and test whether DD is a stronger determinant of behavior in environments with more proximal costs than in environments with more proximal benefits (e.g., presence of enjoyable sedentary activity such as a television). Such tests of boundary conditions are rare in behavioral weight loss management studies. Further, our EMA and clinic-based methodology will allow us to examine whether the effects of EFT are short-lived or sustained over time. If the latter, this intervention may have important implications for sustained behavior change and for Temporal Self-Regulation Theory.

The PACE Trial has potential to make important contributions to science and to obesity treatment. Thus far, all studies testing the impact of episodic future thinking on DD have been conducted within the lab. Thus, this study will extend laboratory findings on episodic future thinking and DD to obesity clinical research – specifically weight loss maintenance. Further, within the spirit of the experimental medicine approach, results from this study could demonstrate that DD is an important putative target to promote weight loss maintenance. Finally, an examination of contextual factors that could moderate the relationship between DD and physical activity may provide rich data as to when and where delay discounting interventions may be most needed and impactful.

Open Science Plans.

Preregistration.—The PACE trial has been registered at clinicaltrials.gov. This registry was selected as it is the most common registry used in our field and, thus, reaches the appropriate audience.

Data and Code repositories.—Given that this is an R21 pilot feasibility study, and that these data will be used to compete for follow-on funding to support a large trial, we do not plan to add our data or code to a repository. However, overall study results will be posted on clinicaltrials.gov.

Preprints/Open access.—Publications from this trial will be open access.

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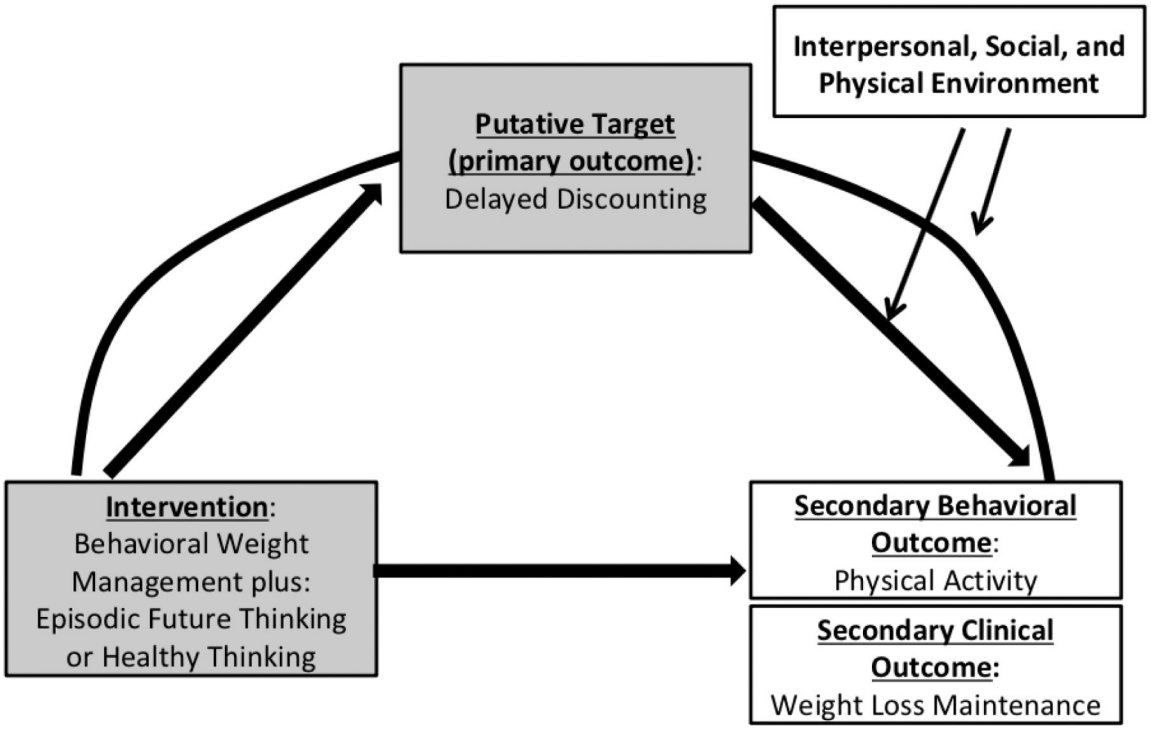

Figure 1.

Experimental medicine approach to weight loss maintenance: The PACE Trial. Shaded boxes highlight the primary aim of this trial, to examine whether WLM+EFT improves DD more so than WLM−STD.

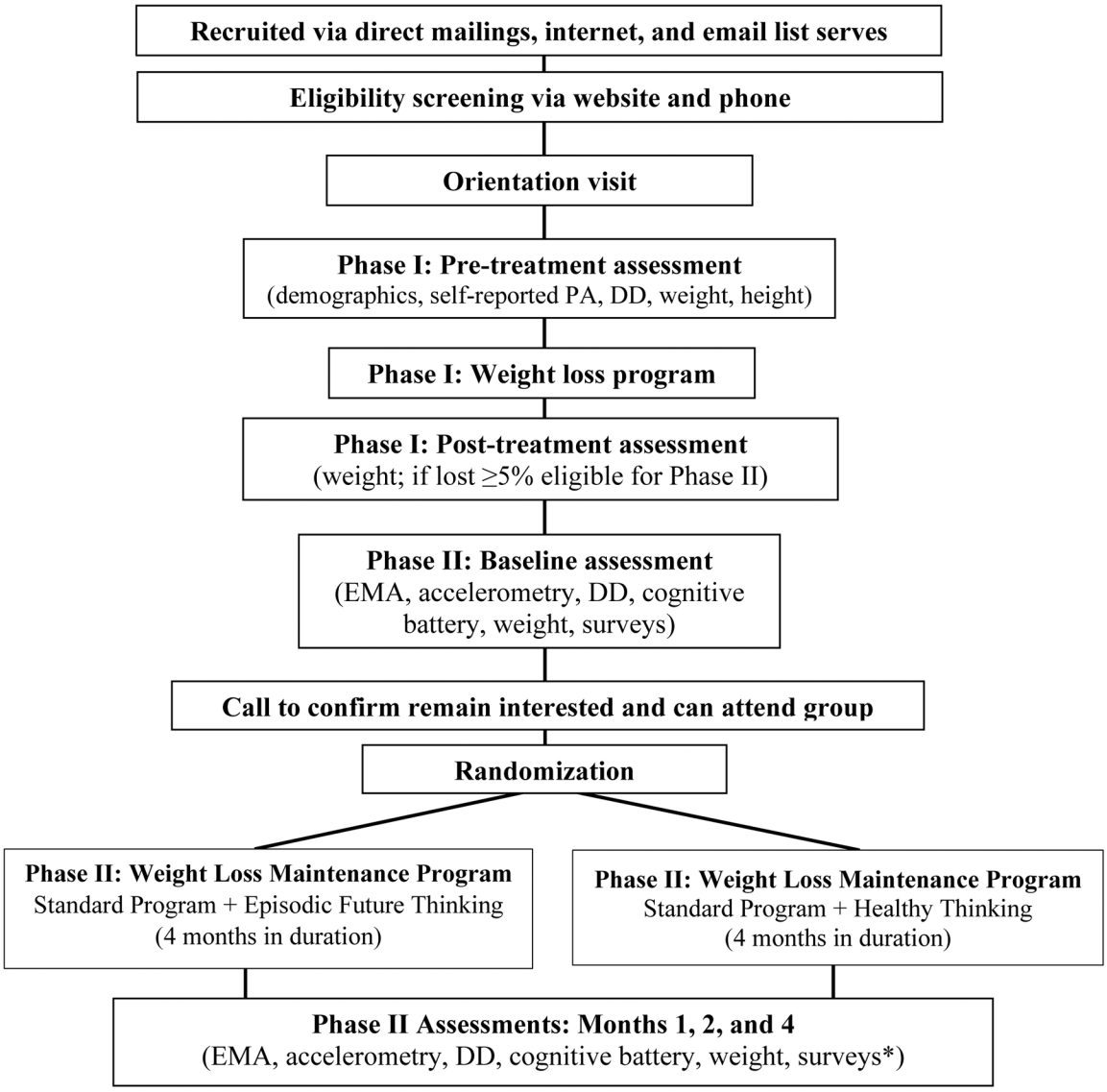

Figure 2.

Overview of the PACE Trial study design.

*See Table 1 for detailed assessment timeline.

Table 1.

Phase I and Phase II assessment measures and timeline.

	Phase I		Phase II (Weight Loss Maintenance RCT)			
	Pre	**Post**	**BL**	**Month 1**	**Month 2**	**Month 4**
Demographics, height	X					
Physical activity	X	X	X	X	X	X
Delay discounting	X	X	X	X	X	X
Weight	X	X	X	X	X	X
EMA (physical, social, and internal contextual factors)			X		X	X
Supplemental cognitive battery (response inhibition, working memory, attentional bias, risk taking, IQ [Phase II baseline only])			X		X	X
Surveys (physical, social, and internal contextual factors)			X	X	X	X
Adverse events			X		X	X