

Study Protocol for a Randomized Controlled Trial Comparing Two Low-Intensity Weight Loss Maintenance Interventions Based on Acceptance and Commitment Therapy or Self-Regulation.

Jason Lillis PhD¹, Leah Schumacher¹, J. Graham Thomas¹, Michael E. Levin², Shira Dunsiger³,
Jessica L. Unick¹, Erin Evans¹, Jacqueline F. Hayes¹, Rena R. Wing¹

¹Department of Psychiatry and Human Behavior, Alpert Medical School of Brown University/The Miriam Hospital Weight Control and Diabetes Research Center, Providence, RI, USA

²Department of Psychology, Utah State University, Logan, UT, USA

³Department of Behavioral and Social Sciences, Brown University, School of Public Health, Providence, RI, USA

Key words: obesity, overweight, acceptance and commitment therapy, self-regulation, weight loss maintenance

Number of pages: 26

Number of tables: 1

Number of Figures: 1

Word Count: 6165

* Corresponding author: Jason Lillis, Ph.D., Department of Psychiatry and Human Behavior, Alpert Medical School of Brown University/The Miriam Hospital Weight Control and Diabetes Research Center, 196 Richmond Street, Providence RI, USA 02903; E-mail: jasonlillis22@gmail.com

ABSTRACT

Background: Weight regain is common following behavioral obesity treatment and attenuates many of the benefits of initial weight loss. This paper describes a randomized controlled trial that will evaluate the efficacy of two low-contact weight loss maintenance interventions based on Acceptance and Commitment Therapy (ACT) and self-regulation (SR). Potential mechanisms of action and moderators of treatment effects will also be evaluated.

Methods: Adults (anticipated N=480) with overweight or obesity will complete an initial 3-month online weight loss program (Phase 1). Participants who achieve ≥ 4 kg weight loss (anticipated N=288) will then be randomized to an ACT or SR weight loss maintenance intervention. Both interventions will entail four 2.5 hour, face-to-face, group-based workshop sessions and 6 months of email contact. Assessments will be conducted at phase 1 baseline, phase 1 completion/pre-randomization, and 6, 12, 18, 24, and 30 months post-randomization. The primary outcome will be weight change for the period from randomization to 30 months. Potential process measures including ACT-based constructs (e.g., psychological acceptance, values-consistent behavior), self-weighing frequency, and motivation will be also be assessed, as will potential moderators (e.g., initial weight loss).

Conclusions: This study will compare the efficacy of two intervention approaches (ACT and SR) delivered in a scalable workshop format for long-term weight loss maintenance. Future research could examine efficacy and cost-effectiveness of these approaches in real world settings.

INTRODUCTION

Obesity carries significant health risks¹⁻⁶, has substantial direct costs⁷ and indirect costs^{8,9}, and is one of the leading causes of preventable morbidity and mortality worldwide. Standard behavioral interventions produce weight loss of 7-10% of initial body weight¹⁰⁻¹³, however these interventions carry significant costs that hinder widespread implementation¹⁴⁻¹⁷. Advances in online behavioral interventions have produced a scalable, cost-effective alternative to face-to-face treatment¹⁸⁻²⁰. Unfortunately, weight regain is a significant problem with respect to online interventions²⁰⁻²³ as it is with face-to-face delivery as well^{24,25}, thereby limiting long-term weight loss. Additionally, current weight loss maintenance interventions fall short of addressing the unique challenges of maintaining weight loss²⁶⁻³³.

Acceptance and Commitment Therapy (ACT)³⁴ is a newer generation behavioral approach that teaches mindfulness, acceptance, and values skills to effect clinically meaningful behavior change for mental and chronic health problems³⁵⁻³⁸, with emerging evidence for use in weight management³⁹⁻⁴¹. ACT may be helpful for weight management in part by adding robust interventions to address barriers to persisting with healthy behavior changes (e.g. difficult thoughts, emotions, cravings, and motivation).⁴² ACT can be effectively delivered in a low-intensity treatment contact format^{40,43-45} and has shown increasing intervention effects after treatment is discontinued^{35,46}. However, ACT has not yet been rigorously tested as a weight loss maintenance intervention.

Another approach to weight loss maintenance is to focus on self-regulation (SR), in which participants are taught to use self-observation (comparing where they are now relative to a pre-specified goal), self-evaluation (determining whether they are currently meeting their goal or need to make behavior changes), and self-reinforcement (providing reinforcers if on track).³³ This approach has been empirically tested and shown to improve weight loss maintenance.⁴⁷ However, SR has not previously been compared to an alternative approach such as ACT.

We recently conducted a pilot randomized controlled trial that tested two interventions based on ACT and SR in comparison to each other and a no-workshop control condition (Control) for improving long-term weight loss. Adults with overweight or obesity (N=188) first received an online, 12-week, previously validated weight loss intervention. Participants who lost $\geq 5\%$ (N=102) then proceeded to a second intervention phase in which they were randomly assigned to a 1-day, 5-hour workshop based on ACT, SR, or no workshop (Control). All three conditions received 3 months of weekly email surveys, asking them to report energy intake and exercise minutes, and this was followed by an 18-month no-contact period. The primary outcome was 24-month weight loss from baseline. At 24 months, ACT had greater overall weight loss (-7.18%, $SE=1.33$) when compared to Control (-1.15%, $SE=1.50$)⁴⁸. Although 24-month weight loss in ACT was not statistically different from SR (-4.18%, $SE=1.32$), ACT showed greater treatment engagement and greater improvements in values-consistent behavior, a theoretically specified process variable⁴⁸. Limitations included that the study was underpowered to detect differences between ACT and SR, and significant weight regain occurred for all groups, possibly due to the intervention being too brief.

Therefore, the goal of the current study is to conduct a fully powered randomized controlled trial to compare the efficacy of an ACT approach to a SR approach for weight loss maintenance. The aims of the study are (1) to compare ACT and SR on changes in weight over the period from randomization (occurring upon completion of a 3-month online weight loss program) to month 30, (2) to compare the potential mechanisms of ACT and SR including acceptance, values-consistent behavior, motivation, and frequency of self-weighing, and, (3) to explore moderation (sex, initial weight loss, hunger) effects.

METHOD

Design

This study is a randomized controlled trial comparing an intervention based on ACT and an intervention based on SR. Poor performance of the no workshop (i.e. email follow up only) control group in the original pilot study on both weight change and retention indicated that there was little value in further development and testing; thus it was dropped in the current study. All study activities will take place at an academic medical research center. In the first phase of the study (Phase 1), all eligible participants will receive a previously validated 3-month online behavioral weight loss intervention⁴⁹. Participants who lose ≥ 4 kg of their baseline weight at the time of their Phase 1 post-treatment assessment will then move onto a second study phase (Phase 2), where they will be randomized to one of two weight loss maintenance conditions (ACT or SR) on a 1:1 ratio using a permuted block randomization scheme stratified by sex and initial weight loss. The 4kg weight loss cutoff will be used to align study procedures with previous trials that have utilized a similar design to assess interventions for weight loss maintenance⁵⁰. There are no additional criteria for moving on to Phase 2. Both conditions will consist of (a) two, 2.5-hour workshops (delivered following randomization in consecutive weeks), (b) two, 2.5-hr booster sessions 2 and 4 months after randomization, and (c) 6 months of weekly email follow-up (beginning following the first group session). Assessments will occur at Phase 1 baseline (prior to the online weight loss intervention), Phase 2 baseline (Phase 1 post-assessment, pre-randomization), and 6, 12, 18, 24, and 30 months after randomization (see Figure 1).

Participants

A total of 480 participants will be recruited for Phase 1 (the online weight loss intervention), with the expectation that 288 (60%) will lose ≥ 4 kg of weight and continue to Phase 2 (the weight loss maintenance experiment); a rate of progression consistent with our previous pilot study⁴⁸. Participants will be between 25 and 70 years of age and have a body mass index (BMI) between 27.5 and 45 kg/m². See Table 1 for full inclusion/exclusion criteria.

Participants will be recruited via online advertisements (e.g. Facebook) and direct mailings sent to random samples of local residents stratified by zip code, with efforts made to reach a diverse range of income, race, and ethnicity. In response to advertisement materials, individuals can (1) call the study directly, or, (2) complete the online screener, which will assess age and BMI only, and then provide contact details so that study staff can call them. Either way, all potential participants will be screened by phone to determine eligibility.

Interventions

Phase 1: Weight Loss (non-randomized pre-experimental). The initial 12-week, online weight loss intervention includes 12 weekly multimedia behavioral lessons, a website for submitting self-monitoring data, and weekly automated feedback provided to each participant on their progress to date. In previous validation studies, participants lost an average of 5.2-6.5 kg over 3 months^{18,49,51}. Participants will be given a goal of losing 1 to 2 lbs/week, a total weight loss goal of $\geq 10\%$ of initial body weight, a calorie goal of 1,200–1,500 kcal/day depending on initial body weight, and a physical activity goal that gradually increases to 200 min/week. Each week participants will view a 10-15-min interactive multimedia lesson incorporating video, animation, audio, quizzes, and exercises to teach standard behavioral strategies such as goal setting, planning, problem-solving, restaurant eating, changing the home environment, and social support. Automatic feedback messages will be generated algorithmically based on participant reporting. Messages will praise participants when goals were met. When goals were not met, messages will provide specific recommendations for behavioral strategies to implement, along with support and encouragement.

Phase 2: Maintenance (randomized experiment). All participants who lose ≥ 4 kg from their baseline weight at the time of their Phase 1 post-treatment assessment will be randomized to either receive an ACT or SR maintenance intervention. As described above, each intervention will consist of four, 2.5-hour workshops (2 sessions delivered in the first 2 weeks following

randomization and the others delivered 2 and 4 months after randomization) and 6 months of weekly email follow-up. Intervention contact schedule adjustments and additions compared to the pilot study⁵² are designed to (1) increase potency of the interventions, (2) increase the length of time participants are in Phase 2, while still maintaining an overall low contact approach, to be consistent with findings that contact schedule length is a significant factor in weight loss maintenance outcomes²⁵, and, (3) be responsive to pilot participant feedback suggesting the need for more opportunities to learn, practice, and consolidate skills taught in the interventions. Interventions groups will be closed and will consist of 6-10 participants, attending live, and facilitated by interventionists (see description of interventionists below). However, if it is unsafe to meet in groups, sessions may be conducted remotely. All participants in Phase 2 are asked to report their average daily calorie intake and current weight once per week via email survey (see below for more details). The overarching goal of both Phase 2 interventions is to prevent weight regain. Participants may still be trying to lose weight; however participant intention is not formally assessed. In general, strategies are presented as helpful in continuing to engage in healthy habits developed during Phase 1 of the study.

ACT Intervention. The ACT intervention will be based on studies by our investigator group.^{40,41,48} Broadly speaking, coping with difficult or unwanted cognitive and emotional experiences seems to play a vital role in predicting long-term weight loss success, with factors such as binge eating psycho-social stressors, disinhibition, emotional or stress eating, depression, and feelings of food-related deprivation predicting weight regain.⁵³⁻⁵⁵ ACT skills could help reduce tendencies to use food and sedentary behavior as a way of coping, while simultaneously improving motivation, and thus bolster one's ability to continue to engage in healthy behaviors. The ACT weight loss maintenance intervention will aim to teach skills in 3 key areas: acceptance of thoughts, acceptance of emotions/sensations, and values. Generally

speaking, ACT skills will be taught in the context of how they affect momentary decisions related to food and activity.

Acceptance of thoughts. Acceptance is the active and open embrace of thoughts without ineffective attempts to change or control them. Through a combination of experiential exercises and didactic presentations, participants will be taught that presence, frequency, and content of thoughts on a moment-to-moment basis is largely outside of their control, and that many thoughts and feelings that arise in particular circumstances are the result of deeply-ingrained, yet not necessarily important or meaningful, learned associations. For example, participants will be instructed to identify an unwanted, self-relevant thought that has caused them distress over the years (e.g., “I wish I was more disciplined”) and to reflect on how many years this thought has been with them despite their best efforts to make it go away. Participants will also be taught to become more aware of, and distanced from, thoughts that tend to trigger unhealthy behaviors. This will include thoughts that focus on short-term comfort-seeking at the expense of one’s health goals (e.g., “Never mind your goals—you deserve a treat!”), self-critical thoughts (e.g., “I will always fail”), and more general excuses (e.g., “It’s too hot / cold / early / late to exercise”). The goal will be to teach participants to recognize common unhelpful thoughts, allow those thoughts to be present without acting on them, and continuing with goal-directed behavior despite their presence.

In-session strategies that will be used to facilitate greater acceptance of unhelpful thoughts will include guided imagery exercises, metaphors, experiential activities, and discussions. For example, participants will complete a guided imagery exercise in which they imagine passively watching their thoughts as large cue cards walking across a stage and they will complete experiential exercises, such as describing critical and permissive avatars for their thoughts, while imagining and ‘hearing’ such thoughts come from these mind avatars to create a sense of distance.

Acceptance of emotions/sensations. Participants will also be taught acceptance-based skills for coping with emotions and physical sensations, including food cravings. A primary focus will be highlighting the limits of emotional change strategies. For example, participants will engage in an interactive exercise where they review a previous example of a time when they responded to stress or another negative emotion by eating and engaging in sedentary behavior, in an attempt to feel better. Participants will be asked to identify the chain of ever-increasing negative emotional and thought content that follows such behavior, and also the strong tendency to re-engage in unhealthy behavior for short-term comfort. Each unhealthy behavior starts a new chain, with all the 'new' negative emotions and thoughts that follow from that behavior.

Participants will also be taught to notice how the intensity of food cravings rises and falls over time and to curiously observe how cravings are experienced in the body. The metaphor of surfing waves in the ocean will be used to illustrate this concept, and participants will practice implementing these skills during an in-session food craving exposure exercise with a personally-tempting food. When experiencing stress and other uncomfortable emotions (e.g., boredom, anxiety), participants will be encouraged to notice, acknowledge, and make room for their feeling states, and then to engage in a goals- or values-consistent behavior—an approach summarized with the acronym NAME. Participants will be engaged in discussions around how accepting uncomfortable feeling states does not necessarily mean that they like them or want to have them, but rather reflects a willingness to experience these emotions as sometimes inevitable parts of the human experience. Decreasing struggle with emotions and increasing acceptance of and willingness to experience these states will allow individuals to focus their energy on their behaviors, and to act more consistently with their values regardless of the particular thoughts or feelings that are present in these moments.

Values. The primary goal of values skills will be to (1) identify participant core values, anchored by self-identified desired qualities of action (e.g. being kind, supportive, engaged, or

productive), in specific domains that matter to them (e.g., work, family, friendships, community, and parenting), and (2) to link those values to health behavior change efforts. For example, a person might identify “Being a caring and present mother” as a core value. Values will be described metaphorically as directions, like traveling east, with behaviors either moving towards (e.g. spending time playing with child) or away from (e.g. using social media on phone in the presence of child) the stated value. In any moment of any day, one can “orient” to their valued direction and identify a behavior that would help move them towards their personal value.

After identifying personally-meaningful values, participants will be asked to identify ways in which health behavior change can empower values-consistent behavior. For example, losing weight and increasing physical activity could provide increased energy and mood regulation. This may allow for increased stamina for active participation in play sessions with children (i.e., greater participation in values-consistent activities), and also limit the irritability that fuels parent-child conflict (i.e., improved quality of interactions in valued relationships). Additional examples of how health behavior change can empower values-consistent behavior that will be discussed include being a positive role model for loved ones, contributing to a sense of personal growth (e.g., from setting and achieving new goals), and being intentionally self-nurturing and caring towards one’s self in a way that feels inherently meaningful.

Values strategies will include free-writing, group brainstorming and discussion, and guided imagery exercises used to uncover core values. For example, participants will be asked to imagine themselves at their 90th birthday celebration and to make note of what they would ideally want loved ones to say about their impact on others, what has been important to them over the years, what meaningful things they have accomplished, and how they have spent their time. Additional activities will help participants identify desired behavior patterns linked to values, set values-based goals, implement action plans linked to values, and evaluate the degree to which their behavior is consistent with their values. Participants will be engaged in discussions about how each health behavior decision point represents an opportunity to make a

'towards move' or 'away move' with respect to the core values they have identified, and brainstorm examples of specific 'towards' and 'away' moves in challenging situations they encounter. For example, when deciding whether to act on a craving for ice cream in the evening, an 'away' move might be eating a large portion of the ice cream that causes the participant to exceed their daily caloric needs, while a 'towards' move might be skipping the ice cream and engaging in an activity with a loved one instead.

ACT Session Outline. Session 1 will focus on acceptance-based skills training for recognizing and separating from excuses and demotivating thoughts, session 2 will target tolerating food cravings and other emotions, and session 3 will aim to bring meaning and motivation to weight control through values clarification and commitment skills. Session 4 will be designated for review and consolidation of all skills.

SR Intervention. The SR intervention will be based on previous studies by our investigator group^{47,48} and will extend and build on skills taught in standard behavioral weight loss treatment. Participants will be taught the 3 key components of self-regulation: self-observation, self-evaluation, and self-reinforcement (described below), as well as strategies to support successful implementation of these components.

Self-observation. Self-observation consists primarily of daily self-weighing. Participants will develop plans to weigh themselves daily, track their weight, and compare their current weight to their goal. The goal for all participants will be to maintain the weight they are at the start of Phase 2 of the program. Multiple strategies will be presented, including use of graphs, apps, and diaries, and participants will explore and commit to strategies identified as having the highest potential to maintain adherence to daily weighing. Daily weighing will be identified as the most important target of the intervention.

Self-evaluation. Participants will be taught to self-evaluate their current weight in relation to their goal and determine whether changes are needed to reduce the discrepancy.

Decisions about whether adjustments to food intake and physical activity are needed will be based on a comparison of current weight vs maintenance goal weight using a system based on color zones. Weight maintenance or weight loss will be in the 'green zone' (go), gains of 1-3 lbs will be in the 'yellow zone' (caution), and gains of 4 or more lbs will be in the 'red zone' (stop). Participants will be instructed to determine their zone each week and to take the following actions based on their zone: green – make one small change in eating and one small change in physical activity per week, to buffer against possible future weight gain; yellow – make one small change in eating and one small change in physical activity each day, to stop minor weight gain; and red – resume intensive weight loss efforts, in an attempt to reverse their weight trajectory. Each small change in eating will be designed to reduce dietary intake by 100 kcal, and each small change in physical activity will be designed to increase energy expenditure by 100 kcal. Justification for this small change approach will be provided by educating participants about biological factors that affect weight loss maintenance (e.g., changes in resting metabolic rate) that can partially be counteracted with behavior changes, as well as by discussing the benefits of responding quickly to behavioral “slips” rather than waiting until larger relapses (“falls”) have occurred for long-term weight management.

Examples of small changes for eating will include modifying portion sizes to save at least 100 kcal (e.g., ordering a small rather than large coffee drink, eating ½ of or skipping the bun with burgers), reducing the calorie content of meals and snacks through volumetric principles and lower-calorie substitutions (e.g., reducing the amount of pasta in a dish and adding in a serving or two of low-starch vegetables), opting for lower calorie methods of food preparation (e.g., grilling rather than frying chicken), and skipping or reducing caloric drinks (e.g., swapping a diet soda for a full-calorie soda or adding seltzer to wine to make a spritzer to drink the same number of fluid oz. for fewer calories). Examples of small changes in physical activity will include increasing daily step count by 2,000 steps through lifestyle changes (e.g., walking during phone calls, walking to run errands rather than driving, tidying up and doing other active

tasks around the home more often), adding in an extra 20 minutes of moderate intensity exercise by increasing exercise frequency (e.g., taking a second brisk walk each day) or increasing exercise duration (e.g., extending the length of one's exercise session by 20 minutes), and increasing the intensity of one's workout to burn an extra 100 kcal (e.g., alternating jogging and walking).

Self-reinforcement. Participants will be taught self-reinforcement techniques to reward themselves for being at or below their goal weight, and also to set contingencies to encourage them to meet their weight goals. For example, participants will engage in discussions about how the rewards associated with trying to lose weight often decrease over time (e.g., the number on the scale is stable rather than dropping, compliments from others may decrease), and will be educated on operant learning principles that highlight the importance of rewards and consequences in shaping behavior. Participants will create personalized plans for self-reinforcing weight loss maintenance, including strategies like providing short- and longer-term external rewards (e.g., buying a small gift or planning a fun activity after a specified amount of time spent in the green zone), behavioral contingencies (e.g., only watching a liked TV show if they have met their daily health goals), and negative reinforcement strategies (e.g., creating a plan with another member of the household in which they get out of having to do a disliked chore during weeks they are in the green zone).

SR Session Outline. The first session will focus on introducing the self-regulation model, self-observation through daily weighing, establishing a traffic light system for self-evaluation, and self-reinforcement when successfully maintaining weight. Sessions 2 and 3 will focus on actions participants should take when they are beginning to regain weight, and strategies that can support the indicated behavior changes. The final session will focus on reviewing key strategies and skills from the first three sessions, discussing barriers to implementation, and effectively using the self-regulation approach long-term.

Weekly Emails and Monthly Feedback. Participants in both groups will receive weekly emails during the 6-month weight loss maintenance intervention. The weekly emails will contain brief reminders of key concepts or micro-interventions of key skills specific to each condition (i.e. ACT participants will only receive ACT interventions and likewise SR participants will only receive SR interventions). Micro interventions will be delivered (via email link) through Qualtrics and range from 1-minute to 7-minutes in length, with shorter interventions providing a suggested strategy to practice for the week and longer interventions including interactive worksheets and exercises (e.g., sorting and ranking valued domains for ACT, identifying and problem solving barriers to self-weighing for SR). The emails will also contain a brief survey for participants to: (1) report their current weight, (2) report their average daily calorie intake, (3) and report their subjective level of skill use for their given condition. Participants will already be familiar with how to weigh themselves and record their calorie intake from the online weight loss intervention, and the weekly survey will allow for participants to either enter a) a value for kcals consumed each day, or, b) an average for kcals consumed over the past week. Once per month, participants will receive an email from the interventionists with brief feedback on their progress based on their answers to the weekly surveys. These emails will be constructed from a previously generated set of feedback messages in order to standardize feedback and maintain a scalable approach. Feedback in the ACT condition will focus primarily on weight change and ACT skills use, while feedback in the SR condition will focus on color zone and self-weighing frequency.

Interventionists and treatment fidelity. Interventionists will be master's degree level or higher in psychology or a related field. Interventionists will administer both interventions to counterbalance interventionists effects across conditions. Detailed treatment manuals will be used, and all therapy staff will be required to carefully read and follow these manuals. Intervention session checklists will be used to guide in-session behavior and will be completed by interventionists as a fidelity check after each session. Intervention sessions will be audio-taped

and reviewed during regular supervision meetings. Formal treatment fidelity analysis will be conducted using blind review of a randomly selected 20% of sessions using two coders and the calculation of inter-rater reliability.

Assessments

Participants will attend assessment appointments at study baseline (Phase 1 baseline/pre-weight loss intervention), Phase 1 post-treatment/Phase 2 baseline (pre-randomization) and 6, 12, 18, 24, and 30 months after randomization. All assessments will be conducted by research staff who are blind to participant condition assignment.

Treatment Outcomes

The primary outcome will be changes in weight over the period from randomization (occurring upon completion of a 3-month weight loss program) to month 30 (i.e. long-term weight loss). Weight will be objectively measured at all assessment appointments to the nearest 0.1 kg using a digital scale with participants in light clothes, and no shoes. Height will be measured to the nearest millimeter with a stadiometer and BMI will be calculated by formula (kg/m^2). Secondly, changes in waist circumference⁵⁶ will be measured at the midpoint between the lower margin of the least palpable rib and the top of the iliac crest, using a stretch-resistant tape that provides constant tension while the participant is relaxed and after a normal exhale of breath. We will also compare groups on outcomes more directly related to weight loss maintenance, including the proportion (a) with no net weight gain from randomization, (b) who gained no more than 3% of weight from randomization, and (c) who maintained ≥ 4 kg weight loss from study entry (pre-weight loss); indices used in previously published studies of similar design⁵⁰.

Physical activity

Physical activity (PA) will be objectively measured for 1-week at each assessment time point (baseline, post-weight loss/ pre-randomization, 6, 18, and 30-month follow-up), using the previously validated Actigraph accelerometer⁵⁷⁻⁵⁹. During each monitoring period, participants will be instructed to wear this device on their waist during all waking hours, exclusive of bathing and swimming. Data will be processed using the ActiLife software (Actigraph Corp, Pensacola FL) using standardized cut points for determining minutes per day spent in moderate-to-vigorous intensity PA. Only days with ≥ 8 hours of wear time will be considered 'valid' and included in the analyses.

Potential mediators of treatment

The following potential mediators will be assessed at all assessments.

Mediators of ACT. Acceptance will be measured by the *Food Acceptance and Awareness Questionnaire (FAAQ)*⁶⁰, which assesses acceptance of urges and cravings to eat, or the extent to which individuals might try to change or control these experiences, and the *Acceptance and Action Questionnaire for Weight*, a 22-item scale designed to assess acceptance related to body weight, food, and eating⁶¹. Values-consistent behavior will be assessed by the Motivation and Activation subscale of the *Comprehensive Assessment of Acceptance and Commitment Therapy Processes (CompACT)*, a 23-item scale designed to assess change in general ACT processes⁶².

Mediators of SR. Changes in self-weighing will be assessed by a single item (During the past 3 weeks, how often did you weigh yourself?" with 7-point Likert scale (range from "never" to "several times a day"). The use of weight control strategies will be assessed by the *Weight Control Strategies Scale (WCSS)*; a 30-item Likert-type questionnaire that probes for use of standard behavioral strategies in four domains: dietary choices, self-monitoring, physical activity, and psychological coping. The WCSS has been shown to have good reliability and validity⁶³, and change in WCSS is associated with change in weight^{64,65}.

Potential mediator for both interventions. Changes in motivation will be assessed via the *Treatment Self-Regulation Questionnaire (TSRQ)*⁶⁶. The 15-item version of the TSRQ will be utilized, which assesses autonomous and controlled forms of motivation, and is validated for use with interventions that target changes in energy intake and physical activity⁶⁷.

Potential Moderators

Demographic variables will be assessed, including sex, race, ethnicity, income, and education. Perceived hunger will be assessed with the Hunger subscale of the *Eating Inventory*,⁶⁸ a widely used and well-validate measure of eating behavior. In addition, percent weight loss during Phase 1 of the program will be examined as a potential moderator.

Treatment adherence

Treatment adherence will be assessed by calculating the percentage of weight loss maintenance treatment sessions attended and weekly email surveys completed.

Statistical Analysis and Power Estimates

Power calculations were conducted to ensure adequate sample size to detect between group differences in the primary and secondary outcomes, and used a combination of G*Power and MPlus Monte Carlo estimation informed by preliminary work from our research team. A series of Mixed Effects Model Monte Carlo simulations were done in MPlus with 1000 replications and three seeds to confirm model stability. Models assumed modest effects of covariates. Although our work has shown low levels of missing data, we modeled a range of missing data. Models converged with low parameter bias. Even with missing data, findings supported excellent power (>80%) to identify even small-medium effects ($f^2=0.09$) in the primary outcome. If we translate this effect size to the weight change scale, with a standard deviation in baseline weight of 15-18 kg, the minimum detectable difference in weight change is 2-6 kg weight change (meaning we will be powered to see as a difference in weight change between

groups of between 2 and 6 kg at follow-ups). Pilot data showed weight change from months 12-24 was significantly better in ACT than SR (weight change of +2.5 vs +5.7 kg). Since this minimum detectable effect is consistent with what we have seen in prior clinical trials, we believe our main hypothesis is adequately powered. Given small-medium effects ($d=0.20-0.44$), simulation models suggest we are sufficiently powered to detect between group differences in secondary outcomes. Using two-tailed type-I error levels of 5% and assuming pre-post correlations in the range .2 to .9, we will be able to detect standardized mean differences in values-consistent behavior in the range of $d = 0.20$ to 0.44 , which are small to medium effects. These effects are feasible given our pilot data and prior work by our research team (Wing, Tate, et al., 2006) . In addition, simulation mixed models converged even with missing data, and supported excellent power (>80%) to identify even small-medium effects ($f^2=0.08$). Therefore, we consider this aim to be adequately powered. Simulation studies for the Third Aim (mediators and moderators of the treatment effect) tested the expected conditional (moderator) effects, assuming a range of effect sizes for both the main condition and interaction terms, with findings supporting power to detect a significant interaction term even with a small-medium effect sizes. Given indirect (mediator) effects in the medium range, we will be more than adequately powered for our third aim as well. Our exploratory aims are considered hypothesis generating, rather than hypothesis testing, and thus we do not present a priori power analysis. Inference in this aim will be based on the estimation of effect sizes and 95% confidence intervals. In sum, with 144 participants randomized to each group in the weight loss maintenance phase (total $N = 288$), we will yield at least 80% power to detect differences in primary and secondary outcomes.

Data analyses will employ the intent-to-treat principle and assume a two-sided alpha of .05. Demographics and baseline data will be summarized across and between groups using Analysis of Variance (ANOVA), chi-squared analyses and non-parametric tests as appropriate. We will use a series of mixed effects regression models to compare treatment groups with respect to the primary and secondary outcomes. If participant characteristics (demographics) or

initial weight loss differ significantly between groups at baseline or time of randomization (i.e. at the end of Phase 1/ start of Phase 2), those variables will be considered potential confounders and therefore be included as a covariate in subsequent outcomes analyses. We will examine potential moderators of the treatment effect using a similar approach described above with the addition of the main effect of the moderators and the interaction between moderator and treatment group. Mediators will be examined using a multiple mediation model implemented with a product of coefficients approach with bootstrapped standard errors (5000 samples with replacement). We will estimate the path coefficients (a path: effects of treatment on changes in each of the mediators over time and b path: effects of changes in mediators on WLM at 30 months, controlling for baseline weight), as well as the indirect effect of treatment (ab path: effect of treatment on weight change through mediators). A variable will be considered a mediator if the indirect effect is significantly different than zero. Mediation models will be estimated using a likelihood-based approach and thus will include all participants regardless of amount of data they contribute to provide consistent estimates of the regression parameters. It should be noted that testing mediation even in the absence of a treatment effect is warranted and encouraged for intervention research.⁶⁹ Finally, we will explore treatment effects on alternative weight loss maintenance indices using a longitudinal model implemented with Generalized Estimating Equations.

Should data not meet model assumptions or groups differ significantly with respect to key variables (e.g. early weight loss), we will explore alternative models for the primary outcomes (e.g. quantile regression, mixture models).

DISCUSSION

Weight regain is a significant problem after behavioral obesity treatment and existing interventions do not adequately address the unique challenges of weight loss maintenance. This randomized controlled trial will be the first to test the efficacy of ACT versus SR—two

approaches that have demonstrated promise for weight loss maintenance in a previous pilot trial—for long-term (30-month follow-up) weight loss maintenance among adults in a fully-powered trial. Importantly, both interventions will be delivered using low intervention contact formats, increasing the scalability and potential for wide dissemination if found to be efficacious. Additionally, we will assess several theorized mechanisms of action of each intervention and moderators of each intervention's effects. This will facilitate future modifications to the interventions to increase their potency and efficacy, and can inform future trials that seek to match participants to the treatment approach most likely to provide benefit.

Particular strengths of the current trial include a randomized design in which participants are stratified by objectively-verified initial weight loss and sex; objective measurement of weight and other exploratory outcome measures (e.g., waist circumference) at several assessments up to 30-months post-randomization; use of a low treatment contact intervention format; and assessment of several potential mediators and moderators. Limitations include recruiting and providing intervention at a single site and in an academic medical center setting (rather than in a more pragmatic setting), which could limit generalizability and use of certain eligibility criteria (e.g., access to regular internet, fluency in English) that were selected to ensure feasibility of the study but may also limit representativeness of the sample. Finally, it is possible that ACT will be perceived as more novel than SR, which in part extends on standard weight loss principles. Thus, we cannot fully rule out potential novelty effects of ACT if it shows superior weight outcomes absent clear mediation data supporting movement in ACT processes.

Future research could examine implementation in real world settings. Such a study could examine (a) the efficacy and cost-effectiveness as compared to current standard of care, and (b) barriers to implementation (e.g. cost of implementation, training interventionists with diverse education and training backgrounds, organizational commitment). If there are no significant differences in weight loss between ACT and SR, we will examine whether there are subgroups

that respond differentially with the aim of developing and testing procedures for treatment matching.

Conclusions

This study will provide important data about whether, why, and for whom a low treatment contact ACT or SR intervention is efficacious in facilitating weight loss maintenance following intentional weight loss. If the evaluated interventions are found to meaningfully improve weight loss maintenance, future studies should evaluate the effectiveness of these approaches when implemented in routine care settings. Data on mediators and moderators of intervention effects can also inform future weight loss maintenance-specific intervention development.

References

1. Billington CJ, Epstein LH, Goodwin NJ, et al. Overweight, obesity, and health risk. *Archives of Internal Medicine* 2000;160:898-904.
2. Mokdad AH, Ford ES, Bowman BA, et al. Prevalence of obesity, diabetes, and obesity-related health risk factors, 2001. *Jama-Journal of the American Medical Association* 2003;289:76-9.
3. Bastien M, Poirier P, Lemieux I, Despres JP. Overview of Epidemiology and Contribution of Obesity to Cardiovascular Disease. *Progress in Cardiovascular Diseases* 2014;56:369-81.
4. Flegal KM, Kruszon-Moran D, Carroll MD, Fryar CD, Ogden CL. Trends in Obesity Among Adults in the United States, 2005 to 2014. *Jama-Journal of the American Medical Association* 2016;315:2284-91.
5. Font-Burgada J, Sun BC, Karin M. Obesity and Cancer: The Oil that Feeds the Flame. *Cell Metabolism* 2016;23:48-62.
6. Smith E, Hay P, Campbell L, Trollor JN. A review of the association between obesity and cognitive function across the lifespan: implications for novel approaches to prevention and treatment. *Obesity Reviews* 2011;12:740-55.
7. Wadden TA, Stunkard AJ, Berkowitz RI. Obesity: A guide for mental health professionals. *Psychiatric Clinics of North America* 2005;28:13-6.
8. Quesenberry CP, Caan B, Jacobson A. Obesity, health services use, and health care costs among members of a health maintenance organization. *Archives of Internal Medicine* 1998;158:466-72.
9. Seidell JC. Societal and personal costs of obesity. *Experimental and Clinical Endocrinology and Diabetes* 1998;106:7-9.
10. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *New England Journal of Medicine* 2002;346:393-403.

11. Wadden TA, Butryn ML, Wilson C. Lifestyle modification for the management of obesity. *Gastroenterology* 2007;132:2226-38.
12. Brownell KD, Jeffery RW. Improving Long-term Weight-Loss - Pushing the Limits of Treatment. *Behavior Therapy* 1987;18:353-74.
13. Wilson GT. Behavioral Treatment of Obesity - 30 Years and Counting. *Advances in Behaviour Research and Therapy* 1994;16:31-75.
14. Wadden TA, West DS, Delahanty LM, et al. The Look AHEAD Study: A description of the lifestyle intervention and the evidence supporting it. *Obesity* 2006;14:737-52.
15. Krukowski RA, Tilford JM, Harvey-Berino J, West DS. Comparing Behavioral Weight Loss Modalities: Incremental Cost-Effectiveness of an Internet-Based Versus an In-Person Condition. *Obesity* 2011;19:1629-35.
16. Andajani-Sutjahjo S, Ball K, Warren N, Inglis V, Crawford D. Perceived personal, social and environmental barriers to weight maintenance among young women: A community survey. *International Journal of Behavioral Nutrition and Physical Activity* 2004;5:15.
17. Welch N, McNaughton SA, Hunter W, Hume C, Crawford D. Is the perception of time pressure a barrier to healthy eating and physical activity among women? *Public Health Nutrition* 2008;12:888-95.
18. Leahey TM, Thomas G, Fava JL, et al. Adding Evidence-Based Behavioral Weight Loss Strategies to a Statewide Wellness Campaign: A Randomized Clinical Trial. *American Journal of Public Health* 2014;104:1300-6.
19. Raaijmakers LCH, Pouwels S, Berghuis KA, Nienhuijs SW. Technology-based interventions in the treatment of overweight and obesity: A systematic review. *Appetite* 2015;95:138-51.
20. Tang JCH, Abraham C, Greaves C, Nikolaou V. Self-directed interventions to promote weight loss: A systematic review and meta-analysis. *Health Psychology Review* 2016;10:358-72.

21. Kozak AT, Buscemi J, Hawkins MAW, et al. Technology-based interventions for weight management: current randomized controlled trial evidence and future directions. *Journal of Behavioral Medicine* 2017;40:99-111.
22. Sorgente A, Pietrabissa G, Manzoni GM, et al. Web-Based Interventions for Weight Loss or Weight Loss Maintenance in Overweight and Obese People: A Systematic Review of Systematic Reviews. *Journal of Medical Internet Research* 2017;19:e229.
23. Ross KM, Qui P, You L, Wing RR. Characterizing the pattern of weight loss and regain in adults enrolled in a 12-week internet-based weight management program. *Obesity* 2018;26:318-23.
24. Loveman E, Frampton GK, Shepherd J, et al. The clinical effectiveness and cost-effectiveness of long-term weight management schemes for adults: a systematic review. *Health Technology Assessment* 2011;15:1-+.
25. Dombrowski SU, Knittle K, Avenell A, Araujo-Soares V, Sniehotta FF. Long term maintenance of weight loss with non-surgical interventions in obese adults: systematic review and meta-analyses of randomised controlled trials. *Bmj-British Medical Journal* 2014;348.
26. Karfopoulou E, Mouliou K, Koutras Y, Yannakoulia M. Weight Loss Methods in Relation to Weight Maintenance Status: Focus Groups Results. *Annals of Nutrition and Metabolism* 2013;63:1296-.
27. McKee H, Ntoumanis N, Smith B. Weight maintenance: Self-regulatory factors underpinning success and failure. *Psychol Health* 2013;28:1207-23.
28. Wang J, Shih PC, Carroll JM. Life After Weight Loss: Design Implications for Community-based Long-term Weight Management. *Computer Supported Cooperative Work-the Journal of Collaborative Computing* 2015;24:353-84.
29. Barnes AS, Goodrick GK, Pavlik V, Markesino J, Laws DY, Taylor WC. Weight loss maintenance in African-American women: Focus group results and questionnaire development. *Journal of General Internal Medicine* 2007;22:915-22.

30. Bertz F, Sparud-Lundin C, Winkvist A. Transformative Lifestyle Change: key to sustainable weight loss among women in a post-partum diet and exercise intervention. *Maternal and Child Nutrition* 2015;11:631-45.
31. Sarlio-Lahteenkorva S, Rissanen A, Kaprio J. A descriptive study of weight loss maintenance: 6 and 15 year follow-up of initially overweight adults. *International Journal of Obesity* 2000;24:116-25.
32. Engstrom M, Forsberg A. Wishing for deburdening through a sustainable control after bariatric surgery. *International Journal of Qualitative Studies on Health and Well-Being* 2011;6.
33. Kwasnicka D, Dombrowski SU, White M, Sniehotta F. Theoretical explanations for maintenance of behaviour change: a systematic review of behaviour theories. *Health Psychology Review* 2016;10:277-96.
34. Hayes SC, Strosahl K, Wilson KG. *Acceptance and Commitment Therapy: An experiential approach to behavior change*. New York: The Guilford Press; 1999.
35. Hayes SC, Luoma JB, Bond FW, Masuda A, Lillis J. Acceptance and commitment therapy: Model, processes and outcomes. *Behaviour Research and Therapy* 2006;44:1-25.
36. Graham CD, Gouick J, Krahe C, Gillanders D. A systematic review of the use of Acceptance and Commitment Therapy (ACT) in chronic disease and long-term conditions. *Clinical Psychology Review* 2016;46:46-58.
37. Hughes LS, Clark J, Colclough JA, Dale E, McMillan D. Acceptance and Commitment Therapy (ACT) for Chronic Pain: A Systematic Review and Meta-Analyses. *Clinical Journal of Pain* 2017;33:552-68.
38. Swain J, Hancock K, Hainsworth C, Bowman J. Acceptance and Commitment Therapy in the treatment of anxiety: A systematic review. *Clinical Psychology Review* 2013;33:965-78.
39. Forman EM, Butryn ML, Manasse SM, et al. Acceptance-Based Versus Standard Behavioral Treatment for Obesity: Results from the Mind Your Health Randomized Controlled Trial. *Obesity* 2016;24:2050-6.

40. Lillis J, Hayes SC, Bunting K, Masuda A. Teaching acceptance and mindfulness to improve the lives of the obese: A preliminary test of a theoretical model. *Annals of Behavioral Medicine* 2009;37:58-69.
41. Lillis J, Niemeier HM, Thomas JG, et al. A Randomized Trial of an Acceptance-Based Behavioral Intervention for Weight Loss in People with High Internal Disinhibition. *Obesity* 2016;24:2509-14.
42. Lillis J, Kendra KE. Acceptance and Commitment Therapy for weight control: Model, evidence, and future directions. *Journal of Contextual Behavioral Science* 2014;3:1-7.
43. Gregg JA, Callaghan GA, Hayes SC, Glenn-Lawson JL. Improving diabetes self-management through acceptance, mindfulness, and values: A randomized controlled trial. *Journal of Consulting and Clinical Psychology* 2007;75:336-43.
44. Bond FW, Bunce D. The role of acceptance and job control in mental health, job satisfaction, and work performance. *Journal of Applied Psychology* 2003;88:1057-67.
45. Butryn ML, Forman E, Hoffman K, Shaw J, Juarascio A. A Pilot Study of Acceptance and Commitment Therapy for Promotion of Physical Activity. *Journal of Physical Activity & Health* 2011;8:516-22.
46. Gifford EV, Kohlenberg BS, Hayes SC, et al. Acceptance-based treatment for smoking cessation. *Behavior Therapy* 2004;35:689-705.
47. Wing RR, Tate DF, Gorin AA, Raynor HA, Fava JL. A self-regulation program for maintenance of weight loss. *New England Journal of Medicine* 2006;355:1563-71.
48. Lillis J, Wing RR. Using novel behavioral interventions to improve long-term weight loss: A randomized trial comparing acceptance and commitment therapy and self-regulation for weight loss treatment seeking adults with overweight and obesity. Annual meeting of the Association for Contextual Behavioral Science. Dublin, Ireland 2019.

49. Thomas JG, Leahey TM, Wing RR. An Automated Internet Behavioral Weight-Loss Program by Physician Referral: A Randomized Controlled Trial. *Diabetes Care* 2015;38:9-15.
50. Svetkey LP, Stevens VJ, Brantley PJ, et al. Comparison of strategies for sustaining weight loss - The weight loss maintenance randomized controlled trial. *Jama-Journal of the American Medical Association* 2008;299:1139-48.
51. Ross KM, Qiu PH, You L, Wing RR. Characterizing the Pattern of Weight Loss and Regain in Adults Enrolled in a 12-Week Internet-Based Weight Management Program. *Obesity* 2018;26:318-23.
52. Lillis J, Wing RR. Using novel behavioral interventions to improve long-term weight loss: A randomized trial comparing acceptance and commitment therapy and self-regulation for weight loss treatment seeking adults with overweight ad obesity. Annual meeting of the Association for Contextual Behavioral Science. Dublin, Ireland2019.
53. Teixeira PJ, Going SB, Houtkooper LB, et al. Pretreatment predictors of attrition and successful weight management in women. *International Journal of Obesity* 2004;28:1124-33.
54. Wing RR, Phelan S. Long-term weight loss maintenance. *American Journal of Clinical Nutrition* 2005;82:222S-5S.
55. Elfhag K, Rossner S. Who succeeds in maintaining weight loss? A conceptual review of factors associated with weight loss maintenance and weight regain. *Obesity Reviews* 2005;6:67-85.
56. Nazare JA, Smith J, Borel AL, et al. Usefulness of Measuring Both Body Mass Index and Waist Circumference for the Estimation of Visceral Adiposity and Related Cardiometabolic Risk Profile (from the INSPIRE ME IAA Study). *American Journal of Cardiology* 2015;115:307-15.
57. Aadland E, Ylvisaker E. Reliability of the Actigraph GT3X+Accelerometer in Adults under Free-Living Conditions. *Plos One* 2015;10.
58. Freedson PS, Melanson E, Sirard J. Calibration of the Computer Science and Applications, Inc. accelerometer. *Medicine and Science in Sports and Exercise* 1998;30:777-81.

59. Matthews CE, Chen KY, Freedson PS, et al. Amount of time spent in sedentary behaviors in the united states, 2003-2004. *American Journal of Epidemiology* 2008;167:875-81.
60. Juarascio A, Forman E, Timko CA, Butryn M, Goodwin C. The development and validation of the food craving acceptance and action questionnaire (FAAQ). *Eating Behaviors* 2011;12:182-7.
61. Lillis J, Hayes SC. Measuring avoidance and inflexibility in weight related problems. *International Journal of Behavioral Consultation and Therapy* 2008;4:30-40.
62. Francis AW, Dawson DL, Golijani-Moghaddam N. The development and validation of the Comprehensive assessment of Acceptance and Commitment Therapy processes (CompACT). *Journal of Contextual Behavioral Science* 2016;5:134-45.
63. Pinto AM, Fava JL, Raynor HA, LaRose JG, Wing RR. Development and validation of the weight control strategies scale. *Obesity* 2013;21:2429-36.
64. Ross KM, Wing RR. Impact of Newer Self-Monitoring Technology and Brief Phone-Based Intervention on Weight Loss: A Randomized Pilot Study. *Obesity* 2016;24:1653-9.
65. Steinberg DM, Bennett GG, Askew S, Tate DF. Weighing Every Day Matters: Daily Weighing Improves Weight Loss and Adoption of Weight Control Behaviors. *Journal of the Academy of Nutrition and Dietetics* 2015;115:511-8.
66. Williams GC, Grow VM, Freedman ZR, Ryan RM, Deci EL. Motivational predictors of weight loss and weight-loss maintenance. *Journal of Personality and Social Psychology* 1996;70:115-26.
67. Levesque CS, Williams GC, Elliot D, Pickering MA, Bodenhamer B, Finley PJ. Validating the theoretical structure of the Treatment Self-Regulation Questionnaire (TSRQ) across three different health behaviors. *Health Education Research* 2007;22:691-702.
68. Stunkard AJ, Messick S. The 3-Factor Eating Questionnaire to Measure Dietary Restraint, Disinhibition and Hunger. *Journal of Psychosomatic Research* 1985;29:71-83.

69. O'Rourke HP, MacKinnon DP. Reasons for Testing Mediation in the Absence of an Intervention Effect: A Research Imperative in Prevention and Intervention Research. *Journal of Studies on Alcohol and Drugs* 2018;79:171-81.

Table 1 Inclusion and Exclusion Criteria

Inclusion	Exclusion
-Age 25-70	-Current or planned pregnancy
-BMI 27.5-45 kg/m	-Previous or planned bariatric surgery
-Can read/ verbally communicate in English	-Currently on weight loss medication
-Consistent access to the internet	-Weight loss of >5% within the past 6 months
	-Current or planned participation in another weight loss program
	-Any health condition that precludes calorie restriction and/or exercise
	-Current or historical diagnosis of Anorexia, Bulimia, Schizophrenia, or Bipolar
	-Psychiatric Hospitalization in the past year

Figure 1: Study Design

