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The BestFIT trial: A SMART Approach to Developing Individualized Weight Loss Treatments

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Abstract

Behavioral weight loss programs help people achieve clinically meaningful weight losses (8–10% of starting body weight). Despite data showing that only half of participants achieve this goal, a “one size fits all” approach is normative. This weight loss intervention science gap calls for adaptive interventions that provide the “right treatment at the right time for the right person.” Sequential Multiple Assignment Randomized Trials (SMART), use experimental design principles to answer questions for building adaptive interventions including whether, how, or when to alter treatment intensity, type, or delivery. This paper describes the rationale and design of the BestFIT study, a SMART designed to evaluate the optimal timing for intervening with sub-optimal responders to weight loss treatment and relative efficacy of two treatments that address self-regulation challenges which impede weight loss: 1) augmenting treatment with portion-controlled meals (PCM) which decrease the need for self-regulation; and 2) switching to acceptance-based behavior treatment (ABT) which boosts capacity for self-regulation. The primary aim is to evaluate the benefit of changing treatment with PCM versus ABT. The secondary aim is to evaluate the best time to intervene with sub-optimal responders. BestFIT results will lead to the

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empirically-supported construction of an adaptive intervention that will optimize weight loss outcomes and associated health benefits.

Keywords

Weight Loss; Obesity; Treatment; Adults

Introduction

Obesity remains a public health problem.^{1–3} State-of-the art behavioral interventions achieve clinically significant weight losses of 8–10%,^{4,5} but only 40–60% of people achieve this goal.⁶ This treatment response heterogeneity calls for the development of adaptive interventions which are sequential, tailored approaches whereby treatment is adapted over time based on an individual's evolving status and specific needs.^{7,8} Adaptive interventions include stepped care intervention designs,^{9–16} which have previously been used in weight loss research. Sequential Multiple Assignment Randomized Trials (SMART) use experimental design principles to answer whether, how, and when to alter treatment intensity, type or delivery¹⁷ to build adaptive interventions.^{18–21}

Choosing candidate “second stage” treatments for sub-optimal responders to “first stage” state-of-the-art behavioral weight loss therapy (SBT), requires consideration of weight loss barriers. In this “obesogenic”^{22,23} environment, the seemingly straightforward process of managing energy balance is challenging. Although nutrition knowledge could interfere, most people experience self-regulation rather than knowledge problems.^{24–28} Moreover, people vary in the extent to which they experience food-specific^{27,29} and general self-regulation difficulties,^{30–32} that contribute to difficulty managing eating in the context of continual cues that trigger overconsumption. Two approaches to address these challenges include augmenting treatment with meal replacements (MRs) which reduce the need for behavioral control and decision-making^{33–39} or augmenting SBT with a skill set drawn from acceptance and commitment therapy designed to boost capacity for self-regulation.^{40–47} Each has an empirical research base, but may not be an optimal “first stage” treatment. Although some MRs (e.g., liquids, bars) can be inexpensive, portion-controlled meals (PCM), most likely to be acceptable long-term, tend to be expensive, i.e., \$100–150.00 per week⁴⁸ and difficult to fit into a person's lifestyle. Empirical support for incorporating acceptance-based principles into SBT is building;^{49–54} acceptance-based behavioral weight loss treatment (ABT) is particularly effective for certain individuals (e.g., those with higher depression levels) and may be a viable “second stage” treatment for sub-optimal responders.⁵⁵ PCM and ABT may have differential short- and long-term effects. MRs reduce the need for self-regulation, but may be less effective long-term given their inflexibility. In contrast, ABT skill development and self-regulation capacity may accelerate over time.

Identifying when to identify sub-optimal responders is also important. Previous studies of stepped care interventions have intensified treatment from 3 to 12 weeks with little empirical justification.^{13–16,56} Data from multiple weight loss trials,^{57–60} including Mind Your Health II (R01 DK095069) and ENACT (R01 DK92374), suggest session 3 and 7 as candidate time

points for intervening with sub-optimal responders. Participants who lost at least 2.5% of their body weight by session 3 were twice as likely to lose 10% of their body weight at 6 months compared to those not meeting this threshold. Participants who lost at least 5.0% of their body weight by session 7 were 3 times more likely than those not meeting this threshold to achieve a 10% weight loss.

This paper describes the BestFIT study, a SMART addressing two critical questions for developing an adaptive weight loss intervention: 1) when to identify SBT sub-optimal responders; and 2) whether PCM or ABT is more effective for sub-optimal responders.

Methods

Trial design overview

The study design is a two-stage sequential multiple assignment randomized trial (SMART). 500 adults with body mass index (BMI) between 30 kg/m² and 45 kg/m² will be offered standard behavioral weight loss treatment (SBT) as first stage treatment (Figure 1). Participants will be randomized initially, with equal probability, to response assessment at Week 3 or Week 7. Participants who are randomized to Week 3 will be considered sub-optimal responders if they lose less than 2.5% of their session 1 starting body weight by week 3 and/or 28 days after session 1 whichever comes first; and those randomized to Week 7 will be considered sub-optimal responders if they lose less than 5.0% of their session 1 starting body weight by week 7 or 63 days after session 1, whichever comes first. Participants identified as sub-optimal responders (at either Week 3 or Week 7) will be re-randomized, with equal probability, to one of two second-stage treatments: augmentation of SBT with portion-controlled meals (PCM) or switching from SBT to an acceptance-based enhanced version of SBT (Acceptance-based behavioral treatment, ABT). Participants identified as responders continue with SBT.

Study aims

The primary aim is to evaluate, among sub-optimal responders to SBT, the benefit of augmenting initial treatment with portion-controlled meals (PCM) versus switching to an acceptance-based behavioral treatment (ABT). The primary hypothesis is that, on average, **a)** sub-optimal responders re-randomized to augmenting SBT with PCMs will weigh less at 6 months relative to those randomized to ABT, but that **b)** those re-randomized to ABT will weigh less at 18 months (12 months post-treatment) relative to those randomized to augmenting SBT with PCMs. The study sample size was chosen to ensure sufficient statistical power for examining this primary aim (see below).

The goal of the secondary aim is to evaluate the optimal timing for identifying sub-optimal responders. Although Session 3 and Session 7 are both potentially good candidates for identifying and intervening with sub-optimal responders to weight loss treatment, we hypothesize that intervening at the later time point may be less beneficial because participants who are having difficulty losing weight may begin to feel less optimistic about their likelihood of success and less motivated to make the necessary changes due to their

lack of success.⁶¹ Thus, it is hypothesized that participants who undergo Session 3 response assessment will weigh less at 6 and 18 months relative those assessed at Session 7.

The goal of the exploratory third aim is to make further progress toward building an individually-tailored adaptive intervention, by examining food-specific (e.g., binge eating) and general self-regulation (e.g., executive functioning) as moderators of the effect of potential variation in responsiveness to different treatment sequences. We will explore whether individual variation in the levels of food-specific and general self-regulation is differentially associated with response to PCM and ABT.

Eligibility and Exclusions

Study participants recruited through the community, will meet the following inclusion criteria: 1) aged 21 – 70 years; 2) initial BMI 30.0 and 45 kg/m²; 3) willing and able to participate in study activities for 18 months. Exclusion criteria include: 1) inability to participate in physical activity; 2) pregnancy or breastfeeding or planning a pregnancy within the next 18 months; 3) involvement in another diet intervention study or organized weight loss program; 4) dietary restrictions (e.g., gluten-free); 5) insulin-dependent diabetes, and 6) and presence of a significant psychiatric disorder (e.g., schizophrenia) that could interfere with trial participation.

Recruitment

Participants will be recruited through several methods that we have used successfully in prior weight loss trials including radio, print, web-based advertisements, and direct mailings. The study phone number and email address will be included in the advertisements and those interested will be directed to contact the study team using their preferred communication mode to indicate their interest. These potential participants will be asked screening questions over the phone to assess their eligibility. Respondents who confirm eligibility and interest will be invited to an orientation session during which they will learn more about the study and requirements of participation. BMI eligibility will also be determined at this visit based on staff-measured height and weight. Interested and eligible respondents will then schedule a phone call to discuss and confirm that the respondent understands and is willing and able to complete the study recruitments. Next, a baseline intake measurement visit is scheduled which takes place at the Institute, a convenient location for metropolitan area residents. At the intake visit, informed consent will be obtained and the baseline measures will be collected.

Randomizations

Stratified randomizations will ensure equal representation between treatment groups based on key predictors of weight loss, including sex, and BMI. The first randomization (to Week 3 versus Week 7) is stratified by sex (female, male) and baseline BMI categories (30.0–34.9, 35.0–39.9, 40.0–44.9). The second randomization (to PCM versus ABT, among sub-optimal responders) is stratified by stage 1 treatment (Week 3 versus Week 7), sex, baseline BMI categories, and the amount of weight lost prior to the re-randomization. Blocks will be used within each stratum to ensure approximately equal numbers of participants in Week 3 and Week 7 and sub-optimal responders in PCM and ABT.

Interventions

All participants are offered a total of 20 treatment sessions delivered in-person at the Institute over an approximately 20 week time period.

Standard Behavioral Weight Loss Treatment (SBT). This is a multi-component, in-person individual weight loss intervention based on state of the art behavioral weight loss treatment programs^{33,57,58,60,62–68} and emphasizes self-monitoring of eating and exercise,^{69–73} stimulus control strategies^{4,69–74}, goal setting,⁴ problem solving,^{4,75} addressing social situations, cognitive strategies, and relapse prevention.⁷⁶ Participants meet weekly with a weight loss coach (master's level training or higher) for at most 20 weekly sessions of SBT. Participants will be assigned a calorie intake goal of 1200, 1500, or 1800 kcal/day based on body weight with the goal of producing a weight loss of 2–3 lbs/wk. Participants will be encouraged to develop an exercise program based primarily on walking with a goal of increasing their physical activity level to about 1 hour of walking per day.^{65,66} As part of SBT, the weight loss coach will measure and document each participant's weight in the study treatment database prior to delivering the weekly treatment session content.

Week 3 Sub-optimal response Definition. Participants who are randomized to Week 3 will be considered sub-optimal responders if they lose less than 2.5% of their session 1 starting body weight by week 3. Week 3 sub-optimal responders transition to second-stage treatment at the beginning of the 3rd SBT session.

Week 7 Sub-optimal response Definition. Participants who are randomized to Week 7 will be considered sub-optimal responders if they lose less than 5.0% of their session 1 starting body weight by week 7. Week 7 sub-optimal responders transition to second-stage treatment at the beginning of the 7th SBT session.

Augment with portion-controlled meals (PCM). Participants re-randomized to PCM will continue weekly individual sessions of SBT with their weight loss coach. Sub-optimal responders re-randomized at Week 3 will receive 17 weeks of pre-prepared fresh meals and those re-randomized at Week 7 will receive 13 weeks of portion-controlled meals. Meals will be provided by Seattle Sutton's Healthy Eating of Minnesota. Seattle Sutton's offers meal plans at different caloric levels (e.g., 1200, 1500 kcals/day); the meals include freshly prepared food with fruits and vegetables. The weight loss coach will help the participant identify the nearest location and will help the participant arrange for twice-weekly pick-up of the appropriate calorie level meals.

Switch to acceptance-based behavioral treatment (ABT). Participants re-randomized to ABT will discontinue weekly SBT sessions and begin ABT sessions. Sub-optimal responders re-randomized at Week 3 will receive 17 weeks of ABT and those re-randomized at Week 7 will receive 13 weeks of ABT. ABT will primarily target the ability to tolerate experiential distress (i.e., increase willingness to engage in valued behavior over the long-term, even when it is uncomfortable). Such skills should increase adherence to behavioral goals and address gaps in standard behavioral strategies. Some SBT skills (e.g., stimulus control) will be present in ABT, but will be taught using an acceptance-based framework. Calorie intake and physical activity goals remain identical to the SBT condition.

The ABT intervention will help participants recognize that biological, environmental, and psychological processes make it challenging to consistently engage in weight control behaviors (a framework especially likely to resonate with sub-optimal responders). Several exercises will prompt participants to come to the conclusion that adaptive behavior (e.g., limiting calorie intake) often depends on the ability to tolerate unpleasant internal experiences (e.g., desire to eat a tasty food). “Willingness” (engaging in a valued action while accepting the discomfort it generates) will be framed as more adaptive than distress intolerance. “Urge surfing” (to “ride” on top of waves of discomfort) and “defusion” (ability to distance oneself from thoughts and feelings in order to see them as transient psychological experiences that need not be believed, acted on, controlled or suppressed) are examples of willingness skills.⁷⁷ Participants will learn to develop willingness to engage in healthy eating and physical activity behaviors even when they are not the preferred activities at that moment (e.g., when they would prefer to go to a fast food drive-through rather than prepare a meal at home). In those moments of decision making, participants learn to tolerate the “distress” that is experienced when one is choosing a relatively less appealing behavior.

Consistent with Acceptance and Commitment Therapy principles and intrinsic motivation theory, ABT emphasizes that participants must choose goals that emanate from freely-chosen, personal life values (e.g., health).⁷⁸ A structured process for the identification of such life values will be followed, and the connections between these values and weight control behaviors will be emphasized. Participants will be taught that commitment to difficult behavioral goals is only likely to be maintained when one connects psychologically with life values meaningful enough to make such effort and sacrifice worthwhile. Participants will learn skills for bringing awareness to their moment-by-moment behavior choices, increasing the likelihood that these choices reflect one’s ultimate values rather than a more immediate wish to decrease an aversive state or gain short-term reward. They also will adopt a heightened sense of responsibility for autonomous regulation of weight control behaviors.

Finally, an important component of ABT is training in experiential awareness. ABT incorporates mindfulness training designed to help individuals increase awareness of their perceptual, cognitive, and affective experiences relevant to weight control. Metaphors and experiential exercises will be utilized to help participants become more present-centered and aware, reducing the likelihood that they will engage in “automatic,” rather than deliberate, decision making. Participants will practice becoming more deliberately conscious of cognitive experiences that occur during eating-related decision making and will learn to identify and interrupt automatic, nonconscious influences on eating behavior. They will learn that awareness is necessary but not sufficient for making healthy decisions, and that it must be coupled with willingness and commitment skills.

Participant timeline, assessments, and measures

All research outcome measures will be administered at baseline, 6 months, and 18 months (12 months post-intervention) by independent evaluators blind to treatment assignment.

Primary Outcome

The primary research outcome is change in body weight from the baseline to the 6 month and the 18 month measurements. Body weight and height will be measured twice in light clothing without shoes using digital scale and a portable, calibrated stadiometer (Seca 876 Flat Scale; Seca 217 Stable Stadiometer; SECA 437 Adapter for Flat Scale). Measurements differing by 0.2 kg or more for weight or 0.5 cm or more for height will be repeated for a third time. Data for the multiple assessments are averaged. To assess validity, a second trained staff member will measure the height and weight of 10% of participants.

Other Measures

Demographic characteristics will include gender, age, race/ethnicity, marital status, highest level of education achieved, and current employment status.

Health Literacy. Health literacy will be assessed with the validated Newest Vital Sign (NVS), a 6-item, interviewer-administered measure assessing the ability to read, comprehend, and use information from a nutrition label.^{79,80}

Physical Activity. The Paffenbarger Physical Activity Questionnaire^{81–83} will be used to assess leisure-time physical activity. Total weekly energy expenditure is calculated as the sum of the caloric expenditure of each activity the participant engaged in during the prior week.

Weight loss goals. A 4-item scale adapted from Foster et al.⁸⁴ will be used to measure participant weight loss goals. Participants will report their dream weight, happy weight, acceptable weight, and disappointed weight.

Weight and weight-loss history. Participants will report the number of times since age 15 that they have lost each of the following number of pounds: 5 to 9, 10 to 19, 20 to 49, 50 to 79, 80 to 99, and 100. A continuous intentional weight-loss measure is created by assigning the midpoint value of the range for the frequency category and summing across the amounts.⁸⁵ Six items from the Weight and Lifestyle Inventory (WALI) will assess participant weight history.⁸⁶ Self-weighing frequency (“ranging from never” to “more than once a day”) will be assessed with one item.⁷² Nine items will assess weight management strategy use including the meal replacement use (e.g., fresh low calorie entrees or frozen low-calorie entrees), self-monitoring, and meal planning.⁸⁵

Self-Regulation: Eating Related—Binge Eating Assessment. A semi-structured interview assessing the presence of binge eating disorder will be administered by trained interviewers^{87,88}

Binge Eating. The Binge Eating Scale⁸⁹ (BES) is a 16-item, self-report measure designed to identify binge eating behaviors. This scale has moderately high internal consistency (alpha coefficient = 0.85) and two-week test-retest reliability ($r = .87; 76$).⁹⁰

The Power of Food Scale (PFS)⁹¹ is a 15-item self-report measure assessing the extent to which food’s availability or presence influences behavior, thinking, and feelings..⁹²

Eating Behaviors. Cognitive restraint, uncontrolled eating, and emotional eating will be assessed using the Three Factor Eating Questionnaire-R18 (TFEQ-R18).⁹³ add 93 Select items from the original Three Factor Eating Questionnaire (TFEQ) will also be used.⁹⁴

Eating self-efficacy will be assessed with the Weight Efficacy Lifestyle Questionnaire (WEL). Individuals rate their confidence for successfully resisting opportunities to overeat and for self-regulating their dietary intake.⁹⁵

Distress tolerance will be measured using an adapted version of the Acceptance and Action Questionnaire⁹⁶ which assesses the ability to tolerate challenging eating-related experiences.

Self-Regulation: General—Planning & Reasoning Skills. The Tower Test is part of the Delis-Kaplan Executive Function System (D-KEFS), a standardized set of executive functioning measures with well-documented test-retest reliability and validity.⁹⁷

Working Memory. Working memory is one component of executive functioning. Problems with working memory may contribute to difficulties holding weight-loss goals or nutritious eating plans “on-line”, making this domain relevant to examination in this study.^{98–100} The NIH Toolbox List Sorting Working Memory Test is a computerized test of working memory which has high test-retest reliability and moderate to high convergent validity.¹⁰¹

Response Inhibition. The Stop-Signal Task,¹⁰² a widely-used computerized measure of response inhibition, has been associated with impulsivity, restrained eating,¹⁰³ and obesity.¹⁰⁴

Risk Taking. The Balloon Analogue Risk Task (BART) is a computerized measure which assesses risk-taking behaviors which have been associated with health risk behaviors and impulsivity.¹⁰⁵

Impulsive behavior will be assessed with two subscales (urgency and sensation seeking) of the UPPS Impulsive Behavior Scale.¹⁰⁶

Depression symptoms will be assessed using the Patient History Questionnaire-9.^{107–113}

Adverse Childhood Experiences. Four items adapted from the Revised Conflict Tactics Scale¹¹⁴ will assess physical and emotional adverse childhood experiences shown to be associated with adult obesity.¹¹⁵

Adverse Health Events. Participants will report any adverse health events in the 6 months prior to the survey.

Statistical Analysis

The primary aim is a comparison of average weight loss among sub-optimal responders re-randomized to “Augment with portion-controlled meals” (PCM) relative to sub-optimal responders re-randomized to “Switch to acceptance-based behavioral therapy” (ABT) at months 6 and 18. As stated above, we hypothesize the effect to be different at 6 months, favoring PCM, and at 18 months (12 months post-treatment), favoring ABT. To address this

aim, we will fit, among sub-optimal responders, the following linear mixed model for the repeated weight loss measures at months 6 and 18 (t) nested within each participant (i):

$$\text{weight loss}_{it} = \gamma_{00} + \gamma_{10} \text{PCM} + \gamma_{01} 18\text{m} + \gamma_{11} \text{PCM} * 18\text{m} + \gamma_{*0}(\text{covariates}) + [u_{0i} + e_{it}],$$

where PCM indicates re-randomization to portion-controlled meals, 18m indicates the 18 month measurement, a series of parameters, γ_{*0} , will estimate relationships between pre-stage 2 covariates (e.g., sex, baseline BMI, timing of transition to second stage) and weight loss, with u_{0ij} and e_{it} estimating random between- and within-participant variances. Parameter γ_{10} estimates weight loss at 6 months among sub-optimal responders who augment with PCM relative to those who switch to ABT; whereas, γ_{11} estimates whether the difference in weight loss among PCM versus ABT sub-optimal responders is different at 18 months compared to at 6 months. The interaction parameter γ_{11} must be statistically significant for the primary hypothesis to be supported. Conclusions as to whether the shape of the interaction is consistent with predictions will be informed by two contrasts comparing weight loss at 6 and at 18 months between sub-optimal responders re-randomized to PCM or to ABT. The contrast with the smaller p-value will be tested $\alpha_2=0.025$, and the second tested at $\alpha_2=0.05$ to ensure a family-wise Type I error rate of 0.05.^{116–118}

The secondary aim analysis compares the two sub-optimal response definitions (timing of transition to second stage). The hypothesis is that participants randomized to the 3 week response assessment will lose more weight at 6 and 18 months relative to participants assessed at 7 weeks. The secondary analysis will also rely on a mixed model approach using 6 and 18 month weight loss measures from all randomized participants, such as,

$$\text{weight loss}_{it} = \gamma_{00} + \gamma_{20} 3\text{weeks} + \gamma_{*0}(\text{covariates}) + [u_{0i} + e_{it}].$$

In this model, weight loss will be predicted from fixed timing (γ_{20}) and person level covariate parameters and a random participant intercept (u_{0i}). A significant parameter γ_{02} will support the prediction that earlier response assessment results in more short- and long-term weight loss.

The exploratory third aim analyses explore moderators of the effect of sequences of treatment. We will use Q-Learning regression, an extension of moderated regression analysis for developing individualized sequences of treatment using data arising from a SMART. The overarching goal of this analysis is to empirically generate a candidate adaptive intervention that deeply tailors the decision to augment with PCMs or switch to ABT as a function of what type of sub-optimal responder the individual is. This analysis aims to take advantage of residual heterogeneity in the data among sub-optimal responders to SBT and generate an adaptive intervention that further optimizes weight loss. It is hypothesized that sub-optimal responders will vary in terms of their general and food-specific regulation, which can be used to tailor ABT or PCM. Specifically, it is hypothesized that sub-optimal responders (i) who are higher in general, but lower in food-specific, self-regulation will attain maximum weight loss under ABT, whereas (ii) those lower in general self-regulation will respond best to PCM. To implement Q-Learning, we will follow the approach in Nahum-Shani et al., for example using the qlaci package in R¹¹⁹ or the PROC QLEARN add-on for SAS.¹²⁰

Sample Size and Power Assumptions

Participants will be randomized equally to be assessed for response to SBT at Week 3 (n=250) or Week 7 (n=250). Analysis of weekly weight data from previous trials informed our expectation that 2.5% and 5.0% weight loss thresholds at weeks 3 and 7, respectively, would identify about 60% of participants as sub-optimal responders. Data from an estimated N=500 randomized * .60 sub-optimal response rate = 300 sub-optimal responders, equally re-randomized to second stage PCM (n=150) and ABT (n=150) treatment approaches, are expected to be available to test the primary hypothesis. The anticipated 90% retention rate at each measurement translates into $N \approx 300$ sub-optimal responders * 1.8 observations per person = 540 weight loss observations. Accounting for the design effect resulting from repeated within-person weight measures and anticipated $ICC_{non-resp}=.70$, the effective sample size for testing the significance of interaction parameter γ_{11} is approximately 346, or $346/4 \approx 86$ per group (PCM vs ABT). The minimum detectable standardized effect for γ_{11} at this sample size is Cohen's $d \approx .43$ (power=.80, $\alpha_2=.05$). Any combination of the difference in weight loss between PCM and ABT at 18 months that is about .43 standard deviations larger (or smaller) than the same difference at 6 months should be statistically significant (e.g., $d(PCM-ABT)=.24$ at 6m, $d(PCM-ABT)=-.20$ at 18m). The between groups contrasts at 6 and 18 months are powered to detect differences of $d=.38$ when $\alpha_2 = 0.025$ and $d=.34$ when $\alpha_2 = 0.05$. Participants in the preliminary analyses lost $M=21.5$ pounds ($SD=12.5$) at 6 months. A 5.4 pound difference in re-randomized treatment group differences at 6 and 18 months should be detectable as well as 4.3 and 4.8 pound differences at the 6 and 18 month measurements.

Discussion

This paper describes the study design and methods for the BestFIT trial, which utilizes the Sequential Multiple Assignment Randomized Trial (SMART) methodology to inform the development of an adaptive intervention that has potential to increase the number of people who achieve a clinically significant weight loss. In randomized controlled trials and real world clinical practice, it is widely recognized that there is no “one size fits all” intervention for most conditions, particularly chronic health issues such as obesity. This treatment response heterogeneity calls for the development of adaptive interventions that provide the right treatment (or sequence of treatments), at the right time, for the right person. SMART designs were developed explicitly to build optimal adaptive interventions by using experimental design principles to answer critical questions for adaptive interventions. SMART designs are increasingly being used to develop adaptive health interventions for a variety of health issues, primarily mental health and substance abuse.¹²¹ Although we are aware of one study utilizing a SMART design for adolescent weight management,¹²² the BestFIT trial is the first we are aware of that applies this innovative methodological approach to the challenges of adult behavioral weight loss intervention.

The BestFIT study will systematically evaluate two theoretically- and empirically-driven therapeutic approaches that address the underlying reasons people have difficulty adhering to behavioral weight loss interventions. We also examine the role of timing of intervention for sub-optimal responders to weight loss interventions. Previous trials evaluating stepped

care interventions designed to enhance outcomes among sub-optimal responders have not explicitly examined this issue. In addition to evaluating variations in timing and therapeutic approach for sub-optimal responders, we will examine the impact of different sequences of treatment as a function of participant baseline and time varying characteristics such food-specific self-regulation and general emotional- and self-regulation constructs. The novel Q learning approach¹²³ will be utilized for these exploratory analyses that will inform the development of a more “deeply tailored” adaptive intervention.

Several study design decisions will need to be considered when interpreting results from the BestFIT trial. First, the decision to provide rather than recommend pre-packaged meals was made in order to enhance compliance in order to better enable us to test the difference between portion-controlled meals and ABT for suboptimal responders. The choice of providing portion-controlled meals will limit our ability to generalize to other types of meal replacements and treatment contexts where pre-packaged meals/meal replacements could be utilized. Another consideration was whether to utilize group-based or individual weight loss treatment. Although there is some evidence that group-based treatment can be more beneficial,^{124–127} we chose to provide individual weight loss treatment because explicitly focusing on non-response and altering treatment course for participants who aren’t doing well can be a sensitive issue which could be exacerbated in the context of a group setting. This could particularly be the case for participants who are randomized to ABT which involves a switch in treatment. Indeed, an interesting area for future work is to understand the acceptability and feasibility of adaptive interventions in the context of group-based therapies.

Results of the BestFIT trial are expected to provide a strong evidence base for the construction of an individualized adaptive intervention for weight loss that will increase the number of adults who are able to lose clinically significant amounts of weight. The next step would be to evaluate the empirically informed adaptive intervention versus a standard behavioral treatment in the context of a traditional randomized clinical trial.¹²⁸

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References

1. Ogden CL, Carroll MD, Curtin LR, McDowell MA, Tabak CJ, Flegal KM. Prevalence of overweight and obesity in the United States, 1999–2004. *JAMA*. 2006; 295(13):1549–1555. [PubMed: 16595758]
2. Ogden, CL.; Carroll, MD.; Kit, BK.; Flegal, KM. Prevalence of obesity in the United States, 2009–2010. Hyattsville, MD: National Center for Health Statistics; 2012.
3. Ogden, CL.; Carroll, MD.; Kit, BK.; KM, F. Prevalence of Obesity Among Adults: United States, 2011–2012. Hyattsville, MD: National Center for Health Statistics; 2013.
4. Butryn ML, Webb V, Wadden TA. Behavioral treatment of obesity. *Psychiatr Clin North Am*. 2011; 34(4):841–859. [PubMed: 22098808]
5. Jeffery RW, Drenowski A, Epstein LH, et al. Long-term maintenance of weight loss: current status. *Health Psychol*. 2000; 19(1 Suppl):5–16. [PubMed: 10709944]

6. Unick JL, Jakicic JM, Marcus BH. Contribution of behavior intervention components to 24-month weight loss. *Med Sci Sports Exerc.* 2010; 42(4):745–753. [PubMed: 19952841]
7. Almirall D, Nahum-Shani I, Sherwood NE, Murphy SA. Introduction to SMART designs for the development of adaptive interventions: with application to weight loss research. *Translational behavioral medicine.* 2014; 4(3):260–274. [PubMed: 25264466]
8. Collins LM, Murphy SA, Bierman KL. A conceptual framework for adaptive preventive interventions. *Prev Sci.* 2004; 5(3):185–196. [PubMed: 15470938]
9. Abrams DB. Treatment issues in tobacco dependence: Towards a stepped-care model. *Tobacco Control.* 1993; 2(s):s17–s37.
10. The sixth report of the joint national committee on prevention, detection, and evaluation, and treatment of high blood pressure. NIH; 1997. NHLBI.
11. EaTiHBP EPoD. Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III). *JAMA.* 2001; 285(19):2486–2497. [PubMed: 11368702]
12. Wadden TA, Brownell KD, Foster GD. Obesity: responding to the global epidemic. *J Consult Clin Psychol.* 2002; 70(3):510–525. [PubMed: 12090366]
13. Carels RA, Darby L, Cacciapaglia HM, et al. Applying a stepped-care approach to the treatment of obesity. *J Psychosom Res.* 2005; 59(6):375–383. [PubMed: 16310019]
14. Carels RA, Darby L, Cacciapaglia HM, et al. Using motivational interviewing as a supplement to obesity treatment: a stepped-care approach. *Health Psychol.* 2007; 26(3):369–374. [PubMed: 17500624]
15. Jakicic JM, Tate DF, Lang W, et al. Effect of a stepped-care intervention approach on weight loss in adults: a randomized clinical trial. *JAMA.* 2012; 307(24):2617–2626. [PubMed: 22735431]
16. Carels RA, Young KM, Coit CB, et al. The failure of therapist assistance and stepped-care to improve weight loss outcomes. *Obesity (Silver Spring).* 2008; 16(6):1460–1462. [PubMed: 18356835]
17. Voils CI, Chang Y, Crandell J, Leeman J, Sandelowski M, Maciejewski ML. Informing the dosing of interventions in randomized trials. *Contemp Clin Trials.* 2012; 33(6):1225–1230. [PubMed: 22841930]
18. Lavori PW, Dawson R, Rush AJ. Flexible treatment strategies in chronic disease: clinical and research implications. *Biol Psychiatry.* 2000; 48(6):605–614. [PubMed: 11018231]
19. Lavori PW, Dawson R. Dynamic treatment regimes: practical design considerations. *Clin Trials.* 2004; 1(1):9–20. [PubMed: 16281458]
20. Murphy SA. An experimental design for the development of adaptive treatment strategies. *Stat Med.* 2005; 24(10):1455–1481. [PubMed: 15586395]
21. Lei H, Nahum-Shani I, Lynch K, Oslin D, Murphy SA. A "SMART" design for building individualized treatment sequences. *Annu Rev Clin Psychol.* 2012; 8:21–48. [PubMed: 22224838]
22. Saelens BE, Sallis JF, Frank LD, et al. Obesogenic neighborhood environments, child and parent obesity: the Neighborhood Impact on Kids study. *Am J Prev Med.* 2012; 42(5):e57–64. [PubMed: 22516504]
23. French SA, Story M, Jeffery RW. Environmental influences on eating and physical activity. *Annu Rev Public Health.* 2001; 22:309–335. [PubMed: 11274524]
24. Teixeira PJ, Mata J, Williams GC, Gorin AA, Lemieux S. Self-regulation, motivation, and psychosocial factors in weight management. *J Obes.* 2012; 2012:582348. [PubMed: 23209888]
25. Methods for voluntary weight loss and control. NIH Technology Assessment Conference Panel. Consensus Development Conference, 30 March to 1 April 1992. *Ann Intern Med.* 1993; 119(7 Pt 2):764–770. [PubMed: 8363212]
26. Teixeira PJ, Palmeira AL, Branco TL, et al. Who will lose weight? A reexamination of predictors of weight loss in women. *Int J Behav Nutr Phys Act.* 2004; 1(1):12. [PubMed: 15287984]
27. Johnson F, Pratt M, Wardle J. Dietary restraint and self-regulation in eating behavior. *Int J Obes (Lond).* 2012; 36(5):665–674. [PubMed: 21829162]

28. Leahey TM, Xu X, Unick J, Wing RR. A preliminary investigation of the role of self-control in behavioral weight loss treatment. *Obesity Research and Clinical Practice*. In press.
29. Wardle J, Carnell S. Appetite is a Heritable Phenotype Associated with Adiposity. *Ann Behav Med*. 2009
30. Stanek KM, Strain G, Devlin M, et al. Body mass index and neurocognitive functioning across the adult lifespan. *Neuropsychology*. 2013; 27(2):141–151. [PubMed: 23527642]
31. McNeill G, Avenell A, Campbell MK, et al. Effect of multivitamin and multimineral supplementation on cognitive function in men and women aged 65 years and over: a randomised controlled trial. *Nutr J*. 2007; 6:10. [PubMed: 17474991]
32. Fitzpatrick S, Gilbert S, Serpell L. Systematic review: are overweight and obese individuals impaired on behavioural tasks of executive functioning? *Neuropsychology review*. 2013; 23(2): 138–156. [PubMed: 23381140]
33. Jeffery RW, Wing RR, Thorson C, et al. Strengthening behavioral interventions for weight loss: a randomized trial of food provision and monetary incentives. *J Consult Clin Psychol*. 1993; 61(6): 1038–1045. [PubMed: 8113481]
34. Rock CL, Flatt SW, Sherwood NE, Karanja N, Pakiz B, Thomson CA. Effect of a free prepared meal and incentivized weight loss program on weight loss and weight loss maintenance in obese and overweight women: a randomized controlled trial. *JAMA*. 2010; 304(16):1803–1810. [PubMed: 20935338]
35. Wing RR, Jeffery RW, Burton LR, Thorson C, Nissinoff KS, Baxter JE. Food provision vs structured meal plans in the behavioral treatment of obesity. *Int J Obes Relat Metab Disord*. 1996; 20(1):56–62. [PubMed: 8788323]
36. Ashley JM, St. Jeor ST, Perumean-Chaney S, Schrage J, Bovee V. Meal Replacements in Weight Intervention. *Obes Res*. 2001; 9(90004):312S–320S. [PubMed: 11707559]
37. Sarwer DB, von Sydow Green A, Vetter ML, Wadden TA. Behavior therapy for obesity: where are we now? *Curr Opin Endocrinol Diabetes Obes*. 2009; 16(5):347–352. [PubMed: 19623061]
38. Wadden TA, Butryn ML, Byrne KJ. Efficacy of lifestyle modification for long-term weight control. *Obes Res*. 2004; 12(Suppl):151S–162S. [PubMed: 15687411]
39. Heymsfield SB, van Mierlo CA, van der Knaap HC, Heo M, Frier HI. Weight management using a meal replacement strategy: meta and pooling analysis from six studies. *Int J Obes Relat Metab Disord*. 2003; 27(5):537–549. [PubMed: 12704397]
40. Niemeier HM, Leahey T, Palm Reed K, Brown RA, Wing RR. An acceptance-based behavioral intervention for weight loss: a pilot study. *Behav Ther*. 2012; 43(2):427–435. [PubMed: 22440077]
41. 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. *Ann Behav Med*. 2009; 37(1):58–69. [PubMed: 19252962]
42. Juarascio A, Shaw J, Forman E, et al. Acceptance and commitment therapy as a novel treatment for eating disorders: an initial test of efficacy and mediation. *Behav Modif*. 2013; 37(4):459–489. [PubMed: 23475153]
43. Forman EM, Shaw JA, Goetter EM, Herbert JD, Park JA, Yuen EK. Long-term follow-up of a randomized controlled trial comparing acceptance and commitment therapy and standard cognitive behavior therapy for anxiety and depression. *Behav Ther*. 2012; 43(4):801–811. [PubMed: 23046782]
44. Forman EM, Herbert JD, Moitra E, Yeomans PD, Geller PA. A randomized controlled effectiveness trial of acceptance and commitment therapy and cognitive therapy for anxiety and depression. *Behav Modif*. 2007; 31(6):772–799. [PubMed: 17932235]
45. Powers MB, Zum Vorde Sive Vording MB, Emmelkamp PM. Acceptance and commitment therapy: a meta-analytic review. *Psychotherapy and psychosomatics*. 2009; 78(2):73–80. [PubMed: 19142046]
46. Hayes SC, Levin ME, Plumb-Villardaga J, Villatte JL, Pistorello J. Acceptance and commitment therapy and contextual behavioral science: examining the progress of a distinctive model of behavioral and cognitive therapy. *Behav Ther*. 2013; 44(2):180–198. [PubMed: 23611068]

47. Forman EM, Butryn ML. A new look at the science of weight control: how acceptance and commitment strategies can address the challenge of self-regulation. *Appetite*. 2015; 84:171–180. [PubMed: 25445199]
48. Commercial Weight-loss Products and Programs. [Accessed October 7, 2013] <http://www.obesityaction.org/obesity-treatments/commercial-programs>.
49. Forman EM, Hoffman KL, McGrath KB, Herbert JD, Brandsma LL, Lowe MR. A comparison of acceptance- and control-based strategies for coping with food cravings: an analog study. *Behav Res Ther*. 2007; 45(10):2372–2386. [PubMed: 17544361]
50. Forman EM, Hoffman KL, Juarascio AS, Butryn ML, Herbert JD. Comparison of acceptance-based and standard cognitive-based coping strategies for craving sweets in overweight and obese women. *Eat Behav*. 2013; 14(1):64–68. [PubMed: 23265404]
51. Hooper N, Sandoz EK, Ashton J, Clarke A, McHugh L. Comparing thought suppression and acceptance as coping techniques for food cravings. *Eat Behav*. 2012; 13(1):62–64. [PubMed: 22177399]
52. Forman EM, Butryn M, Hoffman KL, Herbert J. D An open trial of an acceptance-based behavioral treatment for weight loss. *Cogn Behav Pract*. 2009; 16:223–235.
53. Goodwin CL, Forman EM, Herbert JD, Butryn ML, Ledley GS. A pilot study examining the initial effectiveness of a brief acceptance-based behavior therapy for modifying diet and physical activity among cardiac patients. *Behav Modif*. 2012; 36(2):199–217. [PubMed: 22133992]
54. Butryn ML, Forman E, Hoffman K, Shaw J, Juarascio A. A pilot study of acceptance and commitment therapy for promotion of physical activity. *J Phys Act Health*. 2011; 8(4):516–522. [PubMed: 21597124]
55. Forman EM, Butryn ML, Juarascio AS, et al. The mind your health project: a randomized controlled trial of an innovative behavioral treatment for obesity. *Obesity (Silver Spring)*. 2013; 21(6):1119–1126. [PubMed: 23666772]
56. Carels RA, Wott CB, Young KM, et al. Successful weight loss with self-help: a stepped-care approach. *J Behav Med*. 2009; 32(6):503–509. [PubMed: 19521759]
57. Jeffery RW, Wing RR, Thorson C, Burton LR. Use of personal trainers and financial incentives to increase exercise in a behavioral weight-loss program. *J Consult Clin Psychol*. 1998; 66(5):777–783. [PubMed: 9803696]
58. Wing RR, Jeffery RW. Food provision as a strategy to promote weight loss. *Obes Res*. 2001; 9(Suppl 4):271S–275S. [PubMed: 11707553]
59. Jeffery R, Wing RR, Sherwood NE, Tate, DF Physical activity and weight loss: Does prescribing higher physical activity goals improve outcome? *Am J Clin Nutr*. 2003; 78(4):684–689. [PubMed: 14522725]
60. Wing RR, Jeffery RW. Prescribed "Breaks" as a Means to Disrupt Weight Control Efforts. *Obes Res*. 2003; 11(2):287–291. [PubMed: 12582226]
61. Jeffery RW, Kelly KM, Rothman AJ, Sherwood NE, Boutelle KN. The weight loss experience: a descriptive analysis. *Ann Behav Med*. 2004; 27(2):100–106. [PubMed: 15026294]
62. Wadden TA, West DS, Neiberg RH, et al. One-year weight losses in the Look AHEAD study: factors associated with success. *Obesity (Silver Spring)*. 2009; 17(4):713–722. [PubMed: 19180071]
63. Wadden TA, Neiberg RH, Wing RR, et al. Four-year weight losses in the Look AHEAD study: factors associated with long-term success. *Obesity (Silver Spring)*. 2011; 19(10):1987–1998. [PubMed: 21779086]
64. Ryan DH, Espeland MA, Foster GD, et al. Look AHEAD (Action for Health in Diabetes): design and methods for a clinical trial of weight loss for the prevention of cardiovascular disease in type 2 diabetes. *Control Clin Trials*. 2003; 24(5):610–628. [PubMed: 14500058]
65. Tate DF JR, Sherwood NE, Wing RR. *Am J Clin Nutr*. 2007 Apr;85(4):954-9.. Long-term weight losses associated with prescription of higher physical activity goals. Are higher levels of physical activity protective against weight regain? *Am J Clin Nutr*. 2007; 85(4):954–959. [PubMed: 17413092]

66. Jeffery RW, Wing RR, Sherwood NE, Tate D. Physical activity and weight loss: Does prescribing higher physical activity goals improve outcome? *American Journal of Clinical Nutrition*. 2003; 78(4):669–670. [PubMed: 14522721]
67. Levy RL, Jeffery RW, Langer SL, et al. Maintenance-tailored therapy vs. standard behavior therapy for 30-month maintenance of weight loss. *Prev Med*. 2010; 51(6):457–459. [PubMed: 20869984]
68. The Diabetes Prevention Program (DPP): description of lifestyle intervention. *Diabetes Care*. 2002; 25(12):2165–2171. [PubMed: 12453955]
69. Butryn ML, Phelan S, Hill JO, Wing RR. Consistent self-monitoring of weight: a key component of successful weight loss maintenance. *Obesity (Silver Spring)*. 2007; 15(12):3091–3096. [PubMed: 18198319]
70. Baker RC, Kirschenbaum DS. Self-monitoring may be necessary for successful weight control. *Behav Ther*. 1993; 24:377–394.
71. Carels RA, Darby LA, Rydin S, Douglass OM, Cacciapaglia HM, O'Brien WH. The relationship between self-monitoring, outcome expectancies, difficulties with eating and exercise, and physical activity and weight loss treatment outcomes. *Ann Behav Med*. 2005; 30(3):182–190. [PubMed: 16336069]
72. Linde JA, Jeffery RW, French SA, Pronk NP, Boyle RG. Self-weighing in weight gain prevention and weight loss trials. *Ann Behav Med*. 2005; 30(3):210–216. [PubMed: 16336072]
73. Boutelle KN, Kirschenbaum DS. Further support for consistent self-monitoring as a vital component of successful weight control. *Obes Res*. 1998; 6(3):219–224. [PubMed: 9618126]
74. Foster GD. Clinical implications for the treatment of obesity. *Obesity (Silver Spring)*. 2006; 14(Suppl 4):182S–185S. [PubMed: 16931504]
75. Perri MG, Nezu AM, McKelvey WF, Shermer RL, Renjilian DA, Viegner BJ. Relapse prevention training and problem-solving therapy in the long-term management of obesity. *J Consult Clin Psychol*. 2001; 69(4):722–726. [PubMed: 11550740]
76. Marlatt, G.; Gordon, J. Relapse prevention: maintenance strategies in the treatment of addictive behaviors. New York: Guilford Press; 1985.
77. Hayes, SC.; Strosahl, KD.; Wilson, KG. Acceptance and commitment therapy: An experiential approach to behavior change. New York, NY: Guilford Press; 1999.
78. Deci, E.; Ryan, R. Intrinsic Motivation and Self-Determination in Human Behavior. New York: Plenum; 1985.
79. Weiss BD, Mays MZ, Martz W, et al. Quick assessment of literacy in primary care: the newest vital sign. *Annals of family medicine*. 2005; 3(6):514–522. [PubMed: 16338915]
80. Osborn CY, Weiss BD, Davis TC, et al. Measuring adult literacy in health care: performance of the newest vital sign. *Am J Health Behav*. 2007; 31(Suppl 1):S36–S46. [PubMed: 17931135]
81. Paffenbarger R, Wing A, Hyde R. Paffenbarger physical activity questionnaire. *Am J Epidemiol*. 1978; 108:161–175. [PubMed: 707484]
82. Pereira M, SJ F, EW G, al E. A collection of physical activity questionnaires for health-related research. *Med Sci Sports Exerc*. 1997; 29:S1–S205. [PubMed: 9243481]
83. Harris J, French S, Jeffery R, McGovern P, Wing R. Dietary and physical activity correlates of longterm weight loss. *Obes Res*. 1994; 2:307–313. [PubMed: 16358394]
84. Foster GD, Wadden TA, Vogt RA, Brewer G. What is a reasonable weight loss? Patients' expectations and evaluations of obesity treatment outcomes. *J Consult Clin Psychol*. 1997; 65(1): 79–85. [PubMed: 9103737]
85. French SA, Jeffery RW, Folsom AR, Williamson DF, Byers T. History of intentional and unintentional weight loss in a population-based sample of women aged 55 to 69 years. *Obes Res*. 1995; 3(2):163–170. [PubMed: 7719962]
86. Wadden TA, Butryn ML, Sarwer DB, et al. Comparison of psychosocial status in treatment-seeking women with class III vs. class I–II obesity. *Surg Obes Relat Dis*. 2006; 2(2):138–145. [PubMed: 16925339]
87. Fairburn C, Cooper Z, O'Connor M. Eating Disorder Examination, Edition 17.0 D. The Center for Research on Dissemination at Oxford. 2014 [Accessed 01/16/2015]
88. Fairburn, CG. Cognitive behavior therapy and eating disorders. Guilford Press; 2008.

89. Gormally J, Black S, Daston S, Rardin D. The assessment of binge eating severity among obese persons. *Addict Behav.* 1982; 7(1):47–55. [PubMed: 7080884]
90. Timmerman G. Binge eating scale: Further assessment of validity and reliability. *Journal of Applied Biobehavioral Research.* 1999; 4:1–12.
91. Lowe MR, Butryn ML, Didie ER, et al. The Power of Food Scale. A new measure of the psychological influence of the food environment. *Appetite.* 2009; 53(1):114–118. [PubMed: 19500623]
92. Cappelleri JC, Bushmakina AG, Gerber RA, et al. Evaluating the Power of Food Scale in obese subjects and a general sample of individuals: development and measurement properties. *Int J Obes (Lond).* 2009; 33(8):913–922. [PubMed: 19506564]
93. Karlsson J, Persson LO, Sjostrom L, Sullivan M. Psychometric properties and factor structure of the Three-Factor Eating Questionnaire (TFEQ) in obese men and women. Results from the Swedish Obese Subjects (SOS) study. *Int J Obes Relat Metab Disord.* 2000; 24(12):1715–1725. [PubMed: 11126230]
94. Stunkard AJ, Messick S. The three-factor eating questionnaire to measure dietary restraint, disinhibition and hunger. *J Psychosom Res.* 1985; 29(1):71–83. [PubMed: 3981480]
95. Clark MM, Abrams DB, Niaura RS, Eaton CA, Rossi JS. Self-efficacy in weight management. *J Consult Clin Psychol.* 1991; 59(5):739–744. [PubMed: 1955608]
96. Bond FW, Hayes SC, Baer RA, et al. Preliminary psychometric properties of the Acceptance and Action Questionnaire-II: a revised measure of psychological inflexibility and experiential avoidance. *Behav Ther.* 2011; 42(4):676–688. [PubMed: 22035996]
97. Delis, DC.; Kaplan, E.; Kramer, JH. Delis-Kaplan Executive Function System (D-KEFS): Examiner's manual. San Antonio, TX: The Psychological Corporation; 2001.
98. Manasse SM, Juarascio AS, Forman EM, Berner LA, Butryn ML, Ruocco AC. Executive functioning in overweight individuals with and without loss-of-control eating. *Eur Eat Disord Rev.* 2014; 22(5):373–377. [PubMed: 24962637]
99. Higgs S, Rutter F, Thomas JM, Naish K, Humphreys GW. Top down modulation of attention to food cues via working memory. *Appetite.* 2012; 59(1):71–75. [PubMed: 22450523]
100. Riggs N, Chou CP, Spruijt-Metz D, Pentz MA. Executive cognitive function as a correlate and predictor of child food intake and physical activity. *Child Neuropsychol.* 2010; 16(3):279–292. [PubMed: 20234954]
101. Tulskey DS, Carlozzi N, Chiaravalloti ND, et al. NIH Toolbox Cognition Battery (NIHTB-CB): list sorting test to measure working memory. *Journal of the International Neuropsychological Society : JINS.* 2014; 20(6):599–610. [PubMed: 24959983]
102. Logan GD, Schachar RJ, Tannock R. Impulsivity and inhibitory control. *Psychological Science.* 1997; 8(1):60–64.
103. Nederkoorn C, Van Eijs Y, Jansen A. Restrained eaters act on impulse. *Personality and individual differences.* 2004; 37(8):1651–1658.
104. Nederkoorn C, Smulders FT, Havermans RC, Roefs A, Jansen A. Impulsivity in obese women. *Appetite.* 2006; 47(2):253–256. [PubMed: 16782231]
105. Lejuez CW, Read JP, Kahler CW, et al. Evaluation of a behavioral measure of risk taking: the Balloon Analogue Risk Task (BART). *Journal of Experimental Psychology: Applied.* 2002; 8(2): 75. [PubMed: 12075692]
106. Whiteside SP, Lynam DR, Miller JD, Reynolds SK. Validation of the UPPS impulsive behaviour scale: a four-factor model of impulsivity. *European Journal of Personality.* 2005; 19(7):559–574.
107. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med.* 2001; 16(9):606–613. [PubMed: 11556941]
108. Lowe B, Kroenke K, Herzog W, Grafe K. Measuring depression outcome with a brief self-report instrument: sensitivity to change of the Patient Health Questionnaire (PHQ-9). *Journal of affective disorders.* 2004; 81(1):61–66. [PubMed: 15183601]
109. Martin A, Rief W, Klaiberg A, Braehler E. Validity of the Brief Patient Health Questionnaire Mood Scale (PHQ-9) in the general population. *Gen Hosp Psychiatry.* 2006; 28(1):71–77. [PubMed: 16377369]

110. Unutzer J, Katon W, Callahan CM, et al. Collaborative care management of late-life depression in the primary care setting: a randomized controlled trial. *JAMA*. 2002; 288(22):2836–2845. [PubMed: 12472325]
111. Richards DA, Lovell K, Gilbody S, et al. Collaborative care for depression in UK primary care: a randomized controlled trial. *Psychological medicine*. 2008; 38(2):279–287. [PubMed: 17803837]
112. Richards DA, Hughes-Morley A, Hayes RA, et al. Collaborative Depression Trial (CADET): multicentre randomised controlled trial of collaborative care for depression--study protocol. *BMC health services research*. 2009; 9:188. [PubMed: 19832996]
113. Gensichen J, von Korff M, Peitz M, et al. Case management for depression by health care assistants in small primary care practices: a cluster randomized trial. *Ann Intern Med*. 2009; 151(6):369–378. [PubMed: 19755362]
114. Straus, MA.; Gelles, RJ.; Smith, C. Physical violence in American families: Risk factors and adaptations to violence in 8,145 families. New Brunswick, NJ: Transaction Publishers; 1990.
115. Mason SM, Flint AJ, Field AE, Austin SB, Rich-Edwards JW. Abuse victimization in childhood or adolescence and risk of food addiction in adult women. *Obesity*. 2013; 21(12):E775–E781. [PubMed: 23637085]
116. Holm S. A simple sequentially rejective multiple test procedure. *Scandinavian Journal of Statistics*. 1979; 6:65–70.
117. Lehmann, EL.; Romano, J. Generalizations of the Familywise Error Rate. In: Rojo, J., editor. *Selected Works of E. L. Lehmann*. Springer US; 2012. p. 719-735.
118. Keselman HJ, Miller CW, Holland B. Many tests of significance: new methods for controlling type I errors. *Psychol Methods*. 2011; 16(4):420–431. [PubMed: 22040371]
119. Ertefaie A, Almirall DA, Huang L, Dziak JJ, Wagner AT, Murphy SA. "qlaci" R package". University Park: The Methodology Center, Penn State. 2014 Retrieved from <http://methodology.psu.edu>.
120. Ertefaie A, Almirall DA, Huang L, Dziak JJ, Wagner AT, Murphy SA. SAS PROC QLEARN users' guide (Version 1.0) University Park The Methodology Center, Penn State. 2012 Retrieved from <http://methodology.psu.edu>.
121. Murphy SA, Lynch KG, Oslin D, McKay JR, TenHave T. Developing adaptive treatment strategies in substance abuse research. *Drug and Alcohol Dependence*. 2007; 88(Supplement 2(0)):S24–S30. [PubMed: 17056207]
122. Naar-King S, Ellis DA, Idalski Carcone A, et al. Sequential Multiple Assignment Randomized Trial (SMART) to Construct Weight Loss Interventions for African American Adolescents. *J Clin Child Adolesc Psychol*. 2015:1–14.
123. Nahum-Shani I, Qian M, Almirall D, et al. Q-learning: A data analysis method for constructing adaptive interventions. *Psychological Methods*. 2012; 17(4):478. [PubMed: 23025434]
124. Renjilian DA, Perri MG, Nezu AM, McKelvey WF, Shermer RL, Anton SD. Individual versus group therapy for obesity: effects of matching participants to their treatment preferences. *J Consult Clin Psychol*. 2001; 69(4):717–721. [PubMed: 11550739]
125. Minniti A, Bissoli L, Di Francesco V, et al. Individual versus group therapy for obesity: comparison of dropout rate and treatment outcome. *Eat Weight Disord*. 2007; 12(4):161–167. [PubMed: 18227637]
126. Cresci B, Tesi F, La Ferlita T, et al. Group versus individual cognitive-behavioral treatment for obesity: results after 36 months. *Eat Weight Disord*. 2007; 12(4):147–153. [PubMed: 18227635]
127. Befort CA, Donnelly JE, Sullivan DK, Ellerbeck EF, Perri MG. Group versus individual phone-based obesity treatment for rural women. *Eat Behav*. 2010; 11(1):11–17. [PubMed: 19962115]
128. Collins LM, Nahum-Shani I, Almirall D. Optimization of behavioral dynamic treatment regimens based on the sequential, multiple assignment, randomized trial (SMART). *Clin Trials*. 2014; 11(4):426–434. [PubMed: 24902922]

Figure 1.
Overview of the BestFIT Study Design.