Official Title: Evaluating Options for Non-Responders: A SMART Approach to Enhancing Weight Loss

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PROTOCOL TITLE:

Evaluating Options for Non-Responders: A SMART Approach to Enhancing Weight Loss (BestFIT Study)

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?

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ABBREVIATIONS/DEFINITIONS

Include any abbreviations or definitions for key or technical terms you use in your protocol.

- SBT: Standard Behavioral Treatment
- PCM: Portion-Controlled Meals
- ABT: Acceptance-Based Treatment

STUDY SUMMARY

Study Title	Evaluating Options for Non-Responders: A SMART Approach to Enhancing Weight Loss (BestFIT Study)
Study Design	Sequential Multiple Assignment Randomized Trial
Primary Objective	The primary aim is to evaluate the benefit of changing treatment with Portion-Controlled Meals versus Acceptance-Based Treatment.
Secondary Objective(s)	The secondary aim is to evaluate the best time to intervene with sub-optimal responders.
Primary Study Intervention or Interaction	Behavioral Weight Loss Treatment
Study Population	Adults with Obesity
Sample Size (number of participants)	500
Study Duration for Individual Participants	18 months

1.0 Objectives

1.1 Purpose:

The BestFIT trial is a Sequential Multiple Assignment Randomized Trial (SMART) that is evaluating two key questions for developing an adaptive intervention for weight loss. The first concerns variations in therapeutic approach for non-responders to behavioral weight loss treatment. Therapeutic choice should be informed by the reasons people struggle with weight loss initiation and self-regulation difficulties have been identified as a major adherence barrier. Two attractive options to meet this challenge are: 1) augmenting behavioral treatment with Portion-Controlled Meals(PCM) which reduce the need for self-regulation; and 2) switching therapeutic approaches by providing training in acceptance and commitment skills (ABT) which boost capacity for self-regulation. PCM's are effective, but not necessarily a "first line" of treatment. Research suggests ABT outperforms standard treatment for some vulnerable individuals also making it a potential "second line" of treatment. Of interest, PCM and ABT may have differential short- and long-term efficacy given their different mechanisms of action. The second question concerns the timing of an augmentation or switch in treatment. Waiting too long may be detrimental as people may experience a sense of futility regarding success. Yet, augmenting or switching too early may not allow enough time for the initial treatment to be effective. We propose to evaluate two time points: 1) 3 weeks based upon empirical decision support from prior weight loss trials and 2) 7 weeks based upon average duration used in the extant stepped care literature.

To systematically evaluate the impact of the therapeutic approach and timing for intervening with non-responders, we will recruit 500 adults (30 kg/m2 ≤ BMI ≤ 45 kg/m2). Participants will be randomized to either: 1) Standard Behavioral weight loss (SBT) treatment with response assessment at 3weeks or 2) SBT with response assessment at 7 weeks. Participants identified as non-responders at Week 3 and Week 7 will be re-randomized to either: "Augment with PCM's" or "Switch to ABT." Participants identified as responders at both time points continue with BWL. All participants receive 6 months of intervention; research assessments take place at baseline, 6- and 18-months (12 months post-treatment).

Primary Aim: To evaluate, among non-responders to SBT, the benefit of augmenting initial treatment with PCMs versus switching to ABT.

Hypothesis #1a & b: We hypothesize a) that non-responders randomized to "Augment with PCM" will weigh less at 6 months relative to those randomized to "Switch to ABT" (primary contrast), but that b) those randomized to "Switch to ABT" will weigh less at 12 months post-treatment relative to those randomized to "Augment with PCR" (secondary contrast).

Secondary Aim: To evaluate the optimal timing for identifying non-responders.

Hypothesis #2: We hypothesize participants who undergo response assessment at the earlier time point (3 weeks) will weigh less at 6 months and 12 months post-

treatment relative those who are undergo response assessment at the second time point (7 weeks).

Exploratory Aim: To make further progress toward building an individually-tailored adaptive intervention we will examine whether responsiveness to different sequences of treatment vary as a function of participant characteristics. For example, do non-responders who experience greater food-specific self-regulation challenges respond better to "Switch to ABT"? Do non-responders who experience greater general self-regulation challenges respond best to re-randomization to "Augment with PCM"?

2.0 Background

2.1 Significance of Research Question/Purpose:

State-of-the art behavioral interventions can help people lose 8-10% of body weight over a 6-month period, typically the nadir for weight loss efforts. However, about 40-60% of participating adults do not achieve this goal. Although long-term weight loss maintenance is also a challenge and has received considerable attention in recent years by our group and others, focusing explicitly on initial weight loss and increasing the number of people who are able to lose clinically significant amounts of weight is an important building block to improving overall outcomes for obese adults. Despite the response heterogeneity observed, a "one size fits all" approach has typically been taken with the same treatment intensity level and modality administered regardless of treatment response. This is a major limitation of current treatment approaches given that early signs of non-response are highly predictive of end-of-treatment non-response.

The consistent response heterogeneity that has been observed underscores the importance of developing adaptive interventions. Adaptive interventions are sequential, tailored approaches whereby intervention strategies are adapted and re-adapted over time in response to the evolving status and specific needs of the individual. To date, a stepped care (SC) approach, a type of adaptive intervention, has been investigated as a strategy for improving weight loss outcomes among non-responders. In a SC approach to treatment, patients are transitioned (stepped-up) to more intensive treatment when they are unable to meet treatment goals with less intensive treatment. While stepped-care approaches are generally successful in aiding weight loss, they have produced mixed or null results.

The application of a Sequential Multiple Assignment Randomized Trial (SMART) to behavioral weight loss intervention builds upon traditional stepped care designs and could lead to the development of more effective adaptive interventions. SMARTs have been developed explicitly for the purpose of building optimal adaptive interventions and use experimental design principles to obtain answers to challenging critical questions including the sequence of decision rules that specify whether, how, when, and based on which measures, to alter the intensity, dosage (e.g., duration, frequency or amount), type, or delivery of treatment(s) at critical decision points in the course of care. The application of

SMART designs to behavioral weight loss intervention has potential to address some of the limitations of traditional behavioral weight loss treatment outcome research, including stepped care designs, by experimentally testing competing interventions for non-responders. A SMART involves multiple intervention stages; each stage corresponds to one of the critical decisions involved in an adaptive intervention. Each participant moves through the multiple stages, and at each stage the participant is randomly (re)assigned to one of several intervention options. As in standard intervention trials, the randomization creates the opportunity to make valid causal inferences concerning the relative effectiveness of the intervention options without having to make unverifiable assumptions. Thus, utilizing a SMART design in the context of behavioral weight loss can provide critical empirical, experimental knowledge regarding which type of "stepped care" intervention strategy is most effective for a non-responder to a "first line" weight loss treatment and the optimal timing for offering an alternative treatment to such individuals.

2.2 Preliminary Data: *NA*

2.3 Existing Literature:

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. 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. Sequential Multiple Assignment Randomized Trial designs developed explicitly to build optimal adaptive interventions, use 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. Although we are aware of one study utilizing a SMART design for adolescent weight management (Clinical Trials Identifier: NCT01350531), the proposed trial is the first we are aware of that applies this innovative methodological approach to the challenges of behavioral weight loss interventions in adults.

The proposed SMART will systematically evaluate two theoretically- and empirically-driven therapeutic approaches ("Augment with PCMs" versus "Switch to ABT") that address the underlying reasons people may have difficulty adhering to behavioral weight loss interventions.

The proposed SMART is the first to systematically examine the role of timing of intervention for non-responders (3 weeks versus 7 weeks) to weight loss interventions. Previous stepped care trials designed to enhance outcomes among non-responders have not explicitly examined this issue.

In addition to evaluating variations in timing and therapeutic approach for non-responders, this SMART will also examine whether responsiveness to different sequences of treatment varies as a function of participant baseline and time varying characteristics that are relevant to the conceptual framework underlying the proposed trial and choice of options for non-responders. Specifically, our

measurement protocol includes measures of both food-specific self-regulation and general emotional- and self-regulation constructs. The novel Q learning approach will be utilized for these exploratory analyses that will inform the development of a more "deeply tailored" adaptive intervention.

Results of this SMART trial will lead to the empirically supported 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 will be to evaluate the empirically informed adaptive intervention versus a standard behavioral treatment in the context of a traditional randomized clinical trial.

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/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 is 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

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s):

NA

4.0 Study Intervention(s)/Interaction(s)

4.1 Description:

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 and emphasizes self-monitoring of eating and exercise, stimulus control strategies, goal setting, problem solving, addressing social situations, cognitive strategies, and relapse prevention. 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. 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 up to 17 weeks of pre-prepared fresh meals and those re-randomized at Week 7 will receive up to 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 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.

5.0 Procedures Involved

5.1 Study Design:

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.

5.2 Study Procedures:

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. Measures include:

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

Health Literacy. Health literacy is 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.

Physical Activity. The Paffenbarger Physical Activity Questionnaire is used to assess leisure-time physical activity.

Weight loss goals. A 4-item scale adapted from Foster et al. measures 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. Six items from the Weight and Lifestyle Inventory (WALI) will assess participant weight history.

Self-weighing frequency ("ranging from never" to "more than once a day") will be assessed with one item. 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.

Binge Eating Assessment. A semi-structured interview assessing the presence of binge eating disorder will be administered by trained interviewers.

Binge Eating. The Binge Eating Scale (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.

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

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.

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

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.

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. 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.

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.

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.

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

Depression symptoms will be assessed using the Patient History Questionnaire-9.

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

Adverse Health Events. Participants will report any adverse health events in the 6 months prior to the survey. Procedures to be performed for research purposes and, if relevant, which procedures would be performed regardless of whether the research was conducted, e.g., procedures performed for diagnostic or treatment purposes.

5.3 Follow-Up: *The data to be collected, including long-term follow-up data.*

All of the above measures will be collected at 6- and 18-month follow-up with the exception of the cognitive testing measures which will be collected at baseline only. Additionally, the interviews will be conducted at baseline and 6-months only.

5.4 Individually Identifiable Health Information: *If this research will involve the use of individually identifiable health information, either collecting or having access to, and including Protected Health Information complete and submit the University's Privacy Office online application for data privacy and security review. Print and upload the application with this protocol in Supporting Documents in the ETHOS SmartForm. Complete and submit a HIPAA authorization form if applicable in Supporting Documents in ETHOS: UMN Privacy Office Policies and/or Fairview Health Services Privacy Policies, and UMN HIPAA Agreement Templates. For research conducted at Gillette Children's Specialty Healthcare refer to Gillette Research Administration for guidance.*

NA

6.0 Data Banking

If this study does not involve data banking for future use, type "N/A" and delete the sub-headings below. Otherwise, complete all items below.

N/A

7.0 Sharing of Results with Participants

7.1 Describe whether results (study results or individual participant results, such as survey results) will be shared with participants or others (e.g., participants' parent or school administrators) and, if so, describe how the results will be shared.

Please see the Investigator Manual (HRP-103) for additional information about language that should be included in the consent form related to sharing of results.

We plan on sending a newsletter summarizing the study findings to participants when the study is complete.

8.0 Study Duration

8.1 Describe:

The anticipated duration of participation for each individual participant is 18 months. Enrollment began at the HealthPartners Institute in June 2015 and it is anticipated that enrollment will be complete in September 2017. The last 18-month data collection will be March 2019.

9.0 Study Population

9.1 Inclusion Criteria:

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.

9.2 Exclusion Criteria:

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.

9.3 Screening: *Describe how individuals will be screened or assessed for eligibility.*

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.

10.0 Vulnerable Populations

10.1 Vulnerable Populations: *Identify which of the following populations will be involved in this study. (You may not include members of the populations below as participants in your research unless you indicate this in your inclusion criteria above.)*

☐ Children
☐ Pregnant women/Fetuses/Neonates
☐ Prisoners
☐ Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders
☐ Approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.
☐ Disadvantaged in the distribution of social goods and services such as income, housing, or healthcare
☐ Serious health condition for which there are no satisfactory standard treatments
☐ Fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior)
☐ Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research
☐ Undervalued or disenfranchised social group
☐ Members of the military
☐ Non-English speakers
☐ Those unable to read (illiterate)
☐ Employees of the researcher
☐ Students of the researcher
☒ None of the above

10.2 Adults lacking capacity to consent and/or adults with diminished capacity to consent:

N/A

10.3 Additional Safeguards: *If the research involves individuals Checked in Section 10.1 above, provide justification for their inclusion and describe additional safeguards included to protect their rights and welfare.*

N/A.

11.0 Number of Participants

11.1 Number of Participants to be Consented:

500

11.2 Recruitment Methods

11.3 Recruitment Process:

All recruitment activities take place at the HealthPartners Institute and are conducted by HealthPartner Institute BestFIT study staff.

Potential participants are asked screening questions over the phone to assess their eligibility. Respondents who confirm eligibility and interest are invited to an orientation session during which they will learn more about the study and requirements of participation. BMI eligibility is determined at this visit based on staff-measured height and weight. Interested and eligible respondents 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. At the intake visit, informed is obtained and the baseline measures are collected.

11.4 Source of Participants:

Participants are recruited through several methods including radio advertisements, web-based advertisements, HealthPartners employee e-newsletters and website, and direct mailings to adults with a BMI > 30 kg/m^2 who attended a HealthPartners clinic during that past year that is located within several miles of the Institute. The study phone number and email address is included in the advertisements and those interested are directed to contact the study team using their preferred communication mode to indicate their interest.

11.5 Identification of Potential Participants:

As stated previously, participants are 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 is included in the advertisements and those interested are directed to contact the study team using their preferred communication mode to indicate their interest.

11.6 Recruitment Materials:

Recruitment materials include basic information about the study including that it is a weight loss study for adults and that the focus is on "finding the right weight loss treatment for the right person at the right time".

11.7 Payment:

Participants receive a $25 gift card at the 6-month measurement visit and a $50 gift card at the 18-month measurement visit. They also receive a $10 gift card for completing a 5-minute online survey at 12 months.

12.0 Withdrawal of Participants

12.1 Withdrawal Circumstances:

If there is any evidence that the participant is experiencing any adverse consequences we would communicate with the study participant and encourage him/her to discontinue participating.

12.2 Withdrawal Procedures:

If a participant is withdrawn we would not continue to collect any data on that participant.

12.3 Termination Procedures:

Study staff and/or the PI would have a conversation with the participant if termination was deemed to be the best solution. We would provide the study participant with any referral information as appropriate (e.g., other weight loss counseling resources).

13.0 Risks to Participants

For each risk or set of risks below, include the procedures to be performed to lessen the probability, magnitude, duration, or reversibility of those risks.

13.1 Foreseeable Risks:

Participants may feel embarrassed answering questions about their eating habits, mood, etc. We let participants know that they do not have to answer any questions that they do not want to answer. Participants also may experience disappointment if they do not lose as much weight as they would like to. We work very hard to help participants overcome barriers to their weight loss effort. This study is specifically designed to help "suboptimal responders" lose more weight by identifying them early and testing two different options to increase the likelihood that they will lose weight.

13.2 Reproduction Risks:

If a participant becomes pregnant during the course of the study we would discontinue intervention activities.

13.3 Risks to Others:

N/A

14.0 Incomplete Disclosure or Deception

14.1 Incomplete Disclosure or Deception:

N/A

15.0 Potential Benefits to Participants

15.1 Potential Benefits:

Participants may experience weight loss and associated health benefits.

16.0 Data Management

16.1 Data Analysis Plan: *Describe the data analysis plan, including any statistical procedures.*

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 α_2=0.025, and the second tested at α_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 R or the PROC QLEARN add-on for SAS.[1]

16.2 Power Analysis: *Provide a power analysis, if applicable.*

*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 ≈ 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 ICCnon-resp=.70, the effective sample size for testing the significance of interaction parameter γ11 is approximately 346, or 346/4 ≈ 86 per group (PCM vs ABT). The minimum detectable standardized effect for γ11 at this sample size is Cohen's d ≈ .43 (power=.80, α2=.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 α2 = 0.025 and d=.34 when α2 = 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.*

16.3 Data Integrity: *Describe any procedures that will be used for quality control of collected data.*

Data quality are routinely reviewed and cleaned by the study Project Manager.

17.0 Confidentiality

17.1 Data Security: *Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) for storage, use, and transmission of data.* ***Include also whether a copy of the consent form or other research study information will be placed in the participants' medical, employment, or educational records, and why that is appropriate (if so, this information must be included in the confidentiality section of the consent form).*** *Review the University's Privacy Office guidance on securing and de-identification of data.*

Data are housed on a secure, password-protected server at the HealthPartners Institute.

18.0 Provisions to Monitor the Data to Ensure the Safety of Participants

This section is required when research involves more than Minimal Risk to participants. If you believe that the study is not greater than Minimal Risk, type "N/A" and delete the sub-headings below. Otherwise, complete all items below. The IRB ultimately determines the risk level of the study.

18.1 Data Integrity Monitoring. This is a minimal risk study. However, we do have a Data Safety Monitor who annually reviews progress with respect to recruitment, retention, and adverse events.

18.2 Data Safety Monitoring

See 18.1

19.0 Provisions to Protect the Privacy Interests of Participants

19.1 Protecting Privacy: *Describe the steps that will be taken to protect participants' privacy interest. "Privacy interest" refers to a person's desire to place limits on with whom they interact or to whom they provide personal or sensitive information.*

Describe any privacy concerns and what steps you will take to make the participants feel more comfortable with the research situation in terms of the questions being asked and the procedures being performed. "Comfortable" does not refer to physical discomfort only, but to the sense of intrusiveness a participant might experience in response to questions, procedures, or interactions with researchers or in certain settings.

The following language is included in the consent form:

"The records of this study will be kept private. In any report that might be published or presented, only group data will be shown and no information will be included that will make it possible to identify a specific individual. Data about you will be identified only by a study number or code. We will keep all paper records in a locked filing cabinet in a locked office. Electronic records, including audio recordings, will be password-protected and available only to study personnel."

19.2 Access to Participants: *Explain why the research team is permitted to access medical records, student records, or any other sources of private information about the participants. (Note that you were asked a similar question above about access to information about potential participants. This item refers to information about participants who have consented to participate and about whom you are collecting research data.)*

NA

20.0 Compensation for Research-Related Injury

20.1 Compensation for Research-Related Injury: *If the research involves greater than Minimal Risk to participants, describe the available compensation in the event of research-related injury.*

NA

20.2 Contract Language: *Provide a copy of the contract language, if any, relevant to compensation for research-related injury.*

NA

21.0 Consent Process

Note: You must follow "SOP: Informed Consent Process for Research (HRP-090)" and "SOP: Written Documentation of Consent (HRP-091)."

21.1 Consent Process (when consent will be obtained): *Describe the consent process, including:*

- *Where the consent process will take place.*
    - *The consent process takes place at the HealthPartners Institute*
- *Any waiting period available between informing the prospective participants and obtaining the consent.*
    - *Participants first learn details about the study during a phone call with BestFIT study staff. Then they are invited to an orientation during which they learn more about the study and have a chance to ask questions. A post-orientation phone call takes place which provides another opportunity to ask questions. The consent is signed online at the beginning of their baseline measurement visit.*
- *Any process to ensure ongoing consent.*

    - *Participants attend weekly sessions and then are invited to participate in the measurement visits. Staff always make sure to emphasize that their continued participation is voluntary.*
- *If you will document consent in writing, submit a consent document in ETHOS. If you will obtain consent, but not document consent in writing, submit a consent script in ETHOS. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.*

21.2 Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception): *If you are not requesting a consent alteration or waiver, type "N/A" and delete the bullets below. Otherwise, complete all items below:*

- *NA*

21.3 Non-English Speaking Participants: *Indicate what language(s) other than English is/are understood by prospective participants or their representatives.*

NA

- *As identified in Section 10.1, if participants who do not speak English will be enrolled, describe the process to ensure that the oral or written information provided to those participants will be in their own language. Indicate the language that will be used by those obtaining consent.*
- *If you will be using a translator during recruitment, consent, data collection, or data analysis, specify how you will identify an appropriate translator and what the provisions will be for protecting the confidentiality of participants.*
- *Translated short forms are available on the UMN IRB website: https://www.research.umn.edu/irb/guidance/short-forms.html.*

21.4 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age):

NA

- *Describe the criteria that will be used to determine whether a prospective participant has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., in Minnesota, individuals under the age of 18 years.)*
    - *For research conducted in Minnesota, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

  - *For research conducted outside of Minnesota, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*
- *Describe whether parental permission will be obtained from:*
  - *Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*
  - *One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*
- *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.*
- *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.*
- *When assent of children is obtained describe whether and how it will be documented.*

21.5 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:

NA

- *Describe the process to determine whether an individual is capable of consent. Review "POLICY: Capacity to Consent (HRP-110)" and "POLICY: Research Involving Adults Under Court Jurisdiction (HRP-111)" for additional information. Reference "CHECKLIST: Cognitively Impaired Adults (HRP-417)."*
- *Confirm use of one of the approved validated instruments to assess capacity to consent appropriate for the level of risk associated with the research (i.e., the MacArthur Competence Assessment Tool for Clinical Research for greater than Minimal Risk research or the UCSD Brief Assessment of Capacity to Consent for Minimal Risk research). If you will not be using one of these tools, describe the alternative validated tool(s) you propose to use instead. If available in electronic format, submit the alternative tool(s) for review by the IRB in ETHOS.*
- *Document plans, if any, to avoid seeking consent during periods of greater than normal impairment.*

21.6 Adults Unable to Consent:

NA

- Permission: *List the individuals from whom permission will be obtained in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
  - *For research conducted in Minnesota, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "legally authorized representative." Additionally, be aware of special restrictions regarding recruiting or enrolling persons under a stay of commitment.*
  - *For research conducted outside of Minnesota, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*
- Assent: *Describe the process for assent of the participants. Indicate whether:*
  - *Assent will be required of all, some, or none of the participants. If some, indicate which participants will be required to assent and which will not.*
  - *If assent will not be obtained from some or all participants, an explanation of why not.*
  - *Describe whether assent of the participants will be documented and the process to document assent.*

22.0 Setting

22.1 International Research: *If the research will take place in more than one international location, include information below for each location.*

NA

22.2 Community Based Participatory Research: *If the research will be based in or in partnership with more than one community, include information below for each community.*

NA

22.3 Research Sites: *Describe the sites or locations where your research team will conduct the research.*

All research activities with study participants take place at the HealthPartners Institute. I oversee all aspects of study implementation along

with Dr. Lauren Crain who is Co-PI on the study, including providing supervision to intervention and measurement staff, however, BestFIT study team members are directly supervised by HealthPartners Institute employees. I will also be working on manuscripts and presentations once the baseline data collection is complete and then after all of the data is collected after the last participant's 18-month data collection visit. Data sent to the U will be a limited data set.

23.0 Multi-Site Research

NA

24.0 Resources Available

24.1 Resources Available: *Describe other resources available to conduct the research. For example, as appropriate:*

NA

25.0 References

Include references to any scholarly articles or other materials used to discuss the background for the study or to justify any proposed procedures.

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