Study Protocol for the Ignite Pilot Study

Goal-setting in a standalone, digital weight loss intervention: a pilot factorial trial

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1. Synopsis

Title:	Goal-setting in a standalone, digital weight loss intervention: a pilot factorial trial
Grant Number:	P30DK116074
Study Description:	This pilot optimization trial examines the impact of easier versus harder goals across 4 goal domains--calories, steps, eating window, Red Zone Foods--in a 10-week digital weight loss intervention for adults with overweight or obesity.
Objectives:	The purpose of the study is to evaluate the feasibility and acceptability of these goals.
Endpoints:	The behavioral intervention is 10 weeks in length and will not be terminated early based on efficacy. The study is expected to end after our target sample size is reached and the final participant has completed the intervention.
Study Population:	The study population will consist of adults (ages 18+) with body mass index (BMI) 25.0 to 45.0 kg/m^2 from a national sample of the general population.
Phase or Stage:	Multiphase Optimization Strategy: Preparation Phase
Description of Sites/Facilities Enrolling Participants:	All study procedures, including recruitment, intervention delivery, and assessment, will take place remotely.
Description of Study Intervention/ Experimental Manipulation:	All participants (N=32) receive a 10-week behavioral weight loss intervention that includes the following empirically-supported components: a weight loss goal of 5%, which is consistent with obesity treatment guidelines; daily self-monitoring of body weight, calories, steps, and eating window; daily to weekly self-monitoring of Red Zone Foods; weekly tailored feedback via email; and weekly behavioral lessons and action plans via email. Participants are randomized to 1 of 16 conditions that vary in receipt of easier versus harder goals across 4 different goal domains: calorie goal, step goal, eating window goal, and Red Zone Foods goal.
Study Duration:	The intervention will last 10 weeks.
Participant Duration:	Individual participants will complete study related tasks within 3 months after randomization.

2. Purpose, Background and Rationale

2.1 Objective

The overall goal is to examine the feasibility and acceptability of easier versus harder goals. If feasibility and acceptability are established, efficacy can be evaluated in a subsequent, fully-powered optimization trial. The overarching research question of this line of work is to determine the optimal goal setting intensities that maximize weight loss in a digital intervention for adults with overweight or obesity.

2.2 Aim

Aim 1. To evaluate the feasibility of the four types of goals and the other intervention components.

Aim 2. To determine the acceptability of the four types of goals and the other intervention components.

2.3 Background and Significance

2.3.1 Obesity

Obesity is a significant public health problem. Obesity has become a pervasive health concern in the United States, with rates of 42% among adults and another 30+% overweight. Excess weight heightens risk for chronic diseases, including type 2 diabetes, and can magnify psychological distress as a result of weight stigma. Behavioral weight loss interventions that involve frequent in-person meetings, diet and exercise goals, and behavioral strategies are the gold standard for treating overweight and obesity. These

traditional treatments are effective in producing weight loss up to 10%, but often lack scalability. This research is significant because it will optimize a behavioral weight loss intervention that has potential for broad reach and scalability.

2.3.2 Fully digital weight loss interventions

Digital health interventions that deliver treatment remotely seek to minimize burden and decrease costs compared to in-person interventions. With widespread penetration of smartphones among U.S. adults, digital health interventions have potential to reach booad geographic segments of the population. Compared to traditional interventions with counseling, *standalone* digital interventions offer greater scalability given lower personnel costs, and produce modest weight loss. However, weight loss tends to be modest; thus, more work is needed to enhance the efficacy of fully digital approaches.

2.3.3 Goal setting

Goal setting is a core component of behavioral obesity treatment. Goals can focus on behaviors (e.g., to exercise more) or outcomes (e.g., to lose weight). Many behavioral obesity treatments include goals for weight loss, physical activity, and calories, yet there is large variability in the specific intensities of these goals. Past research has shown that personalized goals are helpful at promoting behavior change, adaptive goals help more than static goals, immediate goals help more than gradual goals, and larger goals help more than smaller goals, However, to our knowledge, no study has examined the optimal goal intensity (i.e., harder versus easier goals) to be given in a fully digital weight loss intervention. Doing so would aid in identifying the most efficacious and least burdensome approach to goal setting in a highly scalable context.

2.4 Theoretical Framework

Self-regulation theories, including Social Cognitive Theory and Control Theory, posit that behavior change occurs through comparison of one's behavior to one's goals or past performance. Meta-analyses have demonstrated that goal setting, self-monitoring, and feedback work in tandem to promote greater behavior change and weight loss.

2.5 Using the Multiphase Optimization Strategy (MOST)

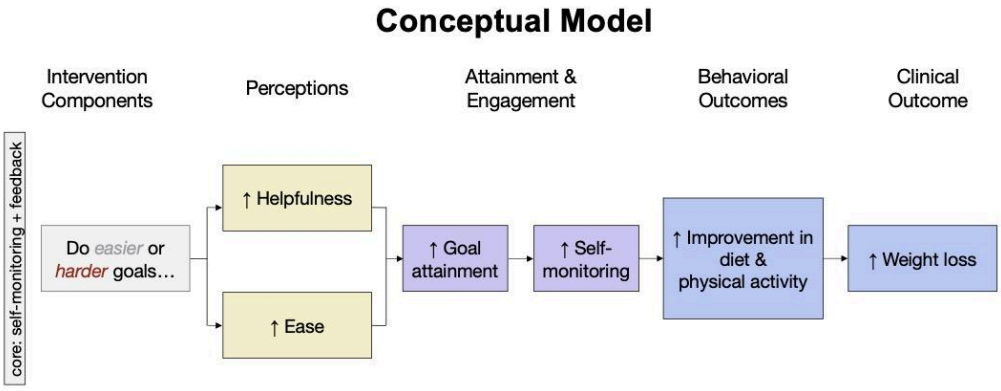
The Multiphase Optimization Strategy (MOST) is an engineering-inspired framework used for systematically constructing multicomponent behavioral interventions. MOST involves three phases: Preparation, Optimization, and Evaluation. In the Preparation phase, components and their respective levels of interest are identified and pilot tested. A conceptual model is created to depict how behavior change occurs through the various components and mechanisms. In the Optimization phase, the unique and combined effects of those components are evaluated in a fully-powered trial. Often, a factorial design is used. Components and component-levels that produce a minimal clinically important difference are retained in the newly optimized intervention, whereas those that produce minimal or iatrogenic effects are removed. Lastly, in the Evaluation phase, the newly optimized intervention is tested against a meaningful comparator to determine efficacy of the intervention package. The goal is to achieve intervention EASE, by balancing the Effectiveness of the intervention against other constraints such as Affordability, Scalability, and Efficiency.

2.6 Advancing Knowledge in the Field

No study, to our knowledge, has examined the optimal goal setting intensity in a fully digital weight loss intervention. Examining both the unique and combined effects of different goal intensities will enable creation of an intervention that maximizes weight loss while minimizing undue patient burden and effort.

3. Research Plan and Design

The study aim is to conduct a 10-week pilot optimization trial (N=32) using a factorial design to evaluate goal setting intensities (easier vs. harder) across 4 goal domains: calorie goal, step goal, eating window goal, and Red Zone Food goal in a fully digital weight loss intervention for adults with overweight/obesity. As shown in the conceptual model (**Figure**), participants will receive either an easier or harder version of 4 goals, and we will examine their effect on perceived helpfulness, perceived ease, goal attainment, self-monitoring engagement, and subsequently, diet and physical activity, and weight loss.



3.1 Overview

All participants will receive a core intervention and either an easier or harder version of 4 goal domains: calorie goal, step goal, eating window goal, and Red Zone Food goal. The intervention will last 10 weeks, with remote assessments at baseline, 4 weeks, and 10 weeks. All procedures, including the intervention and assessment, will occur remotely.

3.2 Study Design

This optimization trial will use a 2^4 full factorial design (i.e., 2x2x2x4) to test easier vs. harder versions of 4 goals. As shown in the **Table**, for each goal domain, half of participants will be randomly assigned to receive the easier version while the other half will receive the harder version. In total, participants will be randomized to 1 of 16 experimental conditions. A factorial trial compares means across c*ombinations* of conditions in order to test main effects of components and their interactions. For example, the main effect of calorie goal intensity is the mean for the participants who receive the easier version of it (i.e., experimental conditions 1-8) versus the mean of those who receive the harder version of it (i.e., conditions 9-16).

Experimental Condition	Core	Calorie Goal	Step Goal	Eating Window Goal	Red Zone Food Goal
1 A	Yes	Easier	Easier	Easier	Easier
2 B	Yes	Easier	Easier	Easier	Harder
3 C	Yes	Easier	Easier	Harder	Easier
4 D	Yes	Easier	Easier	Harder	Harder
5 E	Yes	Easier	Harder	Easier	Easier
6 F	Yes	Easier	Harder	Easier	Harder
7 G	Yes	Easier	Harder	Harder	Easier
8 H	Yes	Easier	Harder	Harder	Harder
9 I	Yes	Harder	Easier	Easier	Easier
10 J	Yes	Harder	Easier	Easier	Harder
11 K	Yes	Harder	Easier	Harder	Easier
12 L	Yes	Harder	Easier	Harder	Harder
13 M	Yes	Harder	Harder	Easier	Easier
14 N	Yes	Harder	Harder	Easier	Harder
15 O	Yes	Harder	Harder	Harder	Easier
16 P	Yes	Harder	Harder	Harder	Harder

3.3 Study Population

3.3.1 Recruitment

Participants will be recruited through several remote channels nationwide and in the San Francisco Bay Area: a) social media posts (Twitter and Facebook), b) research registries (ResearchMatch.org, a national registry of health research volunteers; ClinicalTrials.gov registry; the Stanford Diabetes Research Center's registry comprised of adults with pre-diabetes or type 2 diabetes, as well as healthy individuals); c) community advertisements (Nextdoor, Craigslist), and/or d) university-affiliated research websites. The target recruitment is 32 participants. Briefly, eligibility criteria

include: adults ≥18 years, body mass index (BMI) 25-45 kg/m², smartphone ownership, no recent weight loss ≥10 lbs., and no condition that contraindicates weight loss.

3.3.2 Retention

Retention will be maximized by reimbursing participants for their time spent on the 4-week and 1-week reassessments ($30, $30, respectively) and by providing an additional $20 for completion of dietary recall measures. Study staff will ask permission to collect multiple phone numbers, email addresses, and family or close friend contact information, and assess preferences for contact methods. Reminder text messages/emails will be sent prior to the remote evaluation visits and follow up with participants via various channels (text, phone, email) if they have yet to complete assessments.

3.3.3 Participant Eligibility Criteria

Inclusion Criteria	• adults (ages 18+ years) • body mass index (BMI) 25.0 to 45.0 kg/m² • smartphone ownership • willingness to install the Fitbit mobile app on their phone • access to a personal email account • English language proficiency • interest in losing weight through behavioral strategies • Living in the United States

Exclusion Criteria	• concurrent enrollment in another weight management intervention • loss of ≥10 lbs. in the past 6 months • current use of a weight loss medication • prior or planned bariatric surgery • current or planned pregnancy in the trial period • currently breastfeeding • lives with someone else participating in the study • hospitalization for a mental health condition in the past 12 months • inability to engage in moderate forms of physical activity akin to brisk walking • if weight loss is contraindicated or might be impacted by a condition or medication (e.g., end stage renal disease, cancer, schizophrenia, dementia, steroids, anti-psychotics) • if an individual would be better suited for a more intensive or different type of intervention based on a health condition (e.g., individuals with history of an eating disorder or cardiovascular event, uncontrolled hypertension, or uncontrolled diabetes mellitus) • investigator discretion for safety reasons

3.3.4 Screening and randomization

Recruitment materials will direct interested individuals to an online screening questionnaire (REDCap) that describes the study and assesses initial eligibility. Eligible candidates will then receive an email invitation to sign up for an initial remote visit and

complete an interactive orientation video. At this visit, trained study staff will confirm eligibility and describe study procedures. If individuals are interested in participating, study staff will obtain informed consent to assure that they fully understand the demands and nature of the study before enrolling. Next, study staff will help participants create a Fitbit account, and administer online baseline measures. Once completed, participants will be randomized to 1 of 16 experimental conditions via an algorithm on REDCap. Study staff will mail all participants an e-scale to obtain weight measurement along with a Fitbit activity monitor. Staff will email instructions for setting up the Fitbit app and syncing the e-scale and activity monitor devices, and provide the assigned intervention and corresponding program materials. Staff will troubleshoot, as needed.

3.3.5 Screen Failures

Participants who consent but then become ineligible prior to randomization will be asked to withdraw from the study and will not be randomized. Examples would include if a participant's baseline weight collected via the study-issued scale (after consenting) puts them out of range on the BMI criterion (i.e., no longer being in the 25.0-45.0 kg/m^2 range), or if a participant reports a pregnancy or exclusionary medical condition in the period between consent and randomization. All other reports of changes to eligibility criteria will be decided upon by study investigators prior to randomization.

3.3.6 Withdrawal/Termination Criteria

If after randomization and during the study period the participant no longer meets certain eligibility criteria, they will be asked to withdraw from the study. This includes

the following: if a participant becomes pregnant during the study; finding out that certain criteria were falsified or not reported (e.g., initial age, initial BMI, concurrent enrollment in another weight management intervention, a health condition that contraindicates weight loss or requires more intensive treatment), or investigator discretion for safety reasons.

Participants who become pregnant during the study period will be asked to leave the study. Changes in health behaviors and weight may not be healthy for a baby during pregnancy. Note that if a participant begins use of an antiobesity medication during the study, they will *not* be asked to withdraw from the study.

3.4 Core Intervention

All participants will receive a core intervention consisting of the following empirically- and theoretically- supported components shown to promote self-monitoring engagement:

Fitbit mobile app:

We will leverage an existing state-of-the-art app from Fitbit that is freely available on iPhone and Android platforms. At baseline, participants will install the mobile app.

Weight loss goal:

All participants will receive a goal to achieve 5% weight loss by 10 weeks, which is consistent with obesity treatment guidelines and equates to 0.5-2 lbs weight loss/week.

Self-monitoring diet:

Participants will be instructed to self-monitor their dietary intake daily via the Fitbit mobile app. This app allows users to track all foods and beverages consumed using a

built-in nutritional database, barcode scanner, or manual entry of individual recipes, and to view graphically their change in caloric intake.

Self-monitoring steps:

Participants will be instructed to self-monitor their step count daily via a wrist-worn Fitbit activity monitor (Fibit Inspire 3). The Fitbit activity monitor will be synced with the Fitbit app to allow participants to view their progress towards the step goal.

Self-monitoring weight:

Participants will be instructed to self-monitor their body weight daily via a wireless e-scale (the Fitbit Aria Scale). The e-scale will be synced with the Fitbit mobile app, providing real-time graphical feedback.

Self-monitoring eating window:

Participants will be instructed to self-monitor their prior day's eating window (start and stop times) every morning via a brief web-based survey (REDCap). They will receive immediate feedback as to whether they met their goal.

Self-monitoring Red Zone Foods:

Participants will be instructed to self-monitor their Red Zone Foods (highly caloric foods of limited nutritional value, such as ice cream and soda) via a brief web-based e-checklist (REDCap). They will receive this e-checklist daily in weeks 1 and 10 and weekly in weeks 2-9. They will receive immediate feedback as to whether they met their goal.

Tailored feedback:

Each week, participants will receive an email with tailored feedback pertaining to their progress on their assigned self-monitoring goals (described below) and other

intervention components. Feedback will be automatically generated using Microsoft Office's Mail Merge feature.

Behavioral skills training:

Each week, participants will receive an email with theory-informed skills training materials that include structured behavioral lessons on nutrition and physical activity as well as corresponding action plans. These materials will be adapted from our recent trials as well as from gold standard weight loss curricula. Lessons include topics such as reading nutrition labels and promoting physical activity. Embedded in this email will be a link to a brief action plan survey (Qualtrics) that incorporates motivational interviewing and problem-solving strategies. Specifically, participants will be prompted each week to reflect on their current behaviors and areas for change, generate actionable steps to change, identify confidence in doing so, and brainstorm potential barriers and support people

3.5 Experimental Intervention Components

Participants will be randomized to 1 of 16 conditions (**Table above**) that vary in their receipt of harder vs. easier goals across 4 goal domains. A 2^4 full factorial design will allow for all combinations to be tested.

Calorie goal (*easier* vs. *harder*). It is common in behavioral obesity treatment to assign a tailored calorie goal based on an individual's baseline height, weight, sex, age, and normal activity level, with a minimum of 1200 Calories (kcal)/day for women and 1500 kcal/day for men, based on national guidelines. In this pilot study, participants will be randomized to receive either an *easier* calorie goal (i.e., the tailored calorie goal plus

250 extra calories in daily budget) or a *harder* calorie goal (i.e., the standard calorie goal as is).

Step goal (*easier* vs. *harder*). In the baseline survey, participants will complete the Godin Lesiure-Time Exercise Questionnaire that will provide a leisure score index to be used determine their baseline activity level. Scores of 0-13 (interpreted as "Insufficiently Active") will be assigned a baseline goal of 5,000 steps per day, scores of 14-23 ("Moderately Active") will be assigned a baseline goal of 7,000 steps per day, and scores ≥24 ("Active") will be assigned a baseline goal of 10,000 steps per day. Participants will be randomized to receive either an *easier* step goal (i.e., this baseline step goal as is) or a harder step goal (i.e., this baseline step goal plus 1,500 steps). Beginning in week 2, this step goal will adapt each week based on the prior week's progress. Participants will receive a daily step goal of either the 40th (if easier) or 60th (if harder) percentile of the prior week's daily step count, rounded up to the nearest 500 steps.

Eating window goal (*easier* vs. *harder*). Limiting eating windows is the crux of time restricted eating. Participants who receive the easier version of this goal will be instructed to eat within a 12-hour window every day, while those receiving the harder version will be instructed to eat within a 9-hour window every day. Participants will be able to self-select at baseline their preferred eating window (e.g., 9 AM to 9 PM for someone in the easier version, or noon to 9 PM for someone in the harder version).

Red Zone Food goal (*easier* vs. *harder*). Limiting Red Zone Foods is intended to help lower caloric consumption, aiding in weight loss. Participants who receive the easier version of this goal will be instructed to eat no more than 5 Red Zone Foods every day,

while those receiving the harder version will be instructed to eat no more than 1 Red Zone Food every day.

3.6 Outcomes

3.6.1 Overview of Measures

The primary outcomes of this pilot study relate to the feasibility and acceptability of the various goals and their intensity levels. We will compare these outcomes to our a priori benchmarks listed in the **Table** below. Additional exploratory outcomes are also included in this table, and marked with an asterisk. The planned primary outcome for the subsequent fully-powered optimization trial is weight change. We will collect data on weight change in our pilot study. Based on prior research of digital weight loss interventions, we have set benchmarks for the 3% and 5% thresholds, which have been associated with improved cardiometabolic health. We will measure body weight using smart scales (Fitbit Aria Air) that automatically transmit data to the research team. The smart scales will be mailed to participants. Participants will be provided with best practices prior to each weight assessment: calibrate upon arrival; weigh in the AM without clothing, before eating/drinking, and after voiding. We will also administer behavior change measures that will be used in the subsequent optimization trial. In particular, dietary recalls will be measured using the Automated 24-Hour (ASA-24) Dietary Assessment Tool and physical activity will be measured using the GLTEQ self-report measure as well as objectively via the Fitbit Inspire 3 activity tracker to evaluate step count. We will also assess perceived ease of the goals.

3.6.2 Table of Benchmarks

Feasibility and Acceptability Metric	Benchmark to meet
Intervention engagement over 10 weeks	
% days of self-monitoring body weight, steps, dietary intake (assessed separately)	75%
% days of self-monitoring eating window*	75%
% days of self-monitoring Red Zone Foods (when instructed to do so)*	75%
% action plans completed; feedback emails read; lessons reviewed (assessed separately)*	80%
Goal attainment over 10-week intervention	
% of days meeting the daily calorie goal	75%
% of days meeting the daily step goal	75%
% of days meeting the daily eating window goal	75%
% of days meeting the daily Red Zone Food goal (when instructed to track them)	75%
% of days meeting the daily protein goal*	75%
Recruitment, retention, and survey completion	
% enrolled among those eligible from the online screen*	50%
% retention at 4 weeks*, 10 weeks	80%
% survey completion at baseline, 4 weeks*, 10 weeks	80%
Acceptability	
% of participants who would recommend the weight loss program to a friend who is trying to lose weight	80%
% of participants who indicated the [ ] goal was *moderately*, *very*, or *extremely* helpful (separately for all goals: calorie, steps, eating window, Red Zone Foods, protein, 10-week weight loss, weekly weight loss)*	80%

% of participants who indicated that tracking [ ] was *moderately*, *very*, or *extremely* helpful (assessed separately for all self-monitoring domains: weight, food, steps, weight)*	80%
% of participants who indicated that receiving a personalized progress report, lesson, action plan (assessed separately) was *moderately*, *very*, or *extremely* helpful*	80%
Clinically significant weight loss	
≥ 3% weight loss at 10 weeks*	At least 50% of participants
≥ 5% weight loss at 10 weeks*	At least 33% of participants

* indicates exploratory outcome (not reported on clinicaltrials.gov)

3.7 Data Collection

Data will be collected at baseline, 4 weeks, and 10 weeks. All data collection procedures will occur through remote means. Weights will be collected via e-scale, self-monitoring data will be collected objectively by the digital tools, and all other measures will be collected via online questionnaire (REDCap or a dietary recall tool). Fitabase software will be used to retrieve the objective self-monitoring data via Fitbit's API. At the time of each remote evaluation, participants will be emailed instructions for weighing themselves on their e-scales, and sent a link to the online survey to complete measures. Reminders will be sent if weights are not synced or surveys not completed.

3.7.1 Randomization and Masking

Following recommendations for factorial designs, we will randomize participants to the 16 conditions using permuted block randomization with a block size of 16. The

allocation sequence will be generated by the study's PI and stored in REDCap. Study staff will use REDCap to implement the random allocation sequence (i.e., randomize a participant) once both the baseline weight and web-based surveys are submitted. The first day of the weight loss intervention will occur approximately two days after randomization. On that day, participants will receive an automated email describing their treatment assignment. Participants will not masked to treatment assignment. Study staff will not be masked to treatment assignment due to logistical limitations and the need for quality assurance. However, all surveys will be sent via REDCap and completed without study staff involvement. In addition, study staff will not have access to the allocation sequence.

3.7.2 Quality Assurance

Participants enrolled in this study may not participate in other research studies where weight loss is targeted. In addition, participants will be asked to refrain from self-monitoring behaviors that are not assigned to them and refrain from using any other weight-related apps or activity trackers for the duration of the trial. By explaining the rationale of the study prior to enrollment and setting expectations upfront, we hope to keep compliance with these instructions high.

3.7.3 Research Ethics Approval

The Stanford Institutional Review Board has approved our study protocol.

3.7.4 Protocol Amendments

Protocol modifications will be communicated to all study investigators and approved by

the IRB prior to implementation, and the trial registry will be updated accordingly.

3.7.5 Declaration of Interests

The investigators report no competing interests.

3.8 Sample Size and Statistical Power

Aligning with recommendations for conducting pilot studies, the purpose of our proposed pilot study is to assess feasibility and acceptability of the intervention. As a result, no power analysis will be conducted. The sample size (n=32) was selected to have the same number of participants (n=2) per condition and allows us to meet budget and time restrictions.

3.9 Statistical Analysis

We will use descriptive data to assess feasibility and acceptability outcomes, and will compare them to our *a priori* feasibility benchmarks, outlined in the **Table** above. To evaluate exploratory changes in efficacy outcomes that will be evaluated in a larger-scale trial, we will descriptively assess the main effects of each goal-setting component being tested, along with their interactions. Unlike in an RCT that compares the means of each treatment arm to one another, a factorial trial compares the means across *combinations of experimental conditions* and uses the entire sample, which makes it an efficient and economical study design. For example, the main effect of the Calorie Goal intensity is calculated by computing the mean for the participants who receive the harder goal (i.e., those in experimental conditions 9-16 in the Table above) versus the mean of those who

receive the easier goal (i.e., those in experimental conditions 1-8), collapsed across the other factors. In a subsequent optimization trial, we will be powered to detect these effects.

3.10 Data Management

REDCap will be used for direct data entry, randomization, and tracking participants' status in the study.

3.11 Endpoint

The behavioral intervention is 10 weeks in length and will not be terminated early based on efficacy. The study is expected to end after we reach our target sample size and the final participant has completed the intervention.

4. Risks and Protection Against Risks

4.1 Potential Risks

Potential risks include: 1) breach of confidentiality; 2) psychological distress associated with answering questions about psychological or behavioral content (e.g., perceived stress level, weight bias, body weight) or engaging in the intervention; 3) medical risks associated with participating in a behavioral weight loss treatment. These risks are consistent with typical risks associated with research participation in behavioral weight loss studies and are expected to be minimal. There are no invasive procedures planned. We will monitor the occurrence of adverse events and serious adverse events as required for these types of intervention studies.

4.2 Safeguards to Minimize Risks

4.2.1 Participant Population and Screening

All participants will be adults with overweight/obesity who are otherwise healthy. Individuals who are pregnant or who have a medical condition that would limit participation in a behavioral weight loss intervention or be better suited for a more intensive or different type of intervention are excluded from our trial (e.g., individuals with a history of an eating disorder or cardiovascular event, uncontrolled diabetes mellitus or hypertension, cancer, dementia). Healthy volunteers are included to reduce the risk of any complications that could arise from participation in a behavioral weight loss intervention that is of lower intensity and remotely delivered. Risks to participants are anticipated to be low given that we are examining evidence-based intervention strategies and promoting weight loss through lifestyle change (e.g., decrease intake of unhealthy foods, increase steps). We will not be including a vulnerable population (e.g., children, pregnant women) as participants.

To ensure participant safety in this study, a set of screening procedures that are common in behavioral weight loss interventions, such as ensuring participants are safe to engage in moderate intensity physical activity and ensuring participants do not have a medical condition that is contraindicated in a remote weight loss program will be employed. The content of the weight loss intervention – including moderate-intensity physical activity and dietary change through reduction of unhealthy foods and increase of healthy foods – is commensurate with the current national guidelines for behavioral obesity treatment.

4.2.2 Study Team

The Principal Investigator will be responsible for regular monitoring of data All study procedures involving participant contact will be done by trained research personnel who have completed formal human subjects training (e.g., CITI Certification) to ensure understanding of methods and procedures to protect personal health information, and the importance of maintaining the confidentiality of study participants.

4.2.3 Adverse Events

Information will be collected on all potential types of adverse events, including musculo-skeletal soreness and injury, as well as major medical events including injuries or conditions that result in health care provider visits or hospitalization. Serious adverse events will be reported promptly in writing to the Stanford IRB, and all adverse events reported to the appropriate entities as required throughout the study.

Participants will be provided with contact information for the study team, including a study phone number and study email address that will be checked daily by the study's Research Assistant (RA) and/or the PI. This contact information will be provided to participants on multiple occasions, including in the informed consent form, in weekly intervention-related emails, and in the study evaluation emails sent at baseline, 4 weeks, and 10 weeks. In addition, participants will speak to study staff via phone/video conference at the beginning of the study (before randomization) to ensure eligibility, interest, and understanding of study procedures and assigned intervention components. During this call, participants will be encouraged to report any adverse events, serious adverse events, or discomforts that arise during the trial to the study team.

The RA will be the primary source of contact with participants (e.g., sending intervention materials and survey measures via email). The RA will alert the PI of any negative participant feedback. Based on participant feedback, the PI will revise the intervention and study procedures as necessary to ensure that risks of injury or discomfort are minimized and will seek IRB approval before doing so. All study personnel will have access to each other's contact information, including an email address and phone number, in a centralized database to facilitate easy communication.

4.2.4 Study Procedures

The consent forms and phone/Zoom-based conversations during the screening stage will include disclosures about the purpose of the study, the nature and content of study measures, and participants' rights to decline answering questions or discontinue participation at any time without ramification.

To minimize risks related to experiencing psychological discomfort, participants will be informed upfront of the types of survey questions and assessment measures to expect, and will be made aware they can skip any questions they do not feel comfortable answering with no impact on their participation or compensation. Any participants, including those who experience discomfort as a result of completing intervention components, are able to discontinue participation from the study at any time. We expect minimal adverse psychological effects.

4.2.5 Data Quality

Data quality will be assured by using standardized procedures via comprehensive intervention and assessment protocols. Dr. Patel will also closely monitor the data and will use IRB-approved documentation strategies of research procedures. Any updates to the protocol will first receive approval from the IRB before implementing.

4.3 Privacy

Confidentiality of participant data will be maintained by: 1) handling individual data by participant ID number, rather than by name; 2) storing all individual data in password protected files and electronic hard drives, and in encrypted data servers at Stanford; 3) not disclosing individual data to anyone other than trained study staff; 4) using the Stanford protected version of Qualtrics and REDCap, allowing encrypted transmission of all survey data; 5) presenting study findings in aggregate in publications, presentations, and all other dissemination efforts.

Investigators will be sensitive to issues surrounding confidentiality and other forms of participant risk, including discomfort surrounding talking about personal health issues and behaviors. The study team's onboarding will include a discussion of confidentiality and how this is to be maintained throughout the course of the study. All staff will have taken the required online human subjects course on this topic (e.g., CITI training). In addition, this topic will be regularly addressed during weekly staff meetings where staff will be encouraged to ask questions pertaining to this issue.

All study procedures will occur through remote means. Eligibility screening will initially occur via REDCap questionnaire, and confirmed by study personnel via 1:1 phone or Zoom conversation. Communications about the study and obtaining informed consent will also be conducted individually via phone or Zoom with a member of the study team. These communications will be conducted by a study staff member who is in a private, closed room. Participants will be requested to complete these sessions in a private, closed room when possible to protect their privacy. Only study team members will have access to the email account and telephone line used to communicate with participants. Participant data obtained during the study will be gathered by researchers who are HIPAA and CITI certified. Responses will be entered into a computer database that is password protected. Data will be stored on a remote server (not on a local hard drive) and will be encrypted and accessible only to select study investigators. Data will be coded. This study will impose minimal risk for participants. Confidentiality will be enhanced by assigning a unique participant ID number to each participant. Identifying information will be removed from these datasets; names will be replaced with pseudonyms prior to analysis.

5 Dissemination

5.1 Data Sharing Plan

The clinical trial is registered at ClinicalTrials.gov (NCT05715242) and information about the results will be submitted there for public posting. Results information will be submitted no later than one year after the trial's primary completion date. Consent

documents for this trial will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.

The Stanford University School of Medicine has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements. Specifically, the policy states that the PI will be the Responsible Party for registering, updating, and reporting results from the clinical trial in a timely manner. Registration was completed via the Stanford ClinicalTrials.gov Protocol Registration System (PRS).

Study results will be shared through presentations at national conferences of professional organizations (e.g., Society of Behavioral Medicine; The Obesity Society), submissions in peer-reviewed journals relevant to Dr. Patel's research, and postings on social media channels.

5.2 Access to Data

The principal investigator will retain access to the final trial data set.