Study Protocol for the Spark Trial

Grant Title:	Optimizing self-monitoring in a digital health intervention for weight loss
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Sponsor:	Stanford University
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Statement of Compliance

The trial will be conducted in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP), applicable United States (US) Code of Federal Regulations (CFR), and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Terms and Conditions of Award. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the funding agency and documented approval from the Institutional Review Board (IRB), and the Investigational New Drug (IND) or Investigational Device Exemption (IDE) sponsor, if applicable, except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.
The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

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Table of Contents

1. Synopsis

Grant Title:	Optimizing self-monitoring in a digital health intervention for weight loss
Study Description:	This optimization-RCT will examine the unique and combined efficacy of three self-monitoring strategies for weight loss -- tracking dietary intake, tracking steps, and tracking body weight -- all delivered through digital health tools. A 2x2x2 factorial design will be used, resulting in 8 conditions.
Objectives:	To identify the optimal combination of self-monitoring strategies that maximizes weight loss in a 6-month fully digital intervention for adults with overweight or obesity. Aim 1: Test the unique and combined effects of the three self-monitoring strategies on weight change from baseline to 6 months. Aim 2: Test the unique and combined effects of the three self-monitoring strategies on change in secondary outcomes from baseline to 6 months, including caloric intake, physical activity, BMI, and health-related quality of life, as well as weight change from baseline to 1 and 3 months, and proportion of participants who achieve ≥5% weight loss at 6 months.
Endpoints:	The behavioral intervention is 6 months 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 6 month intervention and assessment.
Study Population:	The sample (N=176) will consist of adults (ages 18+) with body mass index (BMI) 25.0 to 45.0 kg/m² from a nationwide sample of the U.S. population.
Phase or Stage:	Multiphase Optimization Strategy: Optimization Phase
Description of Sites:	All study procedures, including recruitment, intervention delivery, and assessments, will take place remotely.
Description of Study Intervention/ Experimental Manipulation:	All participants will receive a 6-month behavioral weight loss intervention that is delivered in a fully digital context without human counseling. Core components include a 10% weight loss goal and weekly behavioral lessons and action plans. Participants will be randomized to 1 of 8 conditions that vary in their receipt of 3 self-monitoring strategies. Participants randomized to track their dietary intake will be instructed to do so daily via the Fitbit app, and will receive a tailored calorie goal. Those randomized to track their steps will be instructed to do so daily via an activity tracker (Fitbit Inspire 3), and will receive an adaptive step goal. Participants randomized to track their body weight will be instructed to do so daily via an e-scale (Fitbit Aria Air scale) and will receive a weekly weight loss goal. Weekly tailored feedback on self-monitoring and goals will be provided.
Study Duration:	The intervention will last 6 months. We expect the study will require approximately 18-24 months for recruitment, intervention and data collection.
Participant Duration:	Individual participants will complete study related tasks within 6 months after randomization.

2. Purpose, Background and Rationale

2.1. Brief Summary

This optimization randomized clinical trial (i.e., “optimization-RCT”) will examine three self-monitoring strategies for weight loss -- tracking dietary intake, tracking steps, and tracking body weight -- all delivered through digital health tools. The purpose of the study is to evaluate the combination of these strategies that maximizes 6-month weight loss in the context of a fully digital health intervention for adults with overweight or obesity.

The investigators will recruit 176 total participants to the trial. Recruitment will occur through remote channels. Interested individuals will be directed to an online eligibility screen; those who are eligible will then be invited to attend an initial remote baseline session with study staff to ensure interest and eligibility in the study. The weight loss intervention will last 6 months, and all participants will receive a "core" intervention consisting of goal setting, behavioral lessons, and action plans - all of which will be delivered remotely. Using a 2x2x2 factorial design, participants will be randomized to receive 0-3 of the self-monitoring strategies. All study tasks will occur remotely, thus, participants never need to come in-person for any intervention or assessment tasks.

Investigators will use the Multiphase Optimization Strategy (MOST) framework to identify the most effective combination of self-monitoring strategies. The factorial design will allow the research team to determine the unique and combined impact of each self-monitoring component on outcomes. The primary outcome is weight change from baseline to 6 months. To complement the main trial, the research team will also randomize half of participants to receive an interactive orientation session, given prior to the consent process, in order to assess its impact on trial retention at 6 months. Overall, the information gathered from this trial will enable the construction of an optimized digital health intervention for weight loss that can be delivered remotely, which, if found to be effective, could have high potential for public health impact.

2.2 Objective

The overall goal is to identify the optimal combination of self-monitoring strategies that maximizes weight loss in a 6-month fully digital intervention for adults with overweight or obesity.

2.3 Aims

Aim 1: Test the unique and combined effects of the three self-monitoring strategies on

weight change from baseline to 6 months (primary outcome).

Aim 2: Test the unique and combined effects of the three self-monitoring strategies on change in secondary outcomes from baseline to 6 months, including caloric intake, physical activity, BMI, and health-related quality of life, as well as weight change from baseline to 1 and 3 months, and the proportion of participants who achieve ≥5% weight loss at 6 months.

2.4 Background and Significance

2.4.1 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[1] and another 30+% with overweight.[2] Excess weight heightens risk for chronic diseases,[3] including type 2 diabetes, and can magnify psychological distress as a result of weight stigma.[4] 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.[5] These traditional treatments are effective in producing weight loss up to 10%,[6] but often lack scalability.

2.4.2 Digital Interventions

Remotely-delivered interventions show promise, but need enhanced efficacy. Digital health interventions that deliver treatment remotely seek to minimize burden, decrease costs, and broaden reach, compared to in-person interventions. With widespread penetration of home broadband, regular phones, and smartphones among U.S. adults (77%,[7] 97%, and 85%,[8] respectively), digital health tools are increasingly being used in weight loss interventions, with promising efficacy.[9-13] Compared to traditional interventions with counseling, fully standalone digital interventions offer greater scalability given lower personnel costs. However, weight loss tends to be modest[14-15]; thus, more work is needed to enhance the impact of standalone digital approaches.

2.4.3 Self-Monitoring

Self-monitoring via digital health is effective at facilitating weight loss. Self-monitoring is a well-established method of facilitating weight loss for adults with overweight or obesity.[16-18] It involves tracking a behavior (e.g., diet, exercise) or behavioral outcome (e.g., body weight) and allows individuals to pay attention to their behaviors and gain feedback on how specific actions impact their weight.

2.5 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.[19-20] Self-monitoring is one of the strongest predictors of behavior change[21] and weight loss[22] and is thought to work by increasing self-regulatory skills and self-efficacy for making healthy changes.

However, self-monitoring engagement tends to decline over time with common barriers related to time demands, perceived burden, accessibility challenges, waning novelty, and literacy/numeracy constraints.[23,24] Fortunately, there are ways to promote self-monitoring engagement by using digital rather than paper based methods of self-monitoring,[16] and by incorporating theory-informed and empirically-supported self-regulation strategies such as goal setting, tailored feedback, and action planning. Meta-analyses have found that the effects of self-monitoring are magnified when adding these strategies.[25-27] Advantages of using digital platforms for self-monitoring include immediate personalized feedback, reduced tracking time with automated monitoring via devices like fitness trackers and e-scales, and high portability of mHealth tools, which increases the likelihood of use while reducing retrospective errors. A systematic review of 39 randomized trials examined digital self-monitoring strategies used in weight loss interventions and concluded that greater self-monitoring was positively associated with weight loss in over 70% of the reported associations.[16] This pattern was demonstrated across a range of digital health modalities and self-monitored behaviors. In sum, self-monitoring is a theory-informed and evidence-based approach for weight loss that can be delivered via digital tools.

2.6 The Multiphase Optimization Strategy (MOST)

It is important to have interventions that are both efficient and potent, with no extraneous components. Factorial designs can identify active ingredients of an intervention that contribute added impact as well as inactive components that are unnecessarily burdensome and potentially even detrimental. As such, a factorial design can be used to address which combination of self-monitoring strategies maximizes weight loss, and whether any synergistic or antagonistic effects exist, which occur when the combined effect of two or more intervention components is more or less favorable, respectively, than would be expected based solely on main effects.

MOST is an engineering-inspired framework that provides an opportunity for researchers to design effective and efficient multicomponent behavioral interventions.[28] MOST involves three phases: Preparation, Optimization, and Evaluation. First, the Preparation Phase consists of understanding gaps in the field, selecting intervention

components to test, and developing a conceptual model. Second, the Optimization Phase consists of conducting a fully powered optimization-RCT to rigorously test the intervention components' unique and combined effects on the outcome of interest. Third, a subsequent Evaluation Phase involves testing the newly optimized intervention versus a comparator in a traditional two-arm evaluation-RCT.

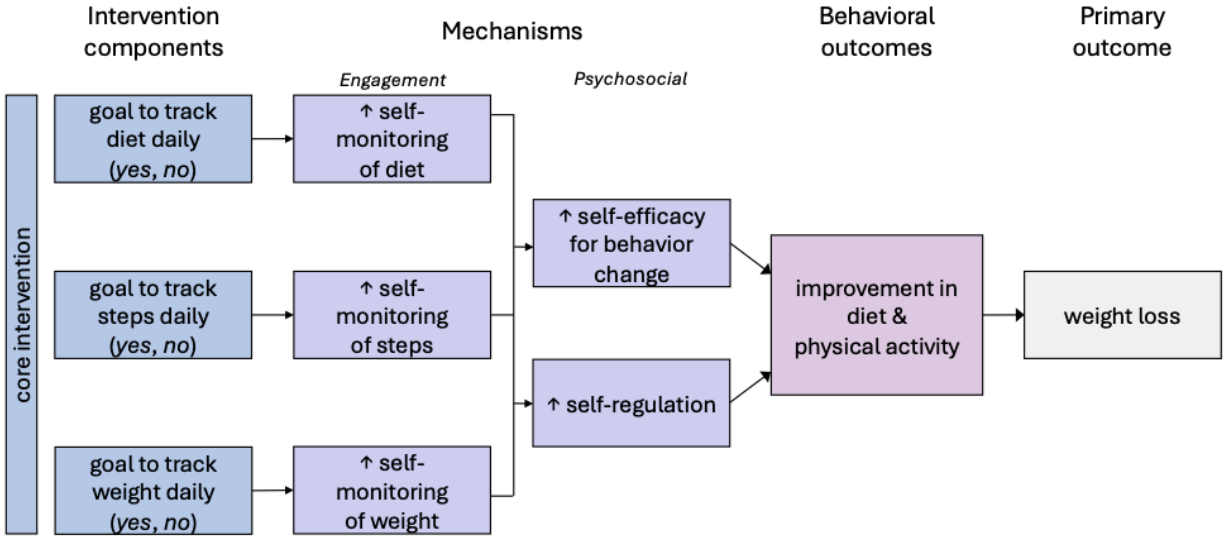
2.7 Gaps & Advancing Knowledge in the Field

No study has examined the optimal *combination* of self-monitoring strategies. While the value of self-monitoring has been demonstrated repeatedly, what remains unknown is which self-monitoring domains actually contribute the greatest amount to weight loss, and whether any combinations diminish weight loss and create undue burden. Examining the unique and combined impact of three popular self-monitoring strategies (diet, steps, and body weight) will allow an evidence-based intervention to be constructed that maximizes weight loss while minimizing undue patient burden.

3. Research Plan and Design

The study purpose is to conduct a 6-month optimization-RCT (N=176) using a factorial design to evaluate three self-monitoring components in a remotely-delivered weight loss intervention for adults with overweight/obesity. As shown in the conceptual model (**Figure 1**, below), participants will be randomized to one level of each of the three self-monitoring components: self-monitoring diet (yes, no); self-monitoring steps (yes, no); self-monitoring body weight (yes, no). Each component has an expected mechanism of action (i.e., increase self-monitoring engagement for its respective domain), which, in turn, is expected to enhance self-efficacy and self-regulatory skills, based on Social Cognitive Theory.[19] Together, these putative mediators are expected to improve healthy behaviors and decrease caloric intake, leading to weight loss.

Figure 1. Conceptual Model of the Spark Trial.



3.1 Overview

All participants will receive a core intervention and will be randomized to receive 0-3 self-monitoring components. The intervention is fully digital without human counseling and will last 6 months, with remote assessments at baseline, 1, 3, and 6 months.

3.2 Study Design

This optimization-RCT will use a 2^3 full factorial design (i.e., 2x2x2) to test three self-monitoring components. As shown in **Figure 2**, below, for each self-monitoring component, half of participants will be assigned to receive it ("Yes") while the other half will not ("No"). In total, participants will be randomized to 1 of 8 experimental

conditions. A factorial trial compares means across c*ombinations of conditions* in order to test main effects of components and their interactions.[28] For example, the main effect of 'Tracking Diet' is the mean weight change for the participants who receive this component (i.e., the "Yes's" in experimental conditions 5-8) versus the mean weight change of those who do not receive it (i.e., the "Nos" in conditions 1-4).

Figure 2. Factorial Design in the Spark Trial.

Experimental Condition	Core	Track Diet	Track Steps	Track Weight
1	Yes	No	No	No
2	Yes	No	No	Yes
3	Yes	No	Yes	No
4	Yes	No	Yes	Yes
5	Yes	Yes	No	No
6	Yes	Yes	No	Yes
7	Yes	Yes	Yes	No
8	Yes	Yes	Yes	Yes

3.3 Study Population

3.3.1 Recruitment

Participants will be recruited through several remote channels across the United States and in the San Francisco Bay Area, which may include the following: 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 d) university-affiliated research websites. The recruitment phase is expected to span up to 15 months and will accumulate a total of 176 participants. Briefly, eligibility criteria include: adults ≥18 years, body mass index (BMI) 25-45 kg/m^2, smartphone ownership, no recent weight loss ≥10 lbs., and no condition that contraindicates weight loss (see section 3.3.3 for more details).

Recruitment efforts will target at least 50% racial/ethnic minority group enrollment given that these groups are under-represented in behavioral obesity treatment research.[29-30] Further, populations who identify as Black and/or Hispanic have disproportionately higher rates of overweight/obesity.[2,31]

3.3.2 Retention

Retention will be maximized by reimbursing participants for their time spent on the 3- and 6-month remote assessments ($20 and $30 e-gift card, respectively) and by providing an additional $10 e-gift card for completion of all 4 dietary recalls (2 at baseline, 2 at 6 months). 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 assessments and follow up with participants via various channels (text, phone, email) if they have yet to complete assessments. Other tactics that we will use to help retain participants include staff available to troubleshoot, personalization of materials, use of technology for self-monitoring, use of a multiple-component intervention (e.g., self-monitoring plus feedback plus goals), and flexibility in participants' completion of remote assessments.

3.3.3 Participant Eligibility Criteria

Table 1. Inclusion and Exclusion Criteria in the Spark Trial.

Inclusion Criteria	• adults (ages 18+ years) • body mass index (BMI) 25.0 to 45.0 kg/m^2 • smartphone ownership • willingness to install a mobile app (Fitbit) on their phone • access to a personal email account • English language proficiency • interest in losing weight through behavioral strategies
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 • living 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 (e.g., end stage renal disease, cancer, schizophrenia, dementia) or medication (e.g., 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

3.4 Study Procedures

3.4.1 Screening and Orientation Session

All study procedures will occur through remote means. Recruitment materials will direct interested individuals to an online screening questionnaire (via REDCap) that describes the study and assesses initial eligibility. As part of an embedded experiment called a Study-Within-A-Trial ("SWAT"),[32] eligible candidates are then randomized 1:1 to either receive a self-directed orientation session or not receive it. Those assigned to receive it will be prompted to complete a 20-25 minute web-based orientation session consisting of video content and interactive activities designed to set expectations, explain the study rationale and details, visualize the time commitment, and ensure the trial is a good fit for their interests. At the end of the orientation session, those individuals will have the option to sign up for a baseline visit (see preregistration repository: protocol SWAT 211)[33]. The orientation session is modeled after the Methods-Motivational Interviewing approach,[34] which was developed to increase clinical trial retention.

3.4.2 Baseline Visit and Randomization

Individuals not randomized to receive the orientation session will receive an email invitation to sign up for a baseline visit. All participants will attend a baseline visit, regardless of orientation session assignment. At this baseline visit (~1-1.5 hours), 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 purpose of the study before enrolling. Next, study staff will help participants create a Fitbit account and download the Fitbit app. Study staff will then administer a web-based dietary recall, an oral health literacy assessment, and a web-based baseline survey. Once the survey is completed, study staff will mail all participants an e-scale to obtain baseline weight measurement. Once the e-scale is delivered, participants will receive an email that provides information on syncing their e-scale with the Fitbit app, and will be prompted to weigh themselves the following morning using a standardized protocol. Within the week after the baseline visit, a 2nd unannounced web-based dietary recall will be administered, with reminders sent if it is not completed.

Once the weight assessment is completed, participants will be randomized to 1 of 8 experimental conditions via an algorithm on REDCap. Study staff will mail an activity

tracker (Fitbit Inspire 3) within 2 business days to those randomized to the conditions with self-monitoring of steps (i.e., conditions 3, 4, 7, 8; **Figure 2**, above). Once the tracker is delivered, participants will receive instructions for syncing the tracker with the Fitbit app. Study staff will be available to troubleshoot with device syncing, as needed. Then, the weight loss intervention will begin -- participants will receive an automated email describing their assigned intervention.

Following recommendations for factorial designs,[35] we will randomize participants to the 8 conditions using restricted randomization. We will stratify by sex assigned at birth and use permuted block randomization with a block size of 8. The allocation sequence was generated using SAS by the study's statistician (JAG) 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 baseline surveys are submitted.

3.4.3 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 e-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), which may occur when their initial BMI that was calculated using self-reported weight put them on the edges of that 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.

3.4.4 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 a weight loss medication / antiobesity medication during the study, they will *not* be asked to withdraw from the study.

3.5 Core Intervention

All participants will receive a 6-month core intervention consisting of the following empirically- and theoretically- supported components:

Fitbit mobile app: Instead of designing our own app, we will leverage an existing state-of-the-art commercial app from Fitbit that is freely available on iPhone and Android platforms. At baseline, participants will install the app. The app will be set up by study staff so that it reflects only the self-monitoring components (tracking diet, steps, and/or weight) to which each participant is assigned. In-app graphical feedback allows participants to view their self-monitoring progress in real time.

Weight loss goal: All participants will receive a goal to achieve 10% weight loss by 6 months, which is consistent with obesity treatment guidelines[5] and equates to 0.5-2 lbs weight loss/week.

Tailored feedback: Each week, participants in conditions 2-8 will receive an email with tailored feedback pertaining to their progress on their assigned self-monitoring goals (described below). Feedback will be automatically generated using Fitbit data (retrieved from Fitabase) and constructed via 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[36-37] as well as from gold standard weight loss curricula.[38] 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[39-40] and problem-solving strategies.[41] 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.

3.6 Experimental Intervention Components

Self-monitoring diet (Yes vs. No): Participants randomized to receive this component 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. Participants will receive a tailored daily calorie goal using data reported at baseline: age, sex, weight, and height. For safety, a minimum of 1200 Calories (kcal)/day is set for women and 1500 kcal/day for men.[3]

Self-monitoring steps (Yes vs. No): Participants randomized to receive this component will be instructed to self-monitor their step count daily via a wrist-worn activity tracker (Fitbit Inspire 3). In conjunction with the self-monitoring goal, a tailored daily step goal will be given (e.g., 7,000 steps) that will adapt based on progress. The initial week's step goal will be based on the participant's baseline scores on the Godin Leisure-Time Exercise Questionnaire (GLTEQ) leisure score index,[42-43] with scores ranging from 0 to 13 (interpreted as *insufficiently active*) assigned to a goal of 5000 steps per day, scores of 14 to 23 (*moderately active*) assigned to 7000 steps per day, and scores ≥ 24 (*active*) assigned to 10,000 steps per day. Starting in the second week of the intervention, an adaptive step goal will be given using an empirically tested algorithm[44-45] whereby the 60th percentile of the past week's daily step counts, rounded up to the nearest multiple of 50, is assigned as the subsequent week's daily step goal. For example, a week with daily steps of 5000, 5100, 6000, 6500, 7000, 8200, and 8500 would result in a daily step goal of 6800 for the subsequent week. The new step goal will appear in each week's progress report. The Fitbit activity tracker will be synced with the Fitbit app to allow participants to view their progress towards the step goal.

Self-monitoring weight (Yes vs. No): Participants randomized to receive this component will be instructed to self-monitor their body weight daily via a Bluetooth enabled e-scale (the Fitbit Aria Air scale). These participants will receive a weekly weight loss goal of 0.5 to 2.0 lbs. (0.23 kg to 0.91 kg) per week, calculated as the magnitude of weight loss that is required to achieve 10% weight loss at 6 months. The e-scale will be synced with the Fitbit mobile app, providing graphical feedback.

3.7 Participant Requirements

Table 2. Participant Time Involvement.

- 10 minute online eligibility screen
- orientation video (~20-25 minutes), if randomized to view it
- baseline visit / informed consent: ~60-90 minutes
- active participation in the intervention: 6 months (~20 minutes of daily tracking of weight-related behaviors, and ~20-30 minutes/week of review of lessons and completion of action plans)
- 4 remote assessments: baseline, 1 month, 3 months, 6 months. The 1-month assessment is expected to be ~5 minutes. The 3 and 6-month assessments are expected to be 30-60 minutes each

3.8 Outcomes

All measures collected are listed in **Table 3**, below.

3.8.1 Primary Outcome

The primary outcome is weight change from baseline to 6 months (in kg), which will be assessed objectively via e-scale (Fitbit Aria Air) that will be mailed to participants. At each assessment, participants will receive an automated email in the morning instructing them to weigh themselves on the e-scale and follow best-practices[46]: place the scale on a hard, flat surface; remove all articles of clothing and accessories; weigh on the scale in the morning before eating or drinking and after emptying their bladder; step on the scale and record the value; and repeat it 2 more times for a total of 3 weight measurements per time point. Weights will sync from the e-scale to the Fitbit app via Bluetooth; as a preventive measure in case of syncing errors, participants will also be asked to input their weight values on a web-based weight check-in form. There is high concordance between weights measured from commercial e-scales and those from scales used in a clinical setting.[47-48]

3.8.2 Secondary and Exploratory Outcomes

Secondary outcomes include the following: 6-month change in caloric intake, physical activity, BMI, and health-related quality of life; 1- and 3-month weight change; and the proportion of participants achieving clinically significant weight loss (≥5% at 6 months). We will also examine additional outcomes: self-monitoring engagement rates and their relation to 6-month weight change; 6-month changes in diet quality; 6-month changes in step count among those assigned to self-monitor steps; the impact of potential moderators on 6-month weight change to determine for whom each self-monitoring strategy works best; and the impact of the orientation session on 6-month retention. In exploratory analyses, 6-month weight change data will be disaggregated by sex.

Caloric intake will be assessed via the Automated Self-Administered 24-hour (ASA24) Dietary Assessment Tool (version 2022 and 2024- beginning in April 2025), which is a free web-based tool developed by the National Cancer Institute.[49] Participants will be asked to complete a total of four 24-hour dietary recalls, including two at baseline and two at 6 months. At both time points, we will request one weekday recall and one weekend day recall. We will send up to 4 reminders per time point. We will exclude from our analyses any recalls with outliers of daily caloric intake reported as a minimum of <800 kcal for everyone, and a maximum of >4400 kcal for women and >5700 kcal for men, in accordance with ASA24 recommended procedures.[50] To compute caloric intake at each time point, we will calculate the mean of the weekday recall and the weekend-day recall; if only one recall is available at a given time point, we will use that

value. Diet quality will be assessed using the Healthy-Eating Index-2020,[51] calculated from ASA24 data.

Physical activity will be assessed via the GLTEQ, a self-report measure that assesses the past week's frequency of different types of exercise (strenuous, moderate, and mild or light) that were engaged in for more than 15 minutes during one's free time.[42-43] Strenuous activities are described as those where one's "heart beats rapidly" (e.g., running, jogging, or swimming), moderate activities are described as "not exhausting" (e.g., fast walking or tennis), and mild activities are described as requiring "minimal effort" (e.g., yoga or easy walking). A leisure score index will be created using the following formula: (strenuous ×9) + (moderate ×5) + (light ×3), with higher scores indicating more frequent exercise. To assess weekly moderate-to-vigorous physical activity (MVPA), a composite score will be created using the same procedures but excluding the light activities; from this MVPA score index, scores of ≥ 24 units will be interpreted as *active* and scores < 24 will be considered *insufficiently active*.[52] We will objectively assess step count using the Fitbit Inspire 3 activity tracker, among those assigned to track steps. We will operationalize the week 1 step count as the average of the first 7 days of the intervention and 6-month step count as the average of the last 7 days (week 26), so long as ≥ 3 valid days (≥1000 steps/day) per week are reported.[53]

Health-related quality of life (HRQoL) will be assessed using the 36-item Short Form Health Survey (SF-36),[54] with scores provided for both the physical component and mental component. It assesses 8 domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health.

Self-monitoring engagement will be assessed objectively for all 182 days (6 months) of the intervention using data collected from the Fitbit digital tools. Engagement will be operationalized as the percent of days in the intervention that participants self-monitor dietary intake, steps, and weight (each reported separately). For self-monitoring of diet, we will count days as valid if they have ≥ 800 kcal recorded, which is a common threshold. For self-monitoring of steps, we will count days as valid only if ≥ 1000 steps are recorded; this minimum threshold is used to minimize the possibility of inaccurately counting days with high amounts of non-wear time.[55] We will also assess engagement in other intervention components, including the percentage of action plans completed, which is objectively assessed via Qualtrics, with 100% indicating completion of all 19 action plans. Via self-report at 6 months, we will assess which of the 19 lessons were read and the frequency with which progress reports were reviewed, with options of *weekly*, *less than 1 time per week*, *less than 1 time per month*, and *never*.

Putative moderators will be assessed via self-report survey measures administered at baseline, including demographic (e.g., sex, age, education), psychosocial (e.g., stress,

self-efficacy), behavioral (e.g., pretreatment caloric intake and physical activity), and clinical (e.g., type 2 diabetes diagnosis) characteristics. A health literacy questionnaire, the Newest Vital Sign, will be administered orally by study staff at the baseline visit.[56]

Table 3. Assessment Schedule in the Spark Trial.

Construct	Measure or assessment tool	Time Point (months)			
		0	1	3	6
Anthropometric, behavioral, and demographic measures					
Weight (primary outcome)	E-scale (Fitbit Aria Air)[46-48]	•	•	•	•
Height	Self-reported[57]	•			
Caloric intake	ASA24 dietary recall (1 weekday, 1 weekend day)[49]	•			•
Diet quality	Healthy Eating Index,[51] measured by ASA24	•			
Physical activity	GLTEQ[42-43]	•	•	•	•
Physical activity guideline adherence	Stanford Leisure-Time Activity Categorical Item (L-Cat)[58]	•		•	•
Step count[a]	Activity tracker (Fitbit Inspire 3)	••••••••••••••••••••••••••			
History of self-monitoring	Self-reported use of self-monitoring of diet, steps, and weight in the month prior to study enrollment[59]	•			
Sociodemographic and clinical characteristics	Self-reported age, race/ethnicity, sex, gender, sexual identity, birth country, marital status, education, employment, income, household size, # children in home, prediabetes, type II diabetes, hypertension, smoking	•			
Engagement metrics					
% days of self-monitoring (diet, steps, weight)	Digital tools (Fitbit app, Fitbit Inspire 3 activity tracker, Fitbit Aria Air e-scale, respectively)	••••••••••••••••••••••••••			
% action plans completed	Action plans in Qualtrics	••••••••••••••••••••••••••			
% lessons read	Self-reported frequency of reading weekly lessons				•
Progress reports viewed	Self-reported frequency of viewing weekly progress reports				•
Psychosocial measures					
Health-related quality of life	SF-36[54]	•			•
Self-efficacy for dietary change	Weight Efficacy Lifestyle Questionnaire Short-Form (WEL-SF)[60]	•		•	•
Self-efficacy for exercise	Exercise Self-Efficacy Scale[61]	•		•	•
Self-regulation for eating	Three Factor Eating Questionnaire (TFEQ-R18)[62]	•		•	•
Sleep	Pittsburgh Sleep Quality Index (PSQI)[63]	•		•	•
Motivation	Treatment Self-Regulation Questionnaire (TSRQ)[64]	•		•	
Mastery for self-monitoring[b]	Self-Report Habit Index (SRHI) Automaticity subscale[65-66]		•		

Construct	Measure or assessment tool	Time Point (months)			
		0	1	3	6
Self-efficacy for self-monitoring[b]	Adapted from Bandura's self-efficacy measure[67] to assess self-efficacy for self-monitoring diet, steps, and weight	•	•		
Outcome expectations/ realizations	Outcome Expectations[68]	•			•
Confidence in participating fully	Investigator-designed 1-item measure to capture confidence in participating in weight loss intervention over next 6 months	•			
Health literacy	Newest Vital Sign (NVS)[56] via interview	•			
Weight bias internalization	Weight Bias Internalization Scale (WBIS)[69]	•			
Stress	Perceived Stress Scale (PSS-10)[70]	•			
Negative life events	Occurrence of negative life events over past 12 months	•			
Stages of change	Stages of change questionnaire in weight management (S-Weight)[71]	•			
Social support	Social Support for Diet & Exercise[72]	•			

[a] This outcome will be collected only in the conditions that were asked to track steps (conditions 3, 4, 7, 8).

[b] At the 1-month assessment, these measures will be specific to what domain is being self-monitored (i.e., diet, steps, weight). Only participants in the conditions that are asked to track a given domain will be administered those measures.

3.9 Data Collection

Data will be collected at baseline, 1, 3, and 6 months. 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, health literacy will be assessed orally, and all other measures will be collected via web-based questionnaire (REDCap and a dietary recall tool[49]). Fitabase software (Small Steps Lab, LLC) will be used to retrieve the objective self-monitoring data via Fitbit's API. At the time of each assessment, participants will be emailed instructions for weighing themselves on their e-scales, and sent a link to the web-based survey to complete measures. Reminders will be sent if weights are not reported or surveys not completed.

3.9.1 Masking

Participants will not be masked to treatment assignment, by design, as they will be informed before enrollment about the three types of self-monitoring to which they could be assigned. 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 study staff will not have access to the allocation sequence. Once all data are collected, the study statistician (JAG) will analyze the primary outcome (weight change) in a masked fashion such that treatment assignment will not be revealed.

3.9.2 Quality Assurance

Participants enrolled in this study may not concurrently 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. In the first 2 weeks of the intervention, study staff will verify whether participants are self-monitoring correctly by checking their Fitbit data. If a deviation is found, staff will flag it in REDCap, and the participant will receive an automated email reminder indicating what they are supposed to self-monitor or not self-monitor. By explaining the rationale of the study prior to enrollment, we hope to minimize contamination between conditions. It is common practice for control group participants to still have their weights assessed for study evaluation purposes even if they are not instructed to weigh regularly. In a prior trial testing a daily self-weighing intervention, all participants received a scale at baseline, and control participants were instructed to use the scale only at the assessment time points[73]; these procedures (which will be replicated here) were successfully enacted with no contamination found and negligible impact on outcomes.

3.9.3 Research Ethics Approval

The Stanford University Institutional Review Board (IRB) approved our study protocol on March 28, 2022. 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.

3.9.4 Declaration of Interests

The investigators report no competing interests.

3.10 Sample Size and Statistical Power

See **Statistical Analysis Plan** for the Spark Trial in a separate document.

3.11 Statistical Analysis

See **Statistical Analysis Plan** for the Spark Trial in a separate document.

3.12 Data Management

REDCap will be used for direct data entry, randomization, and tracking participants' status in the study. REDCap is a secure, web-based software platform for building and managing data, with a particular emphasis on those from clinical research studies.

There is a version hosted at Stanford University. Data will be stored on Stanford Medicine Box, which is a secure, cloud-based document management platform.

3.13 Endpoint

The behavioral intervention is 6 months 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 6 month intervention and assessment.

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). 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.

4.2.2 Minimizing Risks

This study is expected to impose minimal risk for participants. 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.

Communications about the study, confirmation of eligibility, and obtaining informed consent will be conducted via 1:1 phone or Zoom with a member of the study team (see ClinicalTrials.gov for the informed consent form). These communications will be conducted by a study staff member who is in a private room. Participants will be requested to complete these sessions in a private 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. Confidentiality will be enhanced by assigning a unique participant ID number to each participant. Identifying information will be removed from these datasets.

To minimize risks related to experiencing psychological discomfort, participants will be informed upfront of 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.

4.2.3 Data and Safety Monitoring Plan

The Principal Investigator (Dr. Patel) and Co-Investigator (Dr. King) will be responsible for regular monitoring of data and safety in conjunction with an Independent Safety Officer: David J. Maron, MD, Chief of the Stanford Prevention Research Center in the Stanford University School of Medicine. Dr. Maron is board certified in internal medicine, cardiovascular disease, and clinical lipidology and has extensive expertise in leading clinical trials. He will be responsible for reviewing clinical trial data, with particular emphasis on adverse events or clinical safety. As the Independent Safety Officer, Dr. Maron will not be involved in the study's design and conduct nor have any conflict of interests related to the trial. Based on his review of the data, he may propose modifications to the study.

Information that will be monitored by the PI include: (1) adverse events and serious adverse events (SAE) occurring during the study period for events both related and unrelated to the study procedures; (2) feedback from participants about discomfort they are experiencing as a result of completing intervention components; (3) feedback from participants about discomfort related to survey questions or other study procedures; (4) unexpectedly high weight change over time; and (5) any breach of confidentiality.

Dr. Patel will provide at least yearly updates to the investigator team regarding recruitment rates, enrollment rates, participant demographics, retention rates, adverse events, and any other substantive trial-related issues. All team members, including investigators, study staff, and students, will be listed on the IRB protocol and will have up-to-date ethics training (CITI certification). All study procedures involving participant contact will be done by trained research staff 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. Dr. Patel and her study team (Project Coordinator, Research Assistants) will meet weekly during the clinical trial period and will be able meet more frequently if needed.

4.2.4 Adverse Events

Definitions:

- Serious Adverse Event (SAE): Any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:
    - Results in death
    - Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
    - Requires inpatient hospitalization or prolongation of existing hospitalization
    - Results in a persistent or significant disability/incapacity
    - Results in a congenital anomaly/birth defect
    - Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition
    - Examples: chest pain; myocardial infarction (heart attack); stroke; kidney stones; knee replacement; car accident resulting in hospitalization; a fall resulting in hospitalization; fracture
- Unanticipated problem (UP) involving risks to subjects or others: Any incident, experience, or outcome that meets all the following criteria:
    - Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied
    - Related or possibly related to a subject's participation in the research

    - Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized
- a regular Adverse Event (AE): Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research
    - Examples: Skin irritation on wrist from wearing accelerometer wristband; migraine; back pain; knee pain; COVID-19 diagnosis; a cold

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 NIH and 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 on business days by study staff 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 assessment emails sent at baseline, 1 month, 3 months, and 6 months. 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.

Study staff will be the primary source of contact with participants (e.g., sending intervention materials and confirming completion of assessments). Study staff 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. Study staff will flag any unexpectedly high changes in weight and will notify the PI and Co-Investigator of this occurrence. The Independent Safety Officer will then be asked to review these outcomes and help decide next steps, such as whether a participant will be asked to drop out of the trial for safety reasons. Study staff will present all serious adverse events (SAE) and Unexpected Events to the PI by telephone or electronically within 24 hours of the time they are reported, except for life-threatening events where the expectation is that the PI will be alerted immediately. An internal project-specific report will be

generated in REDCap for each event reported. This information will be provided to the Stanford University IRB and NIDDK in a timely manner, in accordance with a protocol approved by the IRB and NIDDK. The study team will collect several channels of contact information for each participant (with their permission), including phone number(s) and e-mail address(es), along with those of a close friend or family member. In addition to standard study purposes, this contact information will be used to reach participants if additional information about an adverse event or SAE is needed. All study staff will have access to each other's contact information, including an email address and phone number, in a centralized database to facilitate easy communication.

4.2.5 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 meeting 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.

If data sharing is required, we will transfer data electronically in accordance with the following guidelines: Transmission of data will be done using File Transfer Protocol (FTP) and encrypted through the use of 128-bit SSL or other industry acceptable methods. Wireless communication will be encrypted using Wi-Fi Protected Access (WPA), VPN, or 128-bit SSL.

5 Dissemination

5.1 Data Sharing Plan

The clinical trial is registered at ClinicalTrials.gov (NCT05249465) 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).

Commensurate with current requirements, once the study data have undergone final data cleaning, analysis, and planned publications, we will make the final data collected as part of the proposed research available in electronic form to researchers who request them. We will request that researchers submit a data request in writing to the project Principal Investigator so that the requested data can be made available while protecting the confidentiality of study participants and ensuring that the proposed research questions do not overlap with planned publication development by the project research team or other groups. The requested dataset will be free of identifiers that would permit linkages to individual research participants and we will remove protected health information in compliance with the HIPAA Privacy Rule. The requestor must agree to maintain the privacy and confidentiality of the data and must indicate how they plan to store the data to demonstrate compliance with secure computing. NIH guidelines, institutional policies, IRB rules, and regulatory policies will be taken into account. Per NIH guidelines, all publications that emerge from this award will be publicly available via PubMed Central.

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

5.2 Access to Data

The principal investigator will retain access to the final trial dataset.

6. Protocol Amendment History

The Stanford University Institutional Review Board (IRB) approved our study protocol on March 28, 2022. Additional details were added to the study protocol prior to the trial beginning on September 22, 2023. No substantive changes to the IRB protocol were made once the trial began. Only minor protocol changes were made after this date, including the following, in **Table 4**, below:

Table 4. Protocol Amendments in the Spark Trial.

Version	Approval Date	Description of Change	Brief Rationale
1.0	Mar. 25, 2022	None (original IRB approval)	--
1.1	June 28, 2023	Changed Protocol Director to Michele Patel (from Abby King); added new team personnel; added David Maron as Independent Safety Officer; changed ASA24 recall reimbursement from $12 to $10; modifications to eligibility screen and surveys; added recruitment flyers; updated orientation slides	Dr. Patel submitted the IRB application as a postdoctoral fellow but is now an Instructor at Stanford; new study personnel joined the team; identified a Safety Officer without prior PI collaborations; modified incentives for ASA24 due to increased costs of shipping Fitbit devices; updated questions before trial deployment
1.2	Sept. 21, 2023	added new team personnel	New study personnel joined the team.
Trial began on September 22, 2023			
1.3	July 2, 2024	added StudyPages as an online recruitment source; added a new vendor for purchasing Fitbit devices; updated office address on the informed consent form; updated the Google and Fitbit Privacy Policy and Terms of Service documents; added new team personnel	Expand recruitment strategy; discontinuation of original Fitbit vendor; change in office address; change to Google and Fitbit legal documents; new study personnel joined the team.
1.4	Aug. 28, 2024	added new team personnel	New study personnel joined the team.
1.5	Dec. 13, 2024	added new team personnel	New study personnel joined the team.
1.6	June 12, 2025	Stylistic/typographical updates to the protocol and updated recruitment dates and ClinicalTrials.gov status information; added new version of ASA24	Improve readability of the document; provide actual recruitment dates; ASA24 retired version-2022 in April 2025
1.7	June 24, 2025	Added date of final data collection; added primary data collection row in synopsis; finalized stylistic/typographical updates	Spark trial has finished data collection; differentiate between primary data collection and completion of all other data collection

[As of June 12, 2025] No changes were made to our trial registration on ClinicalTrials.gov once the trial began on September 22, 2023.

7. References

1. Prevalence of obesity and severe obesity among adults: United States, 2017–2018. 2020. https://stacks.cdc.gov/view/cdc/85451.
2. National Center for Health Statistics: Obesity and Overweight. 2020; http://www.cdc.gov/nchs/fastats/obesity-overweight.htm.
3. Jensen M, Ryan D, Apovian C, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. *Circulation*. 2014;129(25 Suppl 2):S139-S140.
4. Puhl RM, Heuer CA. Obesity stigma: important considerations for public health. *Am J Public Health*. 2010;100(6):1019-1028.
5. Curry SJ, Krist AH, Owens DK, et al. Behavioral weight loss interventions to prevent obesity-related morbidity and mortality in adults: US Preventive Services Task Force recommendation statement. *JAMA*. 2018;320(11):1163-1171.
6. Butryn ML, Webb V, Wadden TA. Behavioral treatment of obesity. *Psychiatric Clinics*. 2011;34(4):841-859.
7. PEW. Mobile Technology and Home Broadband 2021. 2021; https://www.pewresearch.org/internet/2021/06/03/mobile-technology-and-home-broadband-2021/.
8. PEW. Mobile Fact Sheet. *Pew Research Center* 2021; https://www.pewresearch.org/internet/fact-sheet/mobile/.
9. Skinner R, Gonet V, Currie S, Hoddinott P, Dombrowski SU. A systematic review with meta-analyses of text message-delivered behaviour change interventions for weight loss and weight loss maintenance. *Obesity Reviews*. 2020;21(6):e12999.
10. Podina IR, Fodor LA. Critical review and meta-analysis of multicomponent behavioral e-health interventions for weight loss. *Health Psychology*. 2018;37(6):501.
11. Semper H, Povey R, Clark-Carter D. A systematic review of the effectiveness of smartphone applications that encourage dietary self-regulatory strategies for weight loss in overweight and obese adults. *Obesity reviews*. 2016;17(9):895-906.
12. Teasdale N, Elhussein A, Butcher F, et al. Systematic review and meta-analysis of remotely delivered interventions using self-monitoring or tailored feedback to change dietary behavior. *The American journal of clinical nutrition*. 2018;107(2):247-256.
13. Yen HY, Chiu HL. The effectiveness of wearable technologies as physical activity interventions in weight control: A systematic review and meta-analysis of randomized controlled trials. *Obesity Reviews*. 2019;20(10):1485-1493.
14. Tang JC, Abraham C, Greaves CJ, Nikolaou V. Self-directed interventions to promote weight loss: a systematic review and meta-analysis. *Health Psychol Rev*. 2016:1-15.
15. Schippers M, Adam P, Smolenski D, Wong H, Wit J. A meta-analysis of overall effects of weight loss interventions delivered via mobile phones and effect size differences according to delivery mode, personal contact, and intervention intensity and duration. *Obesity Reviews*. 2017;18(4):450-459.
16. Patel ML, Wakayama LN, Bennett GG. Self-Monitoring via Digital Health in Weight Loss Interventions: A Systematic Review Among Adults with Overweight or Obesity. *Obesity*. 2021;29(3):478-499.

17. Burke LE, Wang J, Sevick MA. Self-monitoring in weight loss: a systematic review of the literature. *Journal of the American Dietetic Association*. 2011;111(1):92-102.
18. Baker RC, Kirschenbaum DS. Self-monitoring may be necessary for successful weight control. *Behavior Therapy*. 1993;24(3):377-394.
19. Bandura A. Social cognitive theory of self-regulation. *Organizational behavior and human decision processes*. 1991;50(2):248-287.
20. Carver CS, Scheier MF. Control theory: A useful conceptual framework for personality–social, clinical, and health psychology. *Psychological bulletin*. 1982;92(1):111-135.
21. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. *Health Psychology*. 2009;28(6):690-701.
22. Hartmann-Boyce J, Johns D, Jebb S, Aveyard P. Effect of behavioural techniques and delivery mode on effectiveness of weight management: systematic review, meta-analysis and meta-regression. *Obesity Reviews*. 2014;15(7):598-609.
23. Burke LE, Swigart V, Warziski Turk M, Derro N, Ewing LJ. Experiences of self-monitoring: successes and struggles during treatment for weight loss. *Qualitative health research*. 2009;19(6):815-828.
24. Turner-McGrievy GM, Yang C-H, Monroe C, Pellegrini C, West DS. Is burden always bad? Emerging low-burden approaches to mobile dietary self-monitoring and the role burden plays with engagement. *Journal of Technology in Behavioral Science*. 2021;6(3):447-455.
25. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. *Health Psychology*. 2009;28(6):690-701.
26. Harkin B, Webb TL, Chang BP, et al. Does monitoring goal progress promote goal attainment? A meta-analysis of the experimental evidence. *Psychol Bull*. 2016;142(2):198-229.
27. Dombrowski SU, Sniehotta FF, Avenell A, Johnston M, MacLennan G, Araújo-Soares V. Identifying active ingredients in complex behavioural interventions for obese adults with obesity-related co-morbidities or additional risk factors for co-morbidities: a systematic review. *Health Psychol Rev*. 2012;6(1):7-32.
28. Collins LM. *Optimization of behavioral, biobehavioral, and biomedical interventions*. Springer; 2018.
29. Rosenbaum D, Piers A, Schumacher L, Kase C, Butryn M. Racial and ethnic minority enrollment in randomized clinical trials of behavioural weight loss utilizing technology: a systematic review. *Obesity Reviews*. 2017;18(7):808-817.
30. Haughton CF, Silfee VJ, Wang ML, et al. Racial/ethnic representation in lifestyle weight loss intervention studies in the United States: a systematic review. *Preventive medicine reports*. 2018;9:131-137.
31. Hales CM, Fryar CD, Carroll MD, Freedman DS, Aoki Y, Ogden CL. Differences in obesity prevalence by demographic characteristics and urbanization level among adults in the United States, 2013-2016. *Jama*. 2018;319(23):2419-2429.

32. Treweek S, Bevan S, Bower P, et al. Trial forge guidance 1: what is a study within a trial (SWAT)? *Trials*. 2018;19(1):1-5.

33. Patel ML. SWAT 211: Effects of a self-directed orientation session on retention in a digital weight loss study. *The Northern Ireland Network for Trials Methodology Research* 2023; https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/FileStore/Filetoupload,1950833,en.pdf.

34. Jake-Schoffman DE, Brown SD, Baiocchi M, et al. Methods-Motivational Interviewing Approach for enhanced retention and attendance. *Am J Prev Med*. 2021;61(4):606-617. doi:10.1016/j.amepre.2021.04.005

35. Gallis JA, Bennett GG, Steinberg DM, Askew S, Turner EL. Randomization procedures for multicomponent behavioral intervention factorial trials in the multiphase optimization strategy framework: challenges and recommendations. *Transl Behav Med*. 2019;9(6):1047-1056.

36. Patel ML, Hopkins CM, Brooks TL, Bennett GG. Comparing self-monitoring strategies for weight loss in a smartphone app: Randomized controlled trial. *Journal of medical Internet research*. 2019;21(2).

37. Bennett GG, Steinberg D, Askew S, et al. Effectiveness of an app and provider counseling for obesity treatment in primary care. *American journal of preventive medicine*. 2018;55(6):777-786.

38. National Diabetes Prevention Program: PreventT2 Curriculum and Handouts. 2018; https://www.cdc.gov/diabetes/prevention/lifestyle-program/curriculum.html. Accessed 4/1/2018.

39. Miller WR, Rollnick S. *Motivational interviewing: Helping people change*. Guilford press; 2012.

40. Patel ML, Wakayama LN, Bass MB, Breland JY. Motivational interviewing in eHealth and telehealth interventions for weight loss: A systematic review. *Prev Med*. 2019;126:105738.

41. Perri MG, Nezu AM, McKelvey WF, Shermer RL, Renjilian DA, Viegener BJ. Relapse prevention training and problem-solving therapy in the long-term management of obesity. *Journal of consulting and clinical psychology*. 2001;69(4):722.

42. Godin GS, R. Godin leisure-time exercise questionnaire. *Med Sci Sports Exerc*. 1997;29(6):S36-S38.

43. Godin G, Shephard R. A simple method to assess exercise behavior in the community. *Can J Appl Sport Sci*. 1985;10(3):141-146.

44. Adams MA, Sallis JF, Norman GJ, Hovell MF, Hekler EB, Perata E. An adaptive physical activity intervention for overweight adults: a randomized controlled trial. *PloS one*. 2013;8(12):e82901.

45. Adams MA, Todd M, Angadi SS, et al. Adaptive goals and reinforcement timing to increase physical activity in adults: a factorial randomized trial. *Am J Prev Med*. 2022;62(2):e57-e68.

46. Krukowski RA, Ross KM. Measuring weight with e-scales in clinical and research settings during the COVID-19 pandemic. *Obesity (Silver Spring)*. 2020;28(7):1182-1183.

47. Ross KM, Wing RR. Concordance of in-home 'smart'scale measurement with body weight measured in-person. *Obesity science & practice*. 2016;2(2):224-228.

48. Pebley K, Klesges R, Talcott G, Kocak M, Krukowski R. E-scale measurements in comparison to clinic weight measurements. *Obesity (Silver Spring)*. 2019;27:1107-1114.

49. Subar AF, Kirkpatrick SI, Mittl B, et al. The Automated Self-Administered 24-hour Dietary Recall (ASA24): a resource for researchers, clinicians and educators from the National Cancer Institute. *J Acad Nutr Diet*. 2012;112(8):1134.

50. Automated Self-Administered 24-Hour (ASA24) Dietary Assessment Tool. 2016; https://epi.grants.cancer.gov/asa24/.

51. Shams-White MM, Pannucci TE, Lerman JL, et al. Healthy eating index-2020: review and update process to reflect the dietary guidelines for Americans, 2020-2025. *J Acad Nutr Diet*. 2023;123(9):1280-1288.

52. Amireault S, Godin G. The Godin-Shephard leisure-time physical activity questionnaire: validity evidence supporting its use for classifying healthy adults into active and insufficiently active categories. *Perceptual and motor skills*. 2015;120(2):604-622.

53. Yao J, Tan CS, Lim N, Tan J, Chen C, Müller-Riemenschneider F. Number of daily measurements needed to estimate habitual step count levels using wrist-worn trackers and smartphones in 212,048 adults. *Scientific Reports*. 2021;11(1):9633.

54. Ware Jr JE. SF-36 health survey update. *Spine*. 2000;25(24):3130-3139.

55. Orstad SL, Gerchow L, Patel NR, et al. Defining valid activity monitor data: a multimethod analysis of weight-loss intervention participants' barriers to wear and first 100 days of physical activity. Paper presented at: Informatics2021.

56. Weiss BD, Mays MZ, Martz W, et al. Quick assessment of literacy in primary care: the newest vital sign. *The Annals of Family Medicine*. 2005;3(6):514-522.

57. Cui Z, Stevens J, Truesdale KP, Zeng D, French S, Gordon-Larsen P. Prediction of body mass index using concurrently self-reported or previously measured height and weight. *PloS one*. 2016;11(11):e0167288.

58. Kiernan M, Schoffman DE, Lee K, et al. The Stanford Leisure-Time Activity Categorical Item (L-Cat): a single categorical item sensitive to physical activity changes in overweight/obese women. *Int J Obes (Lond)*. 2013;37(12):1597-1602.

59. Linde JA, Rothman AJ, Baldwin AS, Jeffery RW. The impact of self-efficacy on behavior change and weight change among overweight participants in a weight loss trial. *Health Psychol*. 2006;25(3):282.

60. Clark MM, Abrams DB, Niaura RS, Eaton CA, Rossi JS. Self-efficacy in weight management. *J Consult Clin Psychol*. 1991;59(5):739-744.

61. Sallis JF, Pinski RB, Grossman RM, Patterson TL, Nader PR. The development of self-efficacy scales for health related diet and exercise behaviors. *Health Educ Res*. 1988;3(3):283-292.

62. Karlsson J, Persson L-O, Sjöström 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.

63. Buysse DJ, Reynolds III CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res*. 1989;28(2):193-213.

64. Levesque CS, Williams GC, Elliot D, Pickering MA, Bodenhamer B, Finley PJ. Validating the theoretical structure of the Treatment Self-Regulation Questionnaire (TSRQ) across three different health behaviors. *Health Educ Res*. 2007;22(5):691-702.

65. Verplanken B, Orbell S. Reflections on Past Behavior: A Self‐Report Index of Habit Strength. *J Appl Soc Psychol*. 2003;33(6):1313-1330.

66. Gardner B, Abraham C, Lally P, de Bruijn G-J. Towards parsimony in habit measurement: Testing the convergent and predictive validity of an automaticity subscale of the Self-Report Habit Index. *Int J Behav Nutr Phys Act*. 2012;9(1):1.

67. Bandura A. Guide for constructing self-efficacy scales. *Self-efficacy beliefs of adolescents*. 2006;5(1):307-337.

68. Neff K, King A. Exercise program adherence in older adults: The importance of achieving one's expected benefits. *Med Exerc Nutr Health*. 1995;4:355-362.

69. Durso LE, Latner JD. Understanding self‐directed stigma: development of the weight bias internalization scale. *Obesity*. 2008;16(S2):S80-S86.

70. Cohen S, Kamarck T, Mermelstein R. Perceived stress scale. *Measuring stress: A guide for health and social scientists*. 1994.

71. Andrés A, Saldaña C, Gómez‐Benito J. Establishing the stages and processes of change for weight loss by consensus of experts. *Obesity*. 2009;17(9):1717-1723.

72. Sallis JF, Grossman RM, Pinski RB, Patterson TL, Nader PR. The development of scales to measure social support for diet and exercise behaviors. *Prev Med*. 1987;16(6):825-836.

73. Steinberg DM, Tate DF, Bennett GG, Ennett S, Samuel-Hodge C, Ward DS. The efficacy of a daily self-weighing weight loss intervention using smart scales and e‐mail. *Obesity*. 2013;21(9):1789-1797.