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Study protocol for Log2Lose: A feasibility randomized controlled trial to evaluate financial incentives for dietary self-monitoring and interim weight loss in adults with obesity

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Abstract

The obesity epidemic has negative physical, psychological, and financial consequences. Despite the existence of effective behavioral weight loss interventions, many individuals do not achieve adequate weight loss, and most regain lost weight in the year following intervention. We report the rationale and design for a 2×2 factorial study that involves financial incentives for dietary self-monitoring (yes vs. no) and/or interim weight loss (yes vs. no). Outpatients with obesity participate in a 24-week, group-based weight loss intervention. All participants are asked to record their daily dietary and liquid intake on a smartphone application (app) and to weigh themselves daily at home on a study-provided cellular scale. An innovative information technology (IT) solution collates dietary data from the app and weight from the scale. Using these data, an algorithm classifies participants weekly according to whether they met their group's criteria to receive a cash reward ranging from \$0 to \$30 for dietary self-monitoring and/or interim weight loss. Notice of the reward is provided via text message, and credit is uploaded to a gift card. This pilot study will provide information on the feasibility of using this novel IT solution to provide variable-ratio financial incentives in real time via its effects on recruitment, intervention adherence, retention, and cost. This study will provide the foundation for a comprehensive, adequately-powered, randomized controlled trial to promote short-term weight loss and long-term

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weight maintenance. If efficacious, this approach could reduce the prevalence, adverse outcomes, and costs of obesity for millions of Americans.

More than one-third of the United States population is classified as obese (i.e., body mass index of at least 30 kg/m²).¹ The obesity epidemic has profound negative physical, psychological, and financial consequences.²⁻⁴ Despite the existence of efficacious behavioral weight loss interventions, there is variability in adherence to such interventions, contributing to variability in effectiveness. For example, some people do not achieve weight loss, while others lose less weight than necessary to see improvements in clinical parameters such as blood pressure and serum lipids. To improve adherence to weight loss interventions, novel behavioral strategies are needed.

One promising strategy is reinforcement via financial incentives. Reinforcement may be negative (removal of a disagreeable stimulus to increase desired behavior) or positive (addition of a reward to increase desired behavior) and may be delivered on a fixed-ratio (predictable) or variable-ratio (unpredictable) schedule.⁵ Positive reinforcement delivered on a variable-ratio schedule has theoretical and empirical support in several domains; however, few studies have examined it in the context of weight loss.⁶

A key issue is whether incentives should be provided directly for achieving a clinically desired outcome (i.e., weight loss) or for building behavioral skills that support weight loss, such as dietary self-monitoring.^{7,8} Incenting weight loss alone may not ensure that dietary self-monitoring will be learned because other, less enduring behavioral strategies (e.g., extreme caloric restriction) might be used in the short term. By the same token, incenting dietary self-monitoring alone does not ensure that sufficient weight loss will be achieved (e.g., individuals may continue to overeat even as they log their food and liquid intake). Therefore, incenting dietary self-monitoring and weight loss may be more effective than incenting either alone. Previous studies evaluating incentives for dietary self-monitoring and weight loss have included incentives for either outcome but not both and have provided incentives for weight loss achieved at the end of the study instead of interim weight loss (i.e., achieved during the intervention).⁹⁻¹⁴

To evaluate the effects of incenting dietary self-monitoring and/or interim weight loss, we must be able to incent them individually and in real time. In previous studies that incented these outcomes (primarily using schemes other than positive reinforcement on a variable schedule), participants had to attend in-person sessions to turn in self-monitoring records, be weighed, and receive their payments. This resulted in delayed payment and confounded receipt of reward with attendance.^{10,14} Our research leverages information technology that collates data from a smartphone application (app) and a body weight scale, transmitting results to the study team so that data can be processed remotely in real-time and eliminating the need to attend an in-person session to obtain incentives. We are conducting a planning study to evaluate the feasibility and acceptability of incenting dietary self-monitoring and interim weight loss. Results will be used to design and conduct a larger randomized controlled trial to examine efficacy. In this paper, we report on the study design and methods of the planning study.

Methods

Design

This 2×2 factorial planning study involves incentives for dietary self-monitoring (yes vs. no) and/or interim weight loss (yes vs. no) (see Table 1). One group receives incentives for both; one group just for daily self-monitoring; a third just for weight loss; and the fourth group does not receive incentives. We sequentially enroll three cohorts so that changes can be made to the protocol and tested in subsequent cohorts. In each cohort, four weight loss groups are created, one corresponding to each of the four study conditions. Weight loss program content is identical across all groups, such that the only difference between groups is the presence or absence of incentives. Within each group in each cohort, all participants receive the same incentive structure (i.e., same amount of incentive and same variable schedule) to minimize possible adverse effects associated with social comparison (contamination).

Setting, study population, recruitment, and enrollment

The study is being conducted at Duke University Medical Center in Durham, NC, where approval was received from the Institutional Review Board. Potential participants are recruited from the Durham community. Interested individuals call study staff to complete telephone screening. Those who meet the eligibility criteria (Table 2) are scheduled for an individual, in-person appointment with study staff. At that visit, patients provide written informed consent and complete a medical history to determine final eligibility. The first participant was recruited on May 6, 2016; enrollment was completed in September 2017, and the final outcome assessment is expected to occur in April of 2018.

Sample size considerations

As the goal of this planning study is not to establish efficacy of an intervention, we were not concerned with adequate power to detect significant effects of incentives on outcomes. Our sample size was based on what was feasible for the study timeline of three years and feasibility goals. We selected three cohorts because this allowed us to implement and evaluate changes to our recruitment procedures or study protocol if necessary. We selected a sample size of 32 per cohort (~8 per condition) to provide a reasonable number of participants per group to engender conversation and group dynamics. The data from this feasibility study will provide retention rates and mean and variance estimates of endpoints that can be used to design and power a future randomized controlled trial.

Randomization

After eligibility is confirmed at the screening visit, patients are randomized 1:1 to one of the four conditions using a computer-generated sequence accessible only by the study statistician. Study staff access the randomization assignment and inform patients of their group meeting time at the end of the screening session; in that call, patients are not told of their randomization assignment (i.e., whether they will receive incentives and for what). Therefore, they are not considered randomized until they attend the first group session. We

used this strategy in our previous study to minimize missing data associated with consented patients who never attend the intervention.¹⁵

Weight loss program

All participants receive a group-based behavioral intervention focusing on carbohydrate or caloric and fat restriction, depending on cohort. The low-carbohydrate diet (LCD) was selected for the first and third cohorts because it can lead to greater weight loss in the first several months, and no previous study of financial incentives has used the diet. The low-fat/low-calorie diet (LFD) was evaluated in the second cohort due to feedback received during the first cohort that the guidelines correspond more closely to the app interface (i.e., focus on portion size and caloric intake). Regardless of macronutrient focus, the initial protocol for the weight loss program is delivered for 24 weeks, with 12 in-person, 1.5-hour sessions every other week (except that an extra group session was added at week 1 in cohort 3, creating 13 total sessions for that cohort). The 24-week duration was chosen because patients can achieve clinically significant weight loss on these programs in that time, and maximum weight loss is typically achieved at 24 weeks, allowing for maximum separation between the four study conditions. The meeting frequency is based on our previously tested, effective dietary protocols and is consistent with the 2013 United States Preventive Services Task Force Obesity Guideline.¹⁶

Each group meets every two weeks on the same day of the week and at the same time of day. A registered dietitian leads all meetings. Upon arrival, participants are weighed and, if on the LCD, have their blood pressure measured. At the first meeting, participants create an individualized weight loss goal and receive a BodyTrace™ scale, a lay press diet book (*The New Atkins for a New You* for LCD, or American Heart Association's *No-Fad Diet: A Personal Plan for Healthy Weight Loss*, Second Edition for LFD), and handouts developed in our previous research.¹⁵ In the first meeting, participants are instructed to download MyFitnessPal™. This app is used for dietary self-monitoring because the interface is easy to use and the database is comprehensive. Participants were instructed to install the Fitbit app and tether MyFitnessPal to the Fitbit app. This allows us to retrieve data from the Fitbit app via their application programming interface (API) directly into our software platform, known as Prompt.

The first group session involves initial education about the app and the diet. In the LCD, carbohydrate intake is restricted to 20 grams per day. Caloric intake is specified as *ad libitum* instruction in an LCD because this typically leads to spontaneous calorie reduction.^{17,18} The diet begins with unlimited amounts of animal foods (meat, chicken, turkey, other fowl, fish, shellfish) and eggs, limited amounts of hard cheese, and limited servings of salad and low-carbohydrate vegetables. Artificial sweeteners can be used, whereas caffeine and alcohol are limited. Due to the diuresis that can occur, participants are warned of the symptoms of dehydration and instructed to drink adequate fluids to prevent dehydration. A cup of broth daily is recommended to prevent dehydration and to ensure adequate sodium levels. Participants are monitored for hypotension at the group visits and provided with contact information for the study physician, who is on 24-hour call.

In the LFD, total fat intake is restricted to less than 30% of daily energy intake, and saturated fat is restricted to less than 10% of daily energy intake. The diet consists mainly of complex starches (e.g., whole grain bread, pasta, rice), vegetables, fruits, lean meats (e.g., poultry and fish), and low-fat dairy products. We emphasize intake of whole grain over processed carbohydrates and vegetable oils (e.g., olive and canola oils) that contain high proportions of mono- and polyunsaturated fats rather than solid oils that contain *trans* fats (e.g., shortening). Each participant's daily calorie budget is calculated by subtracting 500 calories per day from the maintenance energy requirement for each individual using the Mifflin-St Jeor formula, as in our previous studies.^{15,19}

At every meeting, participants receive handouts that cover information specific to that session's topic. The first 15 minutes of each meeting are devoted to practicing behavioral goal setting using the protocol from a previous study.²⁰ Group members review goals set at the previous meeting, their level of success achieving those goals, and then refine their goals. To facilitate goal attainment, participants are instructed to log their daily food and liquid intake through MyFitnessPal. They are also asked to weigh themselves every day at the same time of day on their BodyTrace scales.

Incentive structure

Participants receive incentives for daily self-monitoring and/or interim weight loss, depending on their group assignment (Table 1). Our incentive schedule is informed by several learning theory principles. First, we are using primarily a variable-ratio incentive schedule, whereby the timing and amount of incentive is unpredictable to participants. Participants in groups A, B and C are eligible to receive incentives each of the first four weeks because learning new behaviors is facilitated by initial continuous reinforcement; however, the amount varies during these weeks, as it does throughout the study. From weeks 5–24, incentives are delivered intermittently due to the beneficial impact a variable schedule has on maintenance of behaviors;⁶ In other words, some weeks there is no incentive awarded to anyone in any group, regardless of performance. As noted later, this was changed in cohort 3 due to feedback we received from participants indicating that no incentive decreased motivation.

Second, the expected value (i.e., maximum that participants can earn) is the same in all incentive conditions so that any advantage of the combined condition (i.e., incentives for dietary self-monitoring and interim weight loss) cannot be attributed to patients having a larger expected value. For example, in Group A, where participants are incentivized for weight loss and dietary self-monitoring, the maximum a participant can earn in a week is \$30 for both behaviors. In Group B, where participants are incentivized for dietary self-monitoring only, the maximum each participant can earn in a week is also \$30. No study has defined the optimal amount of incentive for various reinforcement schedules. We selected an expected value of \$300 per participant based on provider pay for performance studies, in which providers receive incentives equivalent to 1–3% of their income for optimal clinic performance.^{21,22} Our study population may comprise patients of lower socioeconomic status. We expect that 1% of the median annual per capita income for a single person in Durham, NC (~\$30,000)²³ and the absolute value of \$300 will be perceived as significant by

patients given their relatively low median income and the diminishing marginal utility of income (i.e., \$300 provides more utility to a lower-income person than a higher-income person).²⁴

Third, participants in incentive groups A–C are eligible for incentives in the same weeks so that any differential effects between conditions cannot be attributed to different reinforcement schedules. If participants meet the incentive requirement of their respective group each week (i.e., lost enough weight and/or tracked enough calories), they are eligible to receive between \$0 and \$30 per week.

Instructions to self-monitor dietary intake and self-weigh are identical across conditions; participants receive verbal and written instructions about the criteria. All participants are encouraged to enter everything that they eat and drink in MyFitnessPal. In the combined and dietary self-monitoring conditions, the criterion for reinforcement of dietary self-monitoring is that patients must log at least 1000 kcal for females or 1200 for males for at least five days per week, one of which must be a weekend day. We allow up to two days of inadequate self-monitoring to allow for barriers such as an uncharged smartphone battery or being somewhere without the phone. All participants are encouraged to weigh themselves every day because patients who weigh daily achieve greater weight loss than those who weigh less frequently.⁷ In the combined and interim weight loss conditions, the criterion for an incentive is weight loss within that week, which is calculated using the first and last recorded weights for the week. Because the first and last weights are used to calculate weight loss, participants are encouraged to self-weigh at the beginning and end of the week even if they do not do so daily. Participants are asked to contact study staff if they lose or break their smartphones or scales, or if their smartphone number changes.

To analyze the weight and dietary data and determine if participants qualify for an incentive each week, we use a Duke-developed software system, called Prompt. The software retrieves data from the respective devices' API code that allows software programs to communicate with each other. The data are then aggregated and stored on a secure server. We apply algorithms to the data that analyze weight and diet based upon participants' respective study conditions. Day 1 of each week corresponds to the day of the participant's group visit. If participants qualify for an incentive, then the software reads the incentive schedule and notifies the payment software of the amount of money to pay the participant. Typically within 24 hours (longer during holidays), the research assistant then schedules the payment, which participants receive on a reloadable MasterCard that is provided at the first group session. Participants receive a text message with the amount s/he has earned or could have earned and encouragement to self-monitor and/or weigh daily to maximize loss aversion (i.e., the preference to avoid losses).

Fidelity

To isolate the effects of incentives, fidelity to the intervention must be consistent across the four conditions. The registered dietitian receives training from the study physician on the dietary component of the protocol and from the behavioral scientists on the behavioral intervention strategies. Checklists, including the dietary education and behavioral strategies, were created for the dietitian to follow for each group session.

Measures

All study measurements are performed or collected by study staff. Medical history, demographic information, and use of prior weight loss programs are recorded at baseline. The primary endpoint is 24 weeks. Participants who wish to discontinue study procedures are asked to return for 24-week outcome assessments. For this visit, participants have the option of keeping the BodyTrace scale (worth approximately \$85) or receiving \$25 on their MasterCard.

Body weight is measured for each person at baseline and at 24 weeks for calculation of effect sizes. Body weight is also measured at each visit, and this information is used in analyses that compare home-based weights to verified weights. Participants are instructed to weigh themselves at home and at study visits wearing light clothing and no shoes. For LCD participants, blood pressure (BP) is measured at each visit using an automatic sphygmomanometer with an appropriately-sized cuff on the right arm (left arm if the right arm is missing or unsuitable) after the participant has been seated quietly for five minutes. Participants are asked to refrain from eating, smoking, or drinking caffeine for at least 30 minutes prior to BP measurements. A safety protocol is in place for elevated BP.

To calculate intervention costs, resources required to deliver the intervention and participant time spent on weight loss-associated activities are collected. The TEAM-HF Costing Tool is used to guide data collection to estimate costs associated with the provision of the four conditions, facilities (e.g., space for group sessions, office space for intervention staff), equipment (e.g., computers used by intervention staff), supplies (e.g., BodyTrace scales, educational materials) and personnel time (not including time spent on research activities).²⁵ To estimate participant time and burden, we ask participants to report on the time they spend each week engaging in diet behaviors (e.g., meal planning, preparing meals, tracking calories, etc.), time spent engaging in physical activity, and time spent on other activities related to weight loss (e.g., listening to podcasts or reading about weight loss). We also ask participants to report the amount of time spent traveling to and from the group sessions and combine this information with attendance records. The 5-level EQ-5D, a preference-weighted measure of health-related quality of life, is also administered at baseline and 24 weeks to characterize any changes that might occur as the result of weight loss. Such scores could be used to estimate quality-adjusted life-years in a cost-effectiveness analysis in a future, adequately powered trial.²⁶

To assess acceptability, we created a series of close-ended questions for the 24-week survey. Questions address how participants tracked their dietary intake, how often they used MyFitnessPal for tracking, how often they weighed themselves on the scales provided, reasons for not using MyFitnessPal and the scales (if relevant), to what extent the financial incentives encouraged them to self-weigh and track their dietary intake, and their reactions to the frequency and timing of text messages.

Following the 24-week survey, we conduct structured qualitative interviews with a subsample of participants. In each cohort, interviewees are purposefully selected to represent clinically significant (at least 5%) weight loss and inadequate weight loss (<5%) within each of the four conditions. The interviews are recorded, and notes are taken in a structured

template to facilitate rapid analysis and changes to the protocol between cohorts. Interview questions address participants' experiences in the group sessions and use of the scales and MyFitnessPal. Participants are asked to discuss their reactions to receiving text messages each week. Participants in the three incentive conditions are asked to describe how the incentives affected their motivation to lose weight, the likelihood of self-weighing and recording their dietary intake, and how they reacted to the uncertainty about the amount of incentive they would receive each week.

Changes to the protocol

No changes to eligibility criteria or outcomes were made during the study. The LCD was used in cohorts 1 and 3, and the LFD was used in cohort 2. In cohort 3, one additional group meeting was added between the first and second biweekly meetings to cover additional content.

Safety and data monitoring

Because safety of our two dietary approaches has been established, we are not systematically collecting adverse events. Adverse events are recorded when patients mention them during telephone or in-person contacts and reported according to local IRB requirements. Our data monitoring committee (DMC) comprises the two principal investigators (CIV and RJS), the two study statisticians (JP, SLH), and a biostatistician and endocrinologist who have experience with weight loss interventions but are not affiliated with the study. The DMC meets after each cohort to review recruitment and enrollment rates, weight loss, and adverse events. There are no stopping rules or interim analyses.

Data analyses

The goal of this study is to evaluate key metrics of feasibility and acceptability of providing real-time variable-ratio incentives for dietary self-monitoring and interim weight loss. We analyze data after each cohort is complete and, based on the findings, make changes to the protocol to implement and evaluate in the subsequent cohort. Thus, changes to the dietary approach or recruitment strategies, which may affect weight loss, are consistent with our goals of establishing feasibility and acceptability of the protocol. Ultimately, the results will inform the design and implementation of a future, adequately powered trial to evaluate efficacy of our design.

Aim 1: Determine feasibility of using automated algorithms that analyze dietary self-monitoring and interim weight loss data to provide real-time positive reinforcement using variable-ratio financial incentives.

We developed the incentive algorithms and programming that analyze dietary and self-monitoring data from the mobile diet app and weights from a cellular scale. The algorithms and programming automatically trigger text messages with content based on the incentive thresholds. We program these thresholds into our software and perform quality assurance testing to determine if algorithms appropriately recognize when self-monitoring occurs and send the correct text message responses. Study staff members maintain logs of the technical assistance they provide to participants regarding the diet app and receipt of the incentive

messages. This planning study allows us to characterize and address technical challenges and barriers with the technology prior to conducting an adequately powered trial.

Aim 2: Evaluate intervention acceptability, as indicated by recruitment, intervention adherence, and outcome measurement rates.

Key acceptability information includes rates of recruitment, retention for outcome assessment visits, and intervention adherence. The total number of patients screened by telephone and in person and, when captured, reasons for nonparticipation are recorded in the study database. Also recorded are data on attempts to schedule outcome assessment visits and, when captured, reasons for nonattendance. Recruitment and retention rates will be calculated for each cohort. We will compare recruitment and retention rates across cohorts, particularly if we have to implement changes to recruitment or retention strategies or the protocol during the study. The goal is 80% retention in each cohort.

One aspect of intervention adherence is percent attendance at the in-person sessions. We record attendance at each session and will examine attendance by condition and cohort. We vary the days of week and times of day that each group (A, B, C, or D) takes place across cohorts to help disentangle attendance issues that might be due to randomized condition as opposed to day of week or time of day. Another aspect of intervention adherence is the extent to which participants engage in dietary self-monitoring using the app and weighing using the scales provided. Prompt collects and stores all input (i.e., dietary data and weights). From these data, dichotomous variables are created representing whether each participant met the weekly criteria for dietary self-monitoring and interim weight loss to receive a reward for that week. These variables will be plotted longitudinally by study condition so that we can examine trends. For example, we will examine differences between participants who were incented for dietary self-monitoring compared to participants who were not incented for doing so, and whether this effect was present throughout the study or, for example, just in the first few weeks. We will also examine the weekly proportion of days on which adequate dietary self-monitoring was obtained. Other acceptability information includes consistency between home-based weights and weights obtained at the in-person sessions. We will characterize discrepancies between study-based weights and home-based weights provided on the same day.

To inform changes from one cohort to the next, we descriptively summarize responses to the close-ended acceptability questions administered at 24 weeks. We also analyze the structured qualitative interview notes and create a list of potential problems and solutions. Decisions about protocol changes are made during team meetings.

At the conclusion of the study, we will calculate effect sizes (and confidence intervals) representing main effects and the interaction of incenting weight and dietary intake tracking on 24-week weight change. Although we will not be powered to detect statistically significant differences among conditions, the confidence intervals will provide information on the potential range of effect sizes, which will inform the power analysis for a future study. We will also correlate caloric deficit with weight loss to provide some indication of validity of food logging.

Aim 3: Estimate cost of delivering the intervention and cost to patients for participating in the program.

At the conclusion of the study, we will assess the complete costs for each of the four conditions and then estimate the incremental costs for the three incentive conditions relative to the costs associated with the no-incentive condition. We will partition costs into labor, overhead and supply costs. Labor costs include the dietitian's time preparing for and leading biweekly group sessions in each condition and the coordinator's time spent monitoring and providing incentives. The time spent is tracked in logs that study staff complete during the first week of every month of the study. These logs also track the time staff members spend completing activities associated with group sessions, administering incentive payments and research tasks so that research time costs can be excluded. Time for group sessions will be evenly allocated across the four conditions, and time for administering incentive payments will be allocated across the three financial incentive conditions. Personnel costs for the dietitian and coordinator will be valued using national salary and fringe compensation rates. Overhead costs include office and classroom space. Supply costs include the scales, diet books, handouts, and financial incentives provided to participants in the incentive conditions, and administrative fees associated with providing the cash cards. Costs associated with developing and refining Prompt will not be included in the cost estimate because we will assume that costs to modify the software will be trivial upon scaling in the future trial. Participants' time costs for in-person sessions and weight-loss activities will be valued using the mean post-tax wage with fringe benefits in the United States.

After the complete set of intervention costs is computed for patients in each of the four conditions, we will compare average intervention costs for each condition to estimate the absolute and incremental cost of delivering the three incentive conditions compared to the no-incentive condition. These incremental costs will be largely driven by differences in incentive costs, monthly fees for the cash cards, and coordinator time spent providing incentives to participants because the dietitian's time spent conducting the group meetings, as well as office space and classroom space, will be shared equally among all participants and then assigned to that participant's group. Mean participant time and associated costs for the three incentive conditions will be compared to the no-incentive condition. Also, participant responses to the 5-level EQ-5D will be mapped to corresponding utility weights. If 5-level EQ-5D weights are not available, then responses will be mapped to the original 3-level instrument and assigned corresponding 3-level weights.²⁷ Changes from baseline to 24 weeks will be computed for each person and compared across the four conditions. Estimates of incremental intervention and participant time costs and EQ-5D utilities will inform plans for a cost-effectiveness analysis to be conducted in a future large-scale trial.

Discussion

Our approach to incenting dietary self-monitoring and interim weight loss has several strengths. First, we are among the first to test the hypothesis that incentives delivered on a variable ratio schedule can enhance adherence to a behavioral skill (i.e., dietary self-monitoring) that is important for weight loss initiation. A previous study by Leahey evaluated the effect of variable-ratio incentives for entering weight, dietary intake, and

physical activity information into a website compared to no incentives or optional group sessions.⁹ This previous study differed from ours in four important ways. First, their participants were required to enter self-monitoring data for weight, dietary intake, and physical activity into a website, whereas our participants are required to enter dietary data into an app and weight is transmitted automatically when participants step on the BodyTrace scale. Second, although both studies required participants to enter data on five days of each week to qualify to receive an incentive, we required that one of those days be a weekend day. Third, in Leahey's study, there was no minimum criterion regarding amount of data entered required to earn an incentive, whereas we had a minimum calorie count. Fourth, Leahey incented weight loss achieved at the end of the study by entering participants into a raffle for \$50 (for 5–10% weight loss) or \$100 (for >10% weight loss). Thus, their participants knew the reward amount and were not guaranteed a reward for achieving weight loss.

Another strength of our study is that the factorial design allows us to examine the unique effects of incenting dietary self-monitoring, interim weight loss, or both compared to no incentives. The design of the aforementioned study did not allow a test of the unique and joint effects of incenting dietary self-monitoring and interim weight loss.⁹ Another strength of our study is that, by encouraging self-weighing and incenting some patients for interim weight loss, we are helping patients establish a habit (frequent weight self-monitoring) that is associated with weight loss maintenance.²⁸ Additionally, the current study uses technology to assist patients with dietary self-monitoring, decreasing their burden compared to using paper logs. Because we are incenting behaviors that occur outside the group setting, participants can earn rewards even if they do not attend in-person sessions. Finally, we have created an algorithm for collating self-monitoring and weight loss data and incenting adherence in real time, thus enhancing efficiency and reliability of the data. If effective, this method could be easily disseminated, scaled, and used in a larger trial.

Despite these strengths, there are limitations. First, because a major component of the weight loss intervention is in-person group meetings, access may be limited for patients who do not live close to our medical center. Although research indicates that interventions with high frequency and duration of in-person contact are more efficacious at producing significant weight loss,²⁹ requiring continuous in-person contact may affect dissemination potential. Participants can still earn incentives even if they do not attend the group-based sessions, but information and support provided at the sessions may be important for facilitating weight loss. A second limitation is that, because this intervention requires a mobile phone with a data plan, access will be limited to patients with a smartphone, reducing generalizability. Currently, 95% of U.S. adults own a cellphone, and ~77% own a smartphone.³⁰ Relatedly, the methodology for collecting dietary self-monitoring data is only available to smart phones compatible with the dietary app. Third, we cannot guarantee that dietary intake is accurate as patients may under- or over-report what they eat. We are focusing on the process of recording dietary intake, however, and believe that incenting this behavior will result in improved outcomes. Previous research indicates that abbreviated self-monitoring is as effective as detailed self-monitoring, suggesting that the process is more important than the content.¹² Because participants do not know the incentive timing or amount each week, the likelihood of entering random data for the purposes of receiving an

incentive are reduced. A fifth limitation is that, because each condition has the same expected value, participants in the combined incentive condition receive half the reward for each singular behavior than the other two incentive conditions, representing a confound. If we paid the combined group the same amount for the singular behaviors that the individual groups receive, the total expected value would be \$600 vs. \$300, presenting a different confound. We considered adding a fifth condition testing this option, but decided against it due to budgetary constraints and because healthcare systems/employers are likely to consider two alternatives of the same amount instead of a more versus less expensive option. We are investigating the most promising ways to incent patients given a fixed budget per patient. Sixth, whereas dietary self-monitoring is almost completely under participants' control, factors outside their control (e.g., metabolism) may interfere with weight loss even if they are self-weighing regularly. Finally, provision of money to incent behaviors is unlikely to be feasible over long time periods. We are testing a strategy in which financial incentives can be used initially to help individuals adopt new, healthier habits. When this strategy is combined, with, for example, maintenance-focused behavioral strategies,²⁰ long-term outcomes may be improved. This is an area for future research.

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Table 1

Study design

Condition	Incentive for	Common elements to all conditions
A	Interim weight loss ^a	Group meetings every 2 weeks Weekly text messages encouraging self-weighing and dietary self-monitoring
	Dietary self-monitoring ^b	
B	Dietary self-monitoring	
C	Interim weight loss	
D	No incentive	

^aTo qualify for an incentive for interim weight loss, participants had to have any amount of interim weight loss. Interim weight loss was calculated as the difference between the first and last weights of the week received from cellular scales.

^bTo qualify for an incentive for dietary self-monitoring, participants had to record at least 1000 kcal (female)/1200 kcal (male) per day for at least 5 days of the week, including at least one weekend day.

Table 2**Inclusion and exclusion criteria**

Inclusion criteria determined by telephone <ul style="list-style-type: none"> ages 18–70 years self-reported BMI ≤ 29 kg/m² (to allow for error; final criterion will be BMI ≤ 30 kg/m²) desire to lose weight agree to attend visits per protocol access to reliable transportation no errors on a validated six-item cognitive screener³¹ able to complete study measures English speaking smart phone with data and texting plan 	Exclusion criteria determined by telephone <ul style="list-style-type: none"> pregnancy, breastfeeding, or lack of birth control if premenopausal dementia, psychiatric illness, or substance abuse that might interfere with the intervention weight loss ≥ 4.5 kg in the month prior to screening enrollment in a research study focusing on weight loss or health behavior change residing in a nursing home or receiving home health care impaired hearing medication other than metformin, incretin mimetics and incretin enhancers for type 2 diabetes due to increased risk for hypoglycemia unable to attend sessions at the four scheduled times chronic kidney disease unstable heart disease in the three months prior to screening furosemide ≥ 40 mg or equivalent
Inclusion criteria determined in person <ul style="list-style-type: none"> stable health by medical history BMI ≤ 30 kg/m² 	Exclusion criteria determined in person <ul style="list-style-type: none"> blood pressure $\geq 160/100$ mmHg Pregnancy (determined by urine pregnancy test) pregnancy, breastfeeding, or lack of birth control if premenopausal Weight > 380 lbs.