Log2Lose: Incenting weight loss and dietary self-monitoring in real-time to improve weight management among adults with obesity

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Principal Investigator*: Lisa Cadmus-Bertram, PhD

Sponsor: University of Wisconsin-Madison

Grant Title: Log2Lose: Incenting weight loss and dietary self-monitoring in real-time to improve weight management

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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with the United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and privacy 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.

INVESTIGATOR'S SIGNATURE

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.

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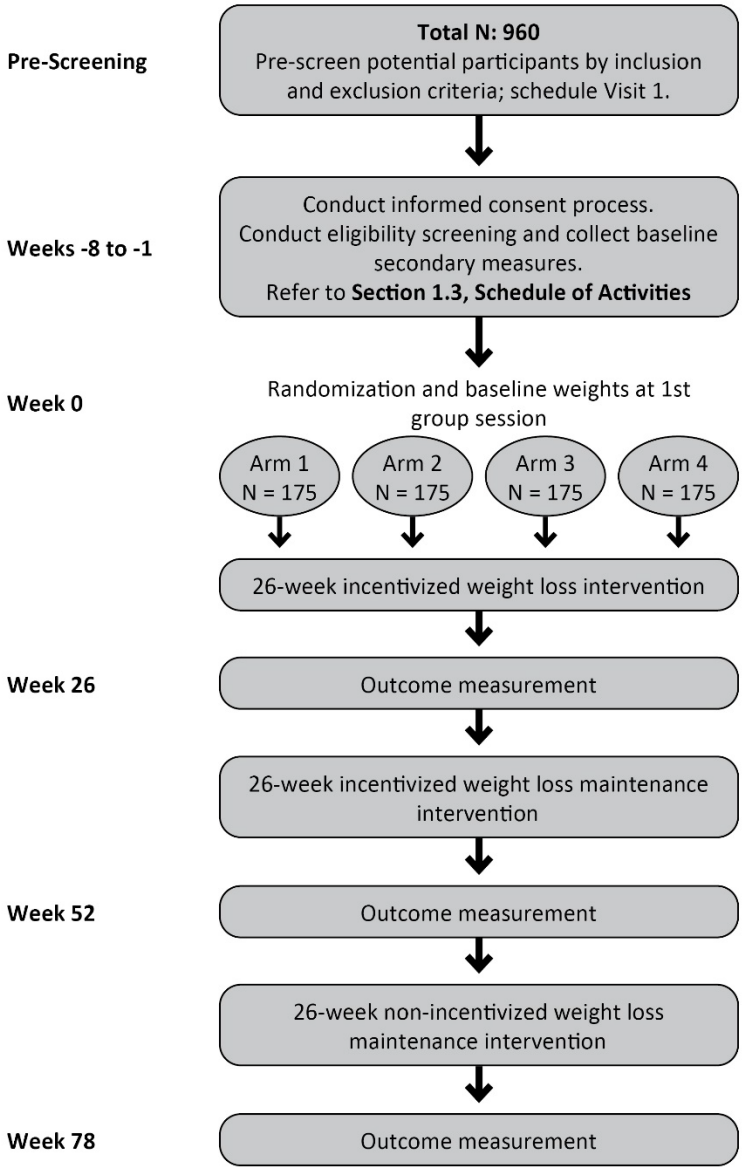
1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title	Log2Lose: Incenting weight loss and dietary self-monitoring in real-time to improve weight management among adults with obesity
Grant Number	UG3HL150558-01
Study Description	In this two-site, randomized, single-masked, longitudinal 2x2 factorial study, called Log2Lose, adults with obesity from Madison, WI and Durham, NC will be offered a 78 week, evidence-based behavioral weight management program comprising an incentivized weight loss intervention for 26 weeks (Phase I), an incentivized weight loss maintenance intervention for 26 weeks (Phase II), and a non-incentivized weight maintenance intervention for 26 weeks (Phase III). Participants will be randomized in a 2x2 design to receive adjunctive incentives for either weekly weight loss or dietary self-monitoring, both, or neither. We will assess the proportion of participants achieving clinically significant weight loss of ≥5% at the end of each phase.
Objectives*:	**Primary Objective:** Compare the proportion of participants who achieve 5% weight loss at 26 weeks across the four arms to assess efficacy of the financial incentive intervention strategies. **Secondary Objectives:** Compare the longitudinal trajectories of participants in the four arms across 26, 52 and 78 weeks on the probability of achieving and maintaining ≥ 5% weight loss from baseline to assess the relative efficacy of the incentive intervention strategies in promoting long-term weight loss. We will also examine impact on blood pressure, cardiovascular medication use, and body weight as a continuous outcome.
Endpoints*:	Primary Endpoint: Weight at 26 weeks. Secondary Endpoints: Weight at 52 and 78 weeks, blood pressure measured every 26 weeks, cardiovascular medication use measured at 78 weeks, program costs measured every 13 weeks, and health related utility measured every 26 weeks.
Study Population	We will enroll 700 adults aged 18 years and older from the communities in and around Madison, WI and Durham, NC, with approximately half of participants enrolled at each site. Participants must have obesity, no contraindications to weight loss, and be capable of participating in the intervention.
Phase* or Stage:	Phase II equivalent
Description of Sites/Facilities Enrolling Participants	This study will be completed by a multidisciplinary team of researchers from the University of Wisconsin-Madison School of Medicine and Public Health (Lisa Cadmus-Bertram, PhD; PI) and the Duke University School of Medicine (Jennifer Gierisch, PhD; site PI). Both teams have expertise in randomized controlled trials, behavioral weight management, intervention delivery, and handling of data collection. Both sites have access to a variety of resources that will ensure the success of this study.
Description of Study Intervention/ Experimental Manipulation	We are testing the addition of financial incentives to an evidence-based weight management program. Accordingly, all participants will receive the same 78-week weight management program. Participants will be randomized to receive/not receive adjunctive incentives for dietary self-monitoring and/or weight loss during weight loss (Phase I) and the first 26 weeks of weight loss maintenance (Phase II). In the last 26 weeks of weight maintenance, participants will not receive incentives (Phase III). To determine if participants qualify for an incentive each week, data will be obtained from the MyFitnessPal and/ or Fitbit apps to be installed on participants' smartphones and BodyTrace scales. Incentives will be delivered on a combined fixed/intermittent schedule, with weekly payments ranging from $0 to 10, unknown to participants.
Study Duration*	60 months (720 weeks)
Participant Duration	78 weeks

1.2 *SCHEMA*


Pre-Screening
Total N: 960
Pre-screen potential participants by inclusion and exclusion criteria; schedule Visit 1.
Weeks -8 to -1
Conduct informed consent process.
Conduct eligibility screening and collect baseline secondary measures.
Refer to Section 1.3, Schedule of Activities
Week 0
Randomization and baseline weights at 1st group session
Arm 1 N = 175
Arm 2 N = 175
Arm 3 N = 175
Arm 4 N = 175
26-week incentivized weight loss intervention
Week 26
Outcome measurement
26-week incentivized weight loss maintenance intervention
Week 52
Outcome measurement
26-week non-incentivized weight loss maintenance intervention
Week 78
Outcome measurement

1.3 SCHEDULE OF ACTIVITIES

	Pre-screening (Pre-consent)	Visit 1: Final screening and consent	0 weeks	13 weeks	Visit 2 26 weeks	39 weeks	Visit 3 52 weeks	65 weeks	Visit 4 78 weeks
Eligibility screening	X								
Demographics		X							
Presence of obesity related co-morbidities		X							
Engagement in previous weight loss attempts		X							
Informed consent		X							
Weight	X	X	X		X		X		X
Systolic and diastolic blood pressure		X			X		X		X
Medication use		X							X
All or nothing thinking		X							
Motivation for weight loss		X		X	X	X	X	X	
Delayed reward discounting		X			X		X		X
Weight loss choice		X			X		X		X
Time spent on intervention		X		X	X		X		X
Weight loss methods					X		X		X
Study experience					X		X		X
Satisfaction with outcomes (Positive or Negative Impacts of Log2Lose Participation)					X		X		X
EQ-5D-5L (health utility)		X		X	X		X		X
Text message evaluation									X
Class feedback survey					X		X		
Randomization		X							
Control & experimental financial incentive interventions									
Weight management program			→	→	→	→	→	→	→
Adverse event reporting			→	→	→	→	→	→	→
Unmasking of randomization assignment			X						

2 INTRODUCTION

2.1 STUDY RATIONALE

Obesity increases risk for many leading causes of death, including heart disease, stroke, some cancers, respiratory diseases, diabetes, and kidney disease. Efficacious behavioral weight loss programs for adults teach participants behavioral strategies to create a caloric deficit. The two strongest predictors of long-term success in such programs are initial weight loss and dietary self-monitoring. These two phenomena decline over time, reducing the proportion of people who achieve clinically significant weight loss and thus limiting population impact. Financial incentives to reward initial weight loss and dietary self-monitoring can be delivered to large populations of adults with relative ease and at low cost. Indeed, employers and payers are providing financial incentives for health behaviors and outcomes despite an inadequate evidence base to inform optimal program design. The proposed study will evaluate which incentive approach has the greatest impact and durability—incentivizing initial weight loss, incentivizing dietary self-monitoring, or both.

Trials testing the effects of incentivizing initial weight loss or dietary self-monitoring have shown some promise for increasing short-term but not long-term weight loss. These studies have flaws, however, such as confounds and delayed delivery of rewards. Additionally, few of these studies have evaluated incentive effects on long-term weight loss or examined the key mediating role of intrinsic or extrinsic motivation. This latter point is important because financial incentives may undermine intrinsic motivation, contributing to weight regain after incentives are withdrawn. Finally, few studies have calculated program costs or cost-effectiveness of financial incentive interventions, the results of which could inform program implementation.

In order to inform recruitment of Black Americans and men in future weight management studies, we will conduct qualitative interviews with members of both groups following completion of the 52-week outcome to evaluate their experience in the study. We will also conduct interviews with community members not involved in the study to identify strategies for engaging Black American adults in studies of behavioral weight management interventions. The interviews with male participants in the study will take place subsequent to the 78-week outcome. These interviews aim to identify effective strategies for engaging Black American adults and men in behavioral weight management interventions.

Additionally, there is an urgent need for a precision medicine approach that distributes incentives in such a way that they maximize the proportion of people who achieve long-term, clinically significant weight loss. In preparation for our future work to address this need, we will conduct secondary data analyses to validate a reinforcement learning model in the Log2Lose data set and extend it to accommodate weight loss maintenance.

2.2 BACKGROUND

Obesity is prevalent, detrimental to health, and costly. One-third of US adults have obesity.[1](Compared to normal-weight peers, individuals with obesity have an increased risk for hypertension, coronary heart disease, and congestive heart failure.[2,3] Obesity is associated with decreased health-related quality of life[4] and high healthcare costs.[5,6]

Obesity-related illnesses can be prevented or alleviated by weight loss of ≥ 5%. A reduction of ≥ 5% of baseline weight decreases systolic and diastolic blood pressure, improves blood lipid profiles,[7,8] and reduces diabetes incidence.[9] Due to these benefits, the joint American Heart Association/American College of Cardiology/The Obesity Society (AHA/ACC/TOS) Obesity Guideline specifies weight loss of

≥ 5% as clinically significant.[10] Programs that target a caloric deficit via dietary change and exercise and teach participants behavioral strategies such as self-monitoring can help people achieve clinically significant weight loss.[11,12] There is variability in adherence to these programs, however, such that some people achieve clinically significant weight loss whereas others do not. Furthermore, many people regain 1-2 kg per year after initial weight loss. Strategies are needed to increase both short- and long-term weight loss.

A promising strategy to increase short- and long-term weight loss is to apply operant conditioning principles. Operant conditioning is the process of learning voluntary behavior and can occur via one of two processes: reinforcement or punishment. Reinforcement is the process of establishing a behavior pattern, whereas punishment is the process is reducing a behavior pattern. Because punishment has rarely been applied to health behavior, we focus on reinforcement. Reinforcement may be positive (i.e., provision of a stimulus) or negative (i.e., removal of a stimulus). Reinforcement schedules may be continuous (i.e., stimulus is provided after every response) or intermittent (i.e., stimulus is provided after a ratio or interval of responses). Intermittent schedules can be further characterized as fixed (i.e., delivery after every n responses or time) or variable (i.e., delivered after a mean of n responses or time). Following withdrawal of a reinforcer, the response rate typically declines, a process referred to as extinction. Continuous reinforcement schedules lead to an early, steady rate of responding. Intermittent schedules are more economical (i.e., because a stimulus is not provided after each instance of the desired response) and produce behavior more resistant to extinction.[13] Thus, a reinforcement scheme involving a fixed- followed by a variable-ratio schedule may be effective and economical for promoting short- and long-term weight loss.

Other relevant operant conditioning principles are quality/quantity and timing of the reinforcer.[14] To perceive a stimulus as reinforcing, one must perceive that a stimulus satisfies a need. There are, however, differences between and within individuals in the extent to which a stimulus is perceived as reinforcing. For example, some may not perceive a gym or grocery voucher as valuable. Money is a common reinforcer that can be exchanged for valued goods/services. Reinforcement timing is also critical. The further away in time the reward is provided from the desired response, the less its perceived present value.[15-17] To maximize impact, incentives need to be perceived as valuable and provided in near real-time.

Previous applications of operant conditioning principles to weight loss have not identified an optimal incentive structure. A 2012 review by Burns et al. included 27 randomized controlled trials (RCTs) involving provision of cash or material incentives to promote weight loss or adherence to behaviors that may lead to weight loss, such as exercising or attending educational sessions.[18] The studies varied with regard to what was incentivized (i.e., outcome vs. behavior), reinforcement procedure (i.e., positive vs. negative reinforcement), reinforcement schedule (i.e., fixed vs. variable), reinforcement amount, duration of time incentives were delivered, and treatment delivered alongside the incentive. Due to this significant heterogeneity, the authors could not perform a meta-analysis or draw firm conclusions about the efficacy of any approach and called for additional research to identify an optimal incentive structure.

One issue is whether to use positive or negative reinforcement. The two typically have not been compared head-to-head. Most RCTs have used negative reinforcement and shown positive effects primarily for the target behavior (e.g., attendance) rather than weight loss.[18] One significant drawback to negative reinforcement (where nonadherent participants lose money) is that low-income populations may be unable “buy into” such programs or may suffer disproportionately if they enroll but fail to lose weight. Thus, positive-reinforcement programs may be preferable. Burns et al. noted that positive reinforcement has rarely been used. Moreover, these few RCTs used gifts or lotteries as incentives (lotteries do not guarantee a reward, and gifts are differentially valued) and incentivized behaviors indirectly associated with weight loss (e.g., participants were incentivized for returning a postcard but evaluated by weight).[18,19] Consistent with Burns et al.’s call for more studies testing positive reinforcement, we structure our incentive interventions as positive reinforcement.

There is uncertainty about the most effective target for incentives: process, outcome, or both? Dietary self-monitoring is one of the strongest predictors of short- and long-term weight loss.[11,20-23] Incentivizing dietary self-monitoring alone may not ensure sufficient weight loss because people may track diligently yet still underestimate their intake or the caloric density of foods. Additionally, people may rush through self-monitoring to earn an incentive if they are not held accountable for the outcome of weight loss. Similarly, incentivizing weight loss alone may not ensure that dietary self-monitoring will be learned because less enduring behavioral strategies, such as extreme caloric restriction, might be used. Incentivizing both dietary self-monitoring and initial weight loss may yield better initial weight loss than incentivizing either alone. Thus, in the proposed RCT, we evaluate the individual and joint effects of incentivizing weight loss and dietary self-monitoring. No RCT, to our knowledge, has evaluated the joint contributions of incentivizing dietary self-monitoring and weekly weight loss delivered as positive reinforcement. Therefore, we have equipoise about whether this approach will be more effective than incentivizing either alone.

Studies of positive reinforcement to promote dietary self-monitoring and/or weight loss are inadequate to inform implementation of real-world programs. We list these limitations, and our project's approach to address them, in Table 1. We demonstrated the feasibility and acceptability of our design features and approach in our pilot study.[24]

Table 1: Limitations to previous RCTs that used positive reinforcement and how our approach will address them

Previous approaches	Our approach
• incentivized weight loss and self-monitoring simultaneously, making it impossible to evaluate the unique and joint contributions of incentives for these two outcomes[25,26]	• employs a 2x2 factorial design to disentangle rewards for weight loss versus dietary self-monitoring
• created a gap between the desired behavior and incentive, which may cause participants to discount the value of incentives[25-29]	• disburses incentives in near real-time (usually within 24 hours of data processing)
• rarely addressed weight loss maintenance [26,29]	• provides a 52-week maintenance period with incentives for the first 26 weeks and no incentives for the last 26 weeks
• incentivized final weight loss or weight loss at infrequent intervals (e.g., monthly)[25-28]	• incentivizes participants for weekly weight loss given the importance of reinforcing successive approximations toward the weight loss goal
• rarely examined mediation by motivation or addressed intervention cost or cost-effectiveness[25,30]	• examines the potential mediating role of intrinsic and extrinsic motivation, estimates intervention cost, and calculates incremental cost-effectiveness ratios

While obesity is present among approximately 40% of U.S. adults, large disparities exist between racial and ethnic groups, with Black Americans experiencing higher rates of obesity and the many comorbidities associated with it.[1] Additionally, these groups experience less average benefit from behavioral weight management interventions compared to White Americans.[2,3] Simultaneously, Black and African Americans continue to be underrepresented in health research, including behavioral weight management interventions. Investigation of barriers to recruitment and retention in behavioral weight management studies is needed.

Strategies to recruit Black Americans into weight loss research have had varying success.[4] These strategies have focused primarily on increasing reach, with the underlying assumption that the traditional, evidence-based, lifestyle weight management strategies are acceptable to and appropriate for this population. Investigations are needed of the experience of Black American participants in behavioral weight management programs and the views and opinions of members of these communities about behavioral weight management interventions. Such investigations could identify

fundamental strategic changes that could be made to improve the reach and effectiveness of weight management programs.

Durham is a majority-minority county where 57% of residents identify as a racial or ethnic minority. In contrast, Madison WI, located in Dane county, has a composition of 79% non-Hispanic White, with only 5% identifying as Black. Therefore, recruitment of Black Americans in Madison is more challenging. Furthermore, while we have been able to recruit a sizable number of Black Americans in Durham, we do not know how Black Americans in Durham or Madison experience the intervention and which factors facilitate or detract from retention in the program.

Although the overweight and obesity rates are similar between men and women,[3] men tend to be underrepresented in weight management research.[4,5] The inadequate representation of men in lifestyle weight loss interventions is a significant issue, particularly considering that men are more prone to experiencing cardiovascular morbidity and mortality, and they have a shorter life expectancy, compared to women.[6]

To increase rates of participation and engagement of men, some researchers have developed weight management interventions specifically tailored to men.[7-9] While concentrating on weight management research exclusively for men can provide valuable insights and solutions, it is vital to include men in broader studies on weight management. Since the majority of weight management programs are not exclusive to one gender or sex, strategies that improve inclusion of men in them is imperative. There is a gap in knowledge concerning the transferability of effective engagement strategies used in men-only interventions to all-gender behavioral weight management programs, such as Log2Lose. Understanding men's perspectives on health behaviors related to weight management is crucial for refining recruitment methodologies and delivering effective weight loss interventions in the future.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

There are a few potential risks associated with participation. The following risks are both immediate as well as long-term:

i. Sensitive questions about personal issues (e.g., motivations for weight loss) may make participants uncomfortable.
ii. There are small risks of injury or heart problems due to increased participation in physical activity.
iii. Dietary changes and/or weight loss can result in low blood pressure or blood glucose levels in participants taking medication for these health problems.
iv. There is a small risk of inadvertent disclosure of participant data.
v. Some participants could become distressed during group visits or telephone calls.
vi. There is a small immediate risk of minor discomfort or bruising at the site of the upper-arm automatic blood pressure cuff.
vii. There is a slight risk of minor skin irritation or discomfort from wearing the Fitbit device.

2.3.2 KNOWN POTENTIAL BENEFITS

Benefits of the weight loss intervention are both immediate and long-term:

All participants will receive evidence-based weight management instruction; thus, we expect all to derive some benefit from participation. This instruction exceeds the available standard of outpatient care available to people in the community and involves no direct cost to participants. People typically must pay to receive weight loss intervention, either through commercial programs or via visits to ancillary providers such as registered dietitians. Participants may learn skills that help them reduce weight by adhering to dietary recommendations and participating in regular physical activity. Participants randomized to one of the incentive arms may experience increased motivation and weight loss.

Although the participants themselves might not derive direct benefit, knowledge gained from the study will assist in the treatment of others with obesity.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Rationale for the necessity of exposing participants to risks
Obesity has become increasingly prevalent in the US and is associated with myriad health problems alleviated by weight loss. Many of these problems (e.g., elevated cholesterol, blood pressure, and blood glucose) are major risk factors for coronary heart disease and increase in prevalence as age increases. Despite the known risk of obesity, many Americans have difficulty losing weight and even more difficulty maintaining their new weight afterward. Therefore, the value of the information gained from this study far outweighs the risks involved.

A summary of how risks are minimized in the study design.
Sensitive questions about personal issues may make participants uncomfortable. Participants do not have to answer any question that they do not wish to answer, as will be explained during the consent process and during subsequent visits.

There are small risks of injury or heart problems due to increased participation in physical activity. We will minimize risks associated with physical activity by:

- Screening for contraindications to physical activity participation (e.g., unstable heart disease in the past 6 months);
- Providing handouts regarding physical activity;
- Providing proper instruction regarding methods for engaging in physical activity safely during the group classes and on their own;
- Educating participants to recognize symptoms consistent with overexertion or adverse health events triggered by exercise;
- If classes are done virtually, asking participants to leave their video on during the physical activity portion of the group classes.

Several aspects of our active intervention will help reduce risks associated with physical activity:

- All participant materials promoting physical activity endorse moderate-intensity physical activity during initiation phases of physical activity.
- Participants are encouraged to establish goals and action plans they feel capable of performing in partnership with the interventionist, who will assess the feasibility of such goals and expectations.
- Our interventionist assesses barriers, which include health problems that may preclude safe physical activity, using American College for Sports Medicine (ACSM) guidelines.
- Our written materials emphasize the need to monitor symptoms of overexertion and other acute health problems (e.g., chest pain, excessive shortness of breath) and recommend participants contact their physician or emergency care (for heart attack or stroke symptoms) if they experience any difficulties.
- The study physician will always be on call to answer participants' questions. Current guidelines from the ACSM and the Department of Health and Human Services (DHHS) do not require

physician approval for initiation of moderate physical activity. In accordance with these guidelines, we will not require participants to check with their personal physician upon enrollment in the study. However, as described above, participants will be instructed about when they should consult with their physician, in accordance with ACSM and DHHS guidelines, about new health problems or symptoms that require a review of physical activity.

Dietary changes and/or weight loss can result in low blood pressure or blood glucose levels in participants taking medication for these health problems. During the intervention participants will be counseled on how to recognize and respond to symptoms of low blood pressure or low blood glucose. Study personnel will also be trained how to respond when participants report symptoms of severely low or high blood pressure. The study physician will provide recommendations to the study team regarding any issues that arise with specific participants. Participants may be provided with contact information for the study physician as deemed necessary. The study physician will address health issues related to physical activity; participants may also be referred to their own primary care provider for additional work-up.

There is a small risk of inadvertent disclosure of participant data. Research personnel will use only those parts of the medical record necessary to send recruitment letters to potentially eligible patients and follow the research protocol, and measures will be taken to maintain privacy during group classes. We will establish ground rules at the group classes, advising participants that they should only communicate information they feel comfortable communicating in public and any information learned about other participants should be kept confidential. In order to prevent the exposure of personal identifying information or protected health information, please see section 10.1.3.

Participants could become psychologically distressed during group visits or telephone calls. If necessary, any individual experiencing notable psychological distress will be discussed with Dr. Cadmus-Bertram (CCC PI at UW) or Dr. Gierisch (site PI at Duke).

To prevent discomfort or bruising from the automatic blood pressure cuff, an appropriately-sized blood pressure cuff (small adult, regular adult, large adult, and extra-large adult) will be used.
Regarding privacy during the qualitative interviews, measures will be taken to maintain confidentiality during interviews, such as conducting them in a private office where others cannot overhear the conversation. Our interviewers will be trained to respond to personal experiences of racism and discrimination (e.g., due to obesity) with empathy and will offer participants to stop the interview at any time.

Justification as to why the value of the information to be gained outweighs the risks of participation in the study:
This study is important because (1) it addresses a highly prevalent problem (obesity) that increases risk for numerous morbid, costly conditions; (2) the incentives intervention is practical and could be paired with various weight loss interventions offered by clinicians or payers if proven efficacious; and (3) the intervention provides a model that could be applied to other group-based interventions (e.g., shared medical appointments), delivery modes (e.g., internet-based), treatments (e.g., bariatric surgery), and contexts (e.g., work places, payers), which could be implemented to help thousands of Americans.

3 OBJECTIVES AND ENDPOINTS

Primary

Objective	Compare the proportion of participants who achieve 5% weight loss at 26 weeks across the four arms to assess efficacy of the financial incentive intervention strategies.

	Hypothesis 1a: Incentivizing either or both phenomena will significantly increase the proportion of participants who achieve 5% weight loss at 26 weeks relative to those who do not receive incentives. **Hypothesis 1b**: Incentivizing both phenomena will result in a greater proportion of participants who achieve 5% weight loss at 26 weeks than incentivizing each single phenomenon. **Hypothesis 1c**: Incentivizing dietary self-monitoring will be more effective in achieving 5% weight loss at 26 weeks than incentivizing weekly weight loss.
Endpoint	Weight measured via calibrated scale at 26 weeks
Justification For Endpoints	We believe it is better to evaluate the percentage of people who achieve clinically significant weight loss rather than average weight loss because this will allow us to understand how the different financial incentive interventions impact population health. Average weight loss can be skewed by a very successful minority. We define clinically significant weight loss as ≥5% consistent with the AHA/ACC/TOS Obesity Guideline, which links this amount to improvements in blood pressure, lipids, and other clinical parameters. Specifying an effect size for average weight loss would be difficult because to the best of our knowledge there is no guideline or literature that suggests what would be considered clinically significant, and RCTs with average weight loss as an outcome have not provided justification for the target effect size. To enable comparisons with these RCTs, however, we will analyze and report effects on average weight loss. We choose 26 weeks as the primary end point because this is when most people achieve their nadir, and the impact of incentives on motivation and effort may have the greatest effect during initial weight loss. Furthermore, initial weight loss is the best predictor of long-term weight loss, and the literature has not yet established an optimal incentive strategy to maximize initial weight loss. Assessing weight at weeks 52 and 78 will allow us to examine the extent to which weight loss maintenance is sustained with and without incentives. This will be an important contribution to the knowledge base, as most positive reinforcement RCTs have had follow-up periods of ≤26 weeks, and the few RCTs with longer durations have yielded inconsistent effects.
Putative mechanisms of Action	Caloric deficit achieved by reducing dietary intake and/or increasing physical activity

Secondary

Objective	Compare the longitudinal trajectories of participants in the four arms across 26, 52 and 78 weeks on the probability of achieving and maintaining ≥ 5% weight loss from baseline to assess the relative efficacy of the incentive intervention strategies in promoting long-term weight loss. We will also examine impact on blood pressure, medication use, and body weight as a continuous outcome.
Endpoint	Weight and blood pressure measured at weeks 52 and 78; cardiovascular medication use at 78 weeks.
Justification For Endpoints	We assess weight at weeks 52 and 78 to understand the impact of weight loss maintenance programming with (Phase II) and without (Phase III) incentives on long-term weight loss. We assess the impact on blood pressure because it is a relevant safety measure and easy and inexpensive to obtain. We assess the impact on cardiovascular medication use at 78 weeks because people often need to have these medications reduced as they lose significant weight. More frequent intervals are likely too short for medication changes to occur given projected weight loss of ≤1.5 lb. per week and because participants would have to see their providers to receive prescription changes.
Putative mechanisms of Action	Caloric deficit achieved by reducing dietary intake and/or increasing physical activity

Tertiary

Objective	Calculate the proportion of 26-week weight loss that is mediated by self-reported intrinsic and extrinsic motivation for weight loss.
Endpoint	Motivation for weight loss measured by survey every 13 weeks.

Justification For Endpoints	It is thought that providing financial incentives will decrease intrinsic motivation for weight loss and increase extrinsic motivation. This is important because intrinsic motivation is hypothesized to drive long-term behavior changes. Mediators are measured at time points prior to the outcome they affect (e.g., week 13 would mediate effect of intervention on week 26 weight).

Exploratory

Objective	Estimate program costs and calculate incremental cost-effectiveness ratios across the four arms to assess which strategies would be most promising for future implementation on a broader scale.
Endpoint	Participant and interventionist time measured via survey every 13 weeks; participant health status measured survey every 26 weeks.
Justification For Endpoints	To inform implementation efforts, it is necessary to calculate program costs.
Objective	Conduct qualitative interviews focused on recruitment, participation, and content of the weight management program with Black and African American participants and community members.
Endpoint	Qualitative interviews of Black and African American participants following the 52-week study assessment and non-participant community members.
Justification For Endpoints	To increase understanding of strategies to increase recruitment of, participation by, and success of Black and African American adults in weight management trials.
Objective	Conduct qualitative interviews focused on recruitment, participation, and content of the weight management program with male participants
Endpoint	Qualitative interviews of male participants following the 78-week study assessment
Justification for Endpoints	To increase understanding of strategies that increase recruitment of, participation by, and success of males in weight management trials.
Objective	Validate a mathematical model that optimizes the distribution of money to individuals to maximize the probability of achieving 5% weight loss over 26 weeks and maintaining 5% weight loss over an additional 26 weeks.
Endpoint	Captured calorie logging, weight tracking, weight loss and distributed incentives out to 52 weeks
Justification For Endpoints	This analysis will provide necessary data to support a future proposal to conduct an adequately powered randomized trial to compare the efficacy of a personalized vs. uniform financial incentives intervention on weight loss and weight loss maintenance

4 STUDY DESIGN

4.1 OVERALL DESIGN

In this two-site, randomized, single-masked, longitudinal 2x2 factorial study, called **Log2Lose**, adults with obesity from Madison, WI and Durham, NC will be offered a 78-week, evidence-based behavioral weight management program comprising an incentivized weight loss intervention for 26 weeks (Phase I), an incentivized weight loss maintenance intervention for 26 weeks (Phase II), and a non-incentivized weight maintenance intervention for 26 weeks (Phase III). Participants will be randomized in a 2x2 design to receive adjunctive incentives for either weekly weight loss or dietary self-monitoring, both, or neither. We will assess the proportion of participants achieving clinically significant weight loss of ≥5% at the end of each phase.

Randomization: We have three strata on which we will randomize: study site (UW vs. Duke), sex assigned at birth (male vs. female), and baseline BMI (≥35 kg/m^2 and <35 kg/m^2). We stratify by site to

account for differences in lifestyle habits that characterize the Midwest vs. South and possible differences in study implementation. We stratify by sex assigned at birth because, on average, men weigh more at baseline and lose more weight than women. Addressing this biological variable is part of rigor and reproducibility. We stratify by BMI ≥35 kg/m^2 (class II or III obesity) because it is a cut-point for eligibility for intensive treatment such as bariatric surgery. Participants will be allocated at the end of the screening and recruitment visit using a computer-generated randomization sequence. Should randomization errors occur we will document the error but not attempt to correct the randomization so as to be consistent with ITT analysis.[31] A staff member will open an envelope to reveal the location, date, and time to which participants have been randomized but will not indicate arm assignment. After participants have provided a baseline weight at the first group class, the registered dietitian (RD) will unmask participants to the randomization assignment, revealing if and for what they will receive financial incentives. This will help minimize attrition for the first class due to the disappointment of not being assigned to a desired arm.

Intervention: Participants can earn up to $150 in Phase I and $150 in Phase II for meeting incentive criteria, depending on randomization assignment. To determine if participants qualify for an incentive each week, data will be obtained from BodyTrace scales provided at the first group class and the MyFitnessPal and/ or Fitbit app to be installed on participants' smartphones with staff assistance at the individual screening visit.

Qualitative interviews: Interviews will be conducted with up to (n=20) study participants in Madison, WI and Durham, NC about participant acceptance and preferences of the weight management program. Interviews will also be conducted with up to (n=10) community members about opinions, values, and beliefs concerning weight management research. Additionally, we will interview up to n=30 male study participants at the Madison, WI and Durham, NC sites.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

This two-site, randomized, single-masked, longitudinal 2x2 factorial study involves incentives for dietary self-monitoring or weekly weight loss, both, or neither. All arms will receive the same 78-week weight management program; the only difference across arms is the presence/absence of incentives. The control group will not receive weekly incentives. This will allow us to test the question of whether incentivizing dietary self-monitoring, weekly weight loss, or both improves the proportion of people achieving clinically significant weight loss from a standard weight management program.

4.3 JUSTIFICATION FOR INTERVENTION

Weight management program. The program is offered through virtual group sessions every 2 weeks for the first 26 weeks given evidence that this frequency leads to clinically significant weight loss. Group sessions make people feel accountable and allow them to gain social support from similar others. The use of virtual sessions will also allow participants to attend sessions safely during COVID-19 and will remove barriers such as transportation. The weight loss maintenance program is delivered primarily by telephone with decreasing frequency (once every 4 weeks to once every 8 weeks). The decreased frequency allows participants to practice weight loss maintenance skills on their own and receive occasional feedback and troubleshooting from the interventionist.

Financial incentive schedule. Throughout the study, the incentive schedule will be unknown to participants. During the first four weeks, the amount will be fixed. Thereafter, the amount will vary,

consistent with an intermittent schedule. The expected value (i.e., maximum participants can earn in the study) is identical across the three incentive arms so any advantage seen in the combined arm cannot be attributed to participants having a larger expected value. Further, the weekly incentives for weight loss and dietary self-monitoring are identical so differences in incentives for the two phenomena do not differentially affect outcomes.

Incentive amount. We selected an expected value of $300 per participant ($150 for weight loss in Phase I and $150 in Phase II), representing 1% of the median annual per capita income for a single person in Madison or Durham (~$30,000).[32] The $300 will be distributed across 52 weeks, with a weekly amount ranging from $0 to $10; the schedule of incentives will be set at study start and identical for all cohorts.

4.4 END-OF-STUDY DEFINITION AND TRIAL CLOSE-OUT

4.4.1 DEFINITION

A participant is considered to have completed the study if they have completed the baseline assessment and the 26-week (6-month), 52-week (12-month), and 78-week (18-month) follow-up assessments.

The end of the study is defined as completion of the 78-week (18-month) follow-up assessment shown in the Schedule of Activities (SoA), **Section 1.3**.

4.4.2 TRIAL CLOSE-OUT

Following the completion of the trial, we will utilize a two-phased approach to communicate study results to all participants: (1) a narrative summary outlining the study's purpose, key findings, and implications will be distributed by email and mail, and (2) two results-disclosure sessions (one in-person and one remotely via video conference) will be led by the principal investigator at each site. The sessions will include disclosure of study findings, participants' responses to study results, and information about participants' perspectives on their participation using prepared group discussion questions.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:
Determined during web screening

1. Aged 18 years or older
2. BMI ≥30 kg/m2
3. Desire to lose weight
4. Agrees to attend outcome visits per protocol
5. Available for class times
6. Transportation and ability to attend in-person study visits at baseline (screening), 26, 52 and 78 weeks
7. Able to stand for weight measurements without assistance
8. Able to speak and read English
9. Able to download and use the MyFitnessPal and Fitbit apps daily
10. Smart phone with data and texting plan
11. Have or willing to create a Gmail address

12. Able to connect to a video conference call using a smartphone, tablet or computer with a webcam and microphone

Determined/reconfirmed during phone screening

1. Score of at least 4 out of 6 on a validated cognitive screener

Determined/reconfirmed during in-person screening visit

1. BMI ≥30 kg/m2

Participant eligibility for qualitative interviews (Black and African Americans)

1. Self-identified as black or African American on demographics questionnaire
2. Completed 52-week assessment

Community member eligibility for qualitative interviews

1. Aged 18 years or older
2. Identified by involvement with community partnership organizations or referred by other community members through snowball sampling

Participant eligibility for qualitative interviews (Male participants)

1. Self-identified male
2. Completed 78-week assessment

5.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participating in this study. These criteria are only assessed at the time points indicated below and not reassessed throughout the study:

Determined during web screening

1. Weight loss of at least 10 lbs in the month prior to screening
2. Weight > 380 lbs
3. Currently enrolled or enrolled in previous month in a clinical, research, or community program focusing on lifestyle change that could affect weight
4. Current use of weight loss medication
5. History of bariatric surgery or planning to have bariatric surgery in the study timeframe
6. Residing in a nursing home or receiving home health care
7. Impaired hearing
8. Significant dementia, drug or alcohol abuse, or unstable psychiatric illness (e.g., schizophrenia, psychosis)
9. Current treatment for cancer or being treated for cancer (besides basal cell carcinoma or squamous cell) in the last 6 months
10. Use of insulin, sulfonylureas, or meglitinides due to increased risk for hypoglycemia
11. Pregnant, breastfeeding, or planning to become pregnant within the study timeframe
12. Diuretic medication doses higher than hydrochlorothiazide 25 mg daily, furosemide 40 mg daily, torsemide 20 mg daily, bumetanide 1 mg daily, or any use of metolazone; use of potassium-sparing diuretics is acceptable
13. Chronic kidney disease at stage 4 or higher
14. Unstable heart disease in the 6 months prior to screening, defined as:
    a. Having acute coronary syndrome (ACS) including STEMI (ST-elevation myocardial infarction), NSTEMI (non-ST elevation myocardial infarction) and unstable angina (UA)

b. Recent or impending coronary revascularization [recent coronary bypass grafting (CABG) or percutaneous coronary intervention (PCI)]
c. Unstable arrhythmia [e.g., hospitalized for unstable atrial fibrillation, supraventricular tachycardia, ventricular tachycardia, ventricular fibrillation and/or firing of implantable cardiac defibrillator (ICD)]
d. Recent acute congestive heart failure exacerbation [requiring increased doses of oral or intravenous (IV) diuretics or hospitalization]
e. Potential participant may be rescreened after 6 months

15. Exertional chest pain
16. Pain, fainting or other conditions that prohibit mild/moderate exercise
17. History of ascites requiring paracentesis

Determined/reconfirmed during phone screening

1. Weight loss of at least 10 lbs in the month prior to screening
2. Currently enrolled or enrolled in previous a clinical, research, or community program focusing on lifestyle change that could affect weight
3. Pregnant, breastfeeding, or planning to become pregnant within the study timeframe

Determined/reconfirmed during in-person screening visit

1. Current use of weight loss medication
2. Use of insulin, sulfonylureas, or meglitinides due to increased risk for hypoglycemia
3. Diuretic medication doses higher than hydrochlorothiazide 25 mg daily, furosemide 40 mg daily, torsemide 20 mg daily, bumetanide 1 mg daily, or any use of metolazone; use of potassium-sparing diuretics is acceptable

5.3 LIFESTYLE CONSIDERATIONS

When blood pressure is measured at baseline and weeks 26, 52 and 78, participants will be asked to refrain from smoking or ingesting caffeine for 30 minutes prior.

5.4 SCREEN FAILURES

Screen failures are defined as participants who complete web and/or screening activities to confirm final eligibility but are not subsequently randomized to the study intervention. Individuals who meet one or more exclusion criteria (e.g., current enrollment or enrollment within the previous 3 months in a clinical, research, or community program focusing on lifestyle changes that could affect weight, or pregnancy/breastfeeding/intention to become pregnant status) that are likely to change over time may be rescreened. Data from people who screen as ineligible will be retained until database lock to enable accurate counting of the number of individuals screened for reporting our results.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

We will conduct the study in four cohorts. We have estimated that we will screen 120 people for each cohort at each site to start 88 people on the group-based intervention (total of 960 individuals screened). At both sites (UW and Duke), we will conduct group classes remotely via video conference, reducing participant burden.

We will recruit from each community via flyers and listservs (e.g., grocery stores, churches, community centers, community-based organizations), paid advertisements in print and on-line publications, and social media (e.g., Facebook, Twitter), and partnerships with community-based organizations. At Duke

we will also post the study on ResearchMatch, a website developed by the NIH National CTSA program to match people in the community to studies for which they might qualify (Duke has access, whereas the UW does not).

All advertisements will direct people to the screening website. Eligibility will be determined via online and/or phone screening. Individuals who screen as eligible will be scheduled for a virtual or in-person screening/consent visit. This determination will be made by the PI based on whether in-person visits are allowed by the institutions and considering the safety of study participants and research staff. The first part of the visit will determine the patient's final eligibility by collecting their weight and height. Once the participant meets all eligibility requirements, they will be asked to provide e-consent and complete the remaining baseline visit measurements.

If we do not achieve sufficient enrollment using these methods for Cohort 1, we will pursue additional strategies, such as referrals from UW or Duke primary care physicians and targeted recruitment via electronic medical record (EMR) recruitment letters. This will involve identifying a cohort of individuals meeting eligibility criteria that can be determined via medical record (e.g., BMI, diagnoses), randomly selecting a subset to receive recruitment letters or alerts through the electronic health record and directing them to the screening website.

To maximize recruitment efforts, we will attempt to reach participants via phone, email, and/or text messaging.

To maximize adherence with the intervention, we will employ the following strategies:

- Conduct the intervention remotely via video conference to reduce participant burden
- Offer group classes at multiple times of the day, including outside conventional work hours (i.e., evenings and weekends), to make attendance less burdensome.
- Send reminder text messages, emails, or phone calls prior to scheduled intervention contacts

To maximize retention for outcome assessments, we will employ the following strategies:

- Send reminder text messages, emails, or phone calls
- Use an online scheduler to schedule outcome assessment visits
- If participants ask to withdraw from the study, we will ask/encourage them to return for the paid outcome assessment visits.

Participant incentives:

- An incentive will be provided for each outcome assessment visit ($40 at 26 weeks vs. $25 at 52 weeks and $50 at 78 weeks).
- The intervention for three of the four arms involves small financial incentives for dietary self-monitoring and/or weekly weight loss. As noted previously, each weekly incentive will range from $0 to $10, for a maximum total of $300 across the 52 weeks of incentives.
- Participants will have the opportunity to keep the Fitbits and BodyTrace scales if desired.

Qualitative Interviews:

Participants enrolled in the study who self-identify as Black American on the baseline demographics survey will be invited to participate in a one-time interview about their experience in the study upon completion of the 52-week study assessment. In the consent form for the Log2Lose study, participants completed the question: "Optional Permissions: I give my permission to have my name and contact information kept, and to perhaps be contacted regarding future research participation opportunities." Individuals who have indicated 'yes' will be contacted and invited to participate. The study team will invite participants via email to complete a one-time one hour interview. After 5 business days, the study team will follow-up with a call to assess interest and schedule the interview.

- The 52-week assessment coincides with the end of the incentivized weight management program and thus will not affect their experience with the intervention being tested. In cohorts 1 and 2, n=72 participants who identified as Black or African American were enrolled in the study between the two sites. We aim to interview up to n=20 participants total. Participants will receive $40 for their participation in the interview. Interviews will occur virtually over Zoom.
- We will invite up to n=10 community members who are not participating in the Log2Lose study from Madison, WI to participate in a **one-time interview** about the study. Community members will be invited from or referred by the community partners listed in the parent grant including the Wisconsin Network for Research Support (WINRS) and the African American Health Network of Dane County. They will receive $50 for their participation in the interview. We will use a snowball sampling approach to ask participants to recommend other interviewees from their communities. Interviews will occur either virtually over Zoom or in-person at a public location of choosing.
- Through this process, the study team will collect contact information, including name, email address and phone number from interested individuals in the AAHN. The study team will then invite members via email to participate in an interview. After 5 business days, the study team will follow up with a call to assess interest and schedule the interview. Upon completion of the interview, the team member will ask the interviewee to identify individuals who might be willing to complete an interview and collect contact information including name, email address and phone number. The team will then follow up in the same way with identified individuals until we have achieved thematic saturation. Following the interview, we will ask the interviewee for the address to which they would like us to mail their payment.
- Following analysis, interviewees will receive a summary of the results by email and be invited to provide feedback within two weeks. The purpose of this communication is to offer participants the opportunity to review and comment on the interpretation of their input. The results will contain no identifiable information. No compensation will be provided, and no follow-up will occur if participants do not respond. Summary feedback may be incorporated into our interpretation of results included in articles and presentations.
- Log2Lose participants who self-identify as male will be invited to participate in a one-time interview about their experience in the weight management program upon completion of the 78-week study assessment. The 78-week assessment is the end of active participation for enrolled participants. We aim to conduct interviews in Winter 2023, when cohorts 1 and 2 will have completed 78-week data collection.
- We will invite up to n=30 male-identifying participants for a one-time, hour-long interview. We will purposefully recruit men who have had higher (attended at least 50% of classes and calls; n=15) and lower (attended <50% of classes and calls; n=15) engagement in the study to obtain viewpoints from both groups.
- Male participants will receive $40 for their participation in the interview. Interviews will occur virtually over Zoom.
- Following analysis, male interviewees will receive a summary of the results by email and be invited to provide feedback within two weeks. The purpose of this communication is to offer participants the opportunity to review and comment on the interpretation of their input. The results will contain no identifiable information. No compensation will be provided, and no follow-up will occur if participants do not respond. Summary feedback may be incorporated into our interpretation of results included in articles and presentations.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

Weight loss program in weeks 0-26 (all participants). This program will be delivered via approved videoconference software. Group meetings will be led primarily by a registered dietitian. Prior to the first meeting, participants will receive a wrist-worn Fitbit activity tracker to promote activity monitoring, educational handouts that are pertinent to the sessions' topics, instructions on using the Fitbit and/ or MyFitnessPal, and a daily calorie budget based on a daily 500 kcal deficit. Participants in cohort 1 will link the Fitbit and MyFitnessPal accounts. Each person's calorie budget will be calculated using their screening weight and the Mifflin St. Jeor formula and may be adjusted to account for unusually high activity levels or slower- or faster-than-expected rate of weight loss. Each meeting will have time devoted to practicing behavioral goal-setting and physical activity demonstration.

Weight loss maintenance program in weeks 27-52 (all participants). Participants will transition to the behavioral maintenance intervention in Week 27. It involves a shift from initiation-oriented to maintenance-oriented skills training, then switches mode from in-person (or video conference) to telephone, and finally decreases contact frequency.[33,34] Three group classes will address metabolic changes that occur with weight loss maintenance; the role of physical activity in maintenance; the importance of relapse prevention planning, including group practice with this skill; and importance of identifying a support person and eliciting supportive behaviors. Eight maintenance calls will have the same structure: review of satisfaction with outcomes of behavior change in several domains (e.g., physical attractiveness, mobility); weight self-monitoring; relapse prevention planning; and social support.

Financial incentive intervention structure and delivery. Participants will be randomized to receive/not receive adjunctive incentives for dietary self-monitoring and/or weight loss during weight loss (Phase I) and the first 26 weeks of weight loss maintenance (Phase II). In the last 26 weeks of weight maintenance, participants will not receive incentives (Phase III). To determine if participants qualify for an incentive each week, data will be obtained from BodyTrace scales and the MyFitnessPal and/ or Fitbit apps to be installed on participants' smartphones with staff assistance (if needed) at the screening/consent visit.

6.1.2 ADMINISTRATION AND/OR DOSING

All incentive activities will be performed by study personnel who are trained to use the software system at Duke. Specific educational or clinical background is not required.

Incentive schedule. Participants will be eligible to receive incentives weekly during Phases I and II.

Incentive amount. Each weekly incentive will range from $0 to $10; the amount will be unknown in advance to participants. The total maximum earnings across the three incentive conditions are $300 per participant.

Incentive notification. Text messages were created for the various scenarios (arm, sex assigned at birth, met or did not meet incentive). Participants who meet their arm's incentive criterion will receive a text message at approximately 8am on Day 1 (allowing for flexibility around key holidays) of the following week informing them they have earned an incentive for the previous week's success with self-monitoring and/or weight loss (depending on study arm) and encouraging them to continue to self-monitor and lose weight. Participants in these arms who do not meet the criterion will receive a text message informing them of the missed incentive amount and encouraging them to self-monitor and lose weight. Participants in the no-incentive arm will receive a text message encouraging them to self-monitor and lose weight. All text messages will be pre-programmed according to the date of the first scheduled group class, and staff will select the appropriate message on the software dashboard to send to each participant.

Incentive provision. All participants will receive a study-provided debit card at the first group class. Participants will be told they will receive the payment for the outcome assessment visit via credit to the card. In the combined-incentive and dietary self-monitoring-only arms, participants will also be told they may receive credits to the card at various times during the study for logging sufficiently in the dietary app; in the combined-incentive and weekly weight loss arm, they may receive credits to the card at various times for losing weight. Participants will be informed of the criteria for a reward but will not be informed of the scheduled incentive amounts.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

The RDs will complete the appropriate training before delivering the weight management program, which will include recommended readings and role-playing. The investigators, project managers, and dietitians will work collaboratively to monitor fidelity to both the weight management program and the financial incentives intervention. Our intervention manual includes the outline and talking points for each group class, the telephone script for each maintenance call, and fidelity checklists corresponding to each intervention contact. Each group class and telephone call will be recorded. Drs. Gierisch and Voils will meet with the dietitians regularly to review recorded phone calls and discuss any emergent issues with weight management program delivery. The primary goal of these meetings is to ensure consistent delivery of the weight management program across sites and study arms. The goal is to review 10% of calls that are both randomly selected and requested for review by the dietitians. Fidelity monitoring meetings are not intended as a mechanism for identifying and reporting adverse events.

To promote fidelity to the financial incentives intervention, the project staff will review incentive delivery reports and meet with department business managers.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND MASKING

Following e-consent, participants will be randomized to the 4 arms, stratified on site, sex assigned at birth (M/F) and initial body mass index (BMI) (<35 vs. >=35 kg/m^2). The data coordinating center's senior biostatistician will generate a stratum-specific, permuted block randomization schedule. The block size will be randomly chosen within a range of reasonable values and will not be revealed to investigators. Study-arm assignment will be available immediately to research staff after consent through the password-protected REDCap electronic data capture (EDC) system and cannot be modified. They will then be able to inform the participant of the date/time of their first group class, where participants will be unmasked to their randomization assignment. This web-based EDC will be set up and maintained by the Duke Data Coordinating Center data management team. People who provide consent and are allocated but do not provide baseline weight will not be considered randomized and thus may be replaced. People who provide consent and baseline weight are considered randomized and will not be replaced.

Participants will not be masked to their study arm, as they will know whether they are eligible to receive incentives, and for what (i.e., dietary self-monitoring or weekly weight loss). The site PIs will be unmasked because they will disclose the arm in the first group session and will listen to recorded classes and calls. However, they will not have access to study data. Only outcome assessors will be masked to study arm.

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

Weight loss program adherence: We will send a reminder text message and/or email in advance of every group class meeting. We will take attendance at each meeting and track the number of maintenance calls participants receive/attend.

Dietary self-monitoring criteria for incentives. Instructions to self-monitor dietary intake will be identical across arms. During group classes, all participants will receive instruction about how to use the MyFitnessPal and/ or Fitbit apps and be urged to enter all food and drinks.

During Phase I, the self-monitoring criterion for the combined-incentive and dietary self-monitoring-incentive arms is logging a daily minimum number of calories ≥ 5 days per week, one of which must be a weekend day.[35]The minimum of daily calories that must be logged is 1200 for males and 1000 for females.

During Phase II, the self-monitoring criterion will be at least 3 days per week, one of which must be a weekend day. This decreased emphasis on dietary self-monitoring during maintenance is consistent with our weight loss maintenance protocol, which has participants focus on weight self-monitoring when maintaining weight loss and return to dietary self-monitoring when they surpass their weight regain threshold.

Weight change criteria for incentives. All participants will be encouraged to weigh themselves every day since people who weigh daily tend to achieve greater initial weight loss and experience less regain than those who weigh less frequently.[36]

During Phase I, the weekly weight loss criterion for the combined and weekly weight-loss arms is that the last weight of the week must be lower than the first weight of the week.

During Phase II, the weekly weight loss criterion is that people must remain within 3 pounds of their 26-week weight. This is consistent with our goal of preventing regain, which is measured against the (presumed) nadir.

The software system sends automated weekly messages that correspond with all possible scenarios a participant could face each week regarding the incentives. Incentive results and amounts are auto populated in the system for a staff member to review.

6.5 CONCOMITANT THERAPY

Recent or current participation in another weight loss program and use of weight loss medications are exclusion criteria. We will query participation in any other weight loss program during study participation every 26 weeks. This information will be used in sensitivity analyses. Participants will not be excluded during the trial if they report engaging in other weight loss efforts (e.g., medications, other lifestyle programs).

6.5.1 RESCUE THERAPY

N/A

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

If a participant indicates a wish to withdraw from the study, we will ask them to consider withdrawing from the intervention but continuing the outcome assessments to minimize bias from missing data.

7.2 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if they fail to provide a 78-week weight. Loss to follow-up will not be determined by intervention adherence.

7.3 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Following randomization, participants will be withdrawn by the study team only in the following scenarios:

- If a participant becomes pregnant during the study, they will be excluded immediately from further participation in all study activities, including outcome assessments.
- If a participant develops cancer and is actively receiving ongoing cancer treatment that the study physician feels could interfere with the intervention or affect the outcomes (except for basal cell carcinoma or squamous cell), they will be excluded from further participation in all activities, including outcome assessments.
- If a participant undergoes bariatric surgery during the study, they will be excluded from further participation in all study activities, including outcome assessments.
- If the study physician determines it would be unsafe to continue participation.
- Participants may withdraw from participation in the study at any time upon request.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Endpoints and Assessments. Assessments will be conducted in-person or virtually, depending on judgment of the PI. Mode of data collection will not have adverse effects on our ability to test our study hypotheses. All study measurements will be collected by a study team member or entered by the participant into REDCap. We will collect baseline data for all measures during the individual screening/consent visit. Weight at the screening visit will be used to determine eligibility, whereas weight collected 7 days prior and one day following the first group class via BodyTrace scales will be used as the outcome measurement in the analyses of weight. This will allow the first outcome measurement to be collected at a uniform time for all participants (given that recruitment and screening visits will occur over a period of up to 8 weeks). Participants will be asked to weigh themselves on the BodyTrace scale 7 days prior and 1 day following the first group class. If participants cannot attend the first class, they must weigh themselves on their BodyTrace scale in the allotted window or they will not be able to participate. The window for data collection visits starting at 13 weeks will be +/- 10 days from the target assessment date for surveys and +/- 7 days from the target assessment date for weight and blood pressure.

Baseline demographic and clinical characteristics (baseline). We will collect date of birth (for calculation of age), ethnicity, race, sex assigned at birth, gender identity, employment, financial stress, highest educational level attained, marital status, insurance status, previous weight loss attempts (yes/no), nicotine use, presence of obesity-related comorbidities (hypertension, dyslipidemia, type 2 diabetes, obstructive sleep apnea, and gastroesophageal reflux disease), depression, and life events

that may affect weight changes. If assessments are done in person, height will be measured using a portable stadiometer, with shoes removed; if remotely, it will be self-reported.

Primary and secondary outcomes: Weight (baseline, every 26 weeks). Weight at 26 weeks will be the primary endpoint; weight at 52 and 78 weeks will be secondary endpoints. If assessments are done in person, participants will be weighed on a calibrated study scale wearing light clothing (i.e., no outerwear such as jackets) and with shoes removed; if remotely, they will be asked to weigh themselves at home on a study-provided scale, also in light clothing and with shoes removed.

Secondary outcome: Blood pressure (baseline, every 26 weeks). Blood pressure will be assessed with an Omron HEM-907XL Professional Blood Pressure Monitor (or equivalent). Cuff size will be determined by arm circumference. An appropriately sized blood pressure cuff (small adult, regular adult, large adult, and extra-large adult) will be used. A blood pressure measurement will be obtained on the right upper arm (or left if the right is unsuitable) after the participant has been seated for 5 minutes with back supported, feet flat on the ground, and arm at heart level. A second reading will be taken one minute after the first. If the difference between the systolic measurements is >15mmHg, then a third reading will be taken, one minute after the second reading. The participant will be instructed to refrain from smoking and ingesting caffeine 30 minutes prior to their visit. If we are unable to collect blood pressure during an in-person visit for any reason, we will count it as missing data.

Secondary outcome: Cardiovascular medication use (baseline, week 78). Self-reported use of medications for blood pressure, cholesterol, or type 2 diabetes will be queried at baseline and 78 weeks. Participants will be asked to bring all medications at these time points. If virtual, participants can take pictures of their pills and/or upload a list of medications from the EMR. Study staff will transcribe medication(s) name, dose, and frequency.

Mediator: Motivation for weight loss (baseline, every 13 weeks). The 15-item Treatment Self-Regulation Questionnaire will measure individual differences in the degree to which motivation for behavior is intrinsic (autonomous) and extrinsic (controlled). Separate scores will be calculated for each subscale by averaging relevant items.

Covariate: Delay reward discounting (baseline, every 26 weeks). The Monetary-Choice Questionnaire is a 27-item self-administered questionnaire. The protocol is scored by calculating where the respondent's answers place them amid reference discounting curves, where placement amid steeper curves indicates higher levels of impulsivity.

Covariate: Weight loss choice (baseline, every 26 weeks). This questionnaire serves to examine temporal/delay discounting based on weight loss rewards specifically. Modeled after the Monetary-Choice questionnaire, this survey includes 27 items in which they choose their preference for one of two reward scenarios presented.

All or nothing thinking (baseline). This 11-item scale assesses participants' eating-specific (4-items) and general aspects (7-items) of dichotomous thinking on a response scale from 1-4. A separate score will be calculated for each of the two subscales.

Cost-related variable: Time spent on intervention activities (baseline, weeks 13, 26, 52 and 78). We will ask participants to report the time spent attending virtual and telephone-based sessions and on intervention-related tasks like dietary self-monitoring and self-weighing. Participants will be asked to estimate the total time spent logging in MyFitnessPal and/ or Fitbit apps and weighing themselves over the previous week at baseline and weeks 13, 26, 52 and 78. These time estimates will be combined with study records on classes attended to estimate total time related to attending group classes. We will use study records to calculate the total time spent on intervention telephone calls during Phases II and III (we will record every telephone call as part of our fidelity monitoring procedures).

Cost-related variable: Health status (baseline, weeks 13, 26, 52 and 78). The 5-level EQ-5D (EQ-5D-5L) is an instrument for measuring general health status. It includes 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), each rated by 1 of 5 response options (*no problems, slight problems, moderate problems, severe problems, and extreme problems*). Items are used to calculate a summary score for use in health economic analyses and are not considered validated when used individually.

Physical activity: Fitbit. (baseline, 26, 52 and 78). The Fitbit has a lower cost and simpler logistical requirements as compared to research-grade accelerometers such as the ActiGraph. Furthermore, it is sufficiently well-validated for steps and minutes of physical activity to support its role as a measure of physical activity as a secondary outcome of the Log2Lose trial. At each time point, physical activity data will be obtained directly from Fitbit.

Concomitant treatment assessment: Weight loss methods (week 26, 52 and 78). Participants will be queried about their weight loss methods through any other means outside of the study.

Satisfaction with outcomes: Positive or Negative Impacts of Log2Lose Participation (week 26, 52 and 78). Nine items will assess satisfaction with outcomes of changes in the following domains: mood, motivation for weight loss, appetite and cravings, physical strength and function, personal relationships, ability to work, compensatory behavior, and physical appearance. Response scales range from -4 (Has worsened a great deal) to +4 (Has improved a great deal).

Process measure: Text message evaluation (week 78). Participants will be asked a short battery of 12 questions concerning their interaction and preference for the text messages about weight loss tips and incentives (only for groups who were randomized to receive incentives).

Class evaluation survey. This survey consists of 18 questions about participants' thoughts and preferences about the virtual class delivery. In order to administer this survey as close as possible to when the classes occur, Cohort 3 will complete this survey at 52 weeks and Cohort 4 will complete this survey at 26 weeks. Cohorts 1 and 2 will not complete this survey as it had been over 26 weeks since their final class when this survey was added.

Qualitative interviews. The interview guide will focus on the participant experience and preference around weight management program topics, behavior change techniques such as self-monitoring, and feeling of belonging in group sessions.

The interview guide for the key community members will focus on perceptions of obesity as a priority health problem in the community and preferences for features of weight management programs.

Both interview guides were submitted as a future amendment before interviews were conducted.

8.2 SAFETY ASSESSMENTS

Weight loss may lower blood pressure, cholesterol, and blood sugar and thus cause symptoms if participants' medications are not adjusted by their provider. During the intervention, participants will be counseled on how to recognize and respond to symptoms of low blood pressure or low blood glucose. Study personnel will also be trained how to respond when participants report symptoms of severely low or high blood pressure. The study physician will provide recommendations to the study team regarding any issues that arise with specific participants. Participants may be provided with contact information for the study physician as deemed necessary. The study physician may address health issues related to physical activity; participants may also be referred to their own primary care provider for additional work-up.

Participants will receive an automated AE survey from REDCap at 9, 18, 26, 35, 44, 52, 61, 70, and 78 weeks. Adverse events can also be brought up by the participant during classes (although unlikely due to limited privacy), maintenance calls, outcome assessments, by email, and in other interactions with the study staff. In such cases, a study team member will follow-up with participants to collect the appropriate adverse event information as described in Section 8.3.

8.3 ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

An adverse event (AE), as defined by the US Department of Health and Human Services' Office of Human Research Protections (OHRP), is, "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." Adverse events encompass both physical and psychological harms.

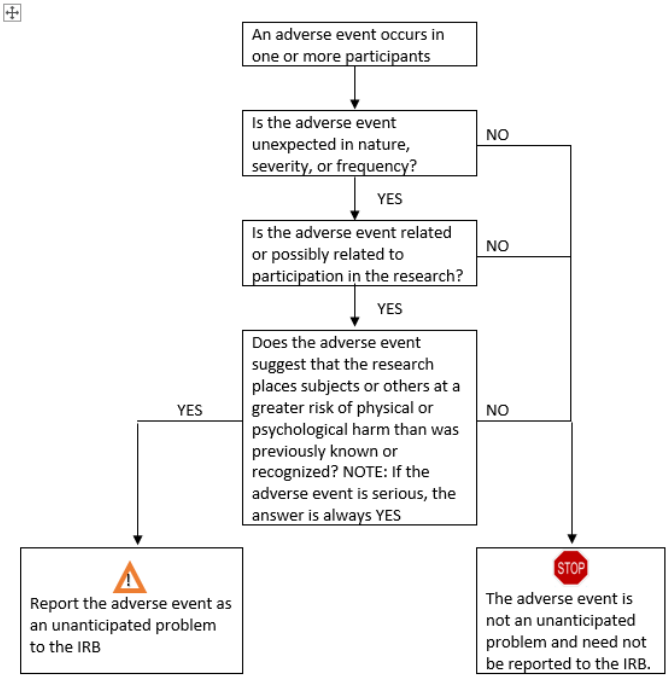
Given the minimal risk nature of this study, we define an AE as including any:

- Injury in which medical attention was sought
- Major medical event (e.g., surgical procedures, illness)
- Hospitalization
- New diagnosis of a medical condition (e.g., new diagnosis of diabetes or major depressive disorder)
- Worsening of a diagnosed medical condition in which medical attention was sought (e.g., arthritis flare requiring medical intervention, increased depression symptoms requiring changes to treatment plan)
- Disordered eating behaviors (new or worsening behavior from baseline) that are intended for weight loss or management that include: a) Self-induced vomiting, b) Laxative/diuretics abuse, c) Severe calorie restriction (based on clinical expertise of a registered dietitian or physician), or d) Excessive exercise that is compulsive (based on clinical expertise of a registered dietitian or physician).

AEs that are classified as:

- 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 participant population being studied; and
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggest that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized OR are *serious*

shall be considered *unanticipated problems (UPs)*. The PI will report all UPs to the University of Wisconsin Madison IRB as per the guidelines published in the UW IRB's Investigator Manual. The OHRP flowchart below provides an algorithm for determining whether an AE is a UP that needs to be reported:



8.3.1 CLASSIFICATION OF AN ADVERSE EVENT

The study physicians will classify all AEs to determine if they meet the criteria for reporting to the IRB (unexpected, related, and serious or suggests the research places subjects or others at a greater risk of harm).

8.3.1.1 UNEXPECTED

OHRP classifies an adverse event as *unexpected* if the event is not consistent with the known or foreseeable risks associated with the procedures involved in the research that are described in the IRB-approved research protocol and consent document, OR the event is not the natural progression of an underlying disease, disorder, or condition of the subject(s) predisposing risk factor profile for adverse events. The study clinician will be responsible for determining whether an AE is expected or unexpected.

8.3.1.2 RELATED

All adverse events (AEs) will have their relationship to study procedures, including the weight loss program, assessed by the study physician based on his clinical judgment. The degree of certainty about causality will be graded using the categories below.

- **Unrelated** – The AE is completely independent of study procedures administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.
- **Unlikely to be related** – A clinical event, including an abnormal laboratory test result, whose temporal relationship to study procedures administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the

study procedures) and in which other drugs or chemicals or underlying disease provide plausible explanations (e.g., the participant's clinical condition, other concomitant treatments).

- **Possibly Related** – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of study procedures). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related", as appropriate.
- **Probably Related** – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time after administration of the study procedures, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal.
- **Definitely Related** – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study procedures administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study procedures should be clinically plausible. The event must be pharmacologically or phenomenologically definitive.

8.3.1.3 SERIOUS OR RISK OF HARM NOT PREVIOUSLY KNOWN OR RECOGNIZED

An AE is serious, as defined by OHRP, if it is temporally associated with the subject's participation in research and 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; or 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.

AEs that are unexpected and related or possibly related to participation in the research, but *not* serious, will also be classified as UPs if they suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

8.3.1.4 SEVERITY

The severity of all AEs will also be classified following the US Dept of Health and Human Services' Common Terminology Criteria for Adverse Events, Version 5.0:

- **Mild** – Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
- **Moderate** – Minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living.
- **Severe** – Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living.
- **Life Threatening -** Life threatening consequences; urgent intervention indicated
- **Fatal -** Death related to AE

8.3.2 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) may come to the attention of study personnel via email or during study visits, group classes, or intervention telephone calls. In such cases, study staff will complete an AE survey on the participant's behalf and will call them to obtain sufficient information to allow the study clinicians to determine expectedness, severity, and relatedness, and whether an adverse event suggests that the research places subject or others at a greater risk of harm than was previously known or recognized. Participants are asked at 9, 18, 26, 35, 44, 52, 61, 70, and 78 weeks via an AE automated online survey if they have experienced any adverse events. Reports of AEs are monitored and followed up by study personnel within 5 business days.

No individual items or complete measures administered at baseline or follow-up time points will be used to determine if an adverse event has occurred because these items and measures have not been validated for determining clinically significant change. However, if a participant answers negatively (i.e., score <0) on the satisfaction with outcomes survey to two questions (i.e., 'How has your mood or emotions changed?' and 'How has your use of vomiting, skipping at least 2 meals in a row, using laxatives, or excessive exercise changed?'), the participant will be directed to complete an AE survey. Participants will also be directed to complete an AE survey if they answer 'Extremely' or 'Severely' depressed/anxious on the EQ-5D-5L survey. Participants may decline to complete the AE survey. If so, we will support participant autonomy and assume they do not wish to disclose anything to the study team. This process will only occur for cohort 4, week 78 reflecting the time when this process was amended.

All AEs reported by the participant during the study will be documented and reported according to institutional requirements for SAEs, AEs, and UPs.

Information to be collected from the participant and stored in REDCap will include event description, date of onset, and date of resolution/stabilization of the event. The study's clinician will classify all AEs to determine if they meet the criteria for reporting to the IRB (unexpected, related, and serious or suggests the research places subjects or others at a greater risk of harm). If they meet the reporting criteria, they will be reported as UPs to the University of Wisconsin Madison IRB within 14 business days (as per the guidelines published in the *UW IRB's Investigator Manual*). Additionally, guidance from the IRB will be sought in occurrences where an adverse event is determined to be unexpected and related to the study. Adverse events that are possibly, probably, or definitely related will be followed for outcome information until resolution, stabilization or until the affected participant's last day of study participation.

The DMC will review all AEs every 12 months or ad hoc depending on the clinical case at the discretion of the study clinician(s) or DMC.

8.3.3 ADVERSE EVENT REPORTING

This study will follow the reporting requirements and submission time-frames as published in the *UW IRB's Investigator Manual*. Because this study does not involve drugs, biologics, or investigational devices, AEs meeting reporting criteria as UPs will be reported to the UW IRB and the DMC within 14 business days.

The UP report to the IRB will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents a UP

- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

8.3.4 REPORTING EVENTS TO PARTICIPANTS

Under the direction of the IRB and/or DMC, corrective actions and/or changes in the research protocol or informed consent process/document will be undertaken to protect the safety, welfare, or rights of subjects or others.

8.3.5 EVENTS OF SPECIAL INTEREST

Crisis Events

If a participant self-reports currently experiencing or is at risk of an imminent crisis event during their participation in the study, the principal investigator, in consultation with the study physicians as appropriate, will be notified for appropriate follow up and reporting. Follow up would be prompted if these disclosures included the following:

- Intimate partner violence
- Increased levels of:
    - depression and anxiety symptoms (a new onset of sustained, or worsening symptoms from baseline such as: profound sadness, a sense of despair, a loss of enjoyment, or uncontrollable anxiety that interferes with ability to function).
    - disordered eating behaviors (see section 8.3)

Using clinical judgment, the interventionist will offer resources at the time (if appropriate). The participant will be offered the opportunity to follow up with the PI or study physician. Participants will be made aware that resources (e.g., list of therapists, domestic abuse hotline) are available as part of the online participant materials. Within 3 business days, the interventionist will follow up with PI to see if further action needs to be taken.

8.3.6 REPORTING OF PREGNANCY

If a participant becomes pregnant, they will be withdrawn from further participation, including intervention and outcome assessments, by the site principal investigator.

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

Primary Endpoint(s): We hypothesize that incentivizing weekly weight loss and dietary self-monitoring will significantly increase the proportion of participants who achieve 5% weight loss at week 26 relative to those who do not receive incentives. Alternatively, our null hypothesis is that there will be no difference in the effects on weight loss of incentivizing weekly weight loss and dietary self-monitoring at week 26.

Secondary Endpoint(s): We hypothesize that incentivizing weekly weight loss and dietary self-monitoring will significantly increase the proportion of participants who achieve 5% weight loss at week 52 and 78 relative to those who do not receive incentives. Alternatively, our null hypothesis is that there will be no difference in the effects on weight of incentivizing weekly weight loss and dietary self-monitoring at week 52 and 78.

9.2 SAMPLE SIZE DETERMINATION

Sample size, clinically significant difference and power. To achieve our study objectives, we will enroll 700 community-dwelling adults with obesity (body mass index ≥ 30 kg/m^2). Inclusion and exclusion criteria are described in the Recruitment and Retention Plan. While the pilot study had 83% retention at 24 weeks, our power analyses conservatively assume 80% retention as this is a common criterion used in weight management studies, resulting in N=560 (140/arm). For objective 1, the presumed effect sizes are presented in scenario (1) in **Table 2**. It was chosen based the results of our pilot study (scenario (2)) and investigator judgment, since there are no clinical guidelines or prior RCTs to suggest the desired magnitude of differences between groups. Other scenarios considered are in scenarios (3) through (10). In each, the proportion achieving 5% weight loss is highest in arm A, followed by B, C and then D (no-incentives).

Table 2: Power Scenarios Considered

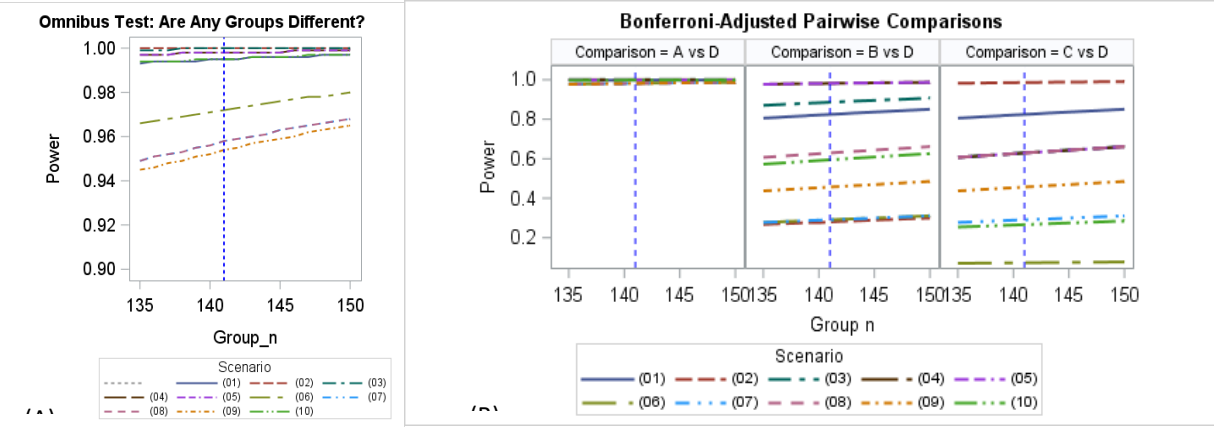
		Incentive for Interim Weight Loss									
		Scenario (1)*		**Scenario (2)****		**Scenario (3)**		**Scenario (4)**		**Scenario (5)**	
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Incentive for Dietary Self-Monitoring	Yes	A: **60%**	B: **49%**	A: **70.0%**	B: **63.2%**	A: **60%**	B: **45%**	A: **60%**	B: **50%**	A: **55%**	B: **50%**
	No	C: **49%**	D: **30%**	C: **47.4%**	D: **36.8%**	C: **40%**	D: **25%**	C: **40%**	D: **25%**	C: **40%**	D: **25%**
		Scenario (6)		**Scenario (7)**		**Scenario (8)**		**Scenario (9)**		**Scenario (10)**	
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Incentive for Dietary Self-Monitoring	Yes	A: **50%**	B: **35%**	A: **50%**	B: **35%**	A: **50%**	B: **40%**	A: **50%**	B: **37.5%**	A: **60%**	B: **45%**
	No	C: **30%**	D: **25%**	C: **35%**	D: **25%**	C: **40%**	D: **25%**	C: **37.5%**	D: **25%**	C: **40%**	D: **30%**

*Target power scenario; ** Observed scenario in R34 pilot study

The power calculations assume a 0.05 Type I error rate and a (conservative) Bernoulli standard error of $\sqrt{\pi}(1-\pi)$ with π= 0.5. The powers for the omnibus test of no difference among the 4 study arms are computed from a $F(3,4(n-1),\phi)$ distribution, where n is the arm sample size and ϕ is the noncentrality parameter from the scenario. As can be seen in **Figure 1(A)**, the omnibus powers are ≥94% for all scenarios and group final arm sample sizes ranging from 135 to 150. Of key interest is a comparison of each incentivized arm to the no-incentive arm. Powers for those 3 pairwise comparisons, using a Bonferroni-corrected t-test, are presented in **Figure 1(B)**. The powers are highest for comparing combined incentives to no incentives and lowest for comparing incentives for weekly weight loss to no incentives, as would be expected due to the ordering in the scenario tables.

For our target sample size of 140 per group (560 total), we estimate our powers to be 99.8%, 82.8% and 82.8% for comparing combined incentives to no incentives (A to D), incentives for dietary self-monitoring to no incentives (B to D), and weekly weight loss to no incentives (C to D) respectively. The omnibus power is 99.5%.

Figure 1. (A) Power for Omnibus test of differences among arms (B) Power for Pairwise comparisons with no-incentive arm



The longitudinal assessment of strategy impact on weight loss maintenance (clinical study Objective 2) will be based on the same participants measured over time.

9.3 POPULATIONS FOR ANALYSES

Intention-to-Treat (ITT) Analysis Population (i.e., all randomized participants, regardless of intervention adherence or dropout.

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

A standard analytic approach to a 2x2 factorial is to estimate main effects of the factors and their interaction (3 degrees of freedom). An alternative, but equivalent, structure is to consider it a one-way, four arm ANOVA design (i.e., simple randomization to 4 groups).[37,38] Given the pre-planned, main research questions are to understand the impact of incentivizing behavior (beyond the weight management plan), it is more straight-forward to frame the analysis as comparisons of the three incentivized arms (A-C) to the non-incentivized arm (D) (also 3 degrees of freedom). While the interpretation of parameters estimated and testing differ between the two approaches, they are equivalent in that, analyzed either way, one would come to the same conclusions.

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

Objective 1: Compare the proportion of patients who achieve 5% weight loss at 26 weeks across the four arms to assess effectiveness of the financial incentive strategies.

Objective 2**:** Compare the longitudinal trajectories of participants in the four arms across 26, 52, and 78 weeks on the probability of achieving and maintaining 5% weight loss from baseline to assess the relative effectiveness of the incentive intervention strategies in promoting long-term weight loss.

The analytic framework proposed here is broad enough to address both clinical study Objectives 1 and 2 above in a single generalized linear mixed model (GLMM). The logit of the probability of a participant achieving 5% weight loss from baseline at 26, 52, and 78 weeks will be modeled within study arm. The outcome measure is an indicator of whether the participant's weight loss at each time point is 5% of

baseline weight. The underlying distribution of will be assumed Bernoulli at the individual level, Binomial at the arm level. Random participant-specific intercepts will be included to account for within-person correlation over time. This generates an exchangeable correlation structure across the 4 study arms, the adequacy of which will be assessed using likelihood-based measures of model fit (e.g., Akaike or (Schwarz) Bayesian Information Criterion) and modified as needed. While the randomization will be stratified, the primary analysis will not be stratified by site. This is because we expect strong consistency in executing the weight-loss intervention in both sites across all participants. In addition, the variability in participant populations in the two sites is expected and enhances the generalizability of the study's findings. The model for clinical study Objectives 1 and 2 is given below in equation (1), using arm D (no incentives) and 26 weeks as the reference group, as the indicator function of and as a vector of random effect for participants *and group*.

$$(1)\ logit(P(Y_{it}=1)= \beta_0+\beta_1 I(A)+\beta_2 I(B)+\beta_3 I(C)+\beta_4 I(\underline{t}=52\text{wk})+\beta_5 I(\underline{t}=78\text{wk})+ \beta_6 I(A) I(\underline{t}=52\text{wk})+\beta_7 I(A) I(\underline{t}=78\text{wk})+ \beta_8 I(B) I(\underline{t}=52\text{wk})+\beta_9 I(B) I(\underline{t}=78\text{wk})+ \beta_{10} I(C) I(\underline{t}=52)+\beta_{11} I(C) I(\underline{t}=78)+ \gamma_i.\ i=1,2,..,N;\ \underline{t}=26,52,78\ \text{weeks}$$

The assigned study arm, times, and their interactions will be tested for significance. This approach allows for the estimation of individual arm trajectories in the logit scale over the 3 time points, which can be converted to trajectories of estimated probabilities. A joint test of the 3 contrasts comparing each incentivized group (A-C) with the non-incentivized group (D) at 26 weeks addresses the clinical study **Hypothesis 1a (Objective 1)**. A joint test of contrasts to compare arm A versus B and C at 26 weeks addresses **Hypothesis 1b (Objective 1)** to determine if incentivizing two behaviors is better than only one**.** A contrast of arms B and C at 26 weeks (**Hypothesis 1c (Objective 1))** compares the two single-behavior incentive groups. Testing the interaction effects of arm and time will determine if the trajectories are parallel over time (clinical **Objective 2**), while main effects assess overall shifts up or down of the trajectories. Follow-up tests, with adjustments for multiple testing, will be used to determine where the major differences lie. Unless otherwise stated, all hypothesis tests, including sets of contrasts for on hypothesis, will be two-sided at the 0.05 level.

Secondary analyses will be used to assess potential explanations for any differences found among study arms at 26 weeks and longitudinally. We will conduct exploratory analyses of **differences in the primary outcome by sex assigned at birth** and consider the impact of baseline weight and race. We will also conduct sensitivity analyses to determine if results differ for participants who did versus did not engage in other weight loss methods during the study. Secondary analyses will be done modeling BP (both systolic and diastolic), weight, and change in medication use for BP, diabetes, and cholesterol (increase/decrease/no change) as outcomes in the extended GLMM framework defined in equation (1), both unadjusted and adjusted for person-level covariates, with appropriate distribution (including multinomial for medication use) and link functions to match the outcome measures. Finally, the longitudinal trajectories of weight change over time, as well as BP and change in medication use, will be done using a GLMM approach, both unadjusted and adjusted for person-level covariates. For continuous outcome measures, we will first consider distributions in the exponential family to find a suitable match or attempt to transform the measure to normality. Although our primary outcome is based on % weight loss, corresponding to the literature linking it to improved health outcomes, results will be also reported in terms of average BMI effect sizes, to be consistent with NHLBI recommendations for results reporting in weight management studies.[39]

Missing Data. We expect missing data on any variable**.** Based on the pilot R34 study, we expect weekly variation on availability of needed data to earn an incentive. However, given that additional efforts were made to bring participants in for an in-person weight measurement at the week-26 endpoint, 77 of 93 (83%) did so with no noted differences by strata (e.g., age, sex and race). Thus, we expect it will be reasonable to assume missing weights at 26 weeks will be low and could be considered either missing completely at random (MCAR) or missing at random (MAR)—either of which is accommodated in GLMMs. To assess sensitivity to the MAR assumption, we will bound the estimates by first assuming that all missing values at 26 weeks did not meet the 5% threshold, and then assume that they did. If the results are sensitive to these extreme bounds, then we will impute the missing value using the closest home cellular weights within 4 days and its inherent variability. In the

R34, we found strong consistency between the in-person and the closest BodyTrace measurement of that week (R^2=.998) with a discernable additive bias of 2.2 pounds, reflecting higher in-person weights (taken late in the day, fully dressed) than home weight (taken in early morning, before dressing). If no proximal weight is available and the missingness is substantial, then we can use multiple imputation to address the problem. Furthermore, we will look for associations between measured characteristics of the participants at baseline and the probability of missing the week-26 measure to look for reasons for missingness that could violate the MAR assumption.

Due to the longitudinal nature of the study, once a participant misses a key in-person measurement (e.g., 26-week), they may be more likely to miss a later measurement (e.g., 52 week). It is often reasonable to assume that 'drop-out missingness' is MAR. We will look for associations of measured values at baseline and 26 weeks with the probability of missing weight to see if that can inform us of causes of such missingness. As with the week 26 measure, sensitivity analyses and imputation will be performed to assess the impact on conclusions drawn.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

Secondary endpoint (weight at 52 and 78 weeks) is not independent of the primary endpoint (weight at 26 weeks) and is described in **section 9.4.2**

9.4.4 SAFETY ANALYSES

N/A

9.4.5 BASELINE DESCRIPTIVE STATISTICS

We expect randomization to distribute baseline characteristics and known and unknown confounders evenly across study arms. We will examine and report baseline demographics across arms to assess whether baseline variables are equally distributed.

9.4.6 PLANNED INTERIM ANALYSES

There is no interim analysis planned. However, we are prepared, if requested by the DMC at any point, to calculate interim statistical power for its review. Projections of interim power can be made under several scenarios for future data, including assumptions that current trends continue or that the future data reflect the relative effects used in the design of the trial. Safety reports will tally adverse events by intervention assignment and postulated relationship to the trial interventions; event rates will be reported per person year of follow-up. Should excessive risk to study participants be determined during the DMC review, the study will be stopped and all participants notified in a manner appropriate to the nature of the risk as defined by the IRB and DMC.

9.4.7 SUB-GROUP ANALYSES

In this study, we anticipate recruiting 70% females and 30% males, and are planning to provide descriptive summaries by sex assigned at birth. While these sample sizes are reasonable to obtain adequate power for a moderate main effect size of sex on the primary outcome, they are likely to leave us underpowered for arm comparisons of the primary outcome within sex. We can, nonetheless, perform such comparisons without expecting high power.

Our anticipated race breakdown in this study is 15% non-white in Wisconsin and 53% in North Carolina,

for overall proportion of 34% non-white. We plan to provide summary measures of differences among race groups, along with confidence intervals on such. We will also statistically test for differences among race groups, but, like sex assigned at birth, do not anticipate achieving high power of those exploratory comparisons.

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

Individual data will not be listed.

9.4.9 EXPLORATORY ANALYSES

Analysis Plan for CCC Objective 3: Calculate the proportion of 26-week weight loss mediated by self-reported intrinsic and extrinsic motivation for weight loss.

We estimate the extent to which self-reported intrinsic and extrinsic motivation mediate the effect of incentivization on weight loss. We primarily focus on 26-week weight as the outcome, Y, for two reasons. First, mediation analysis for later outcomes requires increasingly strong additional assumptions, as noted below. Second, we expect most mediation to occur by 26 weeks because participants are expected to experience the greatest weight change by 26 weeks. We will use the tools of modern causal mediation analysis.[40-42] Treatment, T, is a binary indicator $= 1$ if the participant was randomized to any of the three arms providing incentives and $= 0$ if assigned to no incentives. The two candidate mediating variables, M^I and M^E, are intrinsic and extrinsic motivation at 13 weeks, measured by one continuous index each.[30] We aim to decompose the average total causal treatment effect, TE (estimated in Aim 1) into the sum of the so-called natural indirect causal effect (NIE), or mediated effect, and the natural direct causal effect (NDE).[40] The NIE captures the part of the total effect of being assigned to receiving incentives (vs. not) that operates exclusively through the effect of incentives on intrinsic and extrinsic motivation (by, hypothetically, switching motivation between the values that motivation would take if the participant did, vs. did not, receive incentives). The NDE captures the part of the total effect of being assigned to incentives (vs. not) that would occur if motivation were prevented from affecting motivation (by, hypothetically, holding motivation at whatever levels that would have obtained if the participant had been assigned to receiving no incentives). Finally, we follow VanderWeele[41] in defining the proportion mediated of the total effect of incentivization on 26-week weight as $PM = NIE/TE$

Causal mediation analysis requires additional assumptions beyond the randomization of treatment because we do not (and cannot) externally intervene to fully control the post-treatment mediators intrinsic and extrinsic motivation.[40,41] Due to these added assumptions, our mediation analysis is observational and estimates should be viewed as exploratory. Specifically, we will assume that the mediating motivation variables and 26-week weight do not share unobserved confounders outside of the observed randomized treatment and the vector of observed baseline covariates, $\boldsymbol{C}$. We render this assumption plausible by statistically controlling for a rich set of observed baseline covariates, $\boldsymbol{C}$, which include baseline measures of the outcome, weight; the mediators, intrinsic and extrinsic motivation; the vector of stratification variables derived from baseline BMI and sex; participant demographics, an indicator for having made previous weight loss attempts, and the presence of obesity-related comorbidities (e.g. hypertension, diabetes, dyslipidemia). (We note that our assumption also satisfies Pearl's[40] "no-recanting witness" assumption for the identification of mediation effects: Restricting $\boldsymbol{C}$ to baseline covariates implies that no element of $\boldsymbol{C}$ is affected by T.)

We estimate the NIE, NIDE, and PM using the parametric approach of VanderWeele[41] Vansteelandt[42] by suitably combining coefficients from three linear regression models,

$$E[Y|T, \boldsymbol{M}, \boldsymbol{C}] = a_0 + a_1 T + a_2^I M^I + a_2^E M^E + \boldsymbol{a_3 C} \quad (2)$$

$$E[M^I|T, \boldsymbol{C}] = b_1^I + b_2^I T + \boldsymbol{b}_3^I \boldsymbol{C} \quad (3)$$

$$E[M^E|T, \boldsymbol{C}] = b_1^E + b_2^E T + \boldsymbol{b}_3^E \boldsymbol{C} \quad (4)$$

Given stratified randomization of the assumption of no unobserved confounders, and correct specification of the regression models $(2) - (4)$, the NDE of incentivization (vs. not) on 26-week weight net of the effect of incentivizing on 13-week motivation is identified by $NDE = a_1$. The NIE of incentivizing on 26-week weight via the set of joint mediators intrinsic and extrinsic motivation is given by $NIE = a_2^I b_2^I + a_2^E b_2^E$. Finally, the proportion of the total effect of incentivizing on weight mediated by motivation is given by $PM = (a_2^I b_2^I + a_2^E b_2^E)/(a_1 + a_2^I b_2^I + a_2^E b_2^E)$. We will bootstrap the standard errors for the NIE, NDE, and PM.[51,56,58,59] We will conclude evidence of mediation if the NIE is statistically significant at the level $\alpha = 0.05$ (two-tailed).

We will employ variations of this procedure to explore three secondary questions. First, we will estimate analogous models for weight measured at 52 and 78 weeks with mediators measured at 39 and 65 weeks, respectively. Because the credibility of the required assumption of no-treatment-induced mediator-outcome confounding arguably decreases with the duration of follow up, we will supplement all mediation models with appropriate sensitivity analyses.[42] Second, we will consider adding product terms between the mediating motivation variables and the treatment to the outcomes regression model displayed in (2). This will account for possible interaction effects, for example that the effect of incentivization is stronger for more extrinsically motivated participants, and weaker for more intrinsically motivated participants. We will modify the expressions for NIE, NDE, and PM accordingly.[26] Third, we will explore whether incentivizing differentially affects intrinsic and extrinsic motivation $b_2^I \neq b_2^E$, for example, by increasing extrinsic motivation at the expense of intrinsic motivation. To this end, we will re-estimate regressions (3) and (4) using Zellner's[43,44] seemingly unrelated regression.[45]

Analysis Plan for CCC Objective 4: Estimate program costs and calculate incremental cost-effectiveness ratios across the four study arms.

Costs. Using time estimates and an accounting of resources provided by RDs and other staff, we will estimate the costs required to provide the weight loss program and the financial incentive interventions. To facilitate cost estimation, we will apply a customized version of a costing tool to estimate costs for personnel, facilities, equipment, supplies, and miscellaneous items. Records on incentives paid to study participants will be added to the estimated program costs to estimate individual-level costs. A societal perspective necessitates valuation of participants' time spent attending virtual and phone-based sessions and on intervention-related tasks like logging and weighing. To estimate indirect patient-time costs, we will use data on sessions attended, recorded weights, and dietary logging combined with patient-reported estimates of time for each of these activities**.** These measures will be collected at baseline, 13, 26, 52 and 78 weeks. Patient time will be valued using the average hourly wage in the US regardless of employment status, age or sex.

QALYs. Utility weights from Pickard et al. will be mapped to the EQ-5D-5L responses.[46] Patient-level quality-adjusted life-years (QALYs) will be estimated using the standard trapezoidal rule, combining EQ-5D-5L utility weights collected at baseline, 13, 26, 52 and 78 weeks.[47] Missing values at 26 and/or 52 weeks will be interpolated based on utility values before and after missing values. Terminal missing values will be imputed based on the trajectory measured at the most recent two visits. If only the baseline value is available, that value will be used to impute all missing values at 26, 52 and 78 weeks.

Statistical analyses. The first part of the economic evaluation will focus on estimating and comparing intervention costs, inclusive of participant-level data on monetary incentives and time costs for the societal perspective. Patient time costs will be excluded from the health sector perspective. For descriptive reporting, means and standard errors for costs and EQ-5D utilities will be reported. Mean health utility values will be graphed by visit for each treatment group. We also will report the numbers and percentages choosing each level for each of the 5 EQ-5D domains. To compare total program costs across study arms, we will compare program total costs across arms using ordinary least squares

regression since we expect that program-related costs and incentives will be normally distributed. We will apply GLMMs to evaluate whether EQ-5D-5L health utility weights measured at 26, 52 and 78 weeks are significantly different across intervention groups as measured by fixed-effect group*time interaction terms wherein the group without incentives serves as the reference group. A random intercept term will be used to model differences in baseline health status across participants and to model within-person correlation over time. We also will test whether weight loss ≥5% of body weight at 26 weeks is associated with changes in EQ-5D-5L health utility weights using a GLMM assuming a binomial distribution and logit link to determine whether weight-loss by time interaction terms are statistically significant.

For the cost-effectiveness analysis, the four study interventions will be ordered in terms of mean costs. Then, interventions with higher costs and lower effectiveness will be ruled out (i.e. dominated by less costly, more effective interventions). Incremental cost-effectiveness ratios (ICERs) will be computed by dividing difference in mean costs divided by the difference in mean QALYs between remaining study arms. To avoid problems with negative ICERs, we will calculate net health benefits (QALY*λ – Cost, where λ represents the maximum willingness to pay per QALY) for each participant, and apply linear regression analysis to evaluate whether intervention and baseline characteristics are associated with improved cost-effectiveness.[48] In this analysis, we will apply a $50,000 per QALY threshold for λ. Non-parametric bootstrapping will be used to generate 95% confidence intervals for differences in mean costs,[49] mean QALYs and net health benefits. To facilitate comparisons with other weight-loss interventions, we will estimate the incremental cost per additional participant losing ≥5% body weight and the incremental cost per additional pound of weight loss.

We will perform sensitivity analyses to evaluate the impact of methodological choices. We will evaluate impact of assumptions and sources for unit costs, and we will estimate costs when assuming that virtual sessions could be employed instead of in-person sessions. We also will evaluate the impact of applying a different set of utility weights from Craig et al. to EQ-5D-5L responses.[46] [46,50] We also will apply predicted QALYs from the regression models described above to estimate the impact of extending within-trial benefits to 3, 5, and 10 years to represent base-case scenarios (i.e. assuming the effects of the interventions are maintained) over longer time horizons.

Analysis Plan for qualitative interviews: Audio-recorded interviews will be transcribed verbatim, and the transcripts will be systematically coded for analysis by the study team using a directed approach to content analysis. We will develop separate codebooks for study participants and key community members. Initial codes will based on predetermined categories, such as intervention components; any text that cannot be categorized with the pre-determined scheme will be identified and categorized. The codebooks will be developed and finalized through a process of discussion and consensus among the team and then applied to all transcripts. Through the constant comparison process, the coders will sort related codes into larger thematic categories and refine the categories by comparing them with one another within and between transcripts. Reports for all text segments will be generated for each code to assess fit between our data and the codes. We will generate a summary of data for participants and community stakeholders, including practical recommendations for intervention modification and recruitment and retention procedures.

Exploratory analysis to validate optimization model: We will expand an existing behavioral model to incorporate short-term weight loss decisions and long-term behavior change regarding weight loss maintenance. To do so, we will use data from the the Log2Lose trial. The resulting predictive model will be able to take the full incentive and weight recording history of the individual participant and, given a particular incentive schedule, forecast how their weight will change by the end of the trial.

We will then leverage the model to optimize the financial incentives and calorie goals for each participant individually to maximize the probability they will achieve clinically significant weight loss of at least 5% at the end of 24 weeks and then maintain this weight loss for the remaining 24 weeks of the financial incentives intervention.

We will validate our dynamic previously designed algorithm using a microsimulation based on data from the ongoing, multi-site Log2Lose study. We will use the data to simulate how a cohort of participants, taken from the three arms of the study that received financial incentives for weight loss and/or calorie recording, would react to this dynamically generated intervention over the course of a simulated 48-week trial. We will compare this proposed algorithm against existing one-size-fits all interventions, existing reinforcement learning-based approaches that do not consider a participant behavioral model, and reinforcement learning interventions that do not provide intermittent incentives.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks will be reviewed with the participant. E-consent will be obtained prior to starting the study intervention.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

The informed consent process will occur during the screening/baseline visit. All potential participants will have the capacity to provide informed consent; decisionally impaired adults are excluded from this study. Legally authorized representatives will not be allowed to e-sign the consent form; persons who require legally authorized representatives are excluded from the study. Auditors, witnesses, and translators will not be part of the consent process. Persons who do not speak, read, or write in English will be excluded.

The process of informed consent will be structured to be conducive to rational and thoughtful decision making by the person, include time for discussion and questions, and allow opportunity to reschedule if additional time for consideration is needed. The consent process will include a detailed verbal description of the study, including its risks, potential benefits, and requirements. To ensure comprehension of study activities and participant rights, potential participants will be asked to summarize the study and requested activities. When ready, potential participants will be required to electronically sign the consent form via Duke's REDCap. E-consents for both sites will be stored in Duke instance of REDCap and maintained by the data coordinating center at Duke. A copy of their electronically signed consent form will be emailed to them.

For the qualitative interviews, the informed consent will take place prior to the interview. The consent process will detail a description of the interview, a brief summary of the topic, and compensation. Participants will also be notified that they may not answer any question they wish and can stop the interview at any time. Study staff will ask for participants consent to conduct and record the interview. If participants do not wish to be recorded, the team member conducting the interview will take detailed notes using a printout of the interview script.

10.1.1.3 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, and funding agency. If the study is prematurely terminated or suspended, the PI will promptly inform study participants, the

IRB, and funding agency and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to the study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, or other relevant regulatory or oversight bodies (OHRP, DSMB).

Participant enrollment will be discontinued when we meet the target goal of **700** participants unless there is sample size adjustment that is approved by the University of Wisconsin Institute for Clinical and Translational Research (ICTR) DMC and the NHLBI. Additionally, the NHLBI could terminate the study early if we do not meet our milestones. Finally, if the DMC identifies issues related to study integrity, data integrity, safety concerns, and/or participant enrollment targets not being met, then the DMC will meet with the CCC PI to discuss the challenges and make recommendations. The DMC may recommend more frequent meetings with the PI and study team.

10.1.2 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the funding agency. This confidentiality is extended to the data collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

The study monitor, other authorized representatives of the sponsor or funding agency, representatives of the Institutional Review Board (IRB), regulatory agencies or representatives from companies or organizations supplying the product, may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records. The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long as dictated by the reviewing IRB, Institutional policies, or sponsor/funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the Duke Data Coordinating Center. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by Duke Data Coordinating Center research staff will be secured and password protected. At the end of the study, all study databases will be coded and archived at the Duke Data Coordinating Center.

Measures will be taken to ensure confidentiality of data shared per the NIH Data Sharing Policies. It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see *https://grants.nih.gov/policy/sharing.htm*). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be

traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

All research activities will be conducted in as private of a setting as possible. Research personnel will follow the research protocol and measures will be taken to maintain privacy during group classes. We will establish ground rules at the group classes, advising participants that they should only communicate information they feel comfortable communicating in public and any information learned about other participants should be kept confidential.

Data from the mobile device (Fitbit) will be automatically transferred to the Fitbit smartphone app. The data are then automatically transferred to the Fitbit company servers. We recommend participants not provide identifiable information when signing up for the Fitbit app. The cellular scale by BodyTrace™ automatically transfers data to the BodyTrace servers. There is no personally identifiable information from the scale since it only transmits a weight, time stamp, and the scale's unique identifier. The unique identifier is associated with the participant study ID in the software at Duke University. Data will be maintained on the Fitbit and BodyTrace servers indefinitely.

Data from the Fitbit and BodyTrace servers will be automatically transmitted to the mobile healthLog2Lose software. The platform compiles and analyzes biological, environmental, and behavioral data from mobile devices and sensors. Using these data, algorithms are developed to perform analytics and, in a feedback loop, intervene with participants or their social network, or transmit their data to providers. This software is currently used in NIH-funded trials, including the recently completed R34 of Drs. Voils and Shaw, and approved by the Duke IRB and security office for clinical trial use.

In this study, participants will electronically sign a consent form and HIPAA Authorization (as required by each institution) to allow data from the mobile devices to be transmitted to the platform where the data will be aggregated. The study team will have access to a dashboard in the software system where they can view dietary and weight data from participants. This will allow the study staff to select the appropriate text message participants should receive (depending on their study arm and whether they have met criteria to earn an incentive). The data can be used for ancillary analyses to examine patterns of self-monitoring and engagement with the intervention.

In order to prevent the exposure of personal identifying information or protected health information, we will use the following procedures:

1. During the screening process, each potential participant will be assigned a study participant number for tracking purposes.
2. Participant identifying information will be recorded only at time of screening and kept in Duke REDCap.
3. Potential participants who decline participation or are ruled ineligible during the screening process will have all their identifying information destroyed following database lock as permissible by the IRB.
4. Case report forms will be identified by study participant number only.
5. No results will be reported in a personally identifiable manner.
6. REDCap, an approved electronic database that is only accessible by members of the research team, will be used for randomization, enrollment, and questionnaire/survey completion. Each REDCap user has a unique user ID and can only see projects they have created or that have been shared with them. Duke scans REDCap for vulnerabilities regularly. Participants will be assigned a unique identifier number in REDCap once they are scheduled for their in-person screening visit. The final dataset used for analysis will be downloaded from REDCap and stored in an IRB-approved secure electronic file that will not include participant identifiers.
7. All REDCap data will be password-protected with several levels of protection.
    a. The first password will allow access to the operating system of the computer.

    b. The second password will allow access to the REDCap instance. Our prior research employing similar precautions has demonstrated that these techniques are very successful in assuring the protection of participants.
8. Data from the mobile devices (Fitbit and BodyTrace) will be aggregated using the mobile health software at Duke. The system uses Twilio and Amazon S3. The Log2Lose software will receive dietary data from Fitbit and weights from BodyTrace. We will maintain limited information in this database—only phone number, zip code, name and study ID of each participant, as well as data from Fitbit (dietary) and BodyTrace (weight). Study staff will login to a password-protected database to view study ID and see if participants are using the devices. We will use Amazon S3 to store data; data will be encrypted when they are stored. These are companies outside of Duke that will have access to participants' personal information (phone numbers and data from the devices). If these data are further disclosed by them or their business partners, then the data may no longer be covered under privacy protections:
    a. The mobile health platform is password-protected, and only the necessary investigators (with Duke IRB approval) will have access to the software and participant data. All data that are exported from the platform will be coded with only the participant study ID linked (not their phone number).
    b. Data exported from the mobile health platform will sit on a firewall-protected Duke School of Nursing Server in a secure electronic folder. Only necessary investigators will have access to this folder.
9. We will use Duke's mobile health software to send text messages to participants to encourage them to self-monitor and use the devices. This software interfaces with Twilio to send text messages.
    a. Text messaging does not provide a completely secure and confidential means of communication. No PHI will be sent via text message. All of this information is included in the consent form.
10. Participants will create their own Fitbit accounts. They will register with an e-mail address of their choosing. We will encourage them not to include personally identifiable information when registering for Fitbit. Participants will receive a text message with a special link from Duke's mobile health software. Upon clicking the link, participants will grant authorization for our software to retrieve data from their Fitbit account. Our software links their account with their coded study ID.
11. Participants will be encouraged not to share information with third-party services such as online social networks or other fitness apps. However, some participants may opt to do this. Thus, all participants will be encouraged to read the privacy statement for mobile devices and decide for themselves what information they would like to share.
12. The group sessions and telephone calls will be audio recorded with an approved recorder. The recordings will be uploaded and stored securely in the team's secure Duke Box study folder. The recordings will be stored for a period consistent with institutional guidelines for data storage.
13. Access to study data will be removed for study personnel that are no longer part of the research team.

10.1.3 FUTURE USE OF STORED SPECIMENS AND DATA

Data collected for this study will be analyzed and stored at the Duke University DCC. After the study is completed, the de-identified, archived data will be transmitted to and stored at the Duke Data Repository, for use by other researchers including those outside of the study. Permission to transmit data to the Duke Data Repository will be included in the informed consent.

When the study is completed, access to study data will be provided through the Duke Data Repository.

10.1.4 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator	Contact PI	Medical Monitor
Corrine Voils, PhD, Professor	*Lisa Cadmus-Bertram, PhD, Associate Professor (contact PI)*	*Samantha Pabich, MD, MPH*
University of Utah *Department of Internal Medicine*	*University of Wisconsin* *Department of Kinesiology*	*UW School of Medicine and Public Health* *Department of Medicine*
Williams Building *295 Chipeta Way Suite #3* *Salt Lake City, UT 84108*	*2000 Observatory Drive, 2035 Gymnasium-Natatorium, Madison, WI 53706*	*UW Health West Clinic* *451 Junction Rd* *Madison, WI 53717*
919-412-7768	*608-265-5946*	*708-287-9241*
Corrine.voils@hsc.utah.edu	*cadmusbertra@wisc.edu*	*skpabich@medicine.wisc.edu*

In addition to the PI, contact PI, and Medical Monitor, oversight and conduct of this RCT will be led by three committees:

1. The **Executive Committee** comprises the three Principal Investigators (PIs): Dr. Voils , Dr. Shaw (Multiple PI of the DCC), and Dr. Olsen (Multiple PI of the DCC). As a team, these individuals will have responsibility for scientific decision making, fiscal oversight, compliance, reporting, dissemination, and conflict resolution. They will be responsible for enacting recommendations made by the NHLBI and DMC. Each member has one vote, and decisions will be made by majority vote.
2. The **UW Institute for Clinical and Translational Research Data Monitoring Committee** will provide independent oversight of interim data and safety issues. An NHLBI program officer may call in to DMC meetings and listen to the open part of the meeting.

10.1.5 SAFETY OVERSIGHT

Safety oversight will be under the direction of the UW ICTR DMC, which is composed of individuals with appropriate expertise, including biostatistics and medicine. Members of the DMC will be independent from the study conduct and free of conflict of interest. The DMC will meet at least annually to assess safety and recruitment status. The DMC will operate under the rules of an approved charter that will be written and reviewed at the organizational meeting of the DMC. At this time, each data element that the DMC needs to assess will be clearly defined.

10.1.6 CLINICAL MONITORING

N/A

10.1.7 QUALITY ASSURANCE AND QUALITY CONTROL

Each clinical site will perform internal quality management of study conduct, data collection, documentation and completion. All sites will follow a common quality management plan.

Quality control procedures will be implemented as follows:

Informed consent --- Study staff will review both the documentation of the consenting process as well as a percentage of the completed consent documents. Feedback will be provided to the study team to ensure proper consenting procedures are followed.

Source documents and the electronic data --- Data will be entered directly into REDCap. It will be captured on paper source documents only if there is no access to the Internet (see **Section 10.1.9, Data Handling and Record Keeping**) and will ultimately be entered into the study database. To ensure accuracy, site staff will compare a representative sample of paper copies against the database, targeting key data points in that review.

Intervention Fidelity — Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study. Procedures for ensuring fidelity of intervention delivery are described in **Section 6.2**.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the site PIs will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the funding agency, and inspection by local and regulatory authorities.

10.1.8 DATA HANDLING AND RECORD KEEPING

The CCC and DCC teams will work together to develop a REDCap integrated database to support the enrollment data collection, randomization activities, and study visit data acquisition.

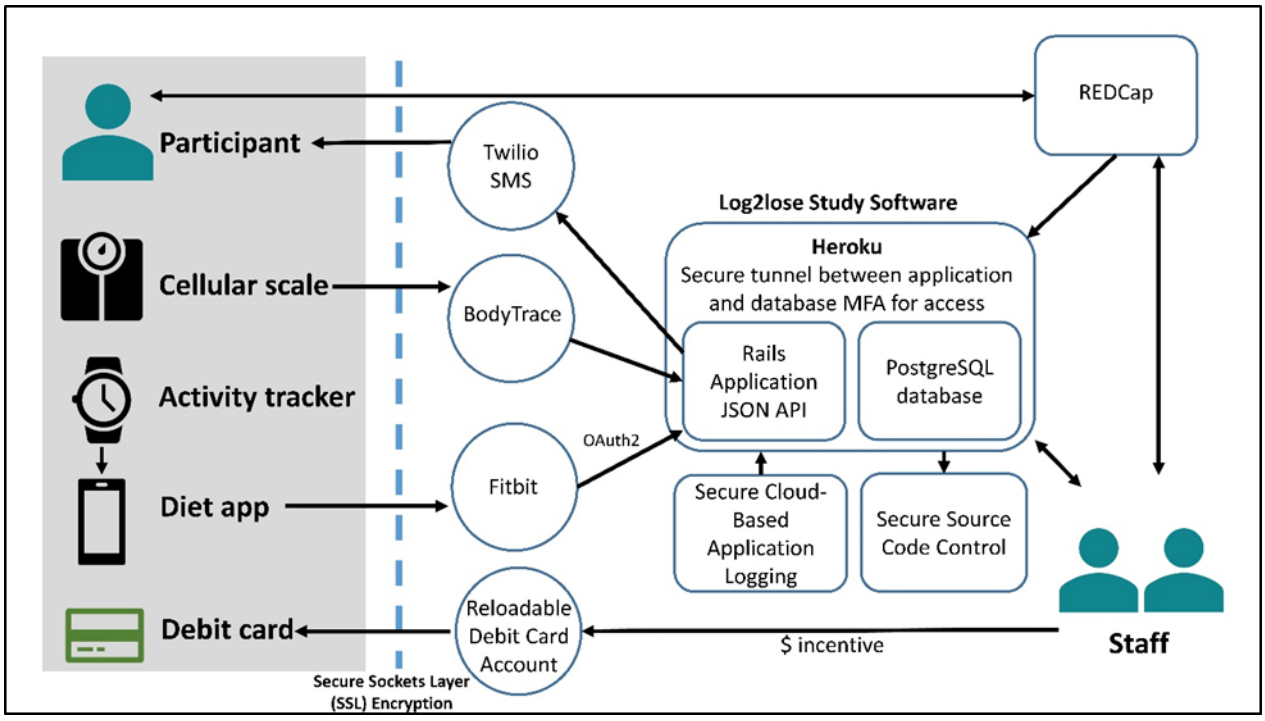


Figure 2. Log2Lose Software and Data Flow Overview

All databases and applications (**Figure 2**) developed for this study will be validated according to a predetermined plan complying with Duke University's software development life cycle and related

standard operating procedures (SOPs). Prior to the start of the database development, the DCC data team will review the protocol and database standards to understand the scope of the project and identify any special needs. Specifications, including use cases, data flow diagrams, metadata specifications, data models, and non-functional requirements will be documented and approved. Programming validation will include the preparation and processing of test data, review of the output, and documentation of the outcome.

Study data will be entered at each site into Duke's REDCap database developed and maintained by the DCC data team. The Madison site will use the same REDCap instance as the Duke site. REDCap is a secure, web-based application that is housed on servers behind the Duke firewall. The Log2Lose software, used to integrate and process incentive-based data, operates on a Heroku® platform as a service (PaaS) cloud server, utilizing a Ruby on Rails application linked to a PostgreSQL database. As the study progresses, the DCC will periodically download the tracking and data entry information from Duke REDCap and the Log2lose software into a secure electronic drive at the Duke University School of nursing.

Each potential participant for whom recruitment data is recorded in REDCap will have a unique ID for tracking purposes. Once a participant has consented and been told their randomized arm, they will be considered a study participant, and their unique ID used as the study ID. At baseline, a research coordinator from the CCC team will link the participant's Fitbit login, serial number of the BodyTrace scale, and the assigned study debit card number to the participant's study ID. All analytic datasets will be created with no identifying information other than study ID, and the crosswalk between study ID and the identity of the participant will be held within REDCap.

The developed analytic datasets will be stored within a secure drive at the Duke University School of Nursing. All data cleaning and reporting processes will be documented by the DCC team and stored on the study Box site at Duke accessible to all IRB-approved study staff. Analytic code management will be done using the accepted standard practices in place within the Duke BERD core of the CTSI. These standards are in place to organize folders, data, code, program naming conventions, and documentation to enable any analytic work to be reproduced by someone else in the future.

Analysis Plan for physical activity data: Participants will be asked to wear Fitbits for one week at baseline and 26, 52, and 78 weeks. Repeated measures analyses will be used to assess changes over time. . We will also evaluate how these changes differ overtime given weight loss, behavior change, incentives, and demographic characteristics.

10.1.8.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the clinical trial staff at the site under the supervision of the site PI. The site PI will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

10.1.8.2 STUDY RECORDS RETENTION

Study documents will be retained in accordance with institutional guidelines.

10.1.9 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, institutional requirements and guidelines, or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

It will be the responsibility of the site investigator to use continuous vigilance to identify and report deviations according to UW Madison IRB policies. All deviations will be addressed in study source documents and reported to the Duke University Data Coordinating Center.

10.1.10 PUBLICATION AND DATA SHARING POLICY

Study data will be made publicly available. Data transfer will occur in accordance with the Limited Access Data Policy established by the NIH and the Health Insurance Portability and Accountability Act (HIPAA) privacy standards. Data will be available for use by investigators not associated with the proposed study within three years after the primary results have been published. Data will be submitted to the Biological Specimen and Data Repository Information Coordinating Center (BioLINCC (*https://biolincc.nhlbi.nih.gov/home/*).

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

NIH Public Access Policy, which ensures that the public has access to the published results of funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers years after the completion of the primary endpoint by contacting Dr. Voils. Considerations for ensuring confidentiality of these shared data are described in Section 10.1.3.

10.1.11 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest among persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, people who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The participating institutions have established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

10.2 ADDITIONAL CONSIDERATIONS

10.3 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
BERD	Biostatistics, Epidemiology and Research Design core
CCC	Clinical Coordinating Center
CFR	Code of Federal Regulations
CMP	Clinical Monitoring Plan
CONSORT	Consolidated Standards of Reporting Trials

CRF	Case Report Form
CTSI	Clinical and Translational Science Institute
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DMC	Data Monitoring Committee
DSMB	Data Safety Monitoring Board
EC	Ethics Committee
eCRF	Electronic Case Report Forms
E-consent	Electronic Informed Consent
FFR	Federal Financial Report
GCP	Good Clinical Practice
GLMM	Generalized Linear Mixed Model
HIPAA	Health Insurance Portability and Accountability Act
ICER	Incremental Cost-Effectiveness Ratio
ICH	International Council on Harmonisation
ICTR	Institute for Clinical and Translational Research
IRB	Institutional Review Board
ITT	Intention-To-Treat
MAR	Missing At Random
MPI	Multiple Principal Investigator
MOP	Manual of Procedures
NCT	National Clinical Trial
NDE	Natural Direct Effect
NHLBI	National Heart Lung and Blood Institute
NIE	Natural Indirect Effect
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PACE	Protected Analytic Computing Environment
PI	Principal Investigator
PM	Proportion Mediated
QA	Quality Assurance
QALY	Quality Adjusted Life Years
RD	Registered Dietitian
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
SOP	Standard Operating Procedure
TE	Total Effect
UP	Unanticipated Problem
US	United States

10.4 PROTOCOL AMENDMENT HISTORY

Date Submitted	Description of Change	Brief Rationale
4/19/21	Adding exclusion criteria: weight > 380 lbs Revising screening process to occur online and/or via phone. Adding the all or nothing thinking and weight loss choice questionnaires.	The scales have an upper weight limit. Completing the screening online and/or via phone allow for flexibility in case the website isn't working. The all or nothing thinking questionnaire is being added in order to better understand the

		role of this type cognitive distortion in behavior change success or failure. The weight loss choice questionnaire is being added since it is specific to weight loss rewards.
5/25/21	Participants will create their own Fitbit/MyFitnessPal accounts. The payments for study visits will be $40 (instead of 50) at 6 months and $35 (instead of 25) at 18 months.	Having participants create their own accounts will make it much easier to authenticate and pull data from the Fitbit server. The higher payment will remain for the primary outcome (6 months) but encourage participation in the final two visits as well.
6/15/21	The upper age limit is being eliminated from the age inclusion criterion. Fainting is being added to the existing exclusion criterion: "Pain, fainting or other condition that prohibits mild/moderate exercise"	There is strict eligibility criteria that would exclude individuals of any age if it weren't safe for them to participate. The RD will educate participants to monitor for signs of an unsafe rate of weight loss. Participants will also be educated about how to safely participate in physical activity. To address the risk of loss of consciousness associated with physical activity (which can happen to anyone regardless of age, but may be more common in the elderly).
8/2/21	Physical activity and sleep data from the Fitbit will be collected from participants at baseline, months 6, 12 and 18.	The study team will evaluate how physical activity and sleep changes differ overtime given weight loss, behavior change, incentives, and demographic characteristics.
8/20/21	Revised the exclusion criterion regarding weight loss in the past month to at least 10 pounds. Added that if two participants are eligible at screening and living in same household, then one participant will be asked to participate in a future cohort. The identifiers that Duke's mobile health software contain is updated. Revisions to the AE/SAE collection and reporting process. Added efforts used to maximize recruitment. Including US Bank and Greenphire, the companies who provide participant payment to group who may have participant information.	Weight loss of at least 10 pounds in the past month is better since 5 pounds for some individuals is their natural variability. Having participants from the same household participate in the same cohort will lead to contamination if they are randomized to different conditions. Since the study is minimal risk, the study team will record and report any adverse events grade 2 and higher and at least possibly related to the intervention.
10/1/21	Removed that data will be transferred to Duke to UW at the conclusion of the study.	This was an error.
3/1/22	The windows for the outcome assessments are being updated to +/- 7 days for weight and blood pressure and +/- 10 days for the surveys. A statement was also added to make exceptions for weight and blood pressure being collected outside of the	The window for the surveys is slightly longer than for the weight and blood pressure. This allows time for participants to complete the surveys before their weight and blood pressure visit. The statement about exceptions to the window for collecting weight and blood

	window on a case by case basis. A lay press diet book will not be given to participants and thus has been removed. The frequency of collecting adverse events has been revised to every 2 months.	pressure are being added since the weight measurement is an important outcome and it's better to collect it outside of the window vs. it being missing. A lay diet press book doesn't need to be given to participants since they will receive class workbooks instead. Adverse events only need to be collected every 2 months since the study is minimal risk.
3/15/22	Removing that two participants from the same household, cannot participate in the same cohort.	Because the study is 18 months long, two people in a household would always overlap at some point in the study. So, either we'd have to prevent it from ever happening or allow it, not just tell them to come back at the next cohort. The risk of contamination always exists when randomizing by individual. In Class 1, we discourage participants from talking to others outside of their group.
4/10/22	Revised the incentive text messages, content of the maintenance telephone calls, and group instructions. Revised the number of calls to 8 and revised the frequency to once every 4 weeks for 4 calls and then once every 8 weeks for 4 calls. Updated that participants in cohorts 2-4 will be using Fitbit. Added emails to address the transition from phase 1 to phase 2.	The incentive text messages needed to be revised since weeks 29-53 focus on weight loss maintenance instead of weight loss. Originally budgeted for 7 maintenance calls, however a mistake was made at some point and 9 calls were added to the protocol. By decreasing the number of calls to 8, we can maintain fidelity to the intended intervention frequency where calls are monthly and then bimonthly. The revisions made to the maintenance calls were to make the calls more concise and understandable to participants. We had difficulties accessing the calorie logging data from MyFitnessPal in cohort 1. The group instructions caused confusion among cohort 1 participants. Email notifications to participants are necessary to address the transition from phase 1 to phase 2 since not all participants will attend class 14 when this is discussed.
6/9/22	Survey at month 18 to ask participants whether we can continue collect their BodyTrace weights from months 19-24. Added the class time availability question to the phone screener too.	The optional permission to collect weight beyond month 18 was already described in the protocol and informed consent. Some individuals answered the question incorrectly in the online screener and were not actually available for all four class times.

7/7/22	Added a new statistician to the team.	Staff changes.
8/1/22	Added Milwaukee as a site to hand out study materials at health fairs and community events. To conduct a drawing at a community event in Milwaukee.	To increase recruitment.
8/16/22	Drafted a pamphlet to be used to recruit participants during a community event in Milwaukee (Fiesta).	To increase recruitment.
8/31/22	Approval of recruitment email to attendees of Mexican Fiesta	To send information about the study to potential participants.
10/3/22	Change of where we store our electronic data.	To make data more accessible to research team members and more secure.
12/1/22	Revised protocol for identifying, classifying, and following-up on Adverse Events	To follow current OHRP and UW IRB guidelines.
12/30/22	Added qualitative interviews of Black and African American participants following the 52 measurements. Added qualitative interviews of Black and African American community members in Madison. We are conducting a secondary analysis.	To improve the recruitment and retention of Black and African American participants. The algorithm will personalize incentive amounts based on participant performance.
2/17/23	Added survey question about intervention-related incentive-text messages received by participants throughout their participation in the study. Added clarifying instructions to "Positive or Negative Impacts of Log2Lose Participation" survey. Revised interview guides for AA qualitative interviews. Added a reminder email and Zoom guide for participants who choose to participate in qualitative interviews. Added a “Thank you letter” to be sent to participants upon their completion of the study.	Survey revisions provide participants with clearer instructions and options for answering. Interview guide questions have been revised to address comments from community members. Communications (letter, email, Zoom guide) provide better instructions to participants.
3/7/23	Addition of qualitative interview informational materials; statement in protocol describing collection of interviewee	These changes were needed to further refine our processes and surveys.

	address to send compensation; revision of two responses to one question on one survey; and clarification in protocol of text message evaluation survey.	
7/13/23	1. Added a qualitative interviews of male participants about their experience in the weight management program and the overall study. 2. Interviews will be transcribed 3. Added a short questionnaire about participants experience with the virtual classes. 4. Included email templates to notify participants of the transition from phase 2 to phase 3. 5. Included a corrected text message survey. 6. We are including a first tasks email for participants. 7. Included a study completion FAQ for participants. 8. Included an email that follow the online screener. 9. Updated the eligibility to include that participants must have or be willing to create a Gmail account, in order to use FitBit in the study.	1.The interviews of men are part of a diversity supplement seeking to understand how to better recruit and retain men in weight management programs and research. 2.Transcription will allow us to code and do qualitative analysis on the interviews. 3. By better understanding participant experiences with the classes through the short questionnaire we can better inform future weight management programs delivered virtually. 4. The emails will help clarify the transition of the weight management program from weight maintenance to self-directed. 5. The new survey has the correct days for when text messages were sent. 6. This will help clarify first steps in the study. 7. This email will be given at the end of the study so participants understand what happens at the end of the study. 8. As this email helps eligible individuals know that we will get back to them but cannot guarantee study participation. 9. Our intervention relies on calorie tracking information as well as physical activity collected through FitBit. Google has recently purchased FitBit and is requiring all users to have a Gmail account. In order to collect the study data, participants must have or be willing to create a Gmail account to link to their FitBit data
8/9/23	1. Updated our consent to include the risk of skin irritation due to the Fitbit. 2. Removed the option for a forearm blood pressure. 3. Included bariatric surgery as a reason for removal from the study.	1. In response to our reportable events, we are making participants aware of the risk of skin irritation from the Fitbit during the consent process. 2. Our blood pressure cuffs are unable to accurately capture blood pressure reading from the forearm. 3. Bariatric surgery is an exclusion criterion and if participants have surgery during the study they will no longer be able to participate due to weight loss because of bariatric surgery.
9/19/23	An email to inform active participants about the potential for skin irritation when using the Fitbit.	A statement about the risk of skin irritation from Fitbit use was added to the consent

		process for the last cohort in the study in response to a reportable event. While we won't require reconsent from previous active participants, we wanted to ensure they were informed about the slight risk of skin irritation.
11/17/23	Added GRANT13734561 "Applying reinforcement learning to create a precision medicine weight loss intervention" grant proposal as part of funding.	Secondary analysis
11/27/23	Update to clarify that only participants in active ongoing cancer treatment which study physician feels could interfere with the intervention or affect the outcomes will be withdrawn.	To reflect original intent of withdrawal language.
1/11/24	Updated the adverse event survey.	Enables the study team to gather more comprehensive adverse event data via the survey prior to any follow-up by a study team member.
2/6/24	Added a Fitbit reminder.	To remind participants to wear their study-provided Fitbit physical tracker for 6, 12, and 18 month assessment windows. Reminder will help minimize missing data.

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