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# Goal-directed versus outcome-based financial incentives for weight loss among low-income patients with obesity: Rationale and design of the Financial Incentives foR Weight Reduction (FIReWoRk) randomized controlled trial

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## ABSTRACT

**Introduction**: Obesity is a major public health challenge and exacerbates economic disparities through employment discrimination and increased personal health expenditures. Financial incentives for weight management may intensify individuals' utilization of evidence-based behavioral strategies while addressing obesity-related economic disparities in low-income populations. Trials have focused on testing incentives contingent on achieving weight loss outcomes. However, based on social cognitive and self-determination theories, providing incentives for achieving intermediate behavioral goals may be preferable to incentivizing outcomes if they enhance an individual's skills and self-efficacy for sustaining long-term weight loss. The objective of this paper is to describe the rationale and design of the Financial Incentives foR Weight Reduction (FIReWoRk) study, a randomized controlled trial to test the comparative- and cost-effectiveness of two financial incentive strategies for weight loss (goal-directed vs. outcome-based) among low-income adults with obesity, as compared to the provision of health behavior change resources alone.

**Methods and analysis**: We are recruiting 795 adults, 18-70 years-old with a body mass index ≥30 kg/m$^2$, from three primary care clinics serving residents of socioeconomically disadvantaged neighborhoods in New York City and Los Angeles. All participants receive a one-year commercial weight loss program membership, self-monitoring tools (bathroom scale, food journal, and Fitbit Alta HR), health education, and monthly check-in visits. In addition to these resources, those in the two intervention groups can earn up to $750 over 6 months for 1) participating in an intensive weight management program, self-monitoring weight and diet, and meeting physical activity guidelines (goal-directed arm); or 2) a ≥1.5% to ≥5% reduction in baseline weight (outcome-based arm). To maximize incentive efficacy, we incorporate concepts

from behavioral economics, including immediacy of payments and framing feedback to elicit regret aversion. We will use generalized mixed-effect models for repeated measures to examine intervention effects on weight at 6, 9, and 12 months.

**Ethics and dissemination**: Human research protection committees at New York University School of Medicine, University of California Los Angeles (UCLA) David Geffen School of Medicine, and Olive-View–UCLA Medical Center granted ethics approval. We will disseminate the results of this research via peer-reviewed publications, conference presentations, and meetings with stakeholders.

**Trial registration**: This trial is registered with the National Institutes of Health at ClinicalTrials.gov under identifier NCT03157713.

## ARTICLE SUMMARY

**Strengths and Limitations**:

- Financial incentives may intensify utilization of evidence-based behavioral strategies while addressing obesity-related economic disparities in low-income adults with obesity.
- This randomized controlled trial addresses an important gap in obesity research by comparing the impact of two financial incentives strategies on weight loss among primary care patients from socioeconomically disadvantaged neighborhoods.
- Resources-only group: patients receive a weight-management program voucher, bathroom scale, food journal, Fitbit Alta HR, and monthly in-person visits. Intervention groups: patients receive same resources plus incentives for achieving behavioral goals (goal-directed) or weight loss outcomes (outcome-based).
- Primary outcome: proportion of patients achieving a ≥5% reduction in body weight at 6 months, with follow-up assessments at 9 and 12 months.
- We anticipate that the results will inform the design of scalable financial incentive programs to address obesity in public and private health systems.

**Keywords**: behavioral economics, behavioral intervention, BMI, cost-effectiveness, health behavior change, health disparities, quality of life, overweight, physical activity, self-monitoring

## INTRODUCTION

The prevalence of obesity among U.S. adults continues to rise, contributing substantially to morbidity and mortality from obesity-related illnesses [1, 2] such as diabetes, heart disease, stroke, and cancer. Obesity is more prevalent among adults with a lower socioeconomic status.[3] Because individuals with obesity also face social stigma, including employment discrimination and bias in educational settings,[4] the increased prevalence of obesity among lower income individuals exacerbates health and socioeconomic disparities. Moreover, the negative externalities of obesity include an attributable annual U.S. healthcare cost of $147 billion.[5]

The U.S. Preventive Services Task Force (USPSTF) recommends universal obesity screening in healthcare settings and intensive, multicomponent behavioral interventions for adults with obesity.[6] However, national data show that physicians often do not provide nutrition, exercise, or weight loss counseling for obese patients.[7] Moreover, 51% of U.S. adults report wanting to lose weight, but only half are actively trying, and an even smaller proportion utilize evidence-based methods.[7-10] A reduction in weight of as little as 5% is associated with cardiovascular health benefits.[11, 12] It is therefore critical to identify novel approaches to increase utilization of effective, evidence-based behavior change strategies and weight management programs (e.g., Weight Watchers, the Diabetes Prevention Program, and the Veterans Affairs MOVE! Program [13-15]) to promote weight loss and improve health outcomes, particularly among socioeconomically disadvantaged individuals. Financial incentives are a potential bridge to increasing utilization of effective weight management behaviors and programs among low-income adults with obesity.[16]

Health insurers, employers, and government agencies are testing the extent to which financial incentive strategies motivate changes in health behavior, particularly for obesity and smoking.[17, 18] Microeconomic theory suggests that financial incentives lead to weight loss because

individuals are influenced by the prospect of rewards. This effect may be enhanced when the incentive design emphasizes *immediacy* (payments provided as soon as possible), so that individuals can more readily associate a payment with the behavior that triggered it,[19, 20] and *regret aversion* (avoidance of regret from losing an anticipated reward).[21, 22] While some theories of motivation have led researchers to raise concerns about the long-term durability of the extrinsic effects of incentives,[23] studies have shown that incentives may promote intermediate-to-long-term weight loss.[23-31] Despite these findings, a key unanswered question is what targets to incentivize.[32]

Incentivizing an individual's participation in *goal-directed*, evidence-based behaviors for weight loss, such as participating in a weight management program, self-monitoring weight and diet, and achieving physical activity goals, may be preferable to incentivizing *outcome-based* attainment of weight loss, since goal-directed financial incentives are designed to encourage individuals to develop specific skills for sustaining weight loss long-term. In addition, attainment of behavioral goals precedes weight loss outcomes, thereby providing earlier opportunities for success, which may increase self-efficacy and intrinsic motivation for weight management.[33] Based on social cognitive theory,[34] incentivizing behavioral practice directly may help patients build the *self-efficacy* to engage in evidence-based strategies and maintain these behaviors even after an incentive is removed. Self-determination theory[35] highlights the role that *intrinsic motivation* may play in an individual's sustained behavior change, since engaging in a strategy she or he has mastered can provide satisfaction and enjoyment (**Figure 1**).

To date, financial incentive interventions for weight loss have favored outcome-based over goal-directed incentive designs. Further research is needed to test whether the effectiveness of financial incentives for weight loss that incorporate immediacy and regret aversion can be

maximized by targeting utilization of effective weight management behaviors and programs. Studies are also needed to assess the economic sustainability of financial incentives, which is a major factor in public and private decision-making.[36] The primary aim of the FIReWoRk study is to examine the effectiveness of goal-directed versus outcome-based financial incentives on ≥5% weight loss among patients with obesity living in socioeconomically disadvantaged neighborhoods, as compared to the provision of health behavior change resources alone. FIReWoRk also examines the impact of these interventions on patients' use of evidence-based weight management programs, waist circumference, blood pressure, and quality of life. A secondary aim is to examine the cost-effectiveness of using goal-directed incentives to promote weight loss as compared to outcome-based incentives or resources without incentives. The purpose of this paper is to describe the rationale and design of the FIReWoRk study.

## METHODS AND ANALYSES

### Study overview and design

The (FIReWoRk) study is a three-arm randomized controlled trial (RCT) to test the effectiveness of two financial incentives strategies on weight loss among primary care patients, compared to the provision of behavior change resources without incentives (i.e., resources-only arm). We are enrolling adults living in socioeconomically disadvantaged neighborhoods from three medical centers that serve predominately low-income populations. Participants in all three study arms receive a voucher for a one-year commercial weight loss program membership, self-monitoring tools (bathroom scale, food journal and Fitbit Alta HR), health education, and monthly check-in visits. In addition, participants in the outcome-based incentives arm can earn up to $750 over 6 months for a 1.5% to 5% reduction in baseline weight, while those in the goal-directed incentive arm can earn the same amount for engaging in the following evidence-based

weight loss behaviors: weight management program participation, self-monitoring weight and diet, and physical activity. The primary outcome is a ≥5% reduction in baseline weight at 6 months.

**Primary care clinics and patients**

We are recruiting patients exclusively from three primary care clinics in New York City (NYC) and Los Angeles (LA), with plans to enroll 795 adults with obesity from low-income neighborhoods. The clinics are part of NYC Health + Hospitals – Bellevue, NYU Langone Hospital – Brooklyn, and Olive View UCLA Medical Center. Bellevue Hospital is the nation's oldest public hospital and the flagship hospital for NYC's primary safety net health system. There are approximately 130,000 outpatient visits in Bellevue's primary care clinic each year. NYU Langone Hospital – Brooklyn is a 450-bed teaching hospital and a clinical campus for primary care education located in Sunset Park, Brooklyn. Its network of nine primary care sites handles over 602,000 visits annually. Olive View UCLA Medical Center is operated by the LA County Department of Health Services, which supports a network of primary care clinics in and around the LA metro area. More than half of Olive View patients are under- or uninsured. All locations serve racially/ethnically diverse, medically underserved populations in which the prevalence of obesity is above the national average.

Each of these hospitals uses an electronic health record (EHR) system that captures detailed inpatient and outpatient information. We conduct EHR queries every six months to identify patients with obesity who have seen a provider in the previous two years. To identify patients with obesity who live in socioeconomically disadvantaged neighborhoods, we cross-reference patients' address information from their EHR with census tracts associated with the lowest 40% of 2015 median household income in the NYC/Tri-State and LA County areas

(approximately <$40,000 per year).[37] Because we are recruiting from neighborhoods with a higher proportion of minority residents and from low-income census tracts, we anticipate that our sample will have a higher proportion of ethnic and racial minorities, particularly Hispanic/Latinos, than is reflected in the general population.

As a primary recruitment method, we mail announcements about the study to the homes of patients identified via the EHR and neighborhood queries and invite them to contact us. We follow up with patients by phone, beginning when we expect the mailing to arrive and continuing until completing four outreach attempts. We also identify upcoming primary care appointments of patients identified via the queries, at which time we approach them in waiting rooms with information about the study. We schedule interested patients who pass an eligibility screening for a baseline visit at or near their home medical center within one month of their screening date. No more than one person per household is eligible to participate. As secondary recruitment methods, we communicate with primary care physicians and medical residents at the study sites who may be willing to refer their patients to the study. We also post recruitment flyers and brochures in areas of the clinic frequented by patients.

**Sample size**

Prior studies suggest that among patients with obesity, the prevalence of obtaining a 5% reduction in baseline weight by 6 months is 10-35%.[38-41] We consider an absolute difference ($rate_2 - rate_1$) of approximately 10% in rates of obtaining a 5% reduction in baseline weight by 6 months to be clinically meaningful. We also assume a 6-month loss-to-follow-up rate of 10%. Therefore, a sample size of 795 provides at least 80% power to detect a meaningful difference in weight loss between the intervention arms with a Type-I error rate $\alpha = 0.05$. It also provides at least 99% power to detect a meaningful difference between the goal-directed incentives arm (rate of

24%) and the resources-only group (rate of 10%) with a Type-I error rate $\alpha = 0.05$.

**Eligibility and enrollment**

We include patients with a body mass index (BMI) ≥30 kg/m$^2$, who are 18-70 years old, speak English or Spanish, have seen their physician within the past two years, have an active U.S. mobile or home phone number and address and live in a qualifying census tract. Patients who weigh >380 pounds are not enrolled, as the HealthOMeter 349KLX Digital Medical Weight Scale is only valid up to 400 pounds and we allow for a 20-pound buffer in case weight gain occurs. We exclude patients who have had a weight loss surgery or procedure in the previous two years or have experienced any of the following in the previous six months: ≥4.5 kg weight loss, completion of an intensive weight management program, active psychosis and/or other cognitive issues, metastatic cancer, or incidence of a myocardial infarction or stroke. We also exclude patients who report abuse of alcohol, have a history of disordered eating, have Stage V Chronic Kidney Disease or End Stage Renal Disease, are pregnant or breastfeeding, plan to become pregnant, or plan to move out of NYC/Tri-State area/LA County in the following 12 months.

Once screened by phone, we invite eligible patients to a baseline study visit at their home medical center and obtain informed consent. To provide informed consent, we 1) describe the study and its risks and benefits in detail from a script tested for eighth grade reading comprehension, 2) assess comprehension by asking the patient to explain the information presented (teach-back method[42]), 3) answer questions about the study and/or consent forms, 4) offer the opportunity to participate, 5) obtain the patient's signature on the consent form.[43] The participant receives a copy of the signed consent form by email.

**Randomization**

Randomization occurs after obtaining informed consent, completing initial weight measures, administering the baseline survey instrument, and providing weight management program referrals, health education materials, and self-monitoring tools. Participants are randomized to one of three study arms: 1) outcome-based incentives, 2) goal-directed incentives, or 3) resources only (**Figure 2**). To ensure comparable group sample sizes, we randomize eligible patients in block sizes of four or six at random using a random number generator in R (www.r-project.org). We stratify randomization by study site and participant's self-reported preference for an outcome-based or goal-directed financial incentive program for weight loss. Stratified randomization prevents imbalance between treatment groups by hospital site and the participant's incentive preference.

**Financial incentives intervention for weight loss**

Trained research coordinators or research assistants (RAs) conduct all study visits. RAs are students or graduates of health-related disciplines such as biomedicine, public health, health promotion, education, psychology, kinesiology, and nutrition. To promote enrollment of Spanish-speaking patients, RAs are required to have full native or professional Spanish proficiency. RAs receive at least 20 hours of standardized training in the responsible conduct of research, study protocols, and cultural sensitivity. RAs observe and role-play a series of study visits in both English and Spanish and can successfully demonstrate intervention delivery before conducting study visits.

At a 2.5 to 3-hour initial study visit, all participants receive a list of local weight management programs that meet criteria for a high-intensity, on-site, comprehensive lifestyle intervention[44] and a voucher for one year of Weight Watchers ® membership.[14] Participants

can choose to attend a different commercial, medical, or community-based weight management program that is offered at least twice monthly and meets guidelines for an intensive comprehensive lifestyle intervention.[44] The RA communicates that the goal is for the participant to register and actively participate in at least 50% of weekly program sessions per month (or a comparable rate associated with evidence-based weight loss). All participants also receive self-monitoring instructions and tools[45-47] including a bathroom scale, a BookFactory food journal, and a Fitbit Alta HR ® wearable fitness tracker[48]. The RA communicates that the goals are for the participant to weigh themselves at least 3 days per week, to record what and how much they eat at least 5 days per week, and accumulate at least 75 physical activity minutes per week (which increases to 150 minutes per week after three months to approximate physical activity guidelines[49]). The behavioral science construct of *emergency reserves* informs how the RA frames the goals; for example, the RA encourages the participant to "track what you eat every day, but you have two emergency 'skip days' per week if you fall behind." Goals with emergency reserves are perceived as more attainable and lead to increased goal persistence.[50] The RA also communicates that the participant is to lose ≥2.5% of their baseline weight by 1 month and ≥5% by 2 months. The RA asks for the participant's understanding of each behavioral goal and weight loss outcome using the teach-back method[42] and discusses how to prevent relapse.[45] The RA then explains what documentation participants must provide to verify their goal attainment at subsequent study visits. In addition, participants receive health education on food types to incorporate and which to limit, portion sizes, healthy recipe ideas, and moderate-intensity physical activity. The RA also assists the participant in setting up their Fitbit device and online Fitbit and Weight Watchers accounts so that they can access the features available through their smartphone or computer.

If a participant is randomized to an intervention arm, the RA informs them of the behavioral goals or weight loss outcomes for which they earn incentives, the amounts they are incentivized, and how they receive their payments. Participants randomized to receive outcome-based incentives can earn up to $750 over 6 months for losing ≥1.5% to ≥5% of their baseline weight, as confirmed at monthly weigh-ins. At 1 month, they receive $50 if they lose ≥1.5% to <2.5% or $100 if they lose ≥2.5%. The weight loss outcomes at 1 month are more modest to discourage overly rapid weight loss. At 2 and 3 months, they receive $50 if they lose ≥2.5% to <5% or $100 if they lose ≥5% of their baseline weight. At 4, 5, and 6 months, they receive $100 if they lose ≥2.5% to <5% or $150 if they lose ≥5% of their baseline weight (**Table 1**).

Participants randomized to goal-directed incentives do not earn money for losing weight, but instead earn up to $750 over six months for meeting goals to participate in an approved comprehensive lifestyle intervention, meet physical activity guidelines, and self-monitor weight and diet. At 1-6 months, they receive a one-time $150 for registration and attendance at ≥50% of weekly weight management program sessions, as verified with documentation from the sessions such as an agenda or weight log or by a record of attendance in the participant's EHR, if available. They continue to receive $60 monthly thereafter for attendance at ≥50% of weekly program sessions (or a comparable rate associated with evidence-based weight loss). At 1-3 months, they receive up to $20 for achieving 75 minutes of physical activity per week ($5 per week), as verified using activity minutes data collected in the participant's Fitbit account. At 4-6 months, they must achieve 150 minutes of physical activity per week to receive up to $20. At 1-6 months, they receive up to $20 for using their food journal 5 days per week ($5 per week) and recording their body weight 3 days per week ($2.50 per week), as verified by RA review of their entries (see **Table 2**).

**Table 1**. Financial Incentives Awarded for Meeting Monthly Behavioral Goals and Weight Loss Outcomes

| | Time point | Goal-directed Incentives[a] | Outcome-based Incentives |
|---|---|---|---|
| **Behavioral Goals** | | | |
| Enrollment and active participation[b] in an evidence-based[c] weight management program | 1, 2, 3, 4, 5, or 6 months | $150 | $0 |
| Active participation[b] in an evidence-based[c] weight management program | 2, 3, 4, 5, and 6 months | $60 | $0 |
| Food journal use[d] | 1, 2, 3, 4, 5, and 6 months | $20 | $0 |
| Achievement of ≥75 minutes of physical activity per week | 1, 2 and 3 months | $20 | $0 |
| Achievement of ≥150 minutes of physical activity per week[e] | 4, 5, and 6 months | $20 | $0 |
| Self-weighing[f] | 1, 2, 3, 4, 5, and 6 months | $10 | $0 |
| **Weight Loss Outcomes** | | | |
| Weight loss (≥1.5% to ≥2.5%) | 1 month | $0 | $50-$100[g] |
| Weight loss (≥2.5% to ≥5%) | 2 and 3 months | $0 | $50-$100[h] |
| Weight loss (≥2.5% to ≥5%) | 4, 5, and 6 months | $0 | $100-$150[i] |
| **Total Incentives** (maximum) | | **$750** | **$750** |

[a]Incentive is proportional to the number of weeks in the previous 28 days this goal is met (e.g., incentive may range from $5 for one week to $20 for 4 weeks).
[b]Attending ≥2 sessions per month or ≥50% of sessions monthly, whichever is greater.
[c]Program participation goal is based on established AHA/ACC/TOS guidelines for the management of overweight and obesity in adults.
[d]Recording diet content and quantity ≥5 days per week.
[e]Physical activity goal is based on established public health guidelines for moderate-vigorous intensity physical activity in adults.
[f]Recording weight ≥3 days per week.
[g]$50 for losing ≥1.5% to <2.5% and $100 for losing ≥2.5% of baseline weight.
[h]$50 for losing ≥2.5% to <5% and $100 for losing ≥5% of baseline weight.
[i]$100 for losing ≥2.5% to <5% and $150 for losing ≥5% of baseline weight.

**Table 2**. Study Measures and Assessment Time Points

| Measure | Baseline | 1-5 Months | 6, 9 Months | 12 Months |
|---|---|---|---|---|
| **Survey Measures** | | | | |
| Socio-demographics | X | | | |
| Chronic health conditions | X | | | |
| Incentives preferences | X | | | |
| Quality of life | X | | X | X |
| Healthy dietary changes | X | | X | X |
| Fruits and vegetables | X | | X | X |
| Sweets and salty snacks | X | | X | X |
| Sugar-sweetened beverages | | | | |
| Physical activity | X | | X | X |
| Self-efficacy | X | | X | X |
| Outcome expectations | X | | X | X |
| Intrinsic motivation | X | | X | X |
| Financial wellbeing | X | | X | X |
| Program adherence | | X | X | X |
| Self-monitoring | X | X | X | X |
| Alcohol and tobacco use | X | | | X |
| Hospitalizations and ER visits | | | X | X |
| **Other Measures** | | | | |
| Height | X | | | |
| Weight | X | X | X | X |
| Waist circumference | X | X | X | X |
| Blood pressure | X | | | X |
| Fitbit active minutes | | X | X | X |
| Lipids | X | | | X |
| Hemoglobin A1c | X | | | X |

Incentives are available to participants in U.S. dollars (USD) via ClinCard © 2016 Greenphire, a secure prepaid debit card system, within 24 hours after goal verification at monthly check-in visits. Participants do not invest any of their own money at any time, and their incentives do not incorporate a lottery structure. Check-in study visits occur monthly at 1-6 months, proceeded by follow-up visits at 9 and 12 months. During check-in visits, RAs measure weight and waist circumference. The majority of the 30 to 45-minute visit is devoted to verifying whether participants met their behavioral goals and weight loss outcome and providing them with feedback on their progress. For the resources-only group, the RA provides words of encouragement for meeting a behavioral goal or weight loss outcome (e.g., "Great job!"). If the participant did not meet a goal or outcome, the RA states, "if you had done x, you would have met this goal." For the goal-directed and outcome-based groups, the RA provides words of encouragement for meeting a behavioral goal or weight loss outcome and informs them of incentive amounts earned. If the participant did not meet a goal or outcome, the RA states, "if you had done x, you could have earned x amount," using framing that leverages regret aversion. The RA also troubleshoots any technology-related issues that arise with the participant's ClinCard, Fitbit, or Weight Watchers membership, and reminds the participant what they must bring to their next visit to verify their progress.

**Intervention standardization and fidelity**

We implement fidelity monitoring procedures to ensure that the delivery of intervention components is standard across all study sites and RAs. All RAs complete a task list at each study visit. A portion of study visits are audio-recorded, and recorded sessions are randomly selected for audit using a fidelity-monitoring checklist. RAs who score less than 80% on an audit receive

remedial training and are required to demonstrate the unattained standard prior to resuming study visits.[51]

**Participant retention strategies**

At the end of each check-in visit, RAs schedule participants for their next visit and place a text message and a phone call within two days prior to their scheduled visit to encourage them to return. To increase participation and minimize attrition, all participants receive a total payment for participation of up to $180 ($20 per visit) for their time and travel, independent of incentives earned in the intervention groups. We also provide participants with periodic tokens of appreciation, including a button with the study logo after their 3-month visit and a thank you text message after their 6- and 9-month visits.[52] In addition, we conduct a process evaluation to explore differences in participant retention and uptake of intervention components (e.g., Fitbit wear) between pre-specified subgroups (women, Black, Hispanic, and recruitment site). If participants do not return for their check-in visits, we attempt to contact them by phone to assess their reasons for leaving the study. If we cannot reach them, we send a paper survey at 6 months with a stamped return envelope.

**Data collection and measures**

Assessments occur at baseline, 30 days, and 2, 3, 4, 5, 6, 9, and 12 months (**Table 2**). Our primary outcome is the percentage of patients who achieve a 5% reduction in baseline weight at 6 months. Our secondary outcomes include waist circumference, blood pressure, and quality of life. At baseline, we confirm contact information; collect demographic characteristics; measure height, weight, and blood pressure; take a brief medical history; and administer survey instruments about diet composition, physical activity, theoretical mechanisms of health behavior change, financial distress, and quality of life. Participants are assured there are “no right or

wrong answers" and to "answer as honestly as possible." At 1 to 6-month check-in visits, we assess adherence to a weight management program, self-monitoring of weight and diet, and physical activity. We administer weight, blood pressure, and the survey instruments again at 6 months (primary outcome time point), 9 months, and 12 months. At 6, 9, and 12 months we also ask participants about hospitalizations and emergency room visits and use of medications that may modify weight (e.g., metformin, insulin, antidepressants, etc.).[53, 54] Whenever possible at 6, 9, and 12 months, an RA who has not met regularly with the participant and who is unaware of their study arm assignment administers the biometric assessments and survey interviews and enters the results into REDCap 7.4.23. All biometric procedures are adapted from the National Health and Nutrition Examination Survey (NHANES)[55] and survey measures are selected based on their validity against an established criterion, and validation with Spanish-speaking adults, when available.

Weight and height – Weight is measured in pounds twice to the nearest 0.1 pound using a HealthOMeter 349KLX Digital Medical Weight Scale. We ask the participant to remove shoes and heavy garments and to stand still with both feet in the center of the scale, hands at sides, looking straight ahead. If the first two weights differ by 0.5 pound or more, we repeat the measure once. Height is measured once, rounded up to the nearest 0.1 centimeter, using a SECA 213 Portable Stadiometer. We ask the participant to remove shoes and extraneous clothing and undo interfering hairstyles, then to stand upright looking straight ahead with heels, buttocks, shoulder blades and back of head positioned against the ruler. Two valid measures are averaged.

Waist circumference – Waist circumference is measured twice, rounding down to the nearest 0.25 inch. We take the measurement on bare skin if possible, at the high point of the iliac crests, drawing the tape measure snug at minimal respiration. If the first two values differ by 0.5

inch or more, we repeat the measure once. Two valid measures are averaged.

Blood pressure – Two resting blood pressure measures are obtained using the Omron HEM 907XL IntelliSense Professional Digital Blood Pressure Monitor, an automated sphygmomanometer. The participant remains seated without consuming caffeine or nicotine for 30 minutes prior to the measurement. We measure arm circumference first to determine the appropriate cuff size, then place the cuff snugly on the left upper arm with the bottom of the cuff approximately one inch above the inner elbow. The arm rests palm-up at heart level and the participant remains silent and still, with both feet on the floor, during the measurement.[56] If the first two systolic or diastolic values differ by 5.0 mmHg or more, we remove and adjust the cuff, and repeat the two measures. Two valid measures are averaged.

Lipids and hemoglobin A1c – Fasting lipids (high- and low-density lipoprotein cholesterol, triglycerides, and total cholesterol) and hemoglobin A1c values from a 12-month period prior to baseline are accessed via the participant's EHR. Since these tests are clinically indicated for patients with obesity, we also recommend that they obtain them at the conclusion of the six-month intervention period. We access available values a second time from a 12-month period following the conclusion of the six-month intervention period.

Quality of life – The PROMIS-29 is used to assess physical, mental, and social health.[57] The PROMIS-29 measures eight domains (fatigue, pain intensity, pain interference, physical function, sleep disturbance, anxiety, depression, and ability to participate in social roles and activities) and yields a composite global health score. The PROMIS-29 is applicable to the general population, as well as to ethnically and socio-demographically diverse groups and to those with chronic health conditions. Substantial evidence supports the validity of the PROMIS-29.[57, 58] In addition, the 7-item Center for Epidemiologic Studies Depression Scale (CES-D)

is used to assess how often a participant felt depressive symptoms during the past week (1=never, 2=hardly ever, 3=some of the time, 4=most of the time). The CES-D has shown adequate reliability and validity in general population samples with a range of demographic characteristics.[59-62]

Incentive program preferences – Using an item adapted from the Financial Incentives for Smoking Treatment (FIESTA) study (ClinicalTrials.gov identifier NCT02506829), the RA describes two hypothetical financial incentive programs for weight loss (one is goal-directed and the other is outcome-based), and then asks which program the participant prefers. This question allows us to test whether participants who are randomized to an incentive structure consistent with their pre-specified incentive program preference are more likely to lose weight than those who are randomized to incentives that are inconsistent with their preference. To understand the participant's program choice, the RA asks open-ended questions to assess the reasons why the participant chose the program they did and what concerns about the program they have, as well as open-ended items adapted from the Health Incentive Program Questionnaire[63] to prompt the participant to describe their reactions to receiving payment for losing weight.

Food behavior – We assess healthy dietary changes in portion sizes and food choices such as fried food, fast food, and white bread using the Latino Dietary Behaviors Questionnaire (LDBQ). This subscale reflects a pattern of dietary behaviors associated with healthier micronutrients and lower calories.[64] Fruit and vegetable consumption is measured using a 7-item subscale from the validated Food Behavior Checklist.[65] We adapted two items from the Rapid Eating Assessment for Participants - Shortened Version (REAP-S) to assess consumption of sweets and salty snacks.[66, 67] The LDBQ is also used to assess consumption of and sugar-sweetened beverages.[64] Binge eating, characterized by a high frequency of consuming

unusually large amounts of food and feeling a loss of control, is assessed using the Eating Disorder Diagnostic Scale.[68] For pragmatic reasons, we did not use longer food behavior questionnaires or 24-hour dietary recalls due to their time-intensiveness.

Physical activity – Walking and moderate-to-vigorous intensity physical activity (MVPA) are measured using the International Physical Activity Questionnaire short form (IPAQ-SF). The IPAQ is well-established in the public health literature as a valid and reliable physical activity assessment tool.[69, 70] For the duration of the study, participants to wear a commercially available fitness tracker (Fitbit Alta HR ®), which has pedometer and accelerometer functions. The validity of similar activity tracker models for assessing MVPA has been established against an accelerometer criterion, with results ranging from near perfect correlation to overestimation of MVPA values.[71] Fitbit algorithms take into account the Alta HR's accelerometer movement and heart rate function, applying minute-by-minute metabolic equivalents (METs) to estimate activity intensity. In 2015 Fitbit improved their algorithm to more closely align with 2008 physical activity guidelines for adults[49] so that moderate-to-vigorous intensity activity minutes must occur in bouts of at least 10 minutes for a minute to be classified as an "active minute." Therefore, ≥150 Fitbit "active minutes" per week are considered an approximation of the recommended ≥150 minutes of MVPA per week.

RAs instruct participants to wear their Fitbit device every day and demonstrate how to charge it and sync it with a smartphone/internet-connected computer, thereby allowing physical activity data to be uploaded to Fitabase. Fitabase is an independent affiliate of Fitbit that allows researchers to centrally access data from Fitbit wearable devices. A participant is considered to have worn their device on any given day if they accumulate >500 steps. Participants considered adherent accumulate ≥150 active minutes per week in the 28 days prior to their study visits. For

participants who do not have a smartphone or computer, the RA syncs the Fitbit during study visits, allowing data stored on the device in the previous 30 days to be uploaded.

Adherence to weight management program participation and self-monitoring weight and diet – To asses past-month participation in a recommended weight management program, participants who report attending a program in the previous month are asked how many sessions (1-5+) they attended, and to provide approved documentation of attendance at each session. Based on thresholds established in previous studies,[14, 44] participants considered adherent attend a session on-site at least twice in the previous month, or at least 50% of sessions offered by the program (whichever is greater), and provide documentation during their study visit. To measure past-month adherence to self-monitoring strategies, participants who report recording their weight and diet in the previous month are asked how many days in a typical week (1-5+) they did so, and then to provide weight and food records. Similar to thresholds identified in previous studies,[72-74] participants considered adherent weigh themselves ≥3 days per week in the previous month and record what and how much they eat ≥5 days per week and provide records during their study visit.

Theoretical indicators of health behavior change – Several theoretical constructs inform the design of this intervention. We use established instruments to assess changes in the following: 1) self-efficacy to resist overeating (Weight Efficacy Lifestyle Questionnaire short form[75]) and engage in regular physical activity,[76] 2) outcome expectations for weight loss and physical activity,[77] and 3) intrinsic motivation for weight loss program participation, self-monitoring (Treatment Self-Regulation Questionnaire[78]) and physical activity (Behavioral Regulation in Exercise Questionnaire[79]).

Medical history and healthcare utilization – We use the EHR, administrative databases,

baseline chart abstraction, and survey items adapted from the NHANES Medical Conditions Survey and Cardiovascular Disease Questionnaire [80] to obtain (1) discharge diagnoses and comorbidities, (2) length of stay, (3) medications prescribed, (4) out-of-pocket expenditures for healthcare services, and (5) number of outpatient visits, emergency department visits, and hospitalizations that occur in the six months prior to enrollment and within one year after enrollment.

Financial wellbeing – The extent to which a participant's financial status contributes to their sense of financial security and wellbeing is captured using the five-item Consumer Financial Protection Bureau Financial Wellbeing Scale[81]. Because adults with lower incomes may be more responsive to financial incentives,[16] higher levels of financial distress may also identify participants with a greater likelihood of weight loss in response to financial incentives.[82] We measure financial wellbeing at baseline and follow-up to assess for this potential effect, because its presence would have implications for the development of incentive interventions that address socioeconomic disparities.[83]

Alcohol and tobacco use – The Alcohol Use Disorders Identification Test Consumption (AUDIT-C), an effective screening tool among primary care patients, is administered at screening and 12 months to assess the extent to which a participant is at risk for alcohol misuse based on DSM-V criteria (i.e., score >8).[84] The participant's history and current frequency and duration of cigarette and e-cigarette smoking are assessed using items adapted from the California Tobacco Survey.[85]

Resource utilization measures – We measure RA time spent obtaining biometric measurements, providing education and resources, confirming program participation, food journaluse and physical activity minutes, and administering incentives. While research-related

costs are not included in our economic analysis, the cost of performing activities like measurements would be incurred if the program is disseminated, since these types of activities must be performed to confirm eligibility for financial incentives. Market prices of weight management programs are used to estimate their economic cost.

Demographic characteristics/covariates – Covariates include but are not limited to age, gender, race/ethnicity, education level, acculturation, marital status, employment status, household composition, use of technology, walking limitations, and chronic conditions/disease.

**Statistical analysis**

Descriptive analysis – We will use descriptive statistics (mean, standard deviation, median, interquartile range and frequency distribution) to summarize baseline demographic, socioeconomic and clinical information to characterize the study population. All outcomes of interest will also be summarized by study visits and by study arms. Graphic displays, such as boxplots and histograms, will be used to inspect the variable distributions and identify possible outliers.

Analysis of weight loss outcomes – To examine the effectiveness of goal-directed versus outcome-based financial incentives on ≥5% weight loss, use of evidence-based weight management programs, waist circumference, blood pressure, and quality of life, as compared to the provision of health behavior change resources alone, we will use generalized mixed-effect models for repeated measures as the main inferential analytic framework. In addition to treatment, time, and treatment-time interaction, the models will include randomization stratification variables of study site and participant's incentive preference as fixed effects. The participant will be included as the random effect to account for within-subject correlation. Appropriate contrast will be used to provide estimates and comparisons of outcome between intervention groups. Variable transformation, such as log-transformation, will be considered if the distribution is skewed and

normality distribution assumption is imperative. All analysis will follow the intention-to-treat principle, all tests will be two-sided, and Bonferroni correction will be applied for multiple comparisons among study arms.

We will handle missing data, whether due to missed visits or early dropout and loss to follow-up, by the mixed effects models in the main analysis, which assume that the missing data mechanisms are 'missing at random'. Pattern mixture models, which allow missing not-at-random data, will be carried out as a missing data sensitivity analysis. In particular, we will impute the missing data according to the worst-case scenario that there is no intervention effect and all missing data follow the distribution of observed data in the control arm.

Cost-effectiveness – To examine the cost-effectiveness of using goal-directed and outcome-based financial incentives to promote weight loss, we will use health economic modeling methods that we have previously applied in other economic evaluations.[86-89] We will estimate the return on investment and cost-effectiveness of financial incentives for weight loss using in-trial utilization and projections of the cost of averted adverse health events. We will estimate the return on investment using the difference between the value of financial incentives provided and incremental healthcare costs or savings, comparing the outcome-based financial incentives arm to the resources only arm, and the goal-directed arm to the outcome-based arm. We will also estimate the cost-effectiveness of the intervention using the ratio of the difference in costs between each of the intervention and control arms to the difference in 5% weight loss attainment rates between each of the intervention and control arms.

**Patient and public involvement**

We sought feedback from patients enrolled in a prior incentives study on their preferences for an incentive structure (i.e., goal-directed versus outcome-based incentives for a preventive health

behavior) and used this feedback to inform FIReWoRk's framework and intervention design. Patients were not involved in the recruitment and conduct of the study. We assess the burden of the intervention among FIReWoRk participants during an exit interview. We will make a summary of the results available to the public after the study's conclusion and publication of the primary outcomes.

## DISCUSSION

### Innovation

In this paper, we outline the protocol and rationale for the FIReWoRk study. FIReWoRk is innovative for several reasons. First, the evaluation of goal-directed versus outcome-based financial incentives is novel in preventive health science, and we are aware of no published trials that have compared these approaches for weight loss.[90] Financial incentive interventions for preventive health have primarily targeted outcomes. Comparing these two incentive strategies is important because it directly addresses outstanding questions about how to structure incentive interventions optimally, while also yielding insights into the value of incentive-based versus non-incentive-based strategies for behavior change. We hypothesize that goal-directed incentives will lead to greater weight loss than outcome-based incentives or the provision of behavior change resources alone. If confirmed, this finding would reinforce the importance of long-standing behavioral approaches to treating obesity and other chronic health conditions with effective, goal-directed strategies (e.g., self-monitoring for weight loss, use of counseling and nicotine replacement therapy for smoking cessation). However, if FIReWoRk demonstrates that outcome-based incentives are more effective than goal-directed incentives or resources alone, this finding would support the need for more rigorous comparisons of target-based incentive strategies versus conventional, non-incentive-based approaches to treating obesity and chronic health conditions.

Measuring the weight of participants at 12 months after enrollment—6 months after removal of incentives—will provide preliminary insight into the durability of financial incentives for weight loss. Understanding the durability of financial incentives is directly relevant to ongoing debates about the effect of incentives on intrinsic vs. extrinsic motivation and patient decision-making about preventive health. Researchers have raised concerns that financial incentives may crowd out intrinsic motivation,[91, 92] though some have noted that levels of intrinsic motivation for activities we incentive may already be low, leaving little motivation at risk for crowd out.[93] The possibility that losing weight may itself increase self-efficacy further complicates the intrinsic-extrinsic motivation dynamic in the context of weight loss.

FIReWoRk is also innovative because it leverages existing clinic and community resources. The United States Preventive Services Task Force recommends that all patients with obesity receive an intensive multicomponent behavioral lifestyle intervention,[94] but most health care centers lack weight management programs. Even when health systems have their own programs (e.g., the Veteran's Affairs MOVE! Program), patients often do not live close enough to them to attend regularly. Thus, we collaborate with Weight Watchers because it is a ubiquitous resource in the community with multiple meeting locations.

A third innovative quality of FIReWoRk is its use of Fitbit wearable devices and Fitabase to facilitate the provision of financial incentives. Fitbit technology provides an interface we use to verify all participants' physical activity goal attainment, allowing us to provide timely incentive payments to participants in the goal-directed arm. These data, which include steps, heart rate, activity intensity, energy expenditure, and sleep, will also allow us to richly evaluate how different biometric measures influence obesity and weight loss outcomes. We chose not to target wearable tracking of physical activity alone with goal-directed incentives given that such

self-monitoring of physical activity may not be effective.[95] Instead, participants must meet public health guidelines for physical activity to receive incentives. We considered adopting other technological innovations to enhance our ability to administer incentives immediately, including scales that wirelessly transmit weight data. However, our concern with using some of these technologies in an incentive intervention is that remote monitoring that cannot readily be verified may tempt some participants to misrepresent their weight or other information. However, even these obstacles can be attenuated or overcome with technology. For example, video monitoring could be embedded into remote weigh-ins.

A fourth innovative component of FIReWoRk is its explicit focus on the effects of incentives on financial wellbeing. To increase our ability to detect such an effect, we are enrolling low-income populations. Low-income patients may be more likely to respond to incentives,[16, 96] and their socioeconomic status suggests that the marginal benefit of gains in health and income may be greater than those experienced by similarly obese patients with greater economic resources. Any potential benefits to financial wellbeing would therefore have implications for the development of incentive interventions that address socioeconomic disparities. Because of its design, FIReWoRk may also contribute to the growing literature on the effects of incentives to induce personal investments in health and social capital through activities such as acquiring vaccinations, saving money, or enrolling in school.[83] Several published trials of income support sample low-income populations, and some have yielded promising results with benefits extending into health and social domains.[83, 97]

Finally, FIReWoRk leverages important constructs from both psychology and behavioral economics, but represent only a fraction of those embedded into prior trials. Effective interventions have applied such constructs;[98, 99] however, it is worth noting that incorporating

these theories does not ensure that an intervention will be successful.[100] We are exploring the application of broader behavioral concepts in future work. In particular, we are interested in leveraging the power of social norms, peer comparisons, and self-image to increase weight loss.[101]

**Limitations**

A major challenge of our intervention design is that simultaneous use of multiple weight loss techniques limits our ability to determine which components of the intervention most effectively promote weight loss. However, we will be able to identify using ad-hoc analyses which components were associated with the highest rates of response to incentive payments. Several of our measures are self-report, which can introduce social desirability bias in patients' responses. RAs are not blinded to participants' intervention group when administering weight and survey measures at 6, 9, and 12 months, which could result in measurements that inadvertently favor the RAs preferred participants or incentive strategy. Our recruitment strategies may entice patients who are more highly motivated to lose weight than a truly representative sample of primary care patients, thus overestimating intervention effects on weight loss. We also screen patients for eligibility based on neighborhood-level rather than individual or household income, which precludes enrollment of low-income patients living in neighborhoods with higher income areas and may affect the generalizability of our sample.

**Public Policy and Public Health Considerations**

We view FIReWoRk's major limitation in the context of public policy to be uncertainty about the sustainability and acceptability of financial incentives for weight loss in individuals with obesity. The use of financial incentives to improve health can be controversial.[17] Sustainability and acceptability largely relate to 1) economic sustainability, in terms of

identifying sources of funding, and 2) ethics, that is public perceptions of the fairness and appropriateness of financial incentives.[98, 102-104] Despite these concerns, some decision-makers have already adopted effective financial incentive programs.[105] For example, the NHS Tayside program in Scotland provided pregnant smokers with support and £50 per month in shopping vouchers for negative carbon monoxide breath tests.[106] Australia addressed low rates of childhood vaccination by linking eligibility for social security payments, childcare rebates, and other payments to immunization status.[107, 108] In 2015, CVS Health launched a financial incentive program to help employees quit smoking, based on the design of a successful randomized trial.[109, 110] A number of health insurance companies and other workplaces have also adopted incentive programs to improve health.

Our view is that challenges related to sustainability and acceptability are surmountable, and that we can design incentive programs in a manner that supports perceptions of fairness.[111] For example, one approach is to broaden the number of individuals eligible for incentives, while tailoring behavioral targets and incentive amounts to ensure that individuals with greatest need benefit most. In terms of funding for incentives, early investment in selective programs may be offset by reductions in future healthcare cost. Some political philosophies may also be receptive to shifting investments from public programs to more targeted programs that directly benefit individuals. FIReWoRk does not address population-based approaches to weight loss, such as reducing sugar-sweetened beverage sales or increasing opportunities for physical activity in the built environment—which may ultimately be most cost-effective—but rather focuses on individual decision-making.

**Summary and Significance**

FIReWoRk responds to gaps in existing evidence by examining the comparative- and cost-effectiveness of goal-directed versus outcome-based financial incentives for weight loss in socioeconomically disadvantaged patients with obesity. We anticipate that the results of this study will inform the design of scalable financial incentive programs to address obesity in public and private health systems.

**Figure legends**:

Figure 1 – FIReWoRk Conceptual Model

Figure 2 – Patient Randomization to Study Groups

**Trial Status**: FIReWoRk began enrollment in November 2017. We expect to complete enrollment in June 2020 and complete the outcome assessment between June and August 2021. Enrollment and study execution have required close collaboration between investigators, research staff, and partners at our multiple clinical sites.

**Author's contributions**: JL and MJ initiated collaboration, conceived of, and obtained funding for the project. SO, CT, and SWi designed data collection tools. CT devised the statistical analysis plan and monitors data collection. SO and MJ developed the conceptual model. SO developed intervention materials and protocols. SO is managing the project day-to-day and supervising RAs. MJ, SO, and VS implement the trial in New York City and SWa implements the trial in LA County. SO, JL and MJ drafted and revised the paper. All coauthors contributed to the conception and/or design of the work and read, revised, and approved the final manuscript.

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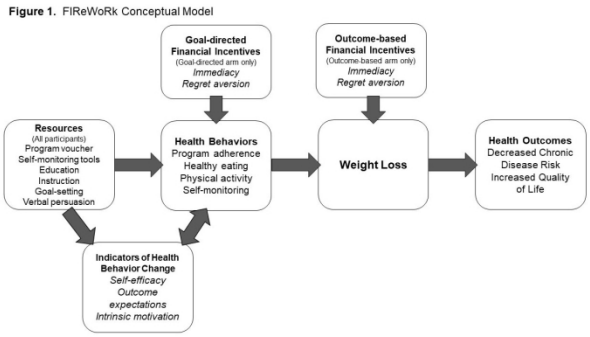


FIReWoRk Conceptual Model

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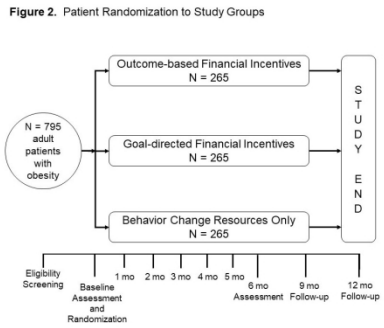


Patient Randomization to Study Groups

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# Goal-directed versus outcome-based financial incentives for weight loss among low-income patients with obesity: Rationale and design of the Financial Incentives foR Weight Reduction (FIReWoRk) randomized controlled trial

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## ABSTRACT

**Introduction**: Obesity is a major public health challenge and exacerbates economic disparities through employment discrimination and increased personal health expenditures. Financial incentives for weight management may intensify individuals' utilization of evidence-based behavioral strategies while addressing obesity-related economic disparities in low-income populations. Trials have focused on testing incentives contingent on achieving weight loss outcomes. However, based on social cognitive and self-determination theories, providing incentives for achieving intermediate behavioral goals may be more sustainable than incentivizing outcomes if they enhance an individual's skills and self-efficacy for maintaining long-term weight loss. The objective of this paper is to describe the rationale and design of the Financial Incentives foR Weight Reduction (FIReWoRk) study, a randomized controlled trial to test the comparative- and cost-effectiveness of two financial incentive strategies for weight loss (goal-directed vs. outcome-based) among low-income adults with obesity, as well as compared to the provision of health behavior change resources alone.

**Methods and analysis**: We are recruiting 795 adults, 18-70 years-old with a body mass index ≥30 kg/m$^2$, from three primary care clinics serving residents of socioeconomically disadvantaged neighborhoods in New York City and Los Angeles. All participants receive a one-year commercial weight-loss program membership, self-monitoring tools (bathroom scale, food journal, and Fitbit Alta HR), health education, and monthly check-in visits. In addition to these resources, those in the two intervention groups can earn up to $750 over 6 months for 1) participating in an intensive weight-management program, self-monitoring weight and diet, and meeting physical activity guidelines (goal-directed arm); or 2) a ≥1.5% to ≥5% reduction in baseline weight (outcome-based arm). To maximize incentive efficacy, we incorporate concepts

from behavioral economics, including immediacy of payments and framing feedback to elicit regret aversion. We will use generalized mixed-effect models for repeated measures to examine intervention effects on weight at 6, 9, and 12 months.

**Ethics and dissemination**: Human research protection committees at New York University School of Medicine, University of California Los Angeles (UCLA) David Geffen School of Medicine, and Olive-View–UCLA Medical Center granted ethics approval. We will disseminate the results of this research via peer-reviewed publications, conference presentations, and meetings with stakeholders.

**Trial registration**: This trial is registered with the National Institutes of Health at ClinicalTrials.gov under identifier NCT03157713.

## ARTICLE SUMMARY

**Strengths and Limitations**:

- This three-arm randomized controlled trial compares the impact of two financial incentives strategies on a ≥5% reduction in body weight at 6 months among primary care patients from socioeconomically disadvantaged neighborhoods.
- Comparing goal-directed versus outcome-based financial incentives is important because it directly addresses outstanding questions about how to structure financial incentive interventions optimally.
- The intervention design leverages principles of behavioral economics to connect patients with existing clinic and community resources and intensify utilization of evidence-based behavioral strategies for weight loss.
- Patients in all three arms receive substantial resources, including weight-loss program membership, bathroom scale, food journal, Fitbit Alta HR, and monthly in-person visits, which may reduce our ability to detect the marginal value of the financial incentives.
- We anticipate that the results will inform the design of scalable financial incentive programs to address obesity in public and private health systems.

**Keywords**: behavioral economics, behavioral intervention, BMI, cost-effectiveness, health behavior change, health disparities, quality of life, overweight, physical activity, self-monitoring

## INTRODUCTION

The prevalence of obesity among U.S. adults is 40% and continues to rise, contributing substantially to morbidity and mortality from obesity-related illnesses such as diabetes, heart disease, stroke, and cancer.[1-3] Obesity prevalence among U.K. adults is 26%, the highest of European countries.[4, 5] Obesity is more prevalent among adults with a lower socioeconomic status.[6] Because individuals with obesity also face social stigma, including employment discrimination and bias in educational settings,[7] the increased prevalence of obesity among lower income individuals exacerbates health and socioeconomic disparities. Moreover, the negative externalities of obesity include an attributable annual U.S. healthcare cost of $147 billion, including services provided by both public and private payers for inpatient care, non-inpatient care, and prescription drugs.[8] The U.K. National Health Service spent an estimated £6.1 billion on overweight and obesity-related illness in 2014 to 2015, with societal costs estimated at £27 billion.[9]

The U.S. Preventive Services Task Force (USPSTF) recommends universal obesity screening in healthcare settings and intensive, multicomponent behavioral interventions for adults with obesity.[10, 11] However, national data show that physicians often do not provide nutrition, exercise, or weight loss counseling for patients with obesity.[12] Moreover, 51% of U.S. adults report wanting to lose weight, but only half are actively trying, and an even smaller proportion utilize evidence-based methods.[12-15] A reduction in weight of as little as 5% is associated with cardiovascular health benefits.[16-18] It is therefore critical to identify novel approaches to increase utilization of effective, evidence-based behavior change strategies and weight-management programs (e.g., Weight Watchers, the Diabetes Prevention Program, and the Veterans Affairs MOVE! Program [19-21]) to promote weight loss and improve health outcomes, particularly among socioeconomically disadvantaged individuals. Financial incentives are a potential bridge to increasing utilization of

effective weight-management behaviors and programs among low-income adults with obesity.[22]

Health insurers, employers, and government agencies are testing the extent to which financial incentive strategies motivate changes in health behavior, particularly for obesity and smoking.[23, 24] Microeconomic theory suggests that financial incentives lead to weight loss because individuals are influenced by the prospect of rewards. This effect may be enhanced when the incentive design emphasizes *immediacy* (payments provided as soon as possible), so that individuals can more readily associate a payment with the behavior that triggered it,[25, 26] and *regret aversion* (avoidance of regret from losing an anticipated reward).[27, 28] While some theories of motivation have led researchers to raise concerns about the long-term durability of the extrinsic effects of incentives,[29] studies have shown that incentives may promote intermediate-to-long-term weight loss.[29-37] Despite these findings, a key unanswered question is what targets to incentivize.[38]

Incentivizing an individual's participation in *goal-directed*, evidence-based behaviors for weight loss, such as participating in a weight-management program, self-monitoring weight and diet, and achieving physical activity goals, may be more sustainable than incentivizing *outcome-based* attainment of weight loss, since goal-directed financial incentives are designed to encourage individuals to develop specific skills for maintaining weight loss long-term. In addition, attainment of behavioral goals precedes weight loss outcomes, thereby providing earlier opportunities for success, which may increase self-efficacy and intrinsic motivation for weight management.[39] Based on social cognitive theory,[40] incentivizing behavioral practice directly may help patients build the *self-efficacy* to engage in evidence-based strategies and maintain these behaviors even after an incentive is removed. Self-determination theory[41] highlights the

role that *intrinsic motivation* may play in an individual's sustained behavior change, since engaging in a strategy she or he has mastered can provide satisfaction and enjoyment (**Figure 1**).

To date, financial incentive interventions for weight loss have favored outcome-based over goal-directed incentive designs. In general, outcome-based designs have been shown to promote weight loss during the intervention period, though few studies have resulted in significant long-term weight loss, when this outcome was measured.[42-44] For example, in a 32-week trial among Veterans with obesity, net weight loss between the incentive and control groups was no longer significant 36 weeks post-intervention.[45] Based on social cognitive and self-determination theories described above, goal-directed incentives may promote short-term weight maintenance. Even if goal-directed incentives do not sustain weight loss, they likely are more effective than outcome-based incentives at promoting health behaviors, such as physical activity,[46] that are associated with decreased morbidity and mortality.

Further research is needed to test whether the effectiveness of financial incentives for weight loss that incorporate immediacy and regret aversion can be maximized by targeting utilization of effective weight-management behaviors and programs. Studies are also needed to assess the economic sustainability of financial incentives, which is a major factor in public and private decision-making.[47] The primary aim of the FIReWoRk study is to compare the effectiveness of goal-directed versus outcome-based financial incentives on ≥5% weight loss among patients with obesity living in socioeconomically disadvantaged neighborhoods, as well as compared to the provision of health behavior change resources alone. FIReWoRk also examines the impact of these interventions on patients' use of evidence-based weight-management programs, waist circumference, blood pressure, and quality of life. A secondary aim is to examine the cost-effectiveness of using goal-directed incentives to promote weight loss as

compared to outcome-based incentives or resources without incentives. The purpose of this paper is to describe the rationale and design of the FIReWoRk study.

## METHODS AND ANALYSES

### Study overview and design

The (FIReWoRk) study is a three-arm randomized controlled trial (RCT) to compare the effectiveness of three approaches to weight loss among primary care patients with obesity. Patients usually achieve maximum weight loss during the first six months of a behavioral intervention.[48] Thus, our primary outcome is a ≥5% reduction in baseline weight at 6 months. Our primary hypothesis is that a greater proportion of participants in the goal-directed incentives arm will obtain a ≥5% reduction in baseline weight at 6-months than in the outcome-based incentives arm or the resources-only arm. Our secondary hypothesis is that a greater proportion of participants in the goal-directed arm will maintain a ≥5% reduction in baseline weight at 12-months than in the outcome-based arm or the resources-only arm. We are enrolling adults living in socioeconomically disadvantaged neighborhoods from three medical centers that serve predominately low-income populations. Participants in all three study arms receive a one-year commercial weight loss program membership, self-monitoring tools (bathroom scale, food journal and Fitbit Alta HR), health education, and monthly check-in visits. In addition, participants in the outcome-based incentives arm can earn up to $750 over 6 months for a 1.5% to 5% reduction in baseline weight, while those in the goal-directed incentive arm can earn the same amount for engaging in the following evidence-based weight loss behaviors: weight-management program participation, self-monitoring weight and diet, and physical activity.

### Primary care clinics and patients

We are recruiting patients exclusively from three primary care clinics in New York City

(NYC) and Los Angeles (LA), with plans to enroll 795 adults with obesity from low-income neighborhoods. The clinics are part of NYC Health + Hospitals – Bellevue, NYU Langone Hospital – Brooklyn, and Olive View UCLA Medical Center. Bellevue Hospital is the nation's oldest public hospital and the flagship hospital for NYC's primary safety net health system. There are approximately 130,000 outpatient visits in Bellevue's primary care clinic each year. NYU Langone Hospital – Brooklyn is a 450-bed teaching hospital and a clinical campus for primary care education located in Sunset Park, Brooklyn. Its network of nine primary care sites handles over 602,000 visits annually. Olive View UCLA Medical Center is operated by the LA County Department of Health Services, which supports a network of primary care clinics in and around the LA metro area. More than half of Olive View patients are under- or uninsured. All locations serve racially/ethnically diverse, medically underserved populations in which the prevalence of obesity is above the national average.

Each of these hospitals uses an electronic health record (EHR) system that captures detailed inpatient and outpatient information. We conduct EHR queries every six months to identify patients with obesity who have seen a provider in the previous two years. To identify patients with obesity who live in socioeconomically disadvantaged neighborhoods, we cross-reference patients' address information from their EHR with census tracts associated with the lowest 40% of 2015 median household income in the NYC/Tri-State and LA County areas (approximately <$40,000 per year).[49] Because we are recruiting from neighborhoods with a higher proportion of minority residents and from low-income census tracts, we anticipate that our sample will have a higher proportion of ethnic and racial minorities, particularly Hispanic/Latinos, than is reflected in the general population. We approach recruitment in ways shown previously to potentially reduce burden and enhance trust among prospective participants

who are racial/ethnic minorities and live in low-income neighborhoods.[50, 51] Examples include recruiting from racial/ethnic minority-serving medical centers, hiring English-Spanish bilingual and racially/ethnically diverse research staff, providing information about the study in the patient's native language, compensating participants for completing study visits, and collecting contact information for at least one relative or friend.

As a primary recruitment method, we mail announcements about the study to the homes of patients identified via the EHR and neighborhood queries and invite them to contact us. We follow up with patients by phone, beginning when we expect the mailing to arrive and continuing until completing four outreach attempts. We also identify upcoming primary care appointments of patients identified via the queries, at which time we approach them in waiting rooms with information about the study. We schedule interested patients who pass an eligibility screening for a baseline visit at or near their home medical center within one month of their screening date. No more than one person per household is eligible to participate. As secondary recruitment methods, we communicate with primary care physicians and medical residents at the study sites who may be willing to refer their patients to the study. There is also a physician within each clinic willing to 'champion' the study by reminding providers to refer their patients, answering questions, and providing study updates. We regularly post recruitment flyers and brochures in areas of the clinic frequented by patients.

**Sample size**

Prior studies suggest that among patients with obesity, the prevalence of obtaining a 5% reduction in baseline weight by 6 months is 10-35%.[52-55] Thus, we assume an absolute difference ($rate_2 - rate_1$) of approximately 10 percentage points in rates of obtaining a 5% reduction in baseline weight by 6 months between the two incentives arms (24% and 14% of participants obtaining a 5%

weight reduction in the goal-directed and outcome-based intervention arms, respectively). Therefore, 241 participants per group provides at least 80% power to detect a meaningful difference in weight loss between the goal-directed and outcome-based intervention arms with a Type-I error rate $\alpha = 0.05$. It also provides at least 99% power to detect a meaningful difference in weight loss between the goal-directed incentives and resources-only arms (24% and 10% of participants obtaining a 5% weight reduction in the goal-directed incentives and resources-only arms, respectively) with a Type-I error rate $\alpha = 0.05$. Since there is only one primary hypothesis, there is no multiple comparison adjustment in the sample size calculation. We also assume a 6-month loss-to-follow-up rate of 10%; therefore, we will enroll an additional 72 patients for a total sample size of 795.

**Eligibility and enrollment**

We include patients with a body mass index (BMI) ≥30 kg/m$^2$, who are 18-70 years old, speak English or Spanish, have seen their physician within the past two years, have an active U.S. mobile or home phone number and address and live in a qualifying census tract. Patients who weigh >380 pounds are not enrolled, as the HealthOMeter 349KLX Digital Medical Weight Scale is only valid up to 400 pounds and we allow for a 20-pound buffer in case weight gain occurs. We exclude patients who have had a weight loss surgery or procedure in the previous two years or have experienced any of the following in the previous six months: ≥4.5 kg weight loss, completion of an intensive weight-management program, active psychosis and/or other cognitive issues, metastatic cancer, or incidence of a myocardial infarction or stroke. We also exclude patients who report abuse of alcohol, have a history of disordered eating, have Stage V Chronic Kidney Disease or End Stage Renal Disease, are pregnant or breastfeeding, plan to become pregnant, or plan to move out of NYC/Tri-State area/LA County in the following 12

months.

Once screened by phone, we invite eligible patients to a baseline study visit at their home medical center and obtain informed consent. To provide informed consent, we 1) describe the study and its risks and benefits in detail from a script tested for eighth grade reading comprehension, 2) assess comprehension by asking the patient to explain the information presented (teach-back method[56]), 3) answer questions about the study and/or consent forms, 4) offer the opportunity to participate, 5) obtain the patient's signature on the consent form.[57] The participant receives a copy of the signed consent form by email.

**Randomization**

Randomization occurs after obtaining informed consent, completing initial weight measures, administering the baseline survey instrument, and providing weight-management program referrals, health education materials, and self-monitoring tools. Participants are randomized to one of three study arms: 1) outcome-based incentives, 2) goal-directed incentives, or 3) resources only (**Figure 2**). To ensure comparable group sample sizes, we randomize eligible patients in block sizes of four or six at random using a random number generator in R (www.r-project.org). We stratify randomization by study site and participant's self-reported preference for an outcome-based or goal-directed financial incentive program for weight loss in order to ensure that both intervention groups contain an equal number of participants preferring each incentive type. Stratified randomization also prevents imbalance between treatment groups by hospital site.

**Financial incentives intervention for weight loss**

Interventionists – Trained research coordinators or research assistants (RAs) conduct all study visits. RAs are students or graduates of health-related disciplines such as biomedicine,

public health, health promotion, education, psychology, kinesiology, and nutrition. To promote enrollment of Spanish-speaking patients, RAs are required to have full native or professional Spanish proficiency. RAs receive at least 20 hours of standardized training in the responsible conduct of research, study protocols, and cultural sensitivity. RAs observe and role-play a series of study visits in both English and Spanish and can successfully demonstrate intervention delivery before conducting study visits.

Baseline study visit – At a 2.5 to 3-hour initial study visit, all participants receive a list of local weight-management programs that meet criteria for a high-intensity, on-site, multicomponent lifestyle intervention[58] and a voucher for one year of WW Freestyle® (formerly Weight Watchers) membership (total value approximately $310 US).[20] Participants can choose to attend a commercial, medical, or community-based weight-management program that is offered at least twice monthly and meets guidelines for an intensive comprehensive lifestyle intervention.[58] The RA communicates that the goal is for the participant to register and actively participate in at least 50% of weekly program sessions per month (or a comparable rate associated with evidence-based weight loss). All participants also receive self-monitoring instructions and tools[59-61] including a bathroom scale, a BookFactory food journal, and a Fitbit Alta HR® wearable fitness tracker (total value approximately $170 US).[62] The RA communicates that the goals are for the participant to weigh themselves at least 3 days per week, to record what and how much they eat at least 5 days per week, and accumulate at least 75 physical activity minutes per week (which increases to 150 minutes per week after three months to approximate physical activity guidelines[63]). The behavioral science construct of *emergency reserves* informs how the RA frames the goals; for example, the RA encourages the participant to "track what you eat every day, but you have two emergency 'skip days' per week if you fall

behind." Goals with emergency reserves are perceived as more attainable and lead to increased goal persistence.[64] The RA also communicates that the participant is to lose ≥2.5% of their baseline weight by 1 month and ≥5% by 2 months and provides their weight in pounds for each target. The RA communicates each behavioral goal and weight loss outcome both verbally and in writing, and then asks for the participant's understanding using the teach-back method.[56] The RA also discusses how to prevent relapse.[59] The RA then explains what documentation participants must provide to verify their goal attainment at subsequent study visits. In addition, participants receive health education and handouts on food types to incorporate and which to limit, portion sizes, healthy recipe ideas, and moderate-intensity physical activity. The RA also assists the participant in setting up their Fitbit device and online Fitbit and WW Freestyle accounts so that they can access the features available through their smartphone or computer.

Outcome-based incentives – If a participant is randomized to an intervention arm, the RA informs them of the behavioral goals or weight loss outcomes for which they earn incentives, the amounts they are incentivized, and how they receive their payments. Participants randomized to receive outcome-based incentives can earn up to $750 over 6 months for losing ≥1.5% to ≥5% of their baseline weight, as confirmed at monthly weigh-ins. At 1 month, they receive $50 if they lose ≥1.5% to <2.5% or $100 if they lose ≥2.5%. The weight loss outcomes at 1 month are more modest to discourage overly rapid weight loss. At 2 and 3 months, they receive $50 if they lose ≥2.5% to <5% or $100 if they lose ≥5% of their baseline weight. At 4, 5, and 6 months, they receive $100 if they lose ≥2.5% to <5% or $150 if they lose ≥5% of their baseline weight (**Table 1**). The maximum value of each incentive intervention is approximately $1,230 US ($750 US plus the $480 US financial value of the control intervention).

Goal-directed incentives – Participants randomized to goal-directed incentives do not earn money for losing weight, but instead earn up to $750 over six months for meeting goals to participate in an approved comprehensive lifestyle intervention, meet physical activity guidelines, and self-monitor weight and diet. At 1-6 months, they receive a one-time $150 for registration and attendance at ≥50% of weekly weight-management program sessions, as verified with documentation from the sessions such as an agenda or weight log or by a record of attendance in the participant's EHR, if available. They continue to receive $60 monthly thereafter for attendance at ≥50% of weekly program sessions (or a comparable rate associated with evidence-based weight loss). At 1-3 months, they receive up to $20 for achieving 75 minutes of physical activity per week ($5 per week), as verified using activity minutes data collected in the participant's Fitbit account. At 4-6 months, they must achieve 150 minutes of physical activity per week to receive up to $20. At 1-6 months, they receive up to $20 for using their food journal 5 days per week ($5 per week) and recording their body weight 3 days per week ($2.50 per week), as verified by RA review of their entries (**Table 1**). Participants receive incentives for multiple behaviors and strategies because of the necessity of a multicomponent approach for successful weight management. One drawback of this approach is that we may be unable to determine the relative impact of each behavior and strategy on weight loss. Incentives are highest for participation in a comprehensive lifestyle intervention such as WW Freestyle because attendance in such programs has been shown to lead to clinically significant weight loss [11, 58], as has engaging in physical activity and self-monitoring diet and weight (considered markers of engagement in WW Freestyle). However, we recognize not everyone can or will participate in a program. Thus, participants also receive incentives for engaging in evidence-based weight-management behaviors and strategies outside of an approved program.

**Table 1**. Financial Incentives Awarded for Meeting Monthly Behavioral Goals and Weight Loss Outcomes

| | Time point | Goal-directed Incentives[a] | Outcome-based Incentives |
|---|---|---|---|
| **Behavioral Goals** | | | |
| Enrollment and active participation[b] in an evidence-based[c] weight-management program | 1, 2, 3, 4, 5, or 6 months | $150 | $0 |
| Active participation[b] in an evidence-based[c] weight-management program | 2, 3, 4, 5, and 6 months | $60 | $0 |
| Food journal use[d] | 1, 2, 3, 4, 5, and 6 months | $20 | $0 |
| Achievement of ≥75 minutes of physical activity per week | 1, 2 and 3 months | $20 | $0 |
| Achievement of ≥150 minutes of physical activity per week[e] | 4, 5, and 6 months | $20 | $0 |
| Self-weighing[f] | 1, 2, 3, 4, 5, and 6 months | $10 | $0 |
| **Weight Loss Outcomes** | | | |
| Weight loss (≥1.5% to ≥2.5%) | 1 month | $0 | $50-$100[g] |
| Weight loss (≥2.5% to ≥5%) | 2 and 3 months | $0 | $50-$100[h] |
| Weight loss (≥2.5% to ≥5%) | 4, 5, and 6 months | $0 | $100-$150[i] |
| **Total Incentives** (maximum) | | **$750** | **$750** |

[a]Incentive is proportional to the number of weeks in the previous 28 days this goal is met (e.g., incentive may range from $5 for one week to $20 for 4 weeks).
[b]Attending ≥2 sessions per month or ≥50% of sessions monthly, whichever is greater.
[c]Program participation goal is based on established AHA/ACC/TOS guidelines for the management of overweight and obesity in adults.
[d]Recording diet content and quantity ≥5 days per week.
[e]Physical activity goal is based on established public health guidelines for moderate-vigorous intensity physical activity in adults.
[f]Recording weight ≥3 days per week.
[g]$50 for losing ≥1.5% to <2.5% and $100 for losing ≥2.5% of baseline weight.
[h]$50 for losing ≥2.5% to <5% and $100 for losing ≥5% of baseline weight.
[i]$100 for losing ≥2.5% to <5% and $150 for losing ≥5% of baseline weight.

**Table 2**. Study Measures and Assessment Time Points

| Measure | Baseline | 1-5 Months | 6, 9 Months | 12 Months |
|---|---|---|---|---|
| **Survey Measures** | | | | |
| Socio-demographics | X | | | |
| Chronic health conditions | X | | | |
| Incentives preferences | X | | | |
| Quality of life | X | | X | X |
| Healthy dietary changes | X | | X | X |
| Fruits and vegetables | X | | X | X |
| Sweets and salty snacks | X | | X | X |
| Sugar-sweetened beverages | X | | X | X |
| Physical activity | X | | X | X |
| Self-efficacy | X | | X | X |
| Outcome expectations | X | | X | X |
| Intrinsic motivation | X | | X | X |
| Financial wellbeing | X | | X | X |
| Weight-loss program adherence | | X | X | X |
| Self-monitoring | X | X | X | X |
| Alcohol and tobacco use | X | | | X |
| Hospitalizations and ER visits | | | X | X |
| Adverse events | | X | X | X |
| **Other Measures** | | | | |
| Height | X | | | |
| Weight | X | X | X | X |
| Waist circumference | X | X | X | X |
| Blood pressure | X | | X | X |
| Fitbit active minutes | | X | X | X |
| Lipids | X | | | X |
| Hemoglobin A1c | X | | | X |

Check-in study visits – Check-in study visits occur monthly at 1-6 months, proceeded by follow-up visits at 9 and 12 months. During check-in visits, RAs measure weight and waist circumference. The RA also troubleshoots any technology-related issues that arise with the participant's Fitbit or WW Freestyle membership. The majority of the 30 to 45-minute visit is devoted to verifying whether participants met their behavioral goals and weight loss outcome

and providing them with feedback on their progress. For the resources-only group, the RA provides words of encouragement for meeting a behavioral goal or weight loss outcome (e.g., "Great job!"). If the participant did not meet a goal or outcome, the RA states, "if you had done x, you would have met this goal." For the goal-directed and outcome-based groups, the RA provides words of encouragement for meeting a behavioral goal or weight loss outcome and informs them of incentive amounts earned. If the participant did not meet a goal or outcome, the RA states, "if you had done x, you could have earned x amount," using framing that leverages regret aversion. We considered using more frequent (e.g., weekly) incentive payments; however we opted to minimize the participant burden of weekly in-person or remote weigh-ins to verify goal attainment, and adhere to an intensity (i.e., monthly) more translatable to a real-world setting. After the RA verifies the participant's goal attainment, the RA communicates the incentive amount earned but does not provide payment during the visit. Immediately after the visit, the RA initiates payment via a secure prepaid debit card system called ClinCard © 2016 Greenphire. Incentives are available to participants in U.S. dollars (USD) via their ClinCard within 24-48 hours after goal verification. We inform participants during the consenting process that if they earn $600 US or more in a calendar year they will receive the appropriate tax form to report their income as well as compensation to offset any tax liability. Participants do not invest any of their own money at any time, nor do the incentives incorporate a lottery structure.

**Intervention standardization and fidelity**

We implement fidelity monitoring procedures to ensure that the delivery of intervention components is standard across all study sites and RAs. All RAs complete a task list at each study visit. A portion of study visits are audio-recorded, and recorded sessions are randomly selected for audit using a fidelity-monitoring checklist. RAs who score less than 80% on an audit receive

remedial training and are required to demonstrate the unattained standard prior to resuming study visits.[65]

**Participant retention strategies**

At the end of each check-in visit, RAs schedule participants for their next visit and place a text message and a phone call within two days prior to their scheduled visit to encourage them to return. To increase participation and minimize attrition, all participants receive a total payment for participation of up to $180 ($20 per visit) for their time and travel, independent of incentives earned in the intervention groups. We also provide participants with periodic tokens of appreciation, including a button with the study logo after their 3-month visit and a thank you text message after their 6- and 9-month visits.[50] In addition, we conduct a process evaluation to explore differences in participant retention and uptake of intervention components (e.g., self-weighing and Fitbit wear) by study arm, hospital site, and pre-specified subgroups (women, Black, and Hispanic). We also explore participants' experiences interacting with the intervention components using a semi-structured interview at 6 months. The process evaluation allows us to assess reasons the intervention may or may not have the intended effects and to improve the acceptability of future interventions. If participants do not return for their check-in visits, we attempt to contact them by phone to assess their reasons for leaving the study.

**Data collection and measures**

Assessments occur at baseline, 30 days, and 2, 3, 4, 5, 6, 9, and 12 months (**Table 2**). Our primary outcome is the percentage of patients who achieve a 5% reduction in baseline weight at 6 months, an amount considered clinically significant for overweight/obese adults because of its associated reductions in cardiometabolic risk.[16, 17] We also will assess the percentage of patients who maintain a 5% reduction in baseline weight at 6 months and compare mean weight

loss achieved in each group at 6 and 12 months. Our secondary outcomes include weight-management program attendance, waist circumference, blood pressure, and quality of life. At baseline, we confirm contact information; collect demographic characteristics; measure height, weight, and blood pressure; take a brief medical history; and administer survey instruments about diet composition, physical activity, theoretical mechanisms of health behavior change, financial distress, and quality of life. The survey is interviewer-administered in the participant's preferred language (English or Spanish). Participants are assured there are "no right or wrong answers" and to "answer as honestly as possible." At 1 to 6-month check-in visits, we assess adherence to a weight-management program, self-monitoring of weight and diet, and physical activity. We administer weight, blood pressure, and the survey instruments again at 6 months (primary outcome time point), 9 months, and 12 months. At 6, 9, and 12 months we also ask participants about hospitalizations and emergency room visits and use of medications that may modify weight (e.g., metformin, insulin, antidepressants, etc.).[66] Whenever possible at 6, 9, and 12 months, an RA who has not met regularly with the participant and who is unaware of their study arm assignment administers the biometric assessments and survey interviews and enters the results into REDCap 7.4.23, a secure web-based application. All biometric procedures are adapted from the National Health and Nutrition Examination Survey (NHANES)[67] and survey measures are selected based on their validity against an established criterion, and validation with Spanish-speaking adults, when available.

Weight and height – Weight is measured in pounds twice to the nearest 0.1 pound using a HealthOMeter 349KLX Digital Medical Weight Scale. We ask the participant to remove shoes and heavy garments and to stand still with both feet in the center of the scale, hands at sides, looking straight ahead. If the first two weights differ by 0.5 pound or more, we repeat the

measure once, and take the average of the two measures closest in value. Height is measured once, rounded up to the nearest 0.1 centimeter, using a SECA 213 Portable Stadiometer. We ask the participant to remove shoes and extraneous clothing and undo interfering hairstyles, then to stand upright looking straight ahead with heels, buttocks, shoulder blades and back of head positioned against the ruler.

Waist circumference – Waist circumference is measured twice, rounding down to the nearest 0.25 inch. We take the measurement on bare skin if possible, at the high point of the iliac crests, drawing the tape measure snug at minimal respiration. If the first two values differ by 0.5 inch or more, we repeat the measure once, and take the average of the two measures closest in value.

Blood pressure – Two resting blood pressure measures are obtained using the Omron HEM 907XL IntelliSense Professional Digital Blood Pressure Monitor, an automated sphygmomanometer. The participant remains seated without consuming caffeine or nicotine for 30 minutes prior to the measurement. We measure arm circumference first to determine the appropriate cuff size, then place the cuff snugly on the left upper arm with the bottom of the cuff approximately one inch above the inner elbow. The arm rests palm-up at heart level and the participant remains silent and still, with both feet on the floor, during the measurement.[68] If the first two systolic or diastolic values differ by 5.0 mmHg or more, we remove and adjust the cuff, repeat the two measures, and take the average of the subsequent two measures that do not differ by 5.0 mmHg or more.

Lipids and hemoglobin A1c – Fasting lipids (high- and low-density lipoprotein cholesterol, triglycerides, and total cholesterol) and hemoglobin A1c values from a 12-month period prior to baseline are accessed via the participant's EHR. Since these tests are clinically

indicated for patients with obesity, we also recommend that they obtain them at the conclusion of the six-month intervention period. We access available values a second time from a 12-month period following the conclusion of the six-month intervention period.

Quality of life – The PROMIS-29 is used to assess physical, mental, and social health.[69] The PROMIS-29 measures eight domains (fatigue, pain intensity, pain interference, physical function, sleep disturbance, anxiety, depression, and ability to participate in social roles and activities) and yields a composite global health score. The PROMIS-29 is applicable to the general population, as well as to ethnically and socio-demographically diverse groups and to those with chronic health conditions. Substantial evidence supports the validity of the PROMIS-29.[69, 70] In addition, the 7-item Center for Epidemiologic Studies Depression Scale (CES-D) is used to assess how often a participant felt depressive symptoms during the past week (1=never, 2=hardly ever, 3=some of the time, 4=most of the time). The CES-D has shown adequate reliability and validity in general population samples with a range of demographic characteristics.[71-74]

Incentive program preferences – Using an item adapted from the Financial Incentives for Smoking Treatment (FIESTA) study (ClinicalTrials.gov identifier NCT02506829), the RA describes two hypothetical financial incentive programs for weight loss (one is goal-directed and the other is outcome-based), and then asks which program the participant prefers. This question allows us to test whether participants who are randomized to an incentive structure consistent with their pre-specified incentive program preference are more likely to lose weight than those who are randomized to incentives that are inconsistent with their preference. To understand the participant's program choice, the RA asks open-ended questions to assess the reasons why the participant chose the program they did and what concerns about the program they have, as well

as open-ended items adapted from the Health Incentive Program Questionnaire[75] to prompt the participant to describe their reactions to receiving payment for losing weight.

Food behavior – We assess healthy dietary changes in portion sizes and food choices such as fried food, fast food, and white bread using the Latino Dietary Behaviors Questionnaire (LDBQ). This subscale reflects a pattern of dietary behaviors associated with healthier micronutrients and lower calories.[76] Fruit and vegetable consumption is measured using a 7-item subscale from the validated Food Behavior Checklist.[77] We adapted two items from the Rapid Eating Assessment for Participants - Shortened Version (REAP-S) to assess consumption of sweets and salty snacks.[78, 79] The LDBQ is also used to assess consumption of and sugar-sweetened beverages.[76] Binge eating, characterized by a high frequency of consuming unusually large amounts of food and feeling a loss of control, is assessed using the Eating Disorder Diagnostic Scale.[80] For pragmatic reasons, we did not use longer food behavior questionnaires or 24-hour dietary recalls due to their time-intensiveness.

Physical activity – Walking and moderate-to-vigorous intensity physical activity (MVPA) are measured using the International Physical Activity Questionnaire short form (IPAQ-SF). The IPAQ is well-established in the public health literature as a valid and reliable physical activity assessment tool.[81, 82] For the duration of the study, participants wear a commercially available fitness tracker (Fitbit Alta HR ®), which has pedometer and accelerometer functions. The validity of similar activity tracker models for assessing MVPA has been established against an accelerometer criterion, with results ranging from near perfect correlation to overestimation of MVPA values.[83] Fitbit algorithms take into account the Alta HR's accelerometer movement and heart rate function, applying minute-by-minute metabolic equivalents (METs) to estimate activity intensity. In 2015 Fitbit improved their algorithm to

more closely align with 2008 physical activity guidelines for adults[63] so that moderate-to-vigorous intensity activity minutes must occur in bouts of at least 10 minutes for a minute to be classified as an "active minute." Therefore, ≥150 Fitbit "active minutes" per week are considered an approximation of the recommended ≥150 minutes of MVPA per week.

RAs instruct participants to wear their Fitbit device at all times, except during bathing and swimming. RAs demonstrate how to charge the device and sync it with a smartphone, thereby allowing physical activity data to be uploaded to Fitabase. Fitabase is an independent affiliate of Fitbit that allows researchers to centrally access data from Fitbit wearable devices. A participant is considered to have worn their device on any given day if they accumulate >500 steps. Participants considered adherent accumulate ≥150 active minutes per week in the 28 days prior to their study visits. For participants who do not have a smartphone or computer, the RA syncs the Fitbit during study visits, allowing data stored on the device in the previous 30 days to be uploaded.

Adherence to weight-management program participation and self-monitoring weight and diet – To asses past-month participation in a recommended weight-management program, participants who report attending a program in the previous month are asked how many sessions (1-5+) they attended, and to provide approved documentation of attendance at each session. Based on thresholds established in previous studies,[20, 58] participants considered adherent attend a session on-site at least twice in the previous month, or at least 50% of sessions offered by the program (whichever is greater), and provide documentation during their study visit. To measure past-month adherence to self-monitoring strategies, participants who report recording their weight and diet in the previous month are asked how many days in a typical week (1-5+) they did so, and then to provide weight and food records. Similar to thresholds identified in

previous studies,[84-86] participants considered adherent weigh themselves ≥3 days per week in the previous month and record what and how much they eat ≥5 days per week and provide records during their study visit.

Theoretical indicators of health behavior change – Several theoretical constructs inform the design of this intervention. We use established instruments to assess changes in the following: 1) self-efficacy to resist overeating (Weight Efficacy Lifestyle Questionnaire short form[87]) and engage in regular physical activity,[88] 2) outcome expectations for weight loss and physical activity,[89] and 3) intrinsic motivation for weight loss program participation, self-monitoring (Treatment Self-Regulation Questionnaire[90]) and physical activity (Behavioral Regulation in Exercise Questionnaire[91]). These constructs will be considered as potential mediators of the effects of the intervention on health behavior change.

Medical history and healthcare utilization – We use the EHR, administrative databases, baseline chart abstraction, and survey items adapted from the NHANES Medical Conditions Survey and Cardiovascular Disease Questionnaire [92] to obtain (1) discharge diagnoses and comorbidities, (2) length of stay, (3) medications prescribed, (4) out-of-pocket expenditures for healthcare services, and (5) number of outpatient visits, emergency department visits, and hospitalizations that occur in the six months prior to enrollment and within one year after enrollment.

Financial wellbeing – The extent to which a participant's financial status contributes to their sense of financial security and wellbeing is captured using the five-item Consumer Financial Protection Bureau Financial Wellbeing Scale[93]. Because adults with lower incomes may be more responsive to financial incentives,[22] higher levels of financial distress may also identify participants with a greater likelihood of weight loss in response to financial

incentives.[94] We measure financial wellbeing at baseline and follow-up to assess for this potential effect, because its presence would have implications for the development of incentive interventions that address socioeconomic disparities.[95]

Alcohol and tobacco use – The Alcohol Use Disorders Identification Test Consumption (AUDIT-C), an effective screening tool among primary care patients, is administered at screening and 12 months to assess the extent to which a participant is at risk for alcohol misuse based on DSM-V criteria (i.e., score >8).[96] The participant's history and current frequency and duration of cigarette and e-cigarette smoking are assessed using items adapted from the California Tobacco Survey.[97]

Resource utilization measures – We measure RA time spent obtaining biometric measurements, providing education and resources, confirming program participation, food journal use and physical activity minutes, and administering incentives. While research-related costs are not included in our economic analysis, the cost of performing activities like measurements would be incurred if the program is disseminated, since these types of activities must be performed to confirm eligibility for financial incentives.

Demographic characteristics/covariates – Covariates include but are not limited to age, gender, race/ethnicity, education level, acculturation, marital status, employment status, household composition, use of technology, walking limitations, and chronic conditions/disease.

**Statistical analysis**

Descriptive analysis – We will use descriptive statistics (mean, standard deviation, median, interquartile range and frequency distribution) to summarize baseline demographic, socioeconomic and clinical information to characterize the study population. We will summarize all outcomes of interest by study visits and by study arms. Graphic displays, such as boxplots and histograms, will be

used to inspect the variable distributions and identify possible outliers.

Analysis of weight loss outcomes – To examine the effectiveness of the intervention on ≥5% weight loss, we will use generalized mixed-effect models for repeated measures as the main inferential analytic framework. In addition to treatment, time, and treatment-time interaction, the models will include randomization stratification variables of study site and participant's incentive preference as fixed effects. The participant will be included as the random effect to account for within-subject correlation. Appropriate contrast will be used to provide estimates and comparisons of outcomes between intervention groups. We will consider variable transformation, such as log-transformation, if the distribution is skewed and normality distribution assumption is imperative. All analysis will follow the intention-to-treat principle, all tests will be two-sided, and Bonferroni correction will be applied for multiple comparisons among study arms. We will analyze goal-directed indicators (weight-management program attendance, self-monitoring, physical activity, and healthy eating) and secondary outcomes (mean weight change, waist circumference, blood pressure, and quality of life) similarly to our primary outcome.

We will handle missing data, whether due to missed visits or early dropout and loss to follow-up, by the mixed effects models in the main analysis, which assume that the missing data mechanisms are 'missing at random'. Pattern mixture models, which allow missing not-at-random data, will be carried out as a missing data sensitivity analysis. In particular, we will impute the missing data according to the worst-case scenario that there is no intervention effect and all missing data follow the distribution of observed data in the control arm.

Cost-effectiveness – We will estimate the cost of the intervention to help guide employers and policymakers considering adopting the program, and to provide inputs for our cost-effectiveness analysis, while adhering to recommendations of the Panel on Cost-

Effectiveness in Health and Medicine.[98] We will estimate the return on investment of our financial incentives intervention from the perspective of the healthcare system (hospitalizations, ambulatory care, and medications) on a per-patient basis, assuming that a healthcare system would administer the program. Using a timeline of 5-10 years,[47] we will determine costs by 1) multiplying staff or employee wages (based on U.S. Bureau of Labor Statistics values[99]) by the projected time they spend on program administration, such as obesity weigh-ins and confirmation of weight loss program participation;[100] 2) using the Red Book to estimate medication costs for hypertension, diabetes, and other conditions, based on average wholesale prices;[101] and 3) estimating bulk purchase prices for other physical materials given to patients with obesity. We have applied these methods to prior economic evaluations.[38, 102-108]

Resources consumed in program activities include personnel time, printed materials, postage, telephone use, and other miscellaneous items. We will estimate personnel time using tracking sheets and/or reports made by study staff, and carefully document other materials used to deliver the intervention. These logs will include information about how the resources contributed to delivering our intervention, so that we can distinguish fixed costs (costs that do not change with the number of participants in the program) from variable costs (costs that increase with the number of participants in the program), an important distinction in economic evaluation.[109] Costs associated with research assessments (e.g., screening, randomization, questionnaires) will not be included.

We will estimate return on investment using the difference between the value of financial incentives provided and incremental healthcare costs or savings, comparing the outcome-based financial incentives arm to the resources-only arm, and the goal-directed arm to the outcome-based arm. To project long-term return on investment (using a lifetime horizon), we will modify

an existing Markov model that we previously developed of treatment interventions for patients with hypertension (cardiometabolic risks incorporated in this model reflect risks faced by obese patients). This model currently uses a 10-year time horizon.

We will also estimate the cost-effectiveness of the intervention (cost per pound of weight loss and cost per life-year gained) using the ratio of the difference in costs between each of the intervention and control arms to the difference in 5% weight loss attainment rates between each of the intervention and control arms. The general equation for a cost-effectiveness ratio (CER) is:[110] (**Figure 3**) Where *i* is the *i*-th time period of a patient's life, cost is determined by resources utilized in the provision of weight loss resources and support in the intervention and control arms, and effectiveness is measured by the primary outcome and quality of life (PROMIS-29). Costs will be determined as described above. In addition, to estimate potential cost-offsets, we will use data from our survey's sociodemographic questions about employment to evaluate changes in productivity. We will also perform nonparametric bootstrapping with 1,000 random samples from our study arms to estimate confidence intervals for cost-effectiveness ratios, using the bias-corrected percentile method described by Efron and others.[111-115] The cost and effectiveness outcomes from each bootstrap sample will be plotted on a cost-effectiveness plane.

**Patient and public involvement**

We sought feedback from patients enrolled in a prior incentives study on their preferences for an incentive structure (i.e., goal-directed versus outcome-based incentives for a preventive health behavior) and used this feedback to inform FIReWoRk's framework and intervention design. Patients were not involved in the recruitment and conduct of the study. We assess the burden of the intervention among FIReWoRk participants during an exit interview. We will make a summary of

the results available to the public after the study's conclusion and publication of the primary outcomes.

## DISCUSSION

### Innovation

In this paper, we outline the protocol and rationale for the FIReWoRk study. FIReWoRk is innovative for several reasons. First, financial incentive interventions for preventive health have primarily targeted outcomes.[42] A few recent weight loss trials have demonstrated effectiveness using a combination of goal-directed and outcome-based incentives versus a non-incentive comparison.[36, 116, 117] The few trials comparing goal-directed versus outcome-based financial incentives for weight loss were underpowered [118] or preceded behavioral economics.[119-122] Testing goal-directed versus outcome-based incentives is important because it directly addresses outstanding questions about how to structure incentive interventions optimally, while also yielding insights into the value of incentive-based versus non-incentive-based strategies for behavior change. A recent cluster-randomized trial [123] compared the effectiveness of earning up to $310 US over 16 weeks for attending Diabetes Prevention Program sessions versus for losing weight versus a combination of the two incentive types. All groups achieved moderate weight loss at 16 weeks, though no differences in weight loss were observed between the three intervention arms. Participants in the goal-directed arm were more likely to meet their program attendance goal than either the outcome-based or combined incentive arms. FIReWoRk expands upon this recent study by providing monthly primary care clinic-based check-in visits, incentivizing multiple behavioral goals, administering larger and more immediate payments (<48 hours vs. <2 months), and assessing short-term weight maintenance at 3- and 6-months post-intervention. We hypothesize that goal-directed incentives

will lead to greater and more sustained weight loss than outcome-based incentives or the provision of behavior change resources alone. If confirmed, this finding would reinforce the importance of long-standing behavioral approaches to treating obesity and other chronic health conditions with effective, goal-directed strategies (e.g., self-monitoring for weight loss, use of counseling and nicotine replacement therapy for smoking cessation). However, if FIReWoRk demonstrates that outcome-based incentives are more effective than goal-directed incentives or resources alone, this finding would support the need to 1) explore the role of outcome-based incentives in maintaining weight loss, and 2) make more rigorous comparisons between economically sustainable outcome-based incentive strategies and conventional, non-incentive-based approaches to treating obesity and chronic health conditions.

Measuring the weight of participants at 12 months after enrollment—6 months after removal of incentives—will provide preliminary insight into the durability of financial incentives for weight loss. Understanding the durability of financial incentives is directly relevant to ongoing debates about the effect of incentives on intrinsic vs. extrinsic motivation and patient decision-making about preventive health. Researchers have raised concerns that financial incentives may crowd out intrinsic motivation,[124, 125] though some have noted that levels of intrinsic motivation for activities we incentive may already be low, leaving little motivation at risk for crowd out.[126] The possibility that losing weight may itself increase self-efficacy and intrinsic motivation[127] further complicates the intrinsic-extrinsic motivation dynamic in the context of weight loss.

FIReWoRk is also innovative because it leverages existing clinic and community resources. The United States Preventive Services Task Force recommends that all patients with obesity receive an intensive multicomponent behavioral lifestyle intervention,[11] but most

health care centers lack weight-management programs. Even when health systems have their own programs (e.g., the Veteran's Affairs MOVE! Program), patients often do not live close enough to attend regularly. Thus, we collaborate with WW International, Inc. because WW Freestyle is a ubiquitous resource in the community with multiple studio locations.

A third innovative quality of FIReWoRk is its use of Fitbit wearable devices and Fitabase to facilitate the provision of financial incentives. Fitbit technology provides an interface we use to verify all participants' physical activity goal attainment, allowing us to provide timely incentive payments to participants in the goal-directed arm. These data, which include step counts, heart rate, activity intensity, energy expenditure, and sleep, will also allow us to richly evaluate how different biometric measures influence obesity and weight loss outcomes. We chose not to target wearable tracking of physical activity with goal-directed incentives given that such self-monitoring of physical activity alone may not be effective for weight loss.[128] Instead, participants must meet public health guidelines for moderate to vigorous physical activity to receive incentives. We considered adopting other technological innovations to enhance our ability to administer incentives immediately, including scales that wirelessly transmit weight data. However, our concern with using some of these technologies in an incentive intervention is that remote monitoring that cannot readily be verified may tempt some participants to misrepresent their weight or other information. However, even these obstacles can be attenuated or overcome with technology. For example, video monitoring could be embedded into remote weigh-ins.

A fourth innovative component of FIReWoRk is its explicit focus on the effects of incentives on financial wellbeing. To increase our ability to detect such an effect, we are enrolling low-income populations. Low-income patients may be more likely to respond to

incentives,[22, 129] and their socioeconomic status suggests that the marginal benefit of gains in health and income may be greater than those experienced by similarly obese patients with greater economic resources. Any potential benefits to financial wellbeing would therefore have implications for the development of incentive interventions that address socioeconomic disparities. Because of its design, FIReWoRk may also contribute to the growing literature on the effects of incentives to induce personal investments in health and social capital through activities such as acquiring vaccinations, saving money, or enrolling in school.[95] Several published trials of income support sample low-income populations, and some have yielded promising results with benefits extending into health and social domains.[95, 130]

Finally, FIReWoRk leverages important constructs from behavioral sciences, but these constructs represent only a fraction of those embedded into prior trials. Effective interventions have applied such constructs;[131, 132] however, it is worth noting that incorporating these theories does not ensure that an intervention will be successful.[133] We are exploring the application of broader behavioral concepts in future work. In particular, we are interested in leveraging the power of social norms, peer comparisons, and self-image to increase weight loss.[134]

**Limitations**

A major challenge of our intervention design is that simultaneous use of multiple weight loss techniques limits our ability to determine which components of the intervention most effectively promote weight loss. However, using ad-hoc analyses, we will be able to identify which components are associated with the highest rates of response to incentive payments. All participants receive substantial resources, including a one-year commercial weight loss program membership (mean 6-month weight loss 4.6 kg),[20] which may reduce marginal sensitivity to

the effects of incentives over resources alone. However, regular program attendance, which is necessary for weight loss success,[20] is often low, and goal-directed financial incentives have been shown to increase weight loss program participation in real-world settings.[123] Adherence to monthly check-in visits is also of concern, so participants are compensated $20 to promote retention and offset transportation costs to study visits. These smaller payments may also reduce our ability to detect the marginal impact of the incentives through their income effect, though this effect is likely negligible. The comparative-effectiveness of goal-directed versus outcome-based incentives may favor goal-directed incentives if the total incentive value were more modest than $750. This possibility is an appropriate subject for future investigation, assuming that incentives that are more modest remain sufficiently large to promote weight loss. By setting the reward amount equally across both incentive arms, cost-effectiveness may favor outcome-based incentives, particularly if weight loss is similar between arms. In the goal-directed arm, participants may inflate their goal attainment in order to increase their incentive amount, though we expect our objective goal verification process to mitigate most of this risk. Several of our measures are self-report, which can introduce social desirability bias in patients' responses. RAs are not blinded to participants' intervention group when administering weight and survey measures at 6, 9, and 12 months, which could result in measurements that inadvertently favor the RAs preferred participants or incentive strategy.

Our recruitment strategies may entice patients who are more highly motivated to lose weight than a truly representative sample of primary care patients, thus overestimating intervention effects on weight loss. We also screen patients for eligibility based on neighborhood-level rather than individual or household income, which precludes enrollment of low-income patients living in neighborhoods with higher income areas and may affect the

generalizability of our sample.

**Public Policy and Public Health Considerations**

We view FIReWoRk's major limitation in the context of public policy to be uncertainty about the sustainability and acceptability of financial incentives for weight loss in individuals with obesity. The use of financial incentives to improve health can be controversial.[23] Sustainability and acceptability largely relate to 1) economic sustainability, in terms of identifying sources of funding, and 2) ethics, that is, public perceptions of the fairness and appropriateness of financial incentives.[131, 135-137] Despite these concerns, some decision-makers have already adopted effective financial incentive programs.[138] For example, the NHS Tayside program in Scotland provided pregnant smokers with support and £50 per month in shopping vouchers for negative carbon monoxide breath tests.[139] Australia addressed low rates of childhood vaccination by linking eligibility for social security payments, childcare rebates, and other payments to immunization status.[140, 141] In 2015, CVS Health launched a financial incentive program to help employees quit smoking, based on the design of a successful randomized trial.[142, 143] A number of health insurance companies and other workplaces have also adopted incentive programs to improve health. Nonetheless, acceptability is an important consideration when designing and implementing financial incentive programs for weight loss, and even effective programs have encountered resistance by those who were not eligible to participate.[144]

Our view is that challenges related to sustainability and acceptability are surmountable, and that we can design incentive programs in a manner that supports public perceptions of fairness.[145, 146] For example, one approach is to broaden the number of individuals eligible for incentives, while tailoring behavioral targets and incentive amounts to ensure that individuals

with greatest need benefit most[147, 148]. In terms of funding for incentives, early investment in selective programs may be offset by reductions in future healthcare cost. Some political philosophies may also be receptive to shifting investments from public programs to more targeted programs that directly benefit individuals. FIReWoRk does not address population-based approaches to weight loss, such as reducing sugar-sweetened beverage sales or increasing opportunities for physical activity in the built environment—which may ultimately be most cost-effective—but rather focuses on individual decision-making.

**Summary and Significance**

FIReWoRk responds to gaps in existing evidence by examining the comparative- and cost-effectiveness of goal-directed versus outcome-based financial incentives for weight loss in socioeconomically disadvantaged patients with obesity. We anticipate that the results of this study will inform the design of scalable financial incentive programs to address obesity in public and private health systems.

**Figure legends**:

Figure 1 – FIReWoRk Conceptual Model

Figure 2 – Patient Randomization to Study Groups

Figure 3 – General Equation for Cost-Effectiveness Ratio

**Trial Status**: FIReWoRk began enrollment in November 2017. We expect to complete enrollment in June 2020 and complete the outcome assessment between June and August 2021. Enrollment and study execution have required close collaboration between investigators, research staff, and partners at our multiple clinical sites.

**Author's contributions**: JA Ladapo and M Jay initiated collaboration, conceived of, and obtained funding for the project. J Wylie-Rosett, SB Shu, and NJ Goldstein helped with study

design. JA Ladapo, M Jay, SL Orstad, C Tseng, S Wittleder, J Wylie-Rosett, SB Shu, and NJ Goldstein developed the survey and data collection tools. C Tseng devised the statistical analysis plan and SL Orstad and C Tseng monitor data collection. M Jay and SL Orstad developed the conceptual model. SL Orstad developed intervention materials and protocols. SL Orstad is managing the project day-to-day and supervising RAs. M Jay, SL Orstad, and V Sweat administer the trial in NYC and S Wali administers the trial in LA County. SL Orstad, JA Ladapo and M Jay drafted and revised the paper. All coauthors contributed to the conception and/or design of the work and critically reviewed and approved the final manuscript.

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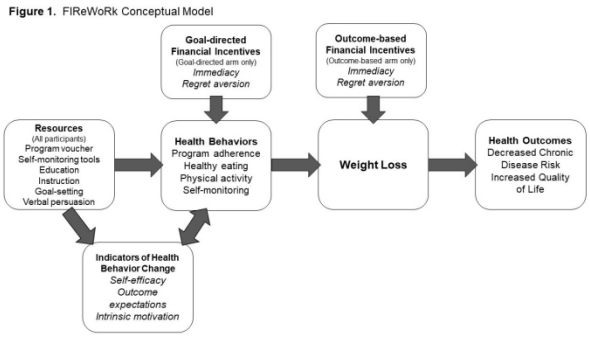
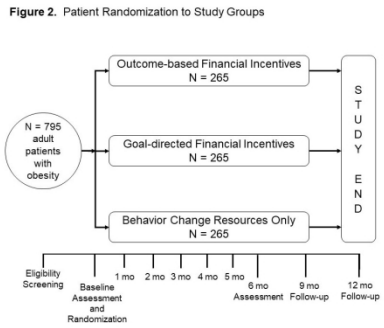



FIReWoRk Conceptual Model

177x127mm (300 x 300 DPI)




Patient Randomization to Study Groups

177x127mm (300 x 300 DPI)

$$CER = \frac{\sum_i \left( Cost_{intervention,i} - Cost_{usual\ care,i} \right)}{\sum_i \left( Effectiveness_{intervention,i} - Effectiveness_{usual\ care,i} \right)}$$

General Equation for Cost-Effectiveness Ratio

181x18mm (300 x 300 DPI)

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | ItemNo | Description | Addressed on page(s) or NA |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 3 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | NA |
| Protocol version | 3 | Date and version identifier | NA |
| Funding | 4 | Sources and types of financial, material, and other support | 37 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 36 |
| | 5b | Name and contact information for the trial sponsor | NA |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | NA |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | NA |
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 5 |

| | | | |
|---|---|---|---|
| | 6b | Explanation for choice of comparators | 7 |
| Objectives | 7 | Specific objectives or hypotheses | 7 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 8 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 8 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 11 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 12 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | NA |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 17 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | NA |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 19 |
| Participant | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), | 19, Table 2, Figure 2 |

| | | | |
|---|---|---|---|
| timeline | | assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 10 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 9 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 12 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 12 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 12 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 34 (NA) |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 20 |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 19 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any | 19 |

| | | | |
|---|---|---|---|
| | | outcome data to be collected for participants who discontinue or deviate from intervention protocols | |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 20 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 26 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 27 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 27 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | NA |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | NA |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | Table 2 |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | NA |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 3 |
| Protocol | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility | 3 |

| | | | |
|---|---|---|---|
| amendments | | criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | |
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 12 |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | 12 |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 20 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 37 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | NA |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | NA |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 3 |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | 36 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | NA |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | NA |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | NA |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

# Goal-directed versus outcome-based financial incentives for weight loss among low-income patients with obesity: Rationale and design of the Financial Incentives foR Weight Reduction (FIReWoRk) randomized controlled trial

| | |
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| Primary Subject Heading: | Health services research |
| Secondary Subject Heading: | General practice / Family practice, Nutrition and metabolism, Evidence based practice, Public health |
| Keywords: | behavioral economics, health behavior change, cost-effectiveness, health disparities, physical activity, quality of life |
| | |

# Goal-directed versus outcome-based financial incentives for weight loss among low-income patients with obesity: Rationale and design of the Financial Incentives foR Weight Reduction (FIReWoRk) randomized controlled trial

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Word count: 8728

## ABSTRACT

**Introduction**: Obesity is a major public health challenge and exacerbates economic disparities through employment discrimination and increased personal health expenditures. Financial incentives for weight management may intensify individuals' utilization of evidence-based behavioral strategies while addressing obesity-related economic disparities in low-income populations. Trials have focused on testing incentives contingent on achieving weight loss outcomes. However, based on social cognitive and self-determination theories, providing incentives for achieving intermediate behavioral goals may be more sustainable than incentivizing outcomes if they enhance an individual's skills and self-efficacy for maintaining long-term weight loss. The objective of this paper is to describe the rationale and design of the Financial Incentives foR Weight Reduction (FIReWoRk) study, a randomized controlled trial to test the comparative- and cost-effectiveness of two financial incentive strategies for weight loss (goal-directed vs. outcome-based) among low-income adults with obesity, as well as compared to the provision of health behavior change resources alone.

**Methods and analysis**: We are recruiting 795 adults, 18-70 years-old with a body mass index ≥30 kg/m$^2$, from three primary care clinics serving residents of socioeconomically disadvantaged neighborhoods in New York City and Los Angeles. All participants receive a one-year commercial weight-loss program membership, self-monitoring tools (bathroom scale, food journal, and Fitbit Alta HR), health education, and monthly check-in visits. In addition to these resources, those in the two intervention groups can earn up to $750 over 6 months for 1) participating in an intensive weight-management program, self-monitoring weight and diet, and meeting physical activity guidelines (goal-directed arm); or 2) a ≥1.5% to ≥5% reduction in baseline weight (outcome-based arm). To maximize incentive efficacy, we incorporate concepts

from behavioral economics, including immediacy of payments and framing feedback to elicit regret aversion. We will use generalized mixed-effect models for repeated measures to examine intervention effects on weight at 6, 9, and 12 months.

**Ethics and dissemination**: Human research protection committees at New York University School of Medicine, University of California Los Angeles (UCLA) David Geffen School of Medicine, and Olive-View–UCLA Medical Center granted ethics approval. We will disseminate the results of this research via peer-reviewed publications, conference presentations, and meetings with stakeholders.

**Trial registration**: This trial is registered with the National Institutes of Health at ClinicalTrials.gov under identifier NCT03157713.

## ARTICLE SUMMARY

**Strengths and Limitations**:

- This three-arm randomized controlled trial compares the impact of two financial incentives strategies on a ≥5% reduction in body weight at 6 months among primary care patients from socioeconomically disadvantaged neighborhoods.
- Comparing goal-directed versus outcome-based financial incentives is important because it directly addresses outstanding questions about how to structure financial incentive interventions optimally.
- The intervention design leverages principles of behavioral economics to connect patients with existing clinic and community resources and intensify utilization of evidence-based behavioral strategies for weight loss.
- Patients in all three arms receive substantial resources, including weight-loss program membership, bathroom scale, food journal, Fitbit Alta HR, and monthly in-person visits, which may reduce our ability to detect the marginal value of the financial incentives.
- We anticipate that the results will inform the design of scalable financial incentive programs to address obesity in public and private health systems.

**Keywords**: behavioral economics, behavioral intervention, BMI, cost-effectiveness, health behavior change, health disparities, quality of life, overweight, physical activity, self-monitoring

## INTRODUCTION

The prevalence of obesity among U.S. adults is 40% and continues to rise, contributing substantially to morbidity and mortality from obesity-related illnesses such as diabetes, heart disease, stroke, and cancer.[1-3] Obesity prevalence among U.K. adults is 26%, the highest of European countries.[4, 5] Obesity is more prevalent among adults with a lower socioeconomic status.[6] Because individuals with obesity also face social stigma, including employment discrimination and bias in educational settings,[7] the increased prevalence of obesity among lower income individuals exacerbates health and socioeconomic disparities. Moreover, the negative externalities of obesity include an attributable annual U.S. healthcare cost of $147 billion, including services provided by both public and private payers for inpatient care, non-inpatient care, and prescription drugs.[8] The U.K. National Health Service spent an estimated £6.1 billion on overweight and obesity-related illness in 2014 to 2015, with societal costs estimated at £27 billion.[9]

The U.S. Preventive Services Task Force (USPSTF) recommends universal obesity screening in healthcare settings and intensive, multicomponent behavioral interventions for adults with obesity.[10, 11] However, national data show that physicians often do not provide nutrition, exercise, or weight loss counseling for patients with obesity.[12] Moreover, 51% of U.S. adults report wanting to lose weight, but only half are actively trying, and an even smaller proportion utilize evidence-based methods.[12-15] A reduction in weight of as little as 5% is associated with cardiovascular health benefits.[16-18] It is therefore critical to identify novel approaches to increase utilization of effective, evidence-based behavior change strategies and weight-management programs (e.g., Weight Watchers, the Diabetes Prevention Program, and the Veterans Affairs MOVE! Program [19-21]) to promote weight loss and improve health outcomes, particularly among socioeconomically disadvantaged individuals. Financial incentives are a potential bridge to increasing utilization of

effective weight-management behaviors and programs among low-income adults with obesity.[22]

Health insurers, employers, and government agencies are testing the extent to which financial incentive strategies motivate changes in health behavior, particularly for obesity and smoking.[23, 24] Microeconomic theory suggests that financial incentives lead to weight loss because individuals are influenced by the prospect of rewards. This effect may be enhanced when the incentive design emphasizes *immediacy* (payments provided as soon as possible), so that individuals can more readily associate a payment with the behavior that triggered it,[25, 26] and *regret aversion* (avoidance of regret from losing an anticipated reward).[27, 28] While some theories of motivation have led researchers to raise concerns about the long-term durability of the extrinsic effects of incentives,[29] studies have shown that incentives may promote intermediate-to-long-term weight loss.[29-37] Despite these findings, a key unanswered question is what targets to incentivize.[38]

Incentivizing an individual's participation in *goal-directed*, evidence-based behaviors for weight loss, such as participating in a weight-management program, self-monitoring weight and diet, and achieving physical activity goals, may be more sustainable than incentivizing *outcome-based* attainment of weight loss, since goal-directed financial incentives are designed to encourage individuals to develop specific skills for maintaining weight loss long-term. In addition, attainment of behavioral goals precedes weight loss outcomes, thereby providing earlier opportunities for success, which may increase self-efficacy and intrinsic motivation for weight management.[39] Based on social cognitive theory,[40] incentivizing behavioral practice directly may help patients build the *self-efficacy* to engage in evidence-based strategies and maintain these behaviors even after an incentive is removed. Self-determination theory[41] highlights the

role that *intrinsic motivation* may play in an individual's sustained behavior change, since engaging in a strategy she or he has mastered can provide satisfaction and enjoyment (**Figure 1**).

To date, financial incentive interventions for weight loss have favored outcome-based over goal-directed incentive designs. In general, outcome-based designs have been shown to promote weight loss during the intervention period, though few studies have resulted in significant long-term weight loss, when this outcome was measured.[42-44] For example, in a 32-week trial among Veterans with obesity, net weight loss between the incentive and control groups was no longer significant 36 weeks post-intervention.[45] Based on social cognitive and self-determination theories described above, goal-directed incentives may promote short-term weight maintenance. Even if goal-directed incentives do not sustain weight loss, they likely are more effective than outcome-based incentives at promoting health behaviors, such as physical activity,[46] that are associated with decreased morbidity and mortality.

Further research is needed to test whether the effectiveness of financial incentives for weight loss that incorporate immediacy and regret aversion can be maximized by targeting utilization of effective weight-management behaviors and programs. Studies are also needed to assess the economic sustainability of financial incentives, which is a major factor in public and private decision-making.[47] The primary aim of the FIReWoRk study is to compare the effectiveness of goal-directed versus outcome-based financial incentives on ≥5% weight loss among patients with obesity living in socioeconomically disadvantaged neighborhoods, as well as compared to the provision of health behavior change resources alone. FIReWoRk also examines the impact of these interventions on patients' use of evidence-based weight-management programs, waist circumference, blood pressure, and quality of life. A secondary aim is to examine the cost-effectiveness of using goal-directed incentives to promote weight loss as

compared to outcome-based incentives or resources without incentives. The purpose of this paper is to describe the rationale and design of the FIReWoRk study.

## METHODS AND ANALYSES

### Study overview and design

The (FIReWoRk) study is a three-arm randomized controlled trial (RCT) to compare the effectiveness of three approaches to weight loss among primary care patients with obesity. Patients usually achieve maximum weight loss during the first six months of a behavioral intervention.[48] Thus, our primary outcome is a ≥5% reduction in baseline weight at 6 months. Our primary hypothesis is that a greater proportion of participants in the goal-directed incentives arm will obtain a ≥5% reduction in baseline weight at 6-months than in the outcome-based incentives arm or the resources-only arm. Our secondary hypothesis is that a greater proportion of participants in the goal-directed arm will maintain a ≥5% reduction in baseline weight at 12-months than in the outcome-based arm or the resources-only arm. We are enrolling adults living in socioeconomically disadvantaged neighborhoods from three medical centers that serve predominately low-income populations. Participants in all three study arms receive a one-year commercial weight loss program membership, self-monitoring tools (bathroom scale, food journal and Fitbit Alta HR), health education, and monthly check-in visits. In addition, participants in the outcome-based incentives arm can earn up to $750 over 6 months for a 1.5% to 5% reduction in baseline weight, while those in the goal-directed incentive arm can earn the same amount for engaging in the following evidence-based weight loss behaviors: weight-management program participation, self-monitoring weight and diet, and physical activity.

### Primary care clinics and patients

We are recruiting patients exclusively from three primary care clinics in New York City

(NYC) and Los Angeles (LA), with plans to enroll 795 adults with obesity from low-income neighborhoods. The clinics are part of NYC Health + Hospitals – Bellevue, NYU Langone Hospital – Brooklyn, and Olive View UCLA Medical Center. Bellevue Hospital is the nation's oldest public hospital and the flagship hospital for NYC's primary safety net health system. There are approximately 130,000 outpatient visits in Bellevue's primary care clinic each year. NYU Langone Hospital – Brooklyn is a 450-bed teaching hospital and a clinical campus for primary care education located in Sunset Park, Brooklyn. Its network of nine primary care sites handles over 602,000 visits annually. Olive View UCLA Medical Center is operated by the LA County Department of Health Services, which supports a network of primary care clinics in and around the LA metro area. More than half of Olive View patients are under- or uninsured. All locations serve racially/ethnically diverse, medically underserved populations in which the prevalence of obesity is above the national average.

Each of these hospitals uses an electronic health record (EHR) system that captures detailed inpatient and outpatient information. We conduct EHR queries every six months to identify patients with obesity who have seen a provider in the previous two years. To identify patients with obesity who live in socioeconomically disadvantaged neighborhoods, we cross-reference patients' address information from their EHR with census tracts associated with the lowest 40% of 2015 median household income in the NYC/Tri-State and LA County areas (approximately <$40,000 per year).[49] Because we are recruiting from neighborhoods with a higher proportion of minority residents and from low-income census tracts, we anticipate that our sample will have a higher proportion of ethnic and racial minorities, particularly Hispanic/Latinos, than is reflected in the general population. We approach recruitment in ways shown previously to potentially reduce burden and enhance trust among prospective participants

who are racial/ethnic minorities and live in low-income neighborhoods.[50, 51] Examples include recruiting from racial/ethnic minority-serving medical centers, hiring English-Spanish bilingual and racially/ethnically diverse research staff, providing information about the study in the patient's native language, compensating participants for completing study visits, and collecting contact information for at least one relative or friend.

As a primary recruitment method, we mail announcements about the study to the homes of patients identified via the EHR and neighborhood queries and invite them to contact us. We follow up with patients by phone, beginning when we expect the mailing to arrive and continuing until completing four outreach attempts. We also identify upcoming primary care appointments of patients identified via the queries, at which time we approach them in waiting rooms with information about the study. We schedule interested patients who pass an eligibility screening for a baseline visit at or near their home medical center within one month of their screening date. No more than one person per household is eligible to participate. As secondary recruitment methods, we communicate with primary care physicians and medical residents at the study sites who may be willing to refer their patients to the study. There is also a physician within each clinic willing to 'champion' the study by reminding providers to refer their patients, answering questions, and providing study updates. We regularly post recruitment flyers and brochures in areas of the clinic frequented by patients.

**Sample size**

Prior studies suggest that among patients with obesity, the prevalence of obtaining a 5% reduction in baseline weight by 6 months is 10-35%.[52-55] Thus, we assume an absolute difference ($rate_2 - rate_1$) of approximately 10 percentage points in rates of obtaining a 5% reduction in baseline weight by 6 months between the two incentives arms (24% and 14% of participants obtaining a 5%

weight reduction in the goal-directed and outcome-based intervention arms, respectively). Therefore, 241 participants per group provides at least 80% power to detect a meaningful difference in weight loss between the goal-directed and outcome-based intervention arms with a Type-I error rate $\alpha = 0.05$. It also provides at least 99% power to detect a meaningful difference in weight loss between the goal-directed incentives and resources-only arms (24% and 10% of participants obtaining a 5% weight reduction in the goal-directed incentives and resources-only arms, respectively) with a Type-I error rate $\alpha = 0.05$. Since there is only one primary hypothesis, there is no multiple comparison adjustment in the sample size calculation. We also assume a 6-month loss-to-follow-up rate of 10%; therefore, we will enroll an additional 72 patients for a total sample size of 795.

**Eligibility and enrollment**

We include patients with a body mass index (BMI) ≥30 kg/m$^2$, who are 18-70 years old, speak English or Spanish, have seen their physician within the past two years, have an active U.S. mobile or home phone number and address and live in a qualifying census tract. Patients who weigh >380 pounds are not enrolled, as the HealthOMeter 349KLX Digital Medical Weight Scale is only valid up to 400 pounds and we allow for a 20-pound buffer in case weight gain occurs. We exclude patients who have had a weight loss surgery or procedure in the previous two years or have experienced any of the following in the previous six months: ≥4.5 kg weight loss, completion of an intensive weight-management program, active psychosis and/or other cognitive issues, metastatic cancer, or incidence of a myocardial infarction or stroke. We also exclude patients who report abuse of alcohol, have a history of disordered eating, have Stage V Chronic Kidney Disease or End Stage Renal Disease, are pregnant or breastfeeding, plan to become pregnant, or plan to move out of NYC/Tri-State area/LA County in the following 12

months.

Once screened by phone, we invite eligible patients to a baseline study visit at their home medical center and obtain informed consent. To provide informed consent, we 1) describe the study and its risks and benefits in detail from a script tested for eighth grade reading comprehension, 2) assess comprehension by asking the patient to explain the information presented (teach-back method[56]), 3) answer questions about the study and/or consent forms, 4) offer the opportunity to participate, 5) obtain the patient's signature on the consent form.[57] The participant receives a copy of the signed consent form by email.

**Randomization**

Randomization occurs after obtaining informed consent, completing initial weight measures, administering the baseline survey instrument, and providing weight-management program referrals, health education materials, and self-monitoring tools. Participants are randomized to one of three study arms: 1) outcome-based incentives, 2) goal-directed incentives, or 3) resources only (**Figure 2**). To ensure comparable group sample sizes, we randomize eligible patients in block sizes of four or six at random using a random number generator in R (www.r-project.org). We stratify randomization by study site and participant's self-reported preference for an outcome-based or goal-directed financial incentive program for weight loss in order to ensure that both intervention groups contain an equal number of participants preferring each incentive type. Stratified randomization also prevents imbalance between treatment groups by hospital site.

**Financial incentives intervention for weight loss**

Interventionists – Trained research coordinators or research assistants (RAs) conduct all study visits. RAs are students or graduates of health-related disciplines such as biomedicine,

public health, health promotion, education, psychology, kinesiology, and nutrition. To promote enrollment of Spanish-speaking patients, RAs are required to have full native or professional Spanish proficiency. RAs receive at least 20 hours of standardized training in the responsible conduct of research, study protocols, and cultural sensitivity. RAs observe and role-play a series of study visits in both English and Spanish and can successfully demonstrate intervention delivery before conducting study visits.

Baseline study visit – At a 2.5 to 3-hour initial study visit, all participants receive a list of local weight-management programs that meet criteria for a high-intensity, on-site, multicomponent lifestyle intervention[58] and a voucher for one year of WW Freestyle® (formerly Weight Watchers) membership (total value approximately $310 US).[20] Participants can choose to attend a commercial, medical, or community-based weight-management program that is offered at least twice monthly and meets guidelines for an intensive comprehensive lifestyle intervention.[58] The RA communicates that the goal is for the participant to register and actively participate in at least 50% of weekly program sessions per month (or a comparable rate associated with evidence-based weight loss). All participants also receive self-monitoring instructions and tools[59-61] including a bathroom scale, a BookFactory food journal, and a Fitbit Alta HR® wearable fitness tracker (total value approximately $170 US).[62] The RA communicates that the goals are for the participant to weigh themselves at least 3 days per week, to record what and how much they eat at least 5 days per week, and accumulate at least 75 physical activity minutes per week (which increases to 150 minutes per week after three months to approximate physical activity guidelines[63]). The behavioral science construct of *emergency reserves* informs how the RA frames the goals; for example, the RA encourages the participant to "track what you eat every day, but you have two emergency 'skip days' per week if you fall

behind." Goals with emergency reserves are perceived as more attainable and lead to increased goal persistence.[64] The RA also communicates that the participant is to lose ≥2.5% of their baseline weight by 1 month and ≥5% by 2 months and provides their weight in pounds for each target. The RA communicates each behavioral goal and weight loss outcome both verbally and in writing, and then asks for the participant's understanding using the teach-back method.[56] The RA also discusses how to prevent relapse.[59] The RA then explains what documentation participants must provide to verify their goal attainment at subsequent study visits. In addition, participants receive health education and handouts on food types to incorporate and which to limit, portion sizes, healthy recipe ideas, and moderate-intensity physical activity. The RA also assists the participant in setting up their Fitbit device and online Fitbit and WW Freestyle accounts so that they can access the features available through their smartphone or computer.

Outcome-based incentives – If a participant is randomized to an intervention arm, the RA informs them of the behavioral goals or weight loss outcomes for which they earn incentives, the amounts they are incentivized, and how they receive their payments. Participants randomized to receive outcome-based incentives can earn up to $750 over 6 months for losing ≥1.5% to ≥5% of their baseline weight, as confirmed at monthly weigh-ins. At 1 month, they receive $50 if they lose ≥1.5% to <2.5% or $100 if they lose ≥2.5%. The weight loss outcomes at 1 month are more modest to discourage overly rapid weight loss. At 2 and 3 months, they receive $50 if they lose ≥2.5% to <5% or $100 if they lose ≥5% of their baseline weight. At 4, 5, and 6 months, they receive $100 if they lose ≥2.5% to <5% or $150 if they lose ≥5% of their baseline weight (**Table 1**). The maximum value of each incentive intervention is approximately $1,230 US ($750 US plus the $480 US financial value of the control intervention).

Goal-directed incentives – Participants randomized to goal-directed incentives do not earn money for losing weight, but instead earn up to $750 over six months for meeting goals to participate in an approved comprehensive lifestyle intervention, meet physical activity guidelines, and self-monitor weight and diet. At 1-6 months, they receive a one-time $150 for registration and attendance at ≥50% of weekly weight-management program sessions, as verified with documentation from the sessions such as an agenda or weight log or by a record of attendance in the participant's EHR, if available. They continue to receive $60 monthly thereafter for attendance at ≥50% of weekly program sessions (or a comparable rate associated with evidence-based weight loss). At 1-3 months, they receive up to $20 for achieving 75 minutes of physical activity per week ($5 per week), as verified using activity minutes data collected in the participant's Fitbit account. At 4-6 months, they must achieve 150 minutes of physical activity per week to receive up to $20. At 1-6 months, they receive up to $20 for using their food journal 5 days per week ($5 per week) and recording their body weight 3 days per week ($2.50 per week), as verified by RA review of their entries (**Table 1**). Participants receive incentives for multiple behaviors and strategies because of the necessity of a multicomponent approach for successful weight management. One drawback of this approach is that we may be unable to determine the relative impact of each behavior and strategy on weight loss. Incentives are highest for participation in a comprehensive lifestyle intervention such as WW Freestyle because attendance in such programs has been shown to lead to clinically significant weight loss [11, 58], as has engaging in physical activity and self-monitoring diet and weight (considered markers of engagement in WW Freestyle). However, we recognize not everyone can or will participate in a program. Thus, participants also receive incentives for engaging in evidence-based weight-management behaviors and strategies outside of an approved program.

**Table 1**. Financial Incentives Awarded for Meeting Monthly Behavioral Goals and Weight Loss Outcomes

| | Time point | Goal-directed Incentives[a] | Outcome-based Incentives |
|---|---|---|---|
| **Behavioral Goals** | | | |
| Enrollment and active participation[b] in an evidence-based[c] weight-management program | 1, 2, 3, 4, 5, or 6 months | $150 | $0 |
| Active participation[b] in an evidence-based[c] weight-management program | 2, 3, 4, 5, and 6 months | $60 | $0 |
| Food journal use[d] | 1, 2, 3, 4, 5, and 6 months | $20 | $0 |
| Achievement of ≥75 minutes of physical activity per week | 1, 2 and 3 months | $20 | $0 |
| Achievement of ≥150 minutes of physical activity per week[e] | 4, 5, and 6 months | $20 | $0 |
| Self-weighing[f] | 1, 2, 3, 4, 5, and 6 months | $10 | $0 |
| **Weight Loss Outcomes** | | | |
| Weight loss (≥1.5% to ≥2.5%) | 1 month | $0 | $50-$100[g] |
| Weight loss (≥2.5% to ≥5%) | 2 and 3 months | $0 | $50-$100[h] |
| Weight loss (≥2.5% to ≥5%) | 4, 5, and 6 months | $0 | $100-$150[i] |
| **Total Incentives** (maximum) | | **$750** | **$750** |

[a]Incentive is proportional to the number of weeks in the previous 28 days this goal is met (e.g., incentive may range from $5 for one week to $20 for 4 weeks).
[b]Attending ≥2 sessions per month or ≥50% of sessions monthly, whichever is greater.
[c]Program participation goal is based on established AHA/ACC/TOS guidelines for the management of overweight and obesity in adults.
[d]Recording diet content and quantity ≥5 days per week.
[e]Physical activity goal is based on established public health guidelines for moderate-vigorous intensity physical activity in adults.
[f]Recording weight ≥3 days per week.
[g]$50 for losing ≥1.5% to <2.5% and $100 for losing ≥2.5% of baseline weight.
[h]$50 for losing ≥2.5% to <5% and $100 for losing ≥5% of baseline weight.
[i]$100 for losing ≥2.5% to <5% and $150 for losing ≥5% of baseline weight.

**Table 2**. Study Measures and Assessment Time Points

| Measure | Baseline | 1-5 Months | 6, 9 Months | 12 Months |
|---|---|---|---|---|
| **Survey Measures** | | | | |
| Socio-demographics | X | | | |
| Chronic health conditions | X | | | |
| Incentives preferences | X | | | |
| Quality of life | X | | X | X |
| Healthy dietary changes | X | | X | X |
| Fruits and vegetables | X | | X | X |
| Sweets and salty snacks | X | | X | X |
| Sugar-sweetened beverages | X | | X | X |
| Physical activity | X | | X | X |
| Self-efficacy | X | | X | X |
| Outcome expectations | X | | X | X |
| Intrinsic motivation | X | | X | X |
| Financial wellbeing | X | | X | X |
| Weight-loss program adherence | | X | X | X |
| Self-monitoring | X | X | X | X |
| Alcohol and tobacco use | X | | | X |
| Hospitalizations and ER visits | | | X | X |
| Adverse events | | X | X | X |
| **Other Measures** | | | | |
| Height | X | | | |
| Weight | X | X | X | X |
| Waist circumference | X | X | X | X |
| Blood pressure | X | | X | X |
| Fitbit active minutes | | X | X | X |
| Lipids | X | | | X |
| Hemoglobin A1c | X | | | X |

Check-in study visits – Check-in study visits occur monthly at 1-6 months, proceeded by follow-up visits at 9 and 12 months. During check-in visits, RAs measure weight and waist circumference. The RA also troubleshoots any technology-related issues that arise with the participant's Fitbit or WW Freestyle membership. The majority of the 30 to 45-minute visit is devoted to verifying whether participants met their behavioral goals and weight loss outcome

and providing them with feedback on their progress. For the resources-only group, the RA provides words of encouragement for meeting a behavioral goal or weight loss outcome (e.g., "Great job!"). If the participant did not meet a goal or outcome, the RA states, "if you had done x, you would have met this goal." For the goal-directed and outcome-based groups, the RA provides words of encouragement for meeting a behavioral goal or weight loss outcome and informs them of incentive amounts earned. If the participant did not meet a goal or outcome, the RA states, "if you had done x, you could have earned x amount," using framing that leverages regret aversion. We considered using more frequent (e.g., weekly) incentive payments; however we opted to minimize the participant burden of weekly in-person or remote weigh-ins to verify goal attainment, and adhere to an intensity (i.e., monthly) more translatable to a real-world setting. After the RA verifies the participant's goal attainment, the RA communicates the incentive amount earned but does not provide payment during the visit. Immediately after the visit, the RA initiates payment via a secure prepaid debit card system called ClinCard © 2016 Greenphire. Incentives are available to participants in U.S. dollars (USD) via their ClinCard within 24-48 hours after goal verification. We inform participants during the consenting process that if they earn $600 US or more in a calendar year they will receive the appropriate tax form to report their income as well as compensation to offset any tax liability. Participants do not invest any of their own money at any time, nor do the incentives incorporate a lottery structure.

**Intervention standardization and fidelity**

We implement fidelity monitoring procedures to ensure that the delivery of intervention components is standard across all study sites and RAs. All RAs complete a task list at each study visit. A portion of study visits are audio-recorded, and recorded sessions are randomly selected for audit using a fidelity-monitoring checklist. RAs who score less than 80% on an audit receive

remedial training and are required to demonstrate the unattained standard prior to resuming study visits.[65]

**Participant retention strategies**

At the end of each check-in visit, RAs schedule participants for their next visit and place a text message and a phone call within two days prior to their scheduled visit to encourage them to return. To increase participation and minimize attrition, all participants receive a total payment for participation of up to $180 ($20 per visit) for their time and travel, independent of incentives earned in the intervention groups. We also provide participants with periodic tokens of appreciation, including a button with the study logo after their 3-month visit and a thank you text message after their 6- and 9-month visits.[50] In addition, we conduct a process evaluation to explore differences in participant retention and uptake of intervention components (e.g., self-weighing and Fitbit wear) by study arm, hospital site, and pre-specified subgroups (women, Black, and Hispanic). We also explore participants' experiences interacting with the intervention components using a semi-structured interview at 6 months. The process evaluation allows us to assess reasons the intervention may or may not have the intended effects and to improve the acceptability of future interventions. If participants do not return for their check-in visits, we attempt to contact them by phone to assess their reasons for leaving the study.

**Data collection and measures**

Assessments occur at baseline, 30 days, and 2, 3, 4, 5, 6, 9, and 12 months (**Table 2**). Our primary outcome is the percentage of patients who achieve a 5% reduction in baseline weight at 6 months, an amount considered clinically significant for overweight/obese adults because of its associated reductions in cardiometabolic risk.[16, 17] We also will assess the percentage of patients who maintain a 5% reduction in baseline weight at 6 months and compare mean weight

loss achieved in each group at 6 and 12 months. Our secondary outcomes include weight-management program attendance, waist circumference, blood pressure, and quality of life. At baseline, we confirm contact information; collect demographic characteristics; measure height, weight, and blood pressure; take a brief medical history; and administer survey instruments about diet composition, physical activity, theoretical mechanisms of health behavior change, financial distress, and quality of life. The survey is interviewer-administered in the participant's preferred language (English or Spanish). Participants are assured there are "no right or wrong answers" and to "answer as honestly as possible." At 1 to 6-month check-in visits, we assess adherence to a weight-management program, self-monitoring of weight and diet, and physical activity. We administer weight, blood pressure, and the survey instruments again at 6 months (primary outcome time point), 9 months, and 12 months. At 6, 9, and 12 months we also ask participants about hospitalizations and emergency room visits and use of medications that may modify weight (e.g., metformin, insulin, antidepressants, etc.).[66] Whenever possible at 6, 9, and 12 months, an RA who has not met regularly with the participant and who is unaware of their study arm assignment administers the biometric assessments and survey interviews and enters the results into REDCap 7.4.23, a secure web-based application. All biometric procedures are adapted from the National Health and Nutrition Examination Survey (NHANES)[67] and survey measures are selected based on their validity against an established criterion, and validation with Spanish-speaking adults, when available.

Weight and height – Weight is measured in pounds twice to the nearest 0.1 pound using a HealthOMeter 349KLX Digital Medical Weight Scale. We ask the participant to remove shoes and heavy garments and to stand still with both feet in the center of the scale, hands at sides, looking straight ahead. If the first two weights differ by 0.5 pound or more, we repeat the

measure once, and take the average of the two measures closest in value. Height is measured once, rounded up to the nearest 0.1 centimeter, using a SECA 213 Portable Stadiometer. We ask the participant to remove shoes and extraneous clothing and undo interfering hairstyles, then to stand upright looking straight ahead with heels, buttocks, shoulder blades and back of head positioned against the ruler.

Waist circumference – Waist circumference is measured twice, rounding down to the nearest 0.25 inch. We take the measurement on bare skin if possible, at the high point of the iliac crests, drawing the tape measure snug at minimal respiration. If the first two values differ by 0.5 inch or more, we repeat the measure once, and take the average of the two measures closest in value.

Blood pressure – Two resting blood pressure measures are obtained using the Omron HEM 907XL IntelliSense Professional Digital Blood Pressure Monitor, an automated sphygmomanometer. The participant remains seated without consuming caffeine or nicotine for 30 minutes prior to the measurement. We measure arm circumference first to determine the appropriate cuff size, then place the cuff snugly on the left upper arm with the bottom of the cuff approximately one inch above the inner elbow. The arm rests palm-up at heart level and the participant remains silent and still, with both feet on the floor, during the measurement.[68] If the first two systolic or diastolic values differ by 5.0 mmHg or more, we remove and adjust the cuff, repeat the two measures, and take the average of the subsequent two measures that do not differ by 5.0 mmHg or more.

Lipids and hemoglobin A1c – Fasting lipids (high- and low-density lipoprotein cholesterol, triglycerides, and total cholesterol) and hemoglobin A1c values from a 12-month period prior to baseline are accessed via the participant's EHR. Since these tests are clinically

indicated for patients with obesity, we also recommend that they obtain them at the conclusion of the six-month intervention period. We access available values a second time from a 12-month period following the conclusion of the six-month intervention period.

Quality of life – The PROMIS-29 is used to assess physical, mental, and social health.[69] The PROMIS-29 measures eight domains (fatigue, pain intensity, pain interference, physical function, sleep disturbance, anxiety, depression, and ability to participate in social roles and activities) and yields a composite global health score. The PROMIS-29 is applicable to the general population, as well as to ethnically and socio-demographically diverse groups and to those with chronic health conditions. Substantial evidence supports the validity of the PROMIS-29.[69, 70] In addition, the 7-item Center for Epidemiologic Studies Depression Scale (CES-D) is used to assess how often a participant felt depressive symptoms during the past week (1=never, 2=hardly ever, 3=some of the time, 4=most of the time). The CES-D has shown adequate reliability and validity in general population samples with a range of demographic characteristics.[71-74]

Incentive program preferences – Using an item adapted from the Financial Incentives for Smoking Treatment (FIESTA) study (ClinicalTrials.gov identifier NCT02506829), the RA describes two hypothetical financial incentive programs for weight loss (one is goal-directed and the other is outcome-based), and then asks which program the participant prefers. This question allows us to test whether participants who are randomized to an incentive structure consistent with their pre-specified incentive program preference are more likely to lose weight than those who are randomized to incentives that are inconsistent with their preference. To understand the participant's program choice, the RA asks open-ended questions to assess the reasons why the participant chose the program they did and what concerns about the program they have, as well

as open-ended items adapted from the Health Incentive Program Questionnaire[75] to prompt the participant to describe their reactions to receiving payment for losing weight.

Food behavior – We assess healthy dietary changes in portion sizes and food choices such as fried food, fast food, and white bread using the Latino Dietary Behaviors Questionnaire (LDBQ). This subscale reflects a pattern of dietary behaviors associated with healthier micronutrients and lower calories.[76] Fruit and vegetable consumption is measured using a 7-item subscale from the validated Food Behavior Checklist.[77] We adapted two items from the Rapid Eating Assessment for Participants - Shortened Version (REAP-S) to assess consumption of sweets and salty snacks.[78, 79] The LDBQ is also used to assess consumption of and sugar-sweetened beverages.[76] Binge eating, characterized by a high frequency of consuming unusually large amounts of food and feeling a loss of control, is assessed using the Eating Disorder Diagnostic Scale.[80] For pragmatic reasons, we did not use longer food behavior questionnaires or 24-hour dietary recalls due to their time-intensiveness.

Physical activity – Walking and moderate-to-vigorous intensity physical activity (MVPA) are measured using the International Physical Activity Questionnaire short form (IPAQ-SF). The IPAQ is well-established in the public health literature as a valid and reliable physical activity assessment tool.[81, 82] For the duration of the study, participants wear a commercially available fitness tracker (Fitbit Alta HR ®), which has pedometer and accelerometer functions. The validity of similar activity tracker models for assessing MVPA has been established against an accelerometer criterion, with results ranging from near perfect correlation to overestimation of MVPA values.[83] Fitbit algorithms take into account the Alta HR's accelerometer movement and heart rate function, applying minute-by-minute metabolic equivalents (METs) to estimate activity intensity. In 2015 Fitbit improved their algorithm to

more closely align with 2008 physical activity guidelines for adults[63] so that moderate-to-vigorous intensity activity minutes must occur in bouts of at least 10 minutes for a minute to be classified as an "active minute." Therefore, ≥150 Fitbit "active minutes" per week are considered an approximation of the recommended ≥150 minutes of MVPA per week.

RAs instruct participants to wear their Fitbit device at all times, except during bathing and swimming. RAs demonstrate how to charge the device and sync it with a smartphone, thereby allowing physical activity data to be uploaded to Fitabase. Fitabase is an independent affiliate of Fitbit that allows researchers to centrally access data from Fitbit wearable devices. A participant is considered to have worn their device on any given day if they accumulate >500 steps. Participants considered adherent accumulate ≥150 active minutes per week in the 28 days prior to their study visits. For participants who do not have a smartphone or computer, the RA syncs the Fitbit during study visits, allowing data stored on the device in the previous 30 days to be uploaded.

Adherence to weight-management program participation and self-monitoring weight and diet – To asses past-month participation in a recommended weight-management program, participants who report attending a program in the previous month are asked how many sessions (1-5+) they attended, and to provide approved documentation of attendance at each session. Based on thresholds established in previous studies,[20, 58] participants considered adherent attend a session on-site at least twice in the previous month, or at least 50% of sessions offered by the program (whichever is greater), and provide documentation during their study visit. To measure past-month adherence to self-monitoring strategies, participants who report recording their weight and diet in the previous month are asked how many days in a typical week (1-5+) they did so, and then to provide weight and food records. Similar to thresholds identified in

previous studies,[84-86] participants considered adherent weigh themselves ≥3 days per week in the previous month and record what and how much they eat ≥5 days per week and provide records during their study visit.

Theoretical indicators of health behavior change – Several theoretical constructs inform the design of this intervention. We use established instruments to assess changes in the following: 1) self-efficacy to resist overeating (Weight Efficacy Lifestyle Questionnaire short form[87]) and engage in regular physical activity,[88] 2) outcome expectations for weight loss and physical activity,[89] and 3) intrinsic motivation for weight loss program participation, self-monitoring (Treatment Self-Regulation Questionnaire[90]) and physical activity (Behavioral Regulation in Exercise Questionnaire[91]). These constructs will be considered as potential mediators of the effects of the intervention on health behavior change.

Medical history and healthcare utilization – We use the EHR, administrative databases, baseline chart abstraction, and survey items adapted from the NHANES Medical Conditions Survey and Cardiovascular Disease Questionnaire [92] to obtain (1) discharge diagnoses and comorbidities, (2) length of stay, (3) medications prescribed, (4) out-of-pocket expenditures for healthcare services, and (5) number of outpatient visits, emergency department visits, and hospitalizations that occur in the six months prior to enrollment and within one year after enrollment.

Financial wellbeing – The extent to which a participant's financial status contributes to their sense of financial security and wellbeing is captured using the five-item Consumer Financial Protection Bureau Financial Wellbeing Scale[93]. Because adults with lower incomes may be more responsive to financial incentives,[22] higher levels of financial distress may also identify participants with a greater likelihood of weight loss in response to financial

incentives.[94] We measure financial wellbeing at baseline and follow-up to assess for this potential effect, because its presence would have implications for the development of incentive interventions that address socioeconomic disparities.[95]

Alcohol and tobacco use – The Alcohol Use Disorders Identification Test Consumption (AUDIT-C), an effective screening tool among primary care patients, is administered at screening and 12 months to assess the extent to which a participant is at risk for alcohol misuse based on DSM-V criteria (i.e., score >8).[96] The participant's history and current frequency and duration of cigarette and e-cigarette smoking are assessed using items adapted from the California Tobacco Survey.[97]

Resource utilization measures – We measure RA time spent obtaining biometric measurements, providing education and resources, confirming program participation, food journal use and physical activity minutes, and administering incentives. While research-related costs are not included in our economic analysis, the cost of performing activities like measurements would be incurred if the program is disseminated, since these types of activities must be performed to confirm eligibility for financial incentives.

Demographic characteristics/covariates – Covariates include but are not limited to age, gender, race/ethnicity, education level, acculturation, marital status, employment status, household composition, use of technology, walking limitations, and chronic conditions/disease.

**Statistical analysis**

Descriptive analysis – We will use descriptive statistics (mean, standard deviation, median, interquartile range and frequency distribution) to summarize baseline demographic, socioeconomic and clinical information to characterize the study population. We will summarize all outcomes of interest by study visits and by study arms. Graphic displays, such as boxplots and histograms, will be

used to inspect the variable distributions and identify possible outliers.

Analysis of weight loss outcomes – To examine the effectiveness of the intervention on ≥5% weight loss, we will use generalized mixed-effect models for repeated measures as the main inferential analytic framework. In addition to treatment, time, and treatment-time interaction, the models will include randomization stratification variables of study site and participant's incentive preference as fixed effects. The participant will be included as the random effect to account for within-subject correlation. Appropriate contrast will be used to provide estimates and comparisons of outcomes between intervention groups. We will consider variable transformation, such as log-transformation, if the distribution is skewed and normality distribution assumption is imperative. All analysis will follow the intention-to-treat principle, all tests will be two-sided, and Bonferroni correction will be applied for multiple comparisons among study arms. We will analyze goal-directed indicators (weight-management program attendance, self-monitoring, physical activity, and healthy eating) and secondary outcomes (mean weight change, waist circumference, blood pressure, and quality of life) similarly to our primary outcome.

We will handle missing data, whether due to missed visits or early dropout and loss to follow-up, by the mixed effects models in the main analysis, which assume that the missing data mechanisms are 'missing at random'. Pattern mixture models, which allow missing not-at-random data, will be carried out as a missing data sensitivity analysis. In particular, we will impute the missing data according to the worst-case scenario that there is no intervention effect and all missing data follow the distribution of observed data in the control arm.

Cost-effectiveness – We will estimate the cost of the intervention to help guide employers and policymakers considering adopting the program, and to provide inputs for our cost-effectiveness analysis, while adhering to recommendations of the Panel on Cost-

Effectiveness in Health and Medicine.[98] We will estimate the return on investment of our financial incentives intervention from the perspective of the healthcare system (hospitalizations, ambulatory care, and medications) on a per-patient basis, assuming that a healthcare system would administer the program. We include a return on investment analysis because prior research has shown that providing return on investment may influence the adoption and sustainability of health improvement programs by health care organizations.[47] Using a timeline of 5-10 years,[47] we will determine costs by 1) multiplying staff or employee wages (based on U.S. Bureau of Labor Statistics values[99]) by the projected time they spend on program administration, such as obesity weigh-ins and confirmation of weight loss program participation;[100] 2) using the Red Book to estimate medication costs for hypertension, diabetes, and other conditions, based on average wholesale prices;[101] and 3) estimating bulk purchase prices for other physical materials given to patients with obesity. We have applied these methods to prior economic evaluations.[38, 102-108] Prior research suggests that private health plans and corporations use a shorter return on investment time horizon (e.g., 5-10 years) for decision-making; however, it is important to note that some health improvement programs may require longer time horizons for economic benefits to accrue.

Resources consumed in program activities include personnel time, printed materials, postage, telephone use, and other miscellaneous items. We will estimate personnel time using tracking sheets and/or reports made by study staff, and carefully document other materials used to deliver the intervention. These logs will include information about how the resources contributed to delivering our intervention, so that we can distinguish fixed costs (costs that do not change with the number of participants in the program) from variable costs (costs that increase with the number of participants in the program), an important distinction in economic

evaluation.[109] Costs associated with research assessments (e.g., screening, randomization, questionnaires) will not be included.

We will estimate return on investment using the difference between the value of financial incentives provided and incremental healthcare costs or savings, comparing the outcome-based financial incentives arm to the resources-only arm, and the goal-directed arm to the outcome-based arm. To project long-term return on investment (using a lifetime horizon), we will modify an existing Markov model that we previously developed of treatment interventions for patients with hypertension (cardiometabolic risks incorporated in this model reflect risks faced by obese patients). This model currently uses a 10-year time horizon.

We will also estimate the cost-effectiveness of the intervention (cost per pound of weight loss and cost per life-year gained) using the ratio of the difference in costs between each of the intervention and control arms to the difference in 5% weight loss attainment rates between each of the intervention and control arms. The general equation for a cost-effectiveness ratio (CER) is:[110] (**Figure 3**) Where *i* is the *i*-th time period of a patient's life, cost is determined by resources utilized in the provision of weight loss resources and support in the intervention and control arms, and effectiveness is measured by the primary outcome and quality of life (PROMIS-29). Costs will be determined as described above. In addition, to estimate potential cost-offsets, we will use data from our survey's sociodemographic questions about employment to evaluate changes in productivity. We will also perform nonparametric bootstrapping with 1,000 random samples from our study arms to estimate confidence intervals for cost-effectiveness ratios, using the bias-corrected percentile method described by Efron and others.[111-115] The cost and effectiveness outcomes from each bootstrap sample will be plotted on a cost-effectiveness plane.

## Patient and public involvement

We sought feedback from patients enrolled in a prior incentives study on their preferences for an incentive structure (i.e., goal-directed versus outcome-based incentives for a preventive health behavior) and used this feedback to inform FIReWoRk's framework and intervention design. Patients were not involved in the recruitment and conduct of the study. We assess the burden of the intervention among FIReWoRk participants during an exit interview. We will make a summary of the results available to the public after the study's conclusion and publication of the primary outcomes.

# DISCUSSION

## Innovation

In this paper, we outline the protocol and rationale for the FIReWoRk study. FIReWoRk is innovative for several reasons. First, financial incentive interventions for preventive health have primarily targeted outcomes.[42] A few recent weight loss trials have demonstrated effectiveness using a combination of goal-directed and outcome-based incentives versus a non-incentive comparison.[36, 116, 117] The few trials comparing goal-directed versus outcome-based financial incentives for weight loss were underpowered [118] or preceded behavioral economics.[119-122] Testing goal-directed versus outcome-based incentives is important because it directly addresses outstanding questions about how to structure incentive interventions optimally, while also yielding insights into the value of incentive-based versus non-incentive-based strategies for behavior change. A recent cluster-randomized trial [123] compared the effectiveness of earning up to $310 US over 16 weeks for attending Diabetes Prevention Program sessions versus for losing weight versus a combination of the two incentive types. All groups achieved moderate weight loss at 16 weeks, though no differences in weight loss were

observed between the three intervention arms. Participants in the goal-directed arm were more likely to meet their program attendance goal than either the outcome-based or combined incentive arms. FIReWoRk expands upon this recent study by providing monthly primary care clinic-based check-in visits, incentivizing multiple behavioral goals, administering larger and more immediate payments (<48 hours vs. <2 months), and assessing short-term weight maintenance at 3- and 6-months post-intervention. We hypothesize that goal-directed incentives will lead to greater and more sustained weight loss than outcome-based incentives or the provision of behavior change resources alone. If confirmed, this finding would reinforce the importance of long-standing behavioral approaches to treating obesity and other chronic health conditions with effective, goal-directed strategies (e.g., self-monitoring for weight loss, use of counseling and nicotine replacement therapy for smoking cessation). However, if FIReWoRk demonstrates that outcome-based incentives are more effective than goal-directed incentives or resources alone, this finding would support the need to 1) explore the role of outcome-based incentives in maintaining weight loss, and 2) make more rigorous comparisons between economically sustainable outcome-based incentive strategies and conventional, non-incentive-based approaches to treating obesity and chronic health conditions.

Measuring the weight of participants at 12 months after enrollment—6 months after removal of incentives—will provide preliminary insight into the durability of financial incentives for weight loss. Understanding the durability of financial incentives is directly relevant to ongoing debates about the effect of incentives on intrinsic vs. extrinsic motivation and patient decision-making about preventive health. Researchers have raised concerns that financial incentives may crowd out intrinsic motivation,[124, 125] though some have noted that levels of intrinsic motivation for activities we incentive may already be low, leaving little motivation at

risk for crowd out.[126] The possibility that losing weight may itself increase self-efficacy and intrinsic motivation[127] further complicates the intrinsic-extrinsic motivation dynamic in the context of weight loss.

FIReWoRk is also innovative because it leverages existing clinic and community resources. The United States Preventive Services Task Force recommends that all patients with obesity receive an intensive multicomponent behavioral lifestyle intervention,[11] but most health care centers lack weight-management programs. Even when health systems have their own programs (e.g., the Veteran's Affairs MOVE! Program), patients often do not live close enough to attend regularly. Thus, we collaborate with WW International, Inc. because WW Freestyle is a ubiquitous resource in the community with multiple studio locations.

A third innovative quality of FIReWoRk is its use of Fitbit wearable devices and Fitabase to facilitate the provision of financial incentives. Fitbit technology provides an interface we use to verify all participants' physical activity goal attainment, allowing us to provide timely incentive payments to participants in the goal-directed arm. These data, which include step counts, heart rate, activity intensity, energy expenditure, and sleep, will also allow us to richly evaluate how different biometric measures influence obesity and weight loss outcomes. We chose not to target wearable tracking of physical activity with goal-directed incentives given that such self-monitoring of physical activity alone may not be effective for weight loss.[128] Instead, participants must meet public health guidelines for moderate to vigorous physical activity to receive incentives. We considered adopting other technological innovations to enhance our ability to administer incentives immediately, including scales that wirelessly transmit weight data. However, our concern with using some of these technologies in an incentive intervention is that remote monitoring that cannot readily be verified may tempt some

participants to misrepresent their weight or other information. However, even these obstacles can be attenuated or overcome with technology. For example, video monitoring could be embedded into remote weigh-ins.

A fourth innovative component of FIReWoRk is its explicit focus on the effects of incentives on financial wellbeing. To increase our ability to detect such an effect, we are enrolling low-income populations. Low-income patients may be more likely to respond to incentives,[22, 129] and their socioeconomic status suggests that the marginal benefit of gains in health and income may be greater than those experienced by similarly obese patients with greater economic resources. Any potential benefits to financial wellbeing would therefore have implications for the development of incentive interventions that address socioeconomic disparities. Because of its design, FIReWoRk may also contribute to the growing literature on the effects of incentives to induce personal investments in health and social capital through activities such as acquiring vaccinations, saving money, or enrolling in school.[95] Several published trials of income support sample low-income populations, and some have yielded promising results with benefits extending into health and social domains.[95, 130]

Finally, FIReWoRk leverages important constructs from behavioral sciences, but these constructs represent only a fraction of those embedded into prior trials. Effective interventions have applied such constructs;[131, 132] however, it is worth noting that incorporating these theories does not ensure that an intervention will be successful.[133] We are exploring the application of broader behavioral concepts in future work. In particular, we are interested in leveraging the power of social norms, peer comparisons, and self-image to increase weight loss.[134]

**Limitations**

A major challenge of our intervention design is that simultaneous use of multiple weight loss techniques limits our ability to determine which components of the intervention most effectively promote weight loss. However, using ad-hoc analyses, we will be able to identify which components are associated with the highest rates of response to incentive payments. All participants receive substantial resources, including a one-year commercial weight loss program membership (mean 6-month weight loss 4.6 kg),[20] which may reduce marginal sensitivity to the effects of incentives over resources alone. However, regular program attendance, which is necessary for weight loss success,[20] is often low, and goal-directed financial incentives have been shown to increase weight loss program participation in real-world settings.[123] Adherence to monthly check-in visits is also of concern, so participants are compensated $20 to promote retention and offset transportation costs to study visits. These smaller payments may also reduce our ability to detect the marginal impact of the incentives through their income effect, though this effect is likely negligible. The comparative-effectiveness of goal-directed versus outcome-based incentives may favor goal-directed incentives if the total incentive value were more modest than $750. This possibility is an appropriate subject for future investigation, assuming that incentives that are more modest remain sufficiently large to promote weight loss. By setting the reward amount equally across both incentive arms, cost-effectiveness may favor outcome-based incentives, particularly if weight loss is similar between arms. In the goal-directed arm, participants may inflate their goal attainment in order to increase their incentive amount, though we expect our objective goal verification process to mitigate most of this risk. Several of our measures are self-report, which can introduce social desirability bias in patients' responses. RAs are not blinded to participants' intervention group when administering weight and survey measures at 6, 9, and 12 months, which could result in measurements that inadvertently favor the

RAs preferred participants or incentive strategy.

Our recruitment strategies may entice patients who are more highly motivated to lose weight than a truly representative sample of primary care patients, thus overestimating intervention effects on weight loss. We also screen patients for eligibility based on neighborhood-level rather than individual or household income, which precludes enrollment of low-income patients living in neighborhoods with higher income areas and may affect the generalizability of our sample.

**Public Policy and Public Health Considerations**

We view FIReWoRk's major limitation in the context of public policy to be uncertainty about the sustainability and acceptability of financial incentives for weight loss in individuals with obesity. The use of financial incentives to improve health can be controversial.[23] Sustainability and acceptability largely relate to 1) economic sustainability, in terms of identifying sources of funding, and 2) ethics, that is, public perceptions of the fairness and appropriateness of financial incentives.[131, 135-137] Despite these concerns, some decision-makers have already adopted effective financial incentive programs.[138] For example, the NHS Tayside program in Scotland provided pregnant smokers with support and £50 per month in shopping vouchers for negative carbon monoxide breath tests.[139] Australia addressed low rates of childhood vaccination by linking eligibility for social security payments, childcare rebates, and other payments to immunization status.[140, 141] In 2015, CVS Health launched a financial incentive program to help employees quit smoking, based on the design of a successful randomized trial.[142, 143] A number of health insurance companies and other workplaces have also adopted incentive programs to improve health. Nonetheless, acceptability is an important consideration when designing and implementing financial incentive programs for weight loss,

and even effective programs have encountered resistance by those who were not eligible to participate.[144]

Our view is that challenges related to sustainability and acceptability are surmountable, and that we can design incentive programs in a manner that supports public perceptions of fairness.[145, 146] For example, one approach is to broaden the number of individuals eligible for incentives, while tailoring behavioral targets and incentive amounts to ensure that individuals with greatest need benefit most[147, 148]. In terms of funding for incentives, early investment in selective programs may be offset by reductions in future healthcare cost. Some political philosophies may also be receptive to shifting investments from public programs to more targeted programs that directly benefit individuals. FIReWoRk does not address population-based approaches to weight loss, such as reducing sugar-sweetened beverage sales or increasing opportunities for physical activity in the built environment—which may ultimately be most cost-effective—but rather focuses on individual decision-making.

**Summary and Significance**

FIReWoRk responds to gaps in existing evidence by examining the comparative- and cost-effectiveness of goal-directed versus outcome-based financial incentives for weight loss in socioeconomically disadvantaged patients with obesity. We anticipate that the results of this study will inform the design of scalable financial incentive programs to address obesity in public and private health systems.

**Figure legends**:

Figure 1 – FIReWoRk Conceptual Model

Figure 2 – Patient Randomization to Study Groups

Figure 3 – General Equation for Cost-Effectiveness Ratio

**Trial Status**: FIReWoRk began enrollment in November 2017. We expect to complete enrollment in June 2020 and complete the outcome assessment between June and August 2021. Enrollment and study execution have required close collaboration between investigators, research staff, and partners at our multiple clinical sites.

**Author's contributions**: JA Ladapo and M Jay initiated collaboration, conceived of, and obtained funding for the project. J Wylie-Rosett, SB Shu, and NJ Goldstein helped with study design. JA Ladapo, M Jay, SL Orstad, C Tseng, S Wittleder, J Wylie-Rosett, SB Shu, and NJ Goldstein developed the survey and data collection tools. C Tseng and JA Ladapo devised the statistical analysis plan and SL Orstad and C Tseng monitor data collection. M Jay and SL Orstad developed the conceptual model. SL Orstad developed intervention materials and protocols. SL Orstad is managing the project day-to-day and supervising RAs. M Jay, SL Orstad, and V Sweat administer the trial in NYC and S Wali administers the trial in LA County. SL Orstad, JA Ladapo and M Jay drafted and revised the paper. All coauthors contributed to the conception and/or design of the work and critically reviewed and approved the final manuscript.

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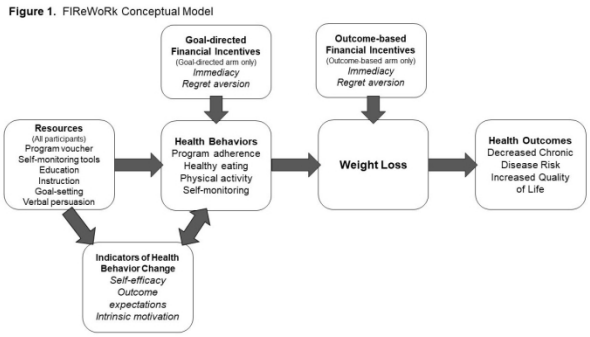
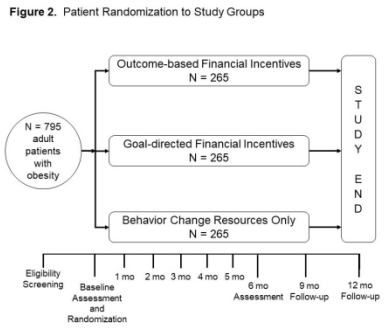



FIReWoRk Conceptual Model

177x127mm (300 x 300 DPI)




Patient Randomization to Study Groups

177x127mm (300 x 300 DPI)

$$CER = \frac{\sum_i \left( Cost_{intervention,i} - Cost_{usual\ care,i} \right)}{\sum_i \left( Effectiveness_{intervention,i} - Effectiveness_{usual\ care,i} \right)}$$

General Equation for Cost-Effectiveness Ratio

181x18mm (300 x 300 DPI)

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | ItemNo | Description | Addressed on page(s) or NA |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 3 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | NA |
| Protocol version | 3 | Date and version identifier | NA |
| Funding | 4 | Sources and types of financial, material, and other support | 37 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 36 |
| | 5b | Name and contact information for the trial sponsor | NA |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | NA |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | NA |
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 5 |

| | | | |
|---|---|---|---|
| | 6b | Explanation for choice of comparators | 7 |
| Objectives | 7 | Specific objectives or hypotheses | 7 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 8 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 8 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 11 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 12 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | NA |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 17 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | NA |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 19 |
| Participant | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), | 19, Table 2, Figure 2 |

| | | | |
|---|---|---|---|
| timeline | | assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 10 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 9 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 12 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 12 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 12 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 34 (NA) |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 20 |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 19 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any | 19 |

| | | | |
|---|---|---|---|
| | | outcome data to be collected for participants who discontinue or deviate from intervention protocols | |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 20 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 26 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 27 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 27 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | NA |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | NA |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | Table 2 |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | NA |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 3 |
| Protocol | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility | 3 |

| | | | |
|---|---|---|---|
| amendments | | criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | |
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 12 |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | 12 |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 20 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 37 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | NA |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | NA |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 3 |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | 36 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | NA |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | NA |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | NA |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.