Version 8
2/5/2021

Financial Incentive Strategies for Weight Loss in Obese Patients Living in Socioeconomically Disadvantaged Neighborhoods

Principal Investigators:

Melanie Jay, MD, MS
Associate Professor
Department of Medicine, Division of General Internal Medicine and Clinical Innovation
New York University School of Medicine
227 E 30th Street, 6th Floor
New York, NY 10016
212-263-4169
Melanie.Jay@nyumc.org

Joseph Ladapo, MD, PhD
Associate Professor
Department of Medicine, Division of General Internal Medicine and Health Services Research
David Geffen School of Medicine at UCLA
911 Broxton Avenue
Los Angeles, CA 90024
310-794-2728
JLadapo@mednet.ucla.edu

I. Purpose of the Study and Background

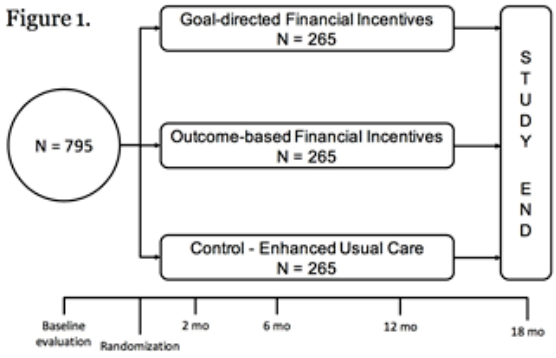
Brief Background and Rationale

Financial incentive strategies for motivating changes in health behaviors, such as healthy eating and physical activity for weight loss in obese individuals, are increasingly being tested by health insurers, employers, and government agencies.[1,2] Interest in these programs is driven by multiple factors, including the association of obesity with morbid illnesses and mortality, and obesity's adverse impact on healthcare costs and productivity.[3] However, a key unanswered question is how to structure these incentive programs to maximize their **(1) effectiveness**, underscored by the fact that most programs have not resulted in significant long-term weight loss[4,5]; and **(2) economic sustainability**, as defined by their return on investment—a major factor in public and private decision-making.[6] Our proposal aims to significantly advance the science and implementation of financial incentives for weight loss among obese individuals by building on our prior experience designing financial incentive programs for health behaviors and implementing obesity reduction interventions.[7-12]

Patients with obesity represent an important population to target for effective weight loss interventions. They suffer from a high prevalence of serious obesity-related illnesses[13,14] including diabetes, hypertension, dyslipidemia, heart disease, stroke, sleep apnea, and cancer. Obesity disproportionately affects those with a low socioeconomic status[15] and imposes $147 billion in costs on the healthcare system annually.[16] These costs are primarily attributable to diabetes. Prior studies testing financial incentives in this population have had variable short-term success and few have yielded long-term weight loss.[17-27] A fundamental question remains unanswered and may partially explain variability in weight loss outcomes: **Are goal-directed incentives (for achieving evidence-based, intermediate goals that increase weight loss but are underutilized, like dietary counseling, physical activity, behavioral self-monitoring, and intensive weight management programs) or outcome-based incentives (for successfully losing weight) more effective for promoting weight loss?** Prior studies of weight loss incentives have largely emphasized outcome-based incentives. The few studies that have compared goal-directed to outcome-based weight loss interventions are at least three decades old,[28-31] were largely underpowered—in terms of sample size and incentive size—and do not reflect contemporary contextual factors that influence body weight.[32] Goal-directed incentives may promote long-term weight loss better than outcome-based incentives by increasing patients' exposure to evidence-based weight loss strategies and support from intensive programs. Moreover, the optimal incentive structure may differ from patient to patient, and personalizing the incentive structure—by allowing patients to choose—could yield the most effective weight loss and return on investment.

Specific Aims

1. To compare the impact of the following **three approaches for obesity treatment** on 1) weight loss (≥5% of baseline weight), 2) use of evidenced-based weight loss programs, and 3) quality of life among obese patients living in socioeconomically disadvantaged urban neighborhoods:
    1. **Enhanced usual care** for obesity comprised of provision of a food and activity diary, bathroom scale, wearable fitness tracker, exercise and nutrition education materials, and referral information for intensive, evidence-based weight loss programs (see **Appendix A – Patient-facing Materials**, to be submitted as an amendment in English and Spanish)
    2. Enhanced usual care plus **goal-directed financial incentives**
    3. Enhanced usual care plus **outcome-based financial incentives**
2. To compare the short-term and long-term return on investment of using goal-directed and outcome-based financial incentives to promote weight loss.



Hypotheses

1. Goal-directed financial incentives will more effectively promote weight loss than outcome-based financial incentives or enhanced usual care.
2. Goal-directed financial incentives will have a more favorable return on investment and cost-effectiveness ratio than outcome-based financial incentives or enhanced usual care.

Study Design

We will conduct a randomized controlled trial to test the effectiveness of these three approaches on weight loss (≥5% of baseline weight), use of evidenced-based weight loss programs, and quality of life among patients of three healthcare systems: two in New York City (NYC Health + Hospitals Bellevue and NYU Langone Hospital – Brooklyn) and one healthcare system in Los Angeles (Olive View UCLA Medical Center). We will compare the outcomes from a goal-directed financial incentives arm and an

outcome-based financial incentives arm to enhanced usual care for obesity.

Background

The prevalence of obesity is increasing, which contributes substantially to morbidity and mortality from obesity-related illnesses. Patients with obesity are an important target for effective weight loss interventions because they suffer from a high prevalence of serious obesity-related illnesses[13,14] including diabetes, hypertension, dyslipidemia, heart disease, stroke, sleep apnea, and cancer; disproportionately have a low socioeconomic status[15]; and impose $147 billion in costs on the healthcare system annually.[16] Patients with a high body mass index (BMI) experience an increased rate of death from all causes and from cardiovascular disease (CVD), particularly if their obesity is severe.[33] Because of obesity's enormous public health impact, the U.S. Preventive Services Task Force (USPSTF) recommends universal obesity screening in healthcare settings and intensive, multicomponent behavioral interventions for obese adults.[34] States have both individually and collectively supported mass media campaigns to reduce obesity, promoted educational programs, and implemented policy changes to increase physical activity and healthy food consumption.[35] The Affordable Care Act also allows patients with obesity to receive screening and counseling without additional cost-sharing, and some insurance plans include coverage and reimbursement for dietary or nutritional screening.[36] However, a major barrier to reducing obesity rates is the low utilization of effective therapies. Most patients with obesity report wanting to lose weight, however, only a small proportion of patients use evidence-based methods.[37-40] Therefore, it is critical that we identify novel approaches to intensify utilization of evidence-based therapies for weight loss.

Obese patients in socioeconomically disadvantaged neighborhoods are an important population to target for weight loss interventions. Obesity is more prevalent among people with a lower socioeconomic status, both within and outside the United States.[15] The reasons for this association are multifactorial but may relate to differences in nutrition education, neighborhood food environments, and characteristics of the built environment, including availability of sidewalks and playgrounds.[41,42] Because persons with obesity also frequently face employment discrimination and bias in educational settings,[43] the higher prevalence of obesity among people with lower income may exacerbate health and socioeconomic disparities. For these reasons, obesity is an especially important problem in patients living in socioeconomically disadvantaged areas. However, new approaches are needed to close the gap in weight loss. Financial incentives are a potential bridge to achieving this goal.

Evidence-based treatments are critical for clinically significant weight loss success. Overweight and obesity are highly prevalent chronic diseases in the U.S. While 51% of Americans report wanting to lose weight, only half of them are actively trying to lose weight, and an even smaller proportion use evidence-based methods.[37] For example, in the

Veterans Health Administration system where brief obesity counseling has been systematically incorporated into care processes, obesity screening rates are approximately 95%. However, only 10%–12% of those screening positive for obesity enroll in MOVE!, the Veterans Health Administration's evidence-based obesity program.[38,44,45] Even among patients enrolled in MOVE!, only 13% are engaged at a level that is adequate for achieving clinically significant weight loss.[38] Nationally, physicians underutilize provision of exercise, nutrition, and weight loss counseling for obese patients.[39] The goal-directed arm in our proposal specifically incentivizes use of these evidence-based therapies, which we hypothesize will increase the prevalence of clinically significant weight loss.

In recent years, significant advances been made in the development of more generalizable weight management interventions, including use of internet-based programs and electronic counseling.[46,47] Our proposed intervention is potentially generalizable because it largely builds on existing infresearch stafftructure, such as clinical and commercially avaialble weight loss programs (e.g., Weight Watchers).

Financial incentives programs for weight loss have favored outcome-based (not goal-directed) designs. Financial incentives for motivating changes in health behavior, particularly for obesity and smoking, are increasingly being tested by health insurers, employers, and government agencies.[1,2] They are potentially effective because individuals are often motivated by the prospect of rewards.[48] While some theories of motivation have led researchers to raise concerns about long-term durability of the extrinsic effects of incentives,[26] some studies have shown incentives promote intermediate/long-term weight loss.[19,20,22-27,49] Despite these findings, a key unanswered question regarding weight loss is how to structure these incentive programs to maximize their (1) effectiveness, (2) acceptability to patients, underscored by the fact that programs that use "commitment" contracts requiring individuals to invest their own money upfront are effective, but often unpopular and inaccessible to low-income populations, and (3) economic sustainability, as defined by their return on investment, which is a major factor in public and private decision-making.[6]

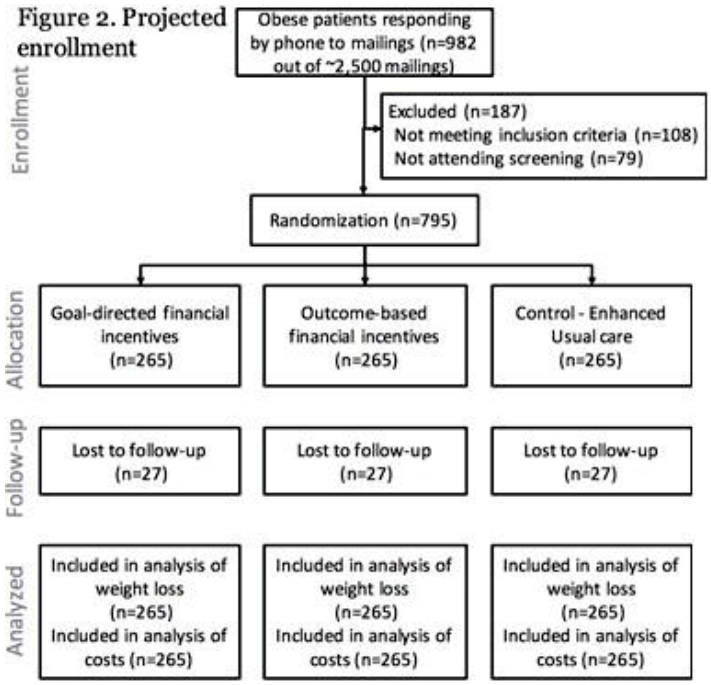
II. Characteristics of the Research Population

Number of Subjects

We aim to enroll a total of 795 obese patients (265 per study arm) to participate in the study. We will enroll two-thirds of the patients at NYC Health + Hospitals Bellevue and NYU Langone Hosptial – Brooklyn. We will enroll one-third of the patients at Olive View UCLA Medical Center. At the New York study sites, we will work with Datacore at the NYU School of Medicine and the Clinical and Translational Science Institute (CTSI) to query lists of potentially eligible patients from Langone and Bellevue based on information from the patient's Electronic Health Record (EHR). We will conduct EHR queries to identify

potentially eligible patients every 6 months over a 24 to 27 month period. We will compare each new query with a list of patients previously invited to the study to avoid contacting patients again. We have successfully used EHRs to identify patients in our previous studies.[9,10]

We will cross-reference the addresses of potentially eligible patients with census tracts associated with the lowest tertile of median household income in the New York and Los Angeles areas (approximately $40,000/year). Our research staff will mail 5,000 announcements about the study to these patients' homes. Research staff will follow up with invited patients by phone one week after the mailing is expected to arrive. Potential subjects who are reached or who respond by phone and complete an eligibility screening will be invited to an orientation/baseline visit at or near their home medical center (no more than one person per household can participate) where written consent to participate will be obtained upon arrival. We expect approximately 20% of patients to respond to our mailings. Therefore, we will mail 5,000 announcements in order to receive 982 responses. Of 982 patients, we may exclude approximately 187 (e.g., 108 not meeting inclusion criteria and 79 not attending initial screening). Our target rate of enrollment is 95-105 patients per quarter for 24-27 months (30-35 patients per quarter per site). We will end with a sample size of 795, which will provide at least 80% power to detect a meaningful difference in weight loss between the intervention arms with a Type-I error rate $\alpha = 0.05$.



Study Sites

Though originally funded through NYU, the grant is now administrated through UCLA because Dr. Ladapo relocated there; therefore UCLA is the lead site.

Olive View UCLA Medical Center ("Olive View"), Los Angeles, CA

Olive View is operated by the Los Angeles (LA) County Department of Health Services (DHS). DHS also supports a network of primary care clinics in and around the Los Angeles metro area and serves a large proportion of the LA County low-income population. More than half of Olive View patients are under- or uninsured, and as high as 75% of ambulatory patients are Latinos. Patients will be recruited exclusively from Olive View.

NYC Health + Hospitals Bellevue ("Bellevue"), New York, NY

Bellevue is the 'flagship' tertiary care hospital for the NYC Health and Hospital Corporation, the largest state or city public hospital system in the United States. Each year Bellevue records approximately 27,000 inpatient, and 472,110 ambulatory and 101,792 Emergency Department visits. Bellevue serves a diverse and medically underserved population, including persons recently released from jail and prison. Forty-five percent of Bellevue patients are of Hispanic ethnicity, 40% are African American (including Caribbean and African immigrants), and 10% are Asian American.

NYU Langone Hospital – Brooklyn ("Langone"), Brooklyn, NY

NYU Langone Hospital – Brooklyn is a 450-bed teaching hospital and affiliate of the State University of New York Health Science Center at Brooklyn and a clinical campus for primary care education. With approximately 99,000 patients, its network of nine primary care sites handles over 602,000 visits annually. Patients will be recruited exclusively from the Adult Medicine and Family Physicians Family Health Centers, located in a predominately Spanish-speaking neighborhood.

Gender of Subjects

We anticipate that 75% of our sample will be female, since women are more likely to enroll in weight management programs than men. This study is not intended to be gender specific and patients of any gender, gender identity, or gender expression will be recruited as part of the study.

Age of Subjects

We will recruit subjects between the ages of 18 and 70 years of age. We will be researching adult obesity and thus subjects must be at least 18 years of age. We will not include individuals older than 70 years of age as the published evidence is unclear

whether weight loss should be a treatment strategy for obese older adults since obesity might be protective against mortality in seniors.

Racial and Ethnic Origin

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 since we will be recruiting from neighborhoods with a higher proportion of minority residents and from census tracts associated with the lowest tertile of median household income. We will not exclude any subject based on their race or ethnicity.

Inclusion/Exclusion Criteria

The following are inclusion and exclusion criteria for our study population.

We will **include** patients who:

- live in a census tract in the lowest tertile of median household income (approximately $40,000/yr)
- are English or Spanish-speaking
- are under the care of a primary care physician, specialist, or provider they see regularly at one of two healthcare systems in New York City (NYC Health + Hospitals Bellevue and Gouverneur and NYU Langone Hospital – Brooklyn) or one healthcare system in Los Angeles (Olive View UCLA Medical Center) and have seen the provider within the last 2 years
- meet the classification for obesity (based on a body mass index (BMI) of ≥30 kg/m^2) as recorded during a healthcare visit in the past 6 months. However, in the event that a patient weighs less when they come for a baseline visit and their BMI is <30 but ≥28 kg/m^2, we will still accept them in the study since weight loss is still indicated.
- are between the age of 18 and 70 years
- have an active U.S. phone number and address

We will **exclude** patients who:

- have lost ≥4.5 kg or participated in an intensive weight loss program during the past 6 months
- have had a weight loss surgery/procedure in the last 2 years or are currently being evaluated for weight loss surgery
- weigh more than 380 lbs in their electronic health record, as our scale is only valid up to 400 lbs and the 20 pound difference will allow us to account for any fluctuations in weight between the time they were last seen for a healthcare visit and when they complete a baseline visit
- report abuse of alcohol

- have had active psychosis and/or other cognitive issues in the past 6 months
- have had metastatic cancer in the last 6 months
- have had a myocardial infarction/stroke in the past 6 months
- have New York Heart Association (NYHA) Class III/IV heart failure
- have Chronic Kidney Disease, Stage V or End Stage Renal Disease
- are pregnant or breastfeeding, or plan to become pregnant within the next 12 months
- have a history of an eating disorder or unsafe weight-loss behaviors (e.g., laxative/diuretic use)
- planning to move out of the NYC/Tri-State area/Los Angeles County on the next 12 months
- report a heart condition, chest tightness or chest pain that prevents them from doing physical activity AND do not obtain physician clearance for exercise.
- are unable to provide informed consent

Vulnerable Subjects

No vulnerable populations will be included as part of this weight loss intervention study. Patients who are also employees of NYC Health + Hospitals Bellevue or NYU Langone Hospital – Brooklyn may incorrectly perceive that this NYU School of Medicine study is affiliated with their employer. We will emphasize to all subjects during the consent process that their employment will not be affected by their decision whether to participate. We will also ensure that record of participation cannot be linked to any type of employee record.

Spanish-Speaking Subjects

To promote enrollment of Spanish-speaking patients, we will require that designated research staff be fully bilingual and engage in cultural sensitivity.

III. Methods and Procedures

Once screened by phone, patients are invited to an orientation/in-person screening/initial assessment where written consent will be obtained upon arrival. To increase subjects' access to assessment sites, research staff will perform the initial and follow-up assessments at or near their respective home medical center (Langone or Bellevue). We will maintain a record of patients who attend the initial screening but do not enroll, and track their reasons for non-enrollment (e.g., inclusion criteria not met, refusal, etc.). In this record, we will document basic demographic data from the patients' EHR, including sex as a biological variable, race/ethnicity, age, and BMI. This tracking will allow us to determine if our enrolled cohort is representative of obese patients in the community and to adjust our recruitment techniques if needed.

We will randomize eligible patients in block sizes of 6 patients to one of the 3

study arms using a random number generator in Stata v14.1. Block design ensures comparable group sample sizes. We will stratify randomization by study site and self-reported patient preference for incentive target (goal-directed or outcome-based). Stratified randomization is considered to eliminate the confounding effect of hospital site and patient preference. In addition, we will ask patients about barriers they face to the adoption and maintenance of evidence-based weight loss programs. This feedback from our early participants will be analyzed by our team and integrated into the intervention design.

All Subjects

As part of participation in the study, all patients will be asked to do the following:

1. provide demographic information
2. provide a medical history to confirm medical eligibility and comorbidities in the EHR
3. provide lipids (HDL, LDL, and total cholesterol) and hemoglobin A1c values from their EHR from a blood test in the 12 months prior to their baseline visit date and a second set of values in the 6 months before and after their 12-month visit date. If these values are not available, patients will be encouraged, but not required, to have their blood test done with their primary care physician and share the results with us.
4. complete survey instruments about dietary intake and physical activity
5. confirm contact information
6. provide height, weight, waist circumference, body composition, and blood pressure measurements
7. complete the PROMIS-29 to assess quality of life
8. report any health care utilization, use of weight-modifying drugs, and/or engagement in weight loss programs or therapies prior to and throughout participation
9. receive monthly phone and/or email reminders to encourage them to return for assessments
10. return in 30 days, and 2, 3, 4, 5, 6, 9, and 12 months from baseline for reassessments
11. receive $20 for each of the 8 follow-up study visits and an additional $20 for the 6 month visit.
12. receive **enhanced usual care** for obesity, which includes
    a. a food and activity diary (e.g., BookFactory Food Journal or another diary, including internet/app-based diaries)
    b. Fitbit Alta wearable fitness tracker to track physical activity. Fitbit is considered a low risk general wellness device and is not regulated by the FDA.

c. a bathroom scale
d. exercise and nutrition education materials (e.g., American Heart Association's How Do I Lose Weight? and How Do I Follow a Healthy Diet?) and other patient information/handouts
e. referral information for evidence-based intensive commercial and hospital-based weight loss programs in their area (e.g., Bellevue's Medical Weight Management Clinic and Weight Watchers) as well as a promo code for 12 months of free Weight Watchers meetings

Intervention Arms

Subjects Randomized to Goal-Directed Incentives Arm

In addition to the items listed under "All Subjects", those in the goal-directed financial incentives arm will receive the following:

1. Information from research staff that they will earn up to $750 in financial incentives over 6 months for:
    a. using a food and activity diary ≥75% of days and recording their body weight 3 days per week, as verified by entries in the BookFactory Food Diary or another diary ($30 monthly)
    b. achieving 75 minutes of physical activity per week, as verified by a wearable device ($20 at 30 days and months 2 and 3)
    c. achieving 150 minutes of physical activity per week, as verified by a wearable device ($20 months 4, 5 and 6)
    d. enrolling and participating in an intensive clinic-based or commercial weight loss program (registration and attendance at ≥50% of sessions or comparable rate associated with evidence-based weight loss), as verified by the program ($150 one time only)
    e. participating in the intensive clinic-based or commercial weight loss program (attendance at ≥50% of sessions or comparable rate associated with evidence-based weight loss), as verified by the program ($60 monthly thereafter)
2. Feedback by research staff at each assessment point about incentives they would have received had they achieved each of their goals, according to the behavioral economics concept of *regret aversion*

Subjects Randomized to Outcome-Based Incentives Arm

In addition to the items listed under "All Subjects", those in the outcome-based financial incentives arm will receive the following:

1. Information from research staff that they will earn up to $750 in financial incentives over 6 months for clinically significant weight loss, as confirmed at monthly weigh-ins.
    a. At 30 days, they will receive $50 if they lose ≥1.5% to <2.5% of baseline weight

or $100 if they lose ≥2.5% of baseline weight. The weight loss goals at 30 days are more modest to not encourage overly rapid weight loss.

b. At 2 months and 3 months, they will receive $50 if they lose ≥2.5% to <5% of baseline weight or $100 if they lose ≥5% of baseline weight.
c. At 4, 5, and 6 months, they will receive $100 if they lose ≥2.5% to <5% of baseline weight or $150 if they lose ≥5% of baseline weight
d. At 9 and 12 months, they will be assessed by study site for long-term weight loss

2. Feedback by research staff at each assessment point about incentives they would have received had they achieved a loss of at least 2.5% of baseline weight, according to the behavioral economics concept of *regret aversion*

Table 1. Goal-directed and Outcome-based Financial Incentives

Table 1. Financial Incentive Summary **Activity**	**Time point**	**Goal-directed Incentives**	**Outcome-based Incentives**
Enrollment and active participation[a] in a clinic-based or commercial weight loss program (verified by patient medical record or provision of program documentation)	30 days or 2, 3, 4, 5, or 6 months (1 time during 6 months of intervention)	$150	$0
Active participation[a] in clinic-based or commercial weight loss program (verified by patient medical record or provision of program documentation)	2, 3, 4, 5, and 6 months (up to 5 times during 6 months of intervention)	$60	$0
Food journal use (log/app verified by on-site research staff)[b]	30 days and 2, 3, 4, 5, and 6 months	$20	$0
Achievement of at least 75 minutes of physical activity per week (Fitbit activity minutes verified by on-site research staff)[c]	30 days and 2 and 3 months	$20	$0
Achievement of at least 150 minutes of physical activity per week (Fitbit activity minutes verified by on-site research staff)[c]	4, 5, and 6 months	$20	$0
Self-weighing (log/app verified by on-site research staff)[d]	30 days and 2, 3, 4, 5, and 6 months	$10	$0
Weight loss (verified by study site weigh-in)	30 days	$0	$50-$100[e]
Weight loss (verified by study site weigh-in)	2 and 3 months	$0	$50-$100[f]
Weight loss (verified by study site weigh-in)	4, 5, and 6 months	$0	$100-$150[g]
Total Incentives (maximum)		$750	$750

[a]We define active program participation as attending at least one session per month or ≥50% of sessions monthly, whichever is greater.

[b]We define food journal use as recording what you eat and how much at least 5 days per week. The dietary tracking incentive is proportional to the number of weeks in the previous 28 days this goal is met, so it may range from $5 for one week to $20 for 4 weeks.

[c]Physical activity goal is based on established guidelines for moderate-vigorous intensity activity necessary for health benefits. The physical activity incentive is proportional to the number of weeks in the previous 28 days the goal is met, so it may range from $5 for one week to $20 for 4 weeks.

[d]We define self-weighing as recording what you weigh on 3 days per week. The self-weighing incentive is proportional to the number of weeks in the previous 28 days this goal is met, so it may range from $2.50 for one week to $10 for 4 weeks.

[e]Patients are eligible for $50 if they lose ≥1.5% to <2.5% of their baseline weight and $100 if they lose ≥2.5% of their baseline weight.

[f]Patients are eligible for $50 if they lose ≥2.5% to <5% of their baseline weight and $100 if they lose ≥5% of their baseline weight.

[g]Patients are eligible for $100 if they lose ≥2.5% to <5% of their baseline weight and $150 if they lose ≥5% of their baseline weight.

Subjects who are Lost to Follow-Up or Drop Out

In addition to the items listed under "All Subjects", those who leave the study will receive the following:

1. a telephone call to assess their reasons for leaving the study
2. if they cannot come to their study site for the 6 month follow-up, but still wish to participate, research staff will attempt to meet them at a public location that is convenient for them
3. if they cannot be reached via telephone, research staff will place a telephone call to a relative or contact person the patient identifies until we reach them or the follow-up window closes
4. if they or their contact cannot be reached via telephone, research staff will mail the subject a paper survey with an honorarium

Data Collection and Measures

The following assessments occur at baseline, 30 days, and 2, 3, 4, 5, 6, 9, and 12 months. All physical assessments and survey questions will be administered in-person by a trained research coordinator or assistant who will work with research staff to enter patient data into a secure database (i.e., REDCap). Survey questions will be administered by phone when a patient cannot complete their 6-month and/or 12-month visit in person.

Table 2. Assessment Time Points

Assessments	Screening	Baseline	1-month	2-month	3-month	4-month	5-month	6-month	9-month	12-month
Inclusion / Exclusion Criteria	X									
Visit Information		X	X	X	X	X	X	X	X	X
Patient Information		X								
Height		X								
Weight and Waist Measures		X	X	X	X	X	X	X	X	X
Blood Pressure		X						X	X	X
Verify Weight for Incentives			X	X	X	X	X	X	X	X
Verify Goals for Incentives			X	X	X	X	X	X	X	X
Demographics	X	X								

Health Technology Use		X								
Incentive Preference		X								
Medical History		X								
Quality of Life / Sleep		X						X	X	X
Healthy Eating		X						X	X	X
Food Insecurity		X								X
Alcohol Use	X							X	X	X
Physical Activity		X						X	X	X
Self-Monitoring		X	X	X	X	X	X	X	X	X
Motivation / Self-Efficacy		X						X	X	X
Food Insecurity		X								X
Financial Situation / SES		X						X	X	X
Neighborhood Environment		X						X	X	X
Depressive Symptoms		X						X	X	X
Consistency and Competitiveness		X								
Tobacco Use		X						X	X	X
Discrimination		X								X
Adverse Events					X			X	X	X
Hospitalizations / ER Visits								X	X	X

During the baseline assessment, research staff will instruct patients how to proceed with the intervention, including what their goals are, how to track progress toward their goals, whether they will be incentivized, the amounts they will be incentivized, and how they will receive the incentives. During their monthly follow-up assessments, research staff will remind patients how to proceed with the intervention and patients in the goal-directed and outcome-based intervention groups will be provided with feedback on their goal progress. **We will use the teach-back method to confirm whether the patient understands what is being explained to him or her.**

The following measures will be used in patient assessments:

<u>Obesity and Quality of Life Outcomes</u>

- *Weight and Height* – We will obtain weight measurements using a standardized protocol, as we have done in prior work,[8-12] which includes: (1) weighing without shoes or heavy garments using a digital scale that will be calibrated monthly; and (2) measuring height with a stadiometer and rounded to the nearest half inch, and (3) calculating body mass index (BMI) based on kilograms of weight per square meter of height (kg/m^2).
- *Waist circumference* – We will measure waist circumference to the nearest 0.1 cm at the high point of the iliac crest at minimal respiration.
- *Blood pressure* – Research staff will obtain 3 blood pressure measurements using an automated sphygmomanometer. The cuff will be placed on the patient's right upper

arm, with the bottom of the cuff placed approximately 1" above the crook of the elbow as per a standard protocol. The standard-sized cuff (9"-13") will used for most patients. If this cuff does not fit, Research staff will measure arm circumference to determine appropriate cuff size.

- *Lipids and Hemoglobin A1c* – if clinically indicated, research staff may recommend that patients obtain a blood test and also send a letter to the patient's physician; lipids (HDL, LDL and total cholesterol) and A1c values (new and from the previous 6 months) will be accessed via the patient's EHR.
- *Quality of life* – We will use the PROMIS-29.

Participation in Weight Loss Programs and Health Technology Use

- *Enrollment and participation in weight loss programs* – Patients will have the option to either (1) provide consent for us to contact and confirm enrollment and participation in evidence-based, clinic or commercial weight loss programs, or (2) procure documentation to confirm enrollment and participation. For patients enrolling in Bellevue's Medical Weight Management Programs or NYU Langone's Weight Management Program, we will use electronic chart review to evaluate their attendance. We will also ask about barriers to accessing weight loss programs.
- *Health Technology Use* – Patients will be asked whether they use tablets, smartphones, or other mobile technology and whether they use health or fitness apps or mobile tracking devices/activity monitors to track their progress.

Dietary and Physical Activity Outcomes

- *Diet composition* – Dietary outcomes include servings of fruits and vegetables, fat intake, refined carbohydrates, and sweetened beverages. We will use a short dietary screener questionnaire to assess fruit, vegetable, fat, fiber, and sweetened beverage intake. For pragmatic reasons, longer food frequency questionnaire and 24 hour dietary recalls will be avoided because they may be too time consuming to complete.
- *Physical activity* – We will measure frequency, duration and intensity of physical activity using items from the International Physical Activity Questionnaire short form (IPAQ-S) and the Neighborhood Physical Activity Questionnaire (NPAQ). Patients will also use a wearable fitness tracker (e.g., Fitbit Alta), which has pedometer and accelerometer functions. These wearable devices do not gather locational information and are not tied to geographic information systems (GIS) with GPS technology. Patients will sync their wearable fitness tracker with their smartphone/internet-connected computer or with our study computer during site weigh-ins and will have their physical activity data automatically uploaded to Fitabase. Fitabase is an independent affiliate of Fitbit that has been used in previous NIH studies. Fitabase allows researchers to centrally access physical activity data from patients' wearable devices.

Self-Monitoring

- *Dietary tracking* – criterion of whether patient has tracked the food they eat on ≥75% of days in the month prior
- *Physical activity tracking* – criterion of whether patient has recorded the physical activities they engage in on ≥75% of days in the month prior
- *Self-weighing* – criterion of whether patient has recorded their body weight at least three days per week in the month prior

Health Economic Measures and Outcomes

- *Healthcare utilization and medical history* – We will use the EHR, administrative databases, baseline chart abstraction, and patient surveys 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 in the 6 months prior to enrollment and during the follow-up period after enrollment. We will also measure staff time spent obtaining anthropometric measurements, contacting weight loss programs, confirming physical activity and food diary use, and administering incentives. Market prices of weight loss programs will be used to estimate their economic cost.
- *Financial distress* –Using items from the Consumer Financial Well-being questionnaire we will assess financial distress, a characteristic that may identify patients more likely to respond to financial incentives. This relationship also has implications for development of incentive interventions that address socioeconomic disparities.
- *Preferences for incentive structure* – At baseline we will describe two hypothetical incentive programs for weight loss (one goal-directed and one outcome-based) and ask patients which program they prefer. This question will allow us to test whether patients who receive personalized incentives—that is, patients randomized to an incentive structure consistent with their pre-specified (before randomization) preference—will be more likely to lose weight than those who do not. Then we will administer five open-ended survey questions to explore their reasons for and concerns about choosing a particular program. We will conduct a content analysis of the responses and use the results to inform the development of a schedule of interview questions. After participants are randomized to goal-directed or outcome-based intervention groups, we will purposively invite a subset of 30 individuals who attain low or high weight loss success at 3 months to participate in a 30-minute, semi-structured in-person interview with a trained, PhD-level researcher (pending IRB approval of the semi-structured interview schedule/questions). We will conduct a thematic analysis of the results.

Other Measures and Outcomes

- *Depressive symptoms* – We will measure depressive symptoms using a subscale from the PROMIS-29 *Consistency, Competitiveness, and Susceptibility* – We will assess

these three psychological constructs using 3-4 items from a validated questionnaire for each construct

- *Medical History* – We will use questions from the NHANES
- *Discrimination* – We will use the NESARC to assess perceived discrimination based on weight and race.
- *Smoking behavior* – We will use measures adapted from the California Tobacco Survey. During follow-up, we will ask about smoking cessation, quit attempts, reduction in daily cigarette smoking, changes in readiness to quit, and use of e-cigarettes.
- *Substance use* – We will use the AUDIT-C to assess alcohol use
- *Self-efficacy and motivation to lose weight* – We will assess self-efficacy, outcome expectancy, and motivation to lose weight using items we adapted to evaluate our 5As Weight Loss Training Intervention.
- *Neighborhood-level socioeconomic factors* – zip code-level percent poverty, median household income based on census tract of residence, and percent of adults with bachelor's degree or higher
- *Neighborhood walkability* – We will assess neighborhood-level walkability using an objectively measured index of residential density, commercial destinations, and street connectivity. We will assess individual-level environmental perceptions using select scales of the abbreviated Neighborhood Environment Walkability Survey (NEWS-A).
- *Food security* – We will use six items from the Household Food Security Scale.
- *Sleep quality* – We will use a brief assessment of sleep quantity from the BRFSS combined with sleep data from the PROMIS-29 and Fitbit Alta activity tracker to measure sleep quality. *Eating Disorder Symptoms* – We will use the EDDS to assess six symptoms of disordered eating.

Exit Interview

- The purpose of the exit interview is to understand participants' experiences with and the acceptability of the various intervention components at the end of their active intervention period (6 months post baseline visit). We will ask a series of quantitative and open-ended questions to assess perceived difficulty of their goals, usefulness of the tools, acceptability of incentives, and satisfaction with the program. Exit interview questions will be administered in-person by a trained research coordinator or assistant, and will take no longer than 30 minutes. If a participant misses their 6-month visit, the interview will be conducted at their 9-month or 12-month visit. Participant responses will be entered into a secure database (i.e., REDCap). We will conduct quantitative and thematic analyses of the results.

<u>COVID-19 and Fitbit Technology Qualitative Supplement</u>

- A sample of 10-15 participants will be purposively sampled to participate in an additional interview to better understand how the COVID-19 crisis and subsequent

stay at home orders have affected physical activity patterns and the Fitbit's role in physical activity patterns. The interviews, conducted by trained research assistants, will occur over video conference and will take no longer than 60 minutes. We will ask a series of open-ended questions using an interview guide to elicit participant perspectives. Interviews will be audio-recorded and all files will be saved in a secure folder in the NYUMC network. Audio files will be anonymized and transcribed for data analysis. We will conduct thematic analyses of the data.

Data 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 (see section 'Data collection and measures') 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.

Primary Inferential Analysis

We will use generalized mixed-effect models for repeated measures as the main inferential analytic framework to evaluate intervention effects for this longitudinal study. In addition to treatment, time and treatment-time interaction, the models will include randomization stratification variables of study site and incentive preference as fixed effects. The subject 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 treatment 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 are 2 sided, and Bonferroni correction will be applied for multiple comparisons among treatment arms.

Missing data, possibly due to patient missed visit, early dropout and loss to follow-up, will be handled by the mixed effects models in the main analysis, which assume that the missing data mechanism is 'missing at random'. Patten mixture models, which allows missing not at random, 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.

Secondary Inferential Analysis

Using health economic modeling methods that we have previously applied in other economic evaluations, 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 enhanced usual care 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.

Data Monitoring

REDCap

Study data will be collected and managed using REDCap (Research Electronic Data Capture), which was developed by Vanderbilt University in collaboration with a consortium of institutional partners. The REDCap database for this study will be housed at UCLA, and approved NYU research staff will be able to access REDCap at UCLA by connecting to a VPN and accessing their server. NYU research staff will not enter PHI into the UCLA REDCap system prior to patient consent. REDCap is a secure web application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g., for data types and range checks), audit trails, and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). REDCap also provides a powerful tool for building and managing online surveys. Another important REDCap feature is the ability to easily build real-time reports that monitor data completeness and quality. REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team. This iterative development and testing process yields a well-planned data collection strategy for individual studies. REDCap is flexible enough to be used for a variety of research methodologies and provides an intuitive user interface for database design and data entry. REDCap servers are housed in a local data center supported by MITS (Medical Information and Technology Services) at UCLA and all web-based information transmission is encrypted with TLS (Transport Layer Security) which provides improved security over SSL (Secured Socket Layer). Web and Database server backups are maintained by MITS with their IBM Tivoli Storage Manager Backup System.

Data Monitoring Plan

There will be no formal data and safety monitoring board for this protocol as there is only minimal risk associated with participation in the current study. The PI will monitor data and safety. As part of data management, data monitoring will be performed on a regular basis to maintain the integrity of the data. Data management activities will

include generating automated reports for the research team with lists of patients due for study calls, as well as messaging to identify patients who are in jeopardy of falling outside the window for a study call. As data is entered into the system, data managers will perform regular checks in all of the clinical databases for recurrent missing documentation, data inaccuracies, errors in submitted data and missing data. These data problems will be sent to the study coordinators for corrections. Logs of these data issues will be maintained to identify problem areas with specific variables, or with specific study teams allowing us to proactively modify the data collection instruments or re-train study coordinator/data entry staff. Logs of communications with study coordinators with regard to data cleaning and management will also be maintained to keep track of corrected issues. Monthly reports will be provided to the PIs on patient accrual, study completion, and early termination to ensure awareness of lags in recruitment or retention of study subjects. A progress report will be completed on regular basis to summarize patient demographics and other baseline criteria data.

Safety Monitoring and Definitions

Should unanticipated internal or external events occur (such as deaths, life-threatening experiences, injuries, breaches of confidentiality, or other problems) at any time during or after the research study, the PI will report them immediately to the IRB. The PI will also report any new information indicating a change to the risks or potential benefits of the research, any deviation from the protocol, and any possible serious or continued non-compliance.

Adverse Event (AE) - Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. We will monitor the following AEs:

- Emergency room visits, not requiring hospitalization
- Breach of confidentiality
- Suicidal ideation not requiring intervention

Serious Adverse Event (SAE) – Any adverse events that result in the following, which we will monitor:

- Death
- Persistent or significant disability/incapacity
- Inpatient hospitalization or prolongation of existing hospitalization
- Are immediately life threatening
- Suicidal attempt or ideation requiring intervention

Study-Related – An AE or SAE is considered study related if the PI determines that the AE or SAE to be definitely, probably, or possibly related where possibly related means there is reasonable possibility that the incident, experience, or outcome may have been caused by the procedures or interventions involved in the research. AEs or SAEs judged as remotely related or not related are not considered study related.

Unanticipated Problem or Unexpected AE/SAE– problems or events in which the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. The term "unanticipated problem" is used in this context because some situations may not have produced an adverse event but is still considered an unanticipated problem (e.g. unsecured or stolen patient data which may not result in an AE). An event is unexpected if it is not described in the package insert of cessation medication, in the study protocol, or in the informed consent document.

SAE/EA Response and Reporting Procedure

1) Research staff becomes aware of AE/SAE (via scheduled survey or other means)
2) Research staff notifies Drs. Ladapo and Jay (Multiple PIs and internal medicine physicians) immediately if the event is an SAE or if immediate psychiatric or medical intervention is required, and within 7 days if the event is an AE.
3) Drs. Ladapo and Jay conduct EMR review when necessary to gather additional information about the event.
4) Drs. Ladapo and Jay make determination for 3 key indices if suspected to be study related:
   a. Severity: Mild, Moderate, Severe
   b. Expectedness: Expected, Unexpected
   c. Study Related: Definitely, Probably, Possibly, Remotely, Not Study-Related
5) Project Director documents SAE/AE and PI determination in study database.
6) Project Director prepares a report for the local IRB as per local, state, and federal reporting requirements.
7) Multiple PIs and Project Director plan measures to prevent future occurrences, if any warranted.
8) Multiple PIs and Project Director make changes to protocol and/or consent form if needed.

Data Storage and Confidentiality

Storage of Subject Data

Many steps will be taken to ensure the security and integrity of all patient data.

1) We will download eligibility, medical history, medications, and healthcare utilization data from the integrated electronic health record systems at each of the study sites. For NYU Lutheran patients, we will work with Datacore and for Bellevue patients we will work with CTSI to query this data. This data will contain personal health information (PHI) including names, dates of birth, date of last medical visit, medical record numbers, home addresses, email address and telephone numbers. However, we will not share PHI with research staff at UCLA prior to patient consent and we will not print copies of any patient data with PHI.
2) We will keep the queries of patients' EHR that contain PHI in encrypted files in a secure folder housed on the NYU Langone Medical Center server accessed only by approved research staff.
3) We will assign each subject a unique participant identification code (Subject ID) and create a key linking PHI (subject name and date of birth) with the Subject ID. We will store Study IDs in a secure folder housed on the NYU Langone Medical Center server accessed only by approved research staff. We will use the Subject ID to merge data from the EHR, surveys and other sources, and with newly collected data for the same subject over time. Only the PI, project manager, research data associate, and statisticians will have access to the key.

Access to Subject Data

Only non-PHI data from Langone and Bellevue patients will be entered in the REDCap database at UCLA prior to patient consent, in accordance with NYU Langone Medical Center's De-identification of PHI and Limited Data Sets policy. To prevent unauthorized access to the PHI dataset, only approved study personnel at NYU will have access to the data for management and analysis prior to patient consent. Healthcare providers who are not key personnel will not be informed of any responses given by subjects during their study visit. Only researchers approved to use the REDCap data files will manage data, conduct data analysis, and only on password-protected computers, which will be maintained with backup by a dedicated IT team.

Retention of Subject Data

Subject data will be kept throughout the duration of the study and beyond the study's conclusion for data analysis. We will implement the same data protection protocol during this time. When data is no longer needed for data analysis and publication purposes, files will be securely erased from all computers. Data gathered via the Fitbit is stored on the Fitabase or similar database for one month before resetting and is accessible by the company indefinitely. Data gathered via Weight Watchers or other online applications is stored and is accessible by the company indefinitely. Subjects will be informed prior to consent of the retention of data, the entities that have access to it and its potential reuse in successive analyses.

IV. Risk/Benefit Assessment

Risk

Participation in this study poses no more than minimal risk to subjects' physical and mental health. Subjects may experience minor discomfort during physical assessments such as blood pressure, height, weight, body composition and waist circumference. Subjects may experience frustration that is often experienced when completing surveys. Some survey questions may be of a sensitive nature, and subjects may therefore become distressed as a result. For example, topics related to weight, diet, and physical activity potentially may cause an emotional reaction, given the societal stigma surrounding obesity and its associated medical conditions. If subjects become distressed by an assessment or survey question, subjects have the right to stop at any time, choose not to answer a question or certain questions, or leave the study.

In the unlikely event that a patient is experiencing other concerns related to their health such as rapid or unsafe weight loss, or mental health or substance abuse issues, research staff will notify the Primary Investigator, who will notify the patient's primary care physician as noted in the patient's EHR.

Participation in this study poses no more than minimal risk to subjects' confidentiality. A breach of confidentiality is highly unlikely due to the aforementioned plan to secure all subject data through an encrypted, password-protected database accessed by approved research staff only.

Protection against Risks

To assure the minimization of any risks, all aspects of the research study will be conducted in a safe setting. All members of the research team have been extensively trained in order to effectively facilitate conversations and minimize the level of physical and emotional discomfort that individuals may face when completing study assessments. Subjects may withdraw from the study at any given point without having their regular care or employment impacted.

Potential Benefits to Subjects and Society

- **Subjects**: The patients who participate in the study will have the opportunity to receive weight loss information, set and achieve lifestyle behavioral goals, lose weight, and potentially reduce their risk for chronic disease and improve their health status. Even for patients who do not change their lifestyle during the study, receiving information about health behavior could serve as support or motivation to move them closer to making changes in the future.
- **Society**: The benefits to society of the proposed research include informing future behavioral economic strategies to promote physical activity and healthy eating, and

therapeutic approaches to reduce overweight and obesity among urban residents living in socioeconomically disadvantaged neighborhoods. Since programs and initiatives such as those tested in this study can be widely implemented at an institutional or community level, their benefits to health may have a broad-reaching impact on both patient and non-patient populations.

V. Investigators' Qualifications and Experience

We have included a CV and financial disclosure form for each personnel involved in the study. We will make modifications as necessary to the protocol when additional research staff are on-boarded. All research personnel have (or will have) completed online training in the protection of human subjects prior to interacting with subjects or accessing study data.

Summary of Research Personnel and Primary Roles

- Principal Investigators: oversee project implementation
  - Dr. Melanie Jay (NYU)
  - Dr. Joseph Ladapo (UCLA)
- Co-Investigators and other significant contributors at NYU:
  - Dr. Judith Wylie-Rosett: health behavior intervention expertise. Dr. Wylie-Rosette will not have access to PHI.
- Co-Investigators and other significant contributors at UCLA:
  - Dr. Chi-hong Tseng: clinical trial statistical and data analysis expertise
- Research Staff at NYU:
  - Dr. Stephanie Orstad: postdoctoral fellow: study management and scholarship
  - Ms. Victoria Sweat, program manager: study management and administration
  - Christina Hernandez, full-time research data associate: study site coordination, participant recruitment, consenting, data collection and management, intervention delivery
  - Susan Parraga, part-time research data associate: study site coordination, participant recruitment, consenting, data collection and management, intervention delivery
  - TBD, 4-6 research assistants/interns: participant recruitment, data collection and management, intervention delivery, administrative tasks

VI. Subject Identification, Recruitment, and Consent/Assent

Method of Subject Identification and Recruitment

For subject identification, we will use an integrated electronic health record (EHR) system at NYC Health + Hospitals Bellevue and NYU Langone Hospital

Brooklyn. We will work with Datacore at the NYU School of Medicine to obtain lists of potentially eligible patients from Langone's Epic EHR system and with CTSI to obtain lists of potentially eligible patients from Bellevue's Quadramed EHR system. The investigators' and research personnel's own staff, employees, and patients will not be recruited for this study. Employees of NYC Health + Hospitals Bellevue and NYU Langone Brooklyn will not be recruited for this study.

We will be recruiting from the same Bellevue patient population as another current study at NYU (the CHORD study, PI: Mark Schwartz, MD). We are adding their study staff to our protocol in order to share the names of patients that are recruited to our study so that they are not approached for CHORD because concurrent participation in both studies would be confounding. The CHORD study will also add our study team members to their protocol for the same purpose.

Patient Recruitment

At NYC Health + Hospitals Bellevue and Gouverneur and NYU Langone Hospital Brooklyn, we will use health information technology to generate lists of obese patients from nursing or physician assessments. We will work with DataCore and the Clinical and Translational Research Institute (CTSI), which provide NYU Langone's and Bellevue Hospital's clinical data expertise and support, to run queries of the EHR systems every 6-12 months for 24-27 months during the study to identify potentially eligible patients. We will cross-reference the addresses of these patients with census tracts associated with the lowest 40% of median household income in the New York/New Jersey region (approximately <$40,000/yr). A research staff member will send via U.S. mail recruitment letters about the study to the identified patients' home addresses. These letters will inform patients that they can call us to let us know if they would like to participate or if they do not, otherwise we will follow up with a phone call in the near future. Research staff will telephone potential patients, field incoming calls from patients, and return voice messages from patients who respond by phone to complete an initial eligibility screening. Eligibility will be based on the inclusion and exclusion criteria established for the study. If eligible, the research staff will invite the patient to an orientation/baseline visit (no more than one invitation per household). Study visits will take place at Bellevue Hospital, Gouverneur Hospital, and NYU Langone Hospital – Brooklyn.

To ensure that we can meet our recruitment goals, we will also use the EHR systems on a weekly basis to identify patients who may be eligible for our study. If a physician is willing to share their patients' office visit dates, we will use our inclusion and exclusion criteria (e.g., home address, age, weight, BMI, absence of previous bariatric surgeries or disqualifying health conditions) to identify if a patient scheduled to come into the clinic is potentially eligible based on information contained in their health record.

If a patient is potentially eligible, trained RAs will introduce themselves to the patient in the waiting areas on the date of their office visit. We have permission from clinic administration to approach patients in waiting areas as we will not require clinic resources or impede clinic workflow. RAs will provide basic information about the study. If interested, the patient will receive a paper-and-pencil screening survey to complete and/or will accompany the RA to a consultation room or other private area for screening. (Screening does not require physical assessments.) If eligible, the RA will obtain permission to schedule the patient for a baseline visit and/or contact them by phone later to schedule one.

We will also accept patients through physician referral and by “cold” recruiting interested patients in cooperating physicians’ waiting areas. RAs will approach individuals or small groups of patients in waiting areas and provide basic information about the study. If interested, the patient will receive a paper-and-pencil screening survey to complete and/or will accompany the RA to a consultation room or other private area for screening. If eligible, the RA will obtain permission to schedule an orientation/baseline visit and/or contact them by phone later to schedule one.

With permission of the appropriate physicians, we will regularly post recruitment flyers and brochures in areas of the clinics frequented by patients (e.g., waiting and exam rooms).

We also will work with DataCore to identify potentially eligible patients from the EHR who are also active on MyChart, a secure online patient portal for patients to access their medical records and receive health information (NYU Langone Hospital – Brooklyn only). We will use MyChart to send active patients an announcement using previously approved language about the study, to which they can respond via MyChart if they are interested in learning more about participating. Participation in the study is completely voluntary and all prospective subjects may refuse to participate or withdraw from the study at any given time.

To promote participant retention and attendance at study visits, emails and/or text messages with visit reminders will be sent to enrolled participants approximately 1 week prior to a scheduled visit using a secure system (i.e., RedCap). Text messages do not contain identifying information or treatment-related content. The message will read: "Hi! This is a reminder that you have a FIReWoRk Study visit at [NYU Langone Hospital Brooklyn/Bellevue Hospital/Gouverneur Hospital] on Monday X/XX/XXXX at 11 am. Please contact us right away at XXX-XXX-XXXX if you need to reschedule." If a participant does not complete 2 monthly check-in visits consecutively during the course of the study, we will invite the participant’s primary care provider to secure message the patient to encourage them to reengage with the study. The template message provided to the primary care provider to send the patient will read, “You are taking important steps to improve your health by joining the FIReWoRk Study! You’ve recently missed your study visits. In order to get the most benefit from study, I encourage you to attend

every FIReWoRk session!" Finally, we will send visit reminder postcards to a participant's home address within the month preceding their 6-month, 9-month, and 12-month study visits. Postcard messages do not contain any treatment-related content.

Process of Consent

Research staff will be intensively trained in consenting protocols and will be prepared to clearly summarize each section of the consent form. They will also be bilingual in order to obtain consent from Spanish-speaking participants. Research staff will obtain consent from patients in groups of 1-10 once they have been identified as eligible, are invited to the initial assessment, and arrive at the designated study site for the initial assessment. At this time, the research staff will 1) describe the study and its risks and benefits in detail from a script tested for eighth grade reading comprehension, 2) assess the subject's comprehension by asking the subject to explain the information presented (teach-back method), 3) answer questions the subject may have about the study and/or consent forms, 4) offer the subject the opportunity to participate, and 5) obtain a yes or no response from the subject to participate, and 6) acquire the subjects signature on the consent form. A copy of the consent form will be available for the patient to take home with them.

Subject Capacity

In order for subjects to be eligible to participate in the study, they must have the capacity to give informed consent. Research staff will assess subjects' capacity with the set of inclusion and exclusion criteria that has been established specifically for this study. In short, children and/or cognitively impaired adults will not be eligible. Participants must be able to travel for in-person assessments approximately monthly.

Subject/Representative Comprehension

A research staff will describe the study and its risks and benefits in detail to the subject's authorized representative. Then the RA will assess the comprehension of the subject's representative by asking them whether they understood the information presented. The RA will answer questions that the subject's representative may have about the study and/or consent forms, then offer the patient the opportunity to participate and help the representative obtain a yes or no response from the patient.

Debriefing Procedures

No information will be purposely withheld from any of the subjects who are recruited and/or are actively enrolled in the study.

Consent Forms

One consent form will be used for all subjects. The consent form will be translated from English into Spanish for Spanish-speaking patients.

Documentation of Consent

We will obtain written informed consent from all subjects who are eligible and agree to participate in this study. We will store documentation of consent securely in a locked file cabinet in the research team's locked office at the VA Harbor Healthcare System, 423 East 23rd Street, New York, NY 10010, 15th Floor North, Room 15028BN, which is where the administrative offices for Dr. Jay's team are located. Only approved research staff will have access to these materials.

Costs to the Subject

There will be no financial costs to the subjects for participating in this study. However, medical care and services provided by subjects' current health care facilities that are not part of the study may require payment, including normal visits and prescription expenses. Any transportation costs incurred by any patient to the study sites for assessment will be offset by payment for their participation.

Payment for Participation

To increase participation and minimize attrition, patients will receive up to$50 for completing each follow-up visit (i.e., $20 for 1, 2, 3, 4, and 5 months and $50 at 9 and 12 months). They will receive $80 for completing their 6-month visit. All subjects can receive a total payment for participation of up to $280. These payments will occur independently of the incentives earned in the intervention arms. Subjects accrue payments as the study progresses; they do not have to complete the entire study to be eligible to receive a payment. Due to the impact of COVID-19 and the inability to see the last few patients in person for their 9 and 12 month visits we increased the incentive from $20 to $50 at the 9 and 12 month visits to gather as much outstanding data as possible. A telephone script has been created to include language informing participants of this change.

Payment for participation (to all patients) and financial incentives (to patients in the goal-directed and outcome-based intervention arms) will be delivered using a pre-paid debit card (Clincard). Research staff will provide patients with a card and, after each completed visit, the money will be added to the card. They can use the card at any store that accepts credit cards or they can use a bank machine to withdraw cash. However, there may be fees charged against the balance of the card for cash withdrawals and inactivity. Patients will receive letters with additional information on how they can use this card and who to call if you have any questions.

The debit card system is administered by Greenphire, which will be given patients' names and contact information, including home address. Greenphire will use this

information only as part of the payment system and will not be used for any other purposes nor be given or sold to any other company. Greenphire will not receive any information about patients' health status or the study in which they are participating.

Due to federal tax law, patients are required to provide their social security number in order to process their payments. If patients receive over $600 from in a single calendar year from the NYU School of Medicine and Langone Medical Center or UCLA (either in a single study or multiple studies), they will be issued an IRS 1099 tax form (nonresidents will be issued a 1042-S tax form). We will provide patients with a preaddressed, stamped envelope to mail the appropriate form to UCLA's finance department. The amount they earn may affect their income taxes, but we will provide them with additional compensation to offset their estimated tax liability. Patients will be notified of the payment process prior to their consent.

References

1. Strickland S. Does it work to pay people to live healthier lives? *BMJ.* 2014;348:g2458.
2. Towers Watson National Business Group on Health. Full Report: Towers Watson/NBGH 2013/2014 Employer Survey on Purchasing Value in Health Care. 2014; http://www.towerswatson.com/en-US/Insights/IC-Types/Survey-Research-Results/2014/05/full-report-towers-watson-nbgh-2013-2014-employer-survey-on-purchasing-value-in-health-care. Accessed August 4, 2015.
3. Andreyeva T, Luedicke J, Wang YC. State-level estimates of obesity-attributable costs of absenteeism. *J Occup Environ Med.* 2014;56(11):1120-1127.
4. Paul-Ebhohimhen V, Avenell A. Systematic review of the use of financial incentives in treatments for obesity and overweight. *Obesity reviews : an official journal of the International Association for the Study of Obesity.* 2008;9(4):355-367.
5. Mantzari E, Vogt F, Shemilt I, Wei Y, Higgins JP, Marteau TM. Personal financial incentives for changing habitual health-related behaviors: A systematic review and meta-analysis. *Prev Med.* 2015;75:75-85.
6. Leatherman S, Berwick D, Iles D, Lewin LS, Davidoff F, Nolan T, Bisognano M. The business case for quality: case studies and an analysis. *Health Aff (Millwood).* 2003;22(2):17-30.
7. U.S. National Institutes of Health. Financial Incentives for Smoking Treatment (FIESTA). PI: Joseph Ladapo. 2016;

https://www.clinicaltrials.gov/ct2/show/NCT02506829. Accessed January 16, 2016.

8. Jay M, Gillespie CC, Schlair SL, Savarimuthu SM, Sherman SE, Zabar SR, Kalet AL. The impact of primary care resident physician training on patient weight loss at 12 months. *Obesity (Silver Spring, Md.).* 2013;21(1):45-50.
9. Mateo KF, Berner N, Vabrinskas W, Sherman SE, Kalet A, Jay M. Development of an online weight tool to facilitate collaborative goal setting for Veterans in primary care. *J Gen Intern Med.* 2015;April(Supplemental 2).
10. Mateo KF, Sikerwar S, Squires A, Kalet A, Sherman SE, Jay M. Development of a tailored, 5A's-based weight management intervention for Veterans within primary care. *J Gen Intern Med.* 2015;April(Supplemental 2).
11. Davis NJ, Ma Y, Delahanty LM, Hoffman HJ, Mayer-Davis E, Franks PW, Brown-Friday J, Isonaga M, Kriska AM, Venditti EM, Wylie-Rosett J, Diabetes Prevention Program Research G. Predictors of sustained reduction in energy and fat intake in the Diabetes Prevention Program Outcomes Study intensive lifestyle intervention. *J Acad Nutr Diet.* 2013;113(11):1455-1464.
12. Jaacks LM, Ma Y, Davis N, Delahanty LM, Mayer-Davis EJ, Franks PW, Brown-Friday J, Isonaga M, Kriska AM, Venditti EM, Wylie-Rosett J, Diabetes Prevention Program Research G. Long-term changes in dietary and food intake behaviour in the Diabetes Prevention Program Outcomes Study. *Diabet. Med.* 2014;31(12):1631-1642.
13. Nguyen NT, Magno CP, Lane KT, Hinojosa MW, Lane JS. Association of hypertension, diabetes, dyslipidemia, and metabolic syndrome with obesity: findings from the National Health and Nutrition Examination Survey, 1999 to 2004. *J Am Coll Surg.* 2008;207(6):928-934.
14. Haslam DW, James WP. Obesity. *Lancet.* 2005;366(9492):1197-1209.
15. Drewnowski A, Rehm CD, Solet D. Disparities in obesity rates: analysis by ZIP code area. *Soc Sci Med.* 2007;65(12):2458-2463.
16. Finkelstein EA, Trogdon JG, Cohen JW, Dietz W. Annual medical spending attributable to obesity: payer-and service-specific estimates. *Health Aff (Millwood).* 2009;28(5):w822-831.
17. John LK, Loewenstein G, Troxel AB, Norton L, Fassbender JE, Volpp KG. Financial incentives for extended weight loss: a randomized, controlled trial. *J Gen Intern Med.* 2011;26(6):621-626.
18. Volpp KG, John LK, Troxel AB, Norton L, Fassbender J, Loewenstein G. Financial incentive-based approaches for weight loss: a randomized trial. *JAMA.* 2008;300(22):2631-2637.
19. Jolly K, Lewis A, Beach J, Denley J, Adab P, Deeks JJ, Daley A, Aveyard P. Comparison of range of commercial or primary care led weight reduction

programmes with minimal intervention control for weight loss in obesity: Lighten Up randomised controlled trial. *BMJ.* 2011;343.

20. Kullgren JT, Troxel AB, Loewenstein G, Asch DA, Norton LA, Wesby L, Tao Y, Zhu J, Volpp KG. Individual- versus group-based financial incentives for weight loss: a randomized, controlled trial. *Ann Intern Med.* 2013;158(7):505-514.
21. Patel MS, Asch DA, Troxel AB, Fletcher M, Osman-Koss R, Brady J, Wesby L, Hilbert V, Zhu J, Wang W, Volpp KG. Premium-Based Financial Incentives Did Not Promote Workplace Weight Loss In A 2013-15 Study. *Health Aff (Millwood).* 2016;35(1):71-79.
22. Finkelstein EA, Linnan LA, Tate DF, Birken BE. A pilot study testing the effect of different levels of financial incentives on weight loss among overweight employees. *J Occup Environ Med.* 2007;49(9):981-989.
23. Garcia DO, Jakicic JM, Davis KK, Gibbs BB, Burke LE, Rickman AD. A Pilot Feasibility Study of a Campaign Intervention for Weight Loss among Overweight and Obese Adults. 2014.
24. Leahey T, Rosen J. Dietbet: a web-based program that uses social gaming and financial incentives to promote weight loss. *JMIR serious games.* 2014;2(1).
25. Leahey TM, Subak LL, Fava J, Schembri M, Thomas G, Xu X, Krupel K, Kent K, Boguszewski K, Kumar R, Weinberg B, Wing R. Benefits of adding small financial incentives or optional group meetings to a web-based statewide obesity initiative. *Obesity (Silver Spring).* 2015;23(1):70-76.
26. Moller AC, McFadden HG, Hedeker D, Spring B. Financial motivation undermines maintenance in an intensive diet and activity intervention. *J Obes.* 2012;2012:740519.
27. Spring B, Schneider K, McFadden HG, Vaughn J, Kozak AT, Smith M, Moller AC, Epstein LH, Demott A, Hedeker D, Siddique J, Lloyd-Jones DM. Multiple behavior changes in diet and activity: a randomized controlled trial using mobile technology. *Arch Intern Med.* 2012;172(10):789-796.
28. Mahoney MJ. Self-reward and self-monitoring techniques for weight control. *Behavior Therapy.* 1974;5(1):48-57.
29. Wing RR, Epstein LH, Marcus M, Shapira B. Strong monetary contingencies for weight loss during treatment and maintenance. *Behavior Therapy.* 1981;12(5):702-710.
30. Kramer FM, Jeffery RW, Snell MK, Forster JL. Maintenance of successful weight loss over 1 year: effects of financial contracts for weight maintenance or participation in skills training. *Behavior Therapy.* 1986;17(3):295-301.
31. Saccone AJ, Israel AC. Effects of experimenter versus significant other-controlled reinforcement and choice of target behavior on weight loss. *Behavior Therapy.* 1978;9(2):271-278.

32. Swinburn BA, Sacks G, Hall KD, McPherson K, Finegood DT, Moodie ML, Gortmaker SL. The global obesity pandemic: shaped by global drivers and local environments. *Lancet.* 2011;378(9793):804-814.
33. McTigue K, Larson JC, Valoski A, Burke G, Kotchen J, Lewis CE, Stefanick ML, Van Horn L, Kuller L. Mortality and cardiac and vascular outcomes in extremely obese women. *JAMA.* 2006;296(1):79-86.
34. Moyer VA, Force USPST. Screening for and management of obesity in adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2012;157(5):373-378.
35. Novak NL, Brownell KD. Role of policy and government in the obesity epidemic. *Circulation.* 2012;126(19):2345-2352.
36. Koh HK, Sebelius KG. Promoting prevention through the Affordable Care Act. *N Engl J Med.* 2010;363(14):1296-1299.
37. McCarthy J. Gallup's Health and Healthcare survey: Americans' Effort to Lose Weight Still Trails Desire. *Gallup* 2014; http://www.gallup.com/poll/179771/americans-effort-lose-weight-trails-desire.aspx. Accessed January 22, 2016.
38. Kahwati LC, Lance TX, Jones KR, Kinsinger LS. RE-AIM evaluation of the Veterans Health Administration's MOVE! Weight Management Program. *Transl Behav Med.* 2011;1(4):551-560.
39. Bleich SN, Pickett-Blakely O, Cooper LA. Physician practice patterns of obesity diagnosis and weight- related counseling. *Patient Educ Couns.* 2011;82(1):123-129.
40. Powell TM, de Lemos JA, Banks K, Ayers CR, Rohatgi A, Khera A, McGuire DK, Berry JD, Albert MA, Vega GL, Grundy SM, Das SR. Body size misperception: a novel determinant in the obesity epidemic. *Arch Intern Med.* 2010;170(18):1695-1697.
41. Dubowitz T, Ghosh-Dastidar MB, Steiner E, Escarce JJ, Collins RL. Are our actions aligned with our evidence? The skinny on changing the landscape of obesity. *Obesity (Silver Spring).* 2013;21(3):419- 420.
42. Drewnowski A. The economics of food choice behavior: why poverty and obesity are linked. *Nestle Nutr Inst Workshop Ser.* 2012;73:95-112.
43. Puhl RM, Heuer CA. Obesity stigma: important considerations for public health. *Am J Public Health.* 2010;100(6):1019-1028.
44. Dahn JR, Fitzpatrick SL, Llabre MM, Apterbach GS, Helms RL, Cugnetto ML, Klaus J, Florez H, Lawler T. Weight management for veterans: examining change in weight before and after MOVE! *Obesity (Silver Spring, Md.).* 2011;19(5):977-981.

45. Kinsinger LS, Jones KR, Kahwati L, Harvey R, Burdick M, Zele V, Yevich SJ. Design and dissemination of the MOVE! Weight-Management Program for Veterans. *Preventing chronic disease.* 2009;6(3):A98- A98.
46. Rao G, Burke LE, Spring BJ, Ewing LJ, Turk M, Lichtenstein AH, Cornier MA, Spence JD, Coons M, American Heart Association Obesity Committee of the Council on Nutrition PA, Metabolism, Council on Clinical C, Council on Cardiovascular N, Council on the Kidney in Cardiovascular D, Stroke C. New and emerging weight management strategies for busy ambulatory settings: a scientific statement from the American Heart Association endorsed by the Society of Behavioral Medicine. *Circulation.* 2011;124(10):1182-1203.
47. Tate DF, Jackvony EH, Wing RR. Effects of Internet behavioral counseling on weight loss in adults at risk for type 2 diabetes: a randomized trial. *JAMA.* 2003;289(14):1833-1836.
48. Camerer C, Ho T-H. Experienced-weighted attraction learning in normal form games. *Econometrica.* 1999:827-874.
49. Jeffery RW, Bjornson-Benson WM, Rosenthal BS, Lindquist RA, Johnson SL. Behavioral treatment of obesity with monetary contracting: two-year follow-up. *Addict. Behav.* 1984;9(3):311-313.

FIREWORK

4/8/2020

Goal Verification Protocol for Remote Study Visits

Goal and tracking method:	**Video visit** Access to internet and/or data during phone visit	**Phone/text visit** No access to internet or data during phone visit, but can text	**Phone only visit** No access to internet, data, or texting during phone visit
Target weight	Instruct patient to weigh self twice during video visit; patient must share their weights via video while standing on the scale	Instruct patient to weigh self twice during phone visit; patient must text pictures of their weights during phone visit	Instruct patient to weigh self twice during phone visit; patient must self-report their weights during phone visit (honor system)
Self-weighing – food journal	Instruct patient to log self-weights 3 times/week in food journal; patient must share their entries via video during video visit	Instruct patient to log weights 3 times/week in food journal; patient must text pictures of entries prior to or during phone visit	Instruct patient to log weights 3 times/week in food journal; patient must self-report the dates they weighed themselves during phone visit (honor system)
Self-weighing – WW or Fitbit app	Instruct patient to log weights 3 times/week in Fitbit or WW app; RA must verify goal via patient's account prior to or during video visit	N/A	N/A
Dietary tracking – food journal	Instruct patient to log food daily in food journal; patient must share their entries via video during video visit	Instruct patient to log food daily in food journal; patient must text pictures of entries prior to or during phone visit	Instruct patient to log food daily in food journal; patient must self-report the dates they tracked their food during phone visit (honor system)
Dietary tracking – WW or Fitbit app	Instruct patient to log food daily in Fitbit or WW app; RA must verify goal via patient's account prior to or during video visit	N/A	N/A
WW Attendance	Instruct patient to attend weekly WW virtual workshops via Zoom; patient must complete virtual "weigh-in" and RA must verify goal via patient's WW account prior to or during video visit	Instruct patient to attend weekly WW virtual workshops by calling into Zoom's toll-free number at the designated meeting time(s); patient must answer questions about 2 separate meetings in the past month (e.g., meeting topic) during phone visit	Instruct patient to attend weekly WW meetings by calling into Zoom toll free number at designated meeting time(s); patient must answer questions about 2 separate meetings in the past month (e.g., what they learned) during phone visit

Goal and tracking method:	Video visit Access to internet and/or data during phone visit	Phone/text visit No access to internet or data during phone visit, but can text	Phone only visit No access to internet, data, or texting during phone visit
Active minutes – food journal	N/A	Instruct patient to log active minutes daily in food journal; patient must text pictures of active minute entries during phone visit; RA must verify if weekly minutes total goal	Instruct patient to log active minutes daily in food journal; patient must self-report their active minute entries during phone visit; RA must verify if weekly minutes total goal (honor system)
Active minutes – Fitbit app	Instruct patient to sync their Fitbit to account; RA must verify goal via patient's Fitbit account prior to or during video visit	N/A	N/A

Notes:
Protocols adapted for COVID-19 in green
Criteria for meeting goals have not changed, and adapted goal verification processes should be implemented the same way for all participants, regardless of their intervention arm

Payment for Study Visits

- 1-5-month phone visits - $20
- 6-month phone visit - $40 ($40 when complete biometrics in person later)
- 9, 12-month phone visits – $20 (additional $20 when complete biometrics later?)

Getting New Information Out to Participants

- Information shared with all participants: ***Instructions for WW Virtual Workshops*** handout and ***How to Meet Your FIReWoRk Goals while Staying In*** handout (English and Spanish versions)
- These handouts will be made available to participants in the following ways:
    - PDF added to Google docs and shared with anyone who has the link, share link condensed using tinyurl.com, and tinyurl shared via email and/or text with those who have access to internet and/or data
    - Handout saved as a JPG and picture texted to those with no access to internet or data, but who can text

    - Each study site coordinator will communicate information and provide assistance by phone to all participants, but especially to those who do not have access to internet, data, or texting. Paper copy can be mailed to participant via USPS upon request.
- Mode of dissemination (phone call, email, text image or web link) can also depend on the participant's contact preferences.
- To make sure everyone who is currently active in the study (within months 0-12) is reached, each study site coordinator should go through list and check participants off as they are contacted.
- Each active participant will be notified about the adaptations by no later than 4/10/2020.

Other Considerations for Visits

1-6-month check-in visits:

- If a participant is checking in with us remotely for the first time, check how much time in their visit window they have, and encourage them to meet their WW attendance goal (>2 workshops) before the last day of their window (or within 1-2 days after). Make a note to verify their WW goal the day of the deadline. Adding this flexibility will be important for this "transition" month of March in which there is a gap between when in-person WW workshops were last offered and when we're able to make participants aware of the WW virtual workshops and how we will be verifying their goals remotely.
- Allow for extra time during phone visits for the extra steps required to verify goals.
- For the target weight goal: encourage the participant to take their weight while they are on the phone with you. Any weights the participant self-reports will be entered into the "Self Weight" fields of the REDCap Weight and BP form.
- For the WW attendance goal: facilitate their understanding of how the WW virtual meetings work to the extent possible.
- For the active minutes goal: ask if the patient has a family member with a smartphone who could download the Fitbit app and log in with the participant's Fitbit ID, and encourage them to sync their device daily.
- For those tracking their weight and diet in their food journal, encourage them to use the Fitbit or WW app instead if they are willing to, which will facilitate remote goal verification.

6, 9 and 12-month follow-up assessments:

- All prior visit reminder and retention protocols remain in place.
- All 6, 9, and 12-month follow-up assessments will be conducted by video or phone call, with the exception of the waist and blood pressure measurements. Inform participants that we will ask them to come in person to complete these assessments once the COVID-19 pause is over, and that they will receive half of their payment for participation now, and half later.

- During the visit reminder call, give the participant the option to have the patient-facing version of the survey in PDF or a tinyurl to link to the PDF on Google docs emailed or texted to them.
- Make every effort to complete a 6, 9, and 12-month visit if the visit window closes within one week.
- For 6, 9, and 12-month remote visits, when weight, waist, and blood pressure measures are not able to be taken, the REDCap Weight and BP form should be marked as “Incomplete” and notes entered into the Patient Issues form that participant was seen remotely due to COVID-19 and needs in-person biometrics taken at a later date.
- At 6, 9, and 12-month remote visits, participants will be scheduled for a (tentative) biometrics visit approximately 6 weeks out, as well as any next (9 or 12-month) study visits 3 months out, so we have something on the calendar for them.
- Protocols for rescheduling missed visits remain in place.

Standard messages about how to meet goals and additional resources during COVID-19:

- Make sure all participants receive the ***How to Meet Your FIReWoRk Goals while Staying In*** handout (English and Spanish versions) via their preferred delivery method, which provides tips for eating healthy and being active while indoors, as well as community and/or clinic-specific tele-mental-health and food security resources that are available to them. (info sheet forthcoming)

TBD:

- Will the 6, 9, and 12-month visit windows be extended?
- How will we address missing verified weight, waist, and blood pressure data to the extent possible?