Bloom Research Study

Protocol and Analysis Plan (Approved by the University of Tennessee Health Science's Institutional Review Board on 6/18/2019)

ClinicalTrials.gov NCT03834194

1. Purpose
To study the impact of different incentive stuctures and weight management practices (i.e. self-weighing, weight goal setting, exercise goal setting) on gestational weight gain management.

2. Rationale
Gestational weight gain (GWG) is a serious public health concern, and 37% of normal weight, 64% of overweight, and 49-64% of obese women exceed the Institute of Medicine's GWG guidelines. Research has found that modest financial incentives are a promising pragmatic strategy for a GWG intervention. Yet, most previous weight management research that has utilized incentives has targeted weight outcomes rather than the behaviors necessary to achieve them. This study to examine the impact of frequent chances to win small, proximal incentives for meeting short-term goals of monthly self-weighing and larger incentives for meeting overall GWG goals by the end of the 36-week gestational period.

3. Study/Project Population
There will be 50 mother and baby pairs (N=100) included to account for screening failures but only 40 of those pairs (N=80) randomize. Pregnant participants (N=100) in their first trimester at an OB-GYN Specialists clinic in Memphis, TN will be randomized in a fractional factorial experiment. Participants must be at least 18 years old and be less than 12 weeks gestation upon recruitment (based on the date of their last menstrual period and then confirmed by their physician at their first prenatal visit), as interventions that begin prior to gestational week 12 are more effective.

4. Research Design
Potential participants will be identified by the clinics' health professionals (i.e., nurses, obstetricians) at their pregnancy confirmation visit or will be self-identified through recruitment materials posted in the obstetric clinic (e.g., exam rooms, lobby and bathrooms). They will encouraged to contact the study team if they wish to learn more about the study and potentially enroll in the study. Interested individuals will be evaluated for the eligibility criteria (see above) and written informed consent will be obtained.

Upon recruitment, individuals who are interested in learning more about the study will be directed to the Way to Health web portal. Upon reaching the portal, potential participants will be asked to create an account and will then be informed of the details of the study, including its objectives, duration, requirements, and financial payments. If participants are still interested in participating, the Way to Health portal will take them through an automated online informed consent. The consent document will be divided into sections and potential participants will have to click a button to advance through each section. This is to help ensure that participants read the consent form thoroughly by breaking down the form into manageable blocks of text. Successive screens will explain the voluntary nature of the study, the risks and benefits of participation, alternatives to participation, and that participants can withdraw from the study at any time. On the final consent screen, potential participants who click a clearly delineated button stating that they agree to participate in the study will be considered to have consented to enroll. After consenting, participants will complete an online questionnaire to determine

their eligibility (i.e. whether participants are 18 years or older, whether they are no more than 12 weeks pregnant, and whether they have wireless internet or a Bluetooth connected device). Eligible participants will first answer a few questions about the number of pregnancies they have prior to the current one, age, annual household income, marital status, employment status, household size, education level, race, and ethnicity. Then, they will be randomized to one of the study arms and led through an automated description of the details specific to that arm. Participants will be provided with details regarding how to contact the research team via email or phone at any time if they subsequently wish to withdraw from the study. This contact information will remain easily accessible via the participants' individual Way to Health web portal dashboards throughout the study.

Participants (N = 40) will be randomized to one of 8 conditions , with combinations of 3 different components of incentive for GWG management and physical activity. Assessments will be conducted at baseline (i.e., in the first trimester), 32 weeks gestation and 36 weeks gestation (if the participant has not yet delivered) and will include measures of body weight and treatment satisfaction. Participants will be asked to complete daily weigh-ins using the scale provided by the study, as well as wear a physical activity tracker (i.e. Fitbit).

Self-Weighing (Lottery)
Participants randomized to an arm that contains the self-weighing (lottery) component will be asked to pick a number between 00 and 99 at randomization, and will be informed that there will be a daily lottery, for which they will be eligible if they have weighed themselves in the previous day on the Withings e-scale. Then, for each day of their pregnancy, participants will be informed of the study's randomly-generated winning lottery number. Participants who weighed themselves the previous day with a one- or two-digit match will be also specifically notified of their reward. A two-digit match (1 in 100 chance) will yield a $15 incentive and a single-digit match (1 in 5 chance; that is, if the participant's lottery number is 27, an example of a one-digit match is 77) will yield a $2 incentive. A maximum of $112 could be earned over the pregnancy. Participants will receive their weekly winnings from weigh-in on Mondays of the following week.

Self-Weighing (Certain Loss)
Participants randomized to an arm that contains the self-weighing (certain loss) component will have a balance shown at the beginning of the study on the participant dashboard and each day that they do not weigh, $0.50 will be subtracted from this account. The beginning balance will be based on the number of days until 36 weeks gestation for each participant, which will vary slightly due to when participants enroll in the study. Participants will receive their weekly payout (a maximum of $3.50 for 7 days) from weigh-in on Mondays of the following week. A maximum of $112 could be earned over the pregnancy.

Monthly GWG component
Participants randomized to an arm that contains the monthly GWG incentive component will receive $14 per month if they have gained within the recommended monthly range for their BMI category (Table 2). "Ineligible for incentive" participants will be specifically notified that

they would have received $14 had they had gained within the recommended range for the month, drawing on research showing that loss aversion can be motivating. Participants will receive their monthly balance on the first weekday of the following month. A maximum of $112 could be earned over the pregnancy.

Table 2. Monthly weight gain goals by weight status

		Monthly Weight Gain Goals		
		Normal Weight	Overweight	Obese
1st Trimester	Week 5-8	< 2.2 lbs	< 2.2 lbs	< 2.2 lbs
	Week 9-12	< 2.2 lbs	< 2.2 lbs	< 2.2 lbs
2nd Trimester	Week 13-16	2 - 4.4 lbs	1 – 3 lbs	1 - 2.2 lbs
	Week 17-20	2 - 4.4 lbs	1 – 3 lbs	1 - 2.2 lbs
	Week 21-24	2 - 4.4 lbs	1 – 3 lbs	1 - 2.2 lbs
3rd Trimester	Week 25-28	2 - 4.4 lbs	1 – 3 lbs	1 - 2.2 lbs
	Week 29-32	2 - 4.4 lbs	1 – 3 lbs	1 - 2.2 lbs
	Week 33-36	2 - 4.4 lbs	1 – 3 lbs	1 - 2.2 lbs

Overall GWG component

Participants randomized to an arm that contains the overall GWG incentive component will be given the Institute of Medicine gestational weight gain recommendation based on their body mass index at randomization, adjusted for data collection at 36 weeks (Table 3). If they achieve the goal at 36 weeks, they will receive $112 after the data collection visit.

Table 3. Overall weight gain goals by weight status (adjusted goals based on data collection at 36 weeks gestation)

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	Normal Weight	Overweight	Obese
Overall Weight Gain	21-31 lbs	13-23 lbs	9-18 lbs

Weekly physical activity

Participants randomized to an arm that contains the physical activity component will be ask to achieve a 150 minute physical activity goal for each week based on the guideline from the American College of Obstetricians and Gynecologists (ACOG), 21 and they will receive $3.50 if they meet their activity goal for the week. Participants who do not meet the activity goal will be notified that they would have received $3.50 had they meet their activity goal, drawing on research showing that loss aversion can be motivating. Participants will receive their weekly payout on Mondays of the following week.

The total amount that any one participant can earn through the incentives is $336.

Measures will be obtained by trained research staff who are blinded to treatment assignment and who will be located within the obstetric clinic. Baseline measures will be obtained just prior

to randomization. In-person follow-up data collection visits will be scheduled at gestational week 32 and week 36. Incentives ($30 for each follow-up visit) will be used to obtain high retention at all follow-up data collection visits. In addition, the research staff will attempt to schedule the data collection visits before or after regular office visits, in order to facilitate retention.

5. Study/Project Procedures
a. recruitment
b. randomization into study arms
c. participants receive feedback about whether their numbers were drawn in the lottery and whether they won the incentive pending weight management results
d. study team analyzes whether different incentive structure affects participants' gestational weight gain

6. Outcome Measures

Intervention Satisfaction: At 32 weeks gestation, participants will be asked to offer insight into program acceptability in each condition, as well as satisfaction to the program in general. We will examine feedback on specific intervention aspects, which will inform program refinement and future implementation.

Recruitment yields observed from enrollment survey: The number of participants initially recruited for the study will be closely monitored.

Program retention observed from enrollment and follow-up surveys: The number of participants stayed in the study within the time frame of the study will be closely monitored.

Gestational Weight Gain (i.e., baseline to final prenatal visit): At all measurement visits, weight will be recorded in kilograms on a calibrated research-grade scale. Weight will be measured on a calibrated digital scale in duplicate, with the participant wearing light clothing and no shoes. While we will obtain the mother's weight at baseline, we will also obtain self-reported preconception weight (before the last menstrual period). We will calculate the participant's GWG goal based on self-reported preconception BMI. Strong concordance between self-reported preconception weight and measured pregravid weight has been demonstrated. 22 The difficulty of anticipating when a final weight should be obtained to capture the fullest extent of GWG was considered, and we elected to use an approach that afforded two possible weights that would be available for analytic purposes. The Week 36 weight will be the primary outcome except for mothers who deliver prior to 36 weeks, in which case we will use the Week 32 weight. Thus, we will have a final observation of GWG for all participants, regardless of whether they deliver earlier than 36 weeks. However, only approximately 11% of pregnant women have their child before 37 weeks; 23 thus, we expect that we will be able to collect Week 36 data on most participants.

Other Measures

Height: Height will be recorded in centimeters.

Demographics: Participants will complete a questionnaire regarding their age, annual household income, marital status, employment status, education level, race, and ethnicity.

Weight Self-Monitoring: We will electronically monitor daily self-weighing as a measure of treatment engagement (coded each day as present or absent).

Physical Activity: We will electronically monitor participants' weekly physical activity as a measure of treatment engagement (measured in active minutes).

Analysis Plan

This is a feasibility study, the primary purpose of which is to gather data that would evaluate the feasibility of recruitment, randomization, and retention, as well as treatment engagement and intervention satisfaction. An additional aim of this study is to pilot the intervention components, consistent with the preparatory stage of the multiphase optimization strategy framework. The trial was not powered to detect a significant difference among the conditions on treatment engagement or GWG.

We will describe characteristics of the sample using counts and percentages for categorical data and means and SDs for continuous data. All analyses will be implemented using R (version 4.0.2; The R Foundation for Statistical Computing).