COVER PAGE

Gestational Weight Gain and Postpartum Weight Loss in Active Duty Women (Moms Fit 2 Fight)

NCT03057808

Study Protocol and Statistical Analysis Plan

January 3, 2019

PROTOCOL FOR CLINICAL INVESTIGATION – NON-EXEMPT HUMAN
(Wilford Hall Ambulatory Surgical Center – WHASC)

PROTOCOL SUMMARY

1. Title:

Behavioral Weight Management for Active Duty Military and DoD TRICARE Beneficiary Pregnant and Postpartum Women
FWH20160036H

2.0. Principal Investigator (PI):	**WHASC PI:**	**SAMMC Co-PI:**
Name	Dr. Gerald W. Talcott, PhD, Col, USAF (ret)	Dr. Callie Cox-Bauer, DO
Rank/Corps or Civilian Rating	N/A	Major
Date of IRB Approved CITI Training	25 Sept 2017	02 Apr 2017
Branch of Service	N/A	USAF
AD Mil/DoD Civilian/Ctr/Non-DoD Civ	Non-DoD Civ	AD Mil
Department & Base	University of Virginia 59MDW/SGOWMP	Chief, Outpatient Services OBGYN Department SAMMC
Phone & Pager #	210-292-3813/210-632-9178(c)	210-916-1162
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DoD Assurance # and Expiration Date	FWA00006183 Expires: 13 Jun 2018	DoD Assurance: A10041 Expires: 1 Mar 2019

3.0. Research Plan:

3.1. Purpose:

1) To randomize 450 participants to 1 of 3 arms: a) a gestational weight gain intervention (GWG-only); b) a postpartum weight loss intervention (PPWL-only), or c) a combined gestational weight gain and postpartum weight loss intervention (GWG+PPWL), and to determine the efficacy of the interventions on GWG as well as PPWL;
2) To identify the impact of the interventions on pregnancy-related medical outcomes and health care utilization (from the electronic medical record) and fitness test data (pregravid to 12-month postpartum, from the military fitness database);
3) To determine the impact of treatment engagement process data (e.g., session participation, self-monitoring, meal replacement adherence) on intervention outcome.

3.2. Hypotheses, Research Questions or Objectives:

Hypothesis 1: Participants randomized to GWG-only and GWG+PPWL arms will gain less weight during pregnancy than in those randomized to the PPWL-only arm.
Hypothesis 2: Participants randomized to the GWG+PPWL and PPWL-only arms will lose significantly more weight postpartum than those randomized to the GWG-only arm.

4. Brief Summary of the study:

We will determine the extent to which a GWG intervention, a PPWL intervention, or a combination of the two interventions are efficacious in improving healthy GWG, PPWL, military readiness and maternal/child health and reducing health care utilization. From the treatment engagement data, we will identify

potentially important mediators of the treatment outcome. These outcomes are expected to have an important positive impact because the intervention(s) could be disseminated to the entire U. S. Military and integrated into standard health care for pregnant/postpartum military women.

5. Subjects:
Study participants will be female, active duty military personnel stationed at Joint Base San Antonio.

6. Inclusion/exclusion criteria:
Inclusion:

- Participants will be female active duty military personnel and DoD beneficiaries (retirees and dependents), stationed at Joint Base San Antonio and at least 18 years old.
- Participants must be less than 12 weeks gestation upon recruitment (based on the date of their last menstrual period and confirmed by first trimester ultrasound at the first prenatal visit).
- Participants must be within the normal, overweight, or obese BMI ranges upon Baseline measurements.
- Participants must have at least 1.5 years left on their current duty assignment.

Exclusion:

- Participants who have any medical conditions that limit a participant's ability to engage in changes in dietary intake or increases in physical activity, based on the determination of physicians on the study team.
- Participants who have a high-risk pregnancy (i.e., Type I or II diabetes at conception or current multiple gestation), based on the determination of physicians on the study team.
- Participants who smoke at the time of conception (smoking cessation during pregnancy has significant benefits for fetal health, but the quitting process can be associated with weight gain and thus offers potential study confounds).

7. Number of Subjects:
TOTAL NUMBER OF SUBJECTS (nation-wide/study-wide): WHASC and SAMMC – 755 with 450 completing the study

8. Use of an Investigational New Drug: N/A

9. Use of an Investigational Device: N/A

10. Use of a Placebo: N/A

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Department & Base	University of Virginia 59MDW/SGOWMP	Chief, Outpatient Services OBGYN Department SAMMC
Phone & Pager #	210-292-3813/210-632-9178(c)	210-916-1162
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DoD Assurance # and Expiration Date	FWA00006183 Expires: 13 Jun 2018	DoD Assurance: A10041 Expires: 1 Mar 2019

2.1. Associate Investigators (AI):
Provide the current list of all "engaged" AIs for the study based on 45 CFR 46.102, e.g., for purposes of research the AI: (1) obtains data through intervention or interaction with a research subject(s); and/or (2) obtains identifiable private information and/or protected health information about the research subject(s); and/or (3) obtains the informed consent of human subjects for research. **All "engaged" investigators must complete IRB approved CITI training.**

Name	**AD/DoD Civ/Ctr/ Non-DoD Civ**	**Rank/Corps or Civilian Rating/Title**	**Date of CITI Training**	**Phone & Pager #**
Rebecca Krukowski, PhD	Non-DoD Civ	Civilian PI/UTHSC	16 Apr 2018	901-448-2426
Robert Klesges, PhD	Non-DoD Civ	AI/UVa	8 Oct 2017	901-448-5900
Melissa Little, PhD	Non-DoD Civ	AI/UVa	6 Dec 2017	901-448-6878
Marion Hare, MD	Non-DoD Civ	AI/UTHSC	23 Jan 2018	901-448-3752
Ann Hryshko-Mullen, PhD	DoD Civ	AI (WHASC)	2 Mar 2017	210-292-5968
Daniel Cassidy, PhD	AD	Maj/AI (WHASC)	13 Jul 2017	210-292-5968
Zoran Bursac, PhD	Non-DoD Civ	AI/Florida International Univ.	29 Nov 2017	901-448-2426
Carol Copeland, PhD	Non-DoD Civ	AI/UVA	3 Oct 2018	210-292-3813

2.2. Research Assistants (RA) & Coordinators (RC):
Provide the current list of all "engaged" RAs & RCs for the study based on 45 CFR 46.102, e.g., for purposes of research the RA or RC: (1) obtains data through intervention or interaction with a research subject(s); and/or (2) obtains identifiable private information and/or protected health information about the research subject(s); and/or (3) obtains the informed consent of human subjects for research. **All "engaged" RAs and RCs must complete IRB approved CITI training.**

Name	AD/DoD Civ/Ctr/ Non-DoD Civ	Rank/Corps or Civilian Rating/Title	Date of CITI Training	Phone & Pager #
Karen LeRoy	Non-DoD Civ	Research Director	18 Apr 2016	210-292-3504
Leslie Gladney	Non-DoD Civ	Program Coordinator	19 Jun 2017	210-671-1997
Allen Jones	Non-DoD Civ	Research Specialist	12 Jan 2016	210-671-1955
Tina Boothe	Non-DoD Civ	Research Specialist	05 Jan 2016	210-671-8175
Lisa McKenna	Non-DoD Civ	Administrative Coordinator	27 Nov 2017	210-292-3813
Mark Amen	Non-DoD Civ	IT Specialist	09 Dec 2017	210-292-4469
Annette Martinez	Non-DoD Civ	Research Specialist	18 May 2018	210-671-0636
Trina Bolden	Non-DoD Civ	Research Specialist	18 April 2016	210-671-8173
Carmen Cardenas	Non-DoD Civ	Research Assistant	22 Jun 2018	210-671-1994
Gloribel Bonilla	Non-DoD Civ	Research Specialist	12 Feb 2018	210-292-3813
Jennifer Oates	Non-DoD	Research Specialist	26 Jan 2017	210-292-3813
Shawnta Vermong	Non-DoD Civ	Research Specialist	7 Aug 2018	210-292-3813

2.3. The research relevance of this protocol focuses on:
[] Diagnosis [x] Treatment [] Medical Utilization/Managed Care [x] Prevention [] Medical Readiness [] Other

2.4. Location(s):

a. Collaborating Facilities: WHASC and SAMMC
b. Air Force Sites seeking Regional IRB: N/A
c. List study sponsors: NIH

3.0 Research Plan:

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3.3. Significance; 3.4. Military Relevance; & 3.5. Background and Review of Literature:

Considerable attention has been given to the alarming prevalence of overweight and obesity in the U.S. population [1]. This epidemic extends to women of childbearing age [1], including women who are active duty personnel in the U.S. military and DoD TRICARE beneficiaries (retirees and dependents). As of 2011, 34% of active duty military women were overweight and 6% were obese [2]. Indeed, excess weight is

associated with $1.1 billion dollars each year in medical costs in the military health care system [3]. Furthermore, specifically for active duty personnel, excess weight and inadequate fitness are frequent causes for discharge. The military must then recruit and train replacements for about $50,000 per person, thus spending more than $60 million a year due to failed first-term enlistees [3]. While the long-term impact of pregnancy on military fitness test performance is unknown, several studies have found that women have significantly lower fitness test scores at 6-months postpartum [4, 5]. Finally, pregravid overweight/obesity has been found to be a key risk factor for perinatal complications in both civilian [6] and military populations [7].

In addition to pregravid weight status, excessive gestational weight gain is another key risk factor for pregnancy and delivery complications (e.g., gestational diabetes, preeclampsia, caesarean delivery) [8-11] and negative health outcomes for infants [6, 10, 12] as well as overweight status later in life [11-14]. Excessive gestational weight gain is also associated with postpartum weight retention [15-19], a key concern for the U.S. military. Thus, gestational weight gain is a critical consideration, because it is a modifiable risk factor that can be addressed upon pregnancy confirmation.

Women are not meeting the Institute of Medicine guidelines for gestational weight gain. Recent research indicates that many pregnant women do not gain within the 2009 Institute of Medicine guidelines; specifically, 53-71% of normal weight women, 77-84% of overweight, and 74-83% of obese women exceeded the Institute of Medicine guidelines [20, 21]. Although there is limited research on excessive gestational weight gain among TRICARE beneficiaries, there is some indication that many active duty women, like the civilian population, are exceeding gestational weight gain guidelines [22].

Excessive gestational weight gain is a key predictor of postpartum weight retention [23, 24]. Postpartum weight retention is critical, not only negatively impacting returning to pregravid fitness levels, but the increased body mass index also places the mother and fetus at higher risk for negative health outcomes in subsequent pregnancies [6, 7, 25]. Furthermore, postpartum weight retention is associated with long-term maternal overweight/obesity [26-28] and increased waist circumference [29].

Clearly, gestational weight gain and postpartum weight retention are important factors in maternal and child health as well as military readiness; however, little is known about gestational weight gain and postpartum weight retention among TRICARE beneficiaries.

3.5.1. Bibliography:

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3.6. Research Design and Methods:
We will implement a stepped-care GWG intervention and a PPWL intervention for women with TRICARE benefits, while accommodating the unique military lifestyle and environment. We will randomize 450 participants to 1 of 3 arms: a) a gestational weight gain intervention (GWG-only); b) a postpartum weight loss intervention (PPWL-only), or c) a combined gestational weight gain and postpartum weight loss intervention (GWG+PPWL) in order to determine the efficacy of the interventions on GWG as well as PPWL. This design will allow the PPWL-only arm to be the comparison group for GWG (at the final pregnancy follow-up visit); the GWG-only arm to be the comparison group for PPWL (at 6-months and 12-months follow-up) and the GWG+PPWL arm to determine the additive or synergistic effects. Study measures will be obtained at screening, baseline, gestational week 32 and 36, and 6-weeks, 6-months, and 12-months postpartum and will include weight, height, maternal and infant medical outcomes, health care utilization, fitness test scores, waist circumference, self-reported exercise behaviors and nausea symptoms, accelerometry, feeding practices, demographics and program satisfaction. Process measures (e.g., session participation, self-monitoring) will be collected throughout the trial.

No inducements, monetary or otherwise, will be offered to terminate a pregnancy. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy and individuals engaged in the research will have no part in determining the viability of a neonate (45 CFR 46.204).

3.6.1. Interventions, Observations, or Data Sought:
Procedure: Interested individuals will be directed from our recruitment materials (e.g., posters, flyers, business cards, listservs, and electronic media) to visit the study recruitment office (located in the obstetric clinics) to learn more and determine whether they meet the eligibility criteria. If, after learning more about the study, individuals continue to be interested, written informed consent will be obtained and measures will be administrated. The potential participant will also be asked to complete a one-week dietary and exercise self-monitoring run-in, turn in a copy of their fitness scores to study staff (if active duty), and receive medical clearance from their obstetrician to participate. (Note: In the unfortunate event that a potential participant miscarries before being randomized, she will have the opportunity to re-screen if she chooses.) Should she continue to be interested, she will return for a Baseline Visit and will be randomized to 1 of 3 conditions: a) GWG-only; b) PPWL-only; or c) GWG+PPWL and oriented to the assigned treatment condition.

Randomization: Participants (n=450) will be randomly allocated to 1 of the 3 conditions, using a computer algorithm under the direction of the study biostatistician, Dr. Bursac, with a sequence blocked by screening BMI category (i.e., normal weight, overweight, obese) in order to ensure equal distribution by condition with respect to BMI category. Each condition will have the same number of subjects.

Intervention Overview: The novel stepped-care behavioral GWG and/or PPWL intervention--designed to assist participants meet the Institute of Medicine (IOM)-recommended GWG guidelines and produce PPWL-- will be based on the Look AHEAD Intensive Lifestyle Intervention. The Look AHEAD Intensive Lifestyle Intervention methods are consistent with those utilized in previous studies of effective approaches to producing appropriate GWG and PPWL. However, the Look AHEAD approach offers greater structure and support than some of the methods used in previous work. We will also tailor our intervention to the military lifestyle (e.g., managing stressors such as increases in dietary intake, reduced physical activity related to spouse deployment, environmental facilitators such as access to the free fitness centers). We have previously tailored our interventions to the military lifestyle and environment, and our programs have been extremely well received by military personnel.

GWG Intervention: The GWG intervention will begin upon randomization to the GWG-only or the GWG+PPWL arm, and continue until the birth of the participant's child. This intervention will provide individual, telephone-based sessions (20-30 minutes each), as detailed in Table 1, by trained interventionists. The number of possible telephone sessions will depend on the gestational age at randomization and the level of support needed by the participant to meet the IOM guidelines. The intervention will focus on self-monitoring, clear goals (i.e., GWG, caloric intake exercise), and problem solving.

Table 1. Stepped-Care Gestational Weight Gain Intervention

	Step 1	**Step 2**	**Step 3**
Trigger to Increase Intervention Intensity	- >0.5 lb above GWG guidelines at any monthly session	- >0.5 lb above GWG guidelines for 2 consecutive biweekly sessions	-N/A
Contact Frequency	-Monthly 20-30 minute telephone session	-Biweekly 20-30 minute telephone session	-Weekly 20-30 minute telephone session - Weekly emailed materials
Dietary Recommendations	1st trimester: Maintain 2nd trimester: ↑ by 340 calories per day 3rd trimester: ↑ by 452 calories per day	Same as Step 1 with portion size measuring and daily dietary intake monitoring	↓ by 100-200 calories per day until appropriate GWG achieved
Exercise	-150 minutes per week of moderate activity -Fitness tracker	-150 minutes per week of moderate activity -Fitness tracker	-150 minutes per week of moderate activity -Fitness tracker
Behavioral Strategies	-Weekly self monitoring of weight -Weekly emailed graph	-Daily self monitoring of weight, daily food intake & exercise -Weekly emailed graph -Goal setting & problem solving	-Daily self monitoring of weight, daily food intake & exercise -Weekly emailed graph -Goal setting & problem solving -Meal replacements & structured meal plans - Adapted Look AHEAD ILI lesson materials -Toolbox resources
Trigger to Reduce Intervention Intensity	N/A	Return to GWG within the IOM guidelines	Return to GWG within the IOM guidelines

Being above the GWG recommendations will trigger an increase in the intervention intensity (i.e., moving to the next step—so gaining more weight at any monthly telephone session for those in Step 1 will trigger an increase in the intervention intensity (i.e., moving to Step 2), and any participant in Step 2 who is above the line for 2 consecutive biweekly sessions will trigger an increase in the intervention intensity (i.e., moving to Step 3). This stepped-care approach will have optimal translation to the practice setting, because it allows targeted allocation of resources. Further, this approach allows greatest tailoring of the intervention intensity to the individual (those who have trouble staying within the guidelines early in pregnancy will get more assistance at that time, with a decrease in intervention intensity when their GWG is within the recommended range; those who stay within guidelines early on but require assistance maintaining adherence with guidelines later in their pregnancy receive assistance when they start to experience challenges). A similar stepped-care approach, designed by Dr. Krukowski, has been well received by pregnant women in the "Glowing" study.

Weight goals: The GWG goals for each participant will reflect the 2009 IOM guidelines[30]: a) for normal weight women (BMI 18.5-24.9 kg/m^2): 11-16 kgs (25-35 lbs); b) for overweight women (BMI 25.0-29.9 kg/m^2): 7-11.5 kgs (15-25 lbs); and c) for obese women (BMI 30-39.9 kg/m^2): 5-9 kgs (11-20 lbs) based on their weight collected at their screening appointments. Ongoing weight self-monitoring will be a central feature of the intervention at all steps. Most experts considered frequent weighing a key component to any weight management program (83-86) and it appears to be important in pregnancy-related weight interventions as well. For this reason, participants will be prompted to weigh themselves at least weekly on an electronic scale, which they will be given at baseline. The electronic scale will be issued to the subject as part of treatment on a hand receipt. Due to depreciation of the scale over 21 months of use during the study, the scales would be valued at near zero, and therefore subjects will not be required to return them. The electronic scales are part of the treatment and not considered a form of compensation for participating in the study. Each time a participant weighs, the electronic scale will upload the weight automatically to a secure website. Each week, participants will receive an email from their interventionist with a weight graph tailored to their screening weight BMI and their current weight trajectory as well as personalized feedback from their interventionist about their trajectory. Participants who gain <u>less</u> weight than the guidelines will be instructed to increase their caloric intake and to monitor their weight daily. Study staff will notify Obstetrics staff about participants who gain less weight than the guidelines at two consecutive intervention sessions, but will be retained in the study.

Dietary goals: Consistent with the IOM recommendations[30], participants will be advised to continue consuming the same number of calories in the first trimester as they did pre-pregnancy, and increase baseline intake (if they are otherwise meeting their GWG goals) by approximately 340 calories in the second trimester, and by 452 calories in the third trimester. Participants will be given examples of 350 and 450 calories of food, in order to guide adherence with these goals. Other dietary recommendations will be consistent with a "healthy" diet for pregnant women (e.g., limiting fish consumption), with an emphasis on consuming a diet high in fruits, vegetables, and whole grains. We will pair self-monitoring, with instructions in food label reading and measuring foods to improve self-monitoring accuracy. However, among women who are gaining in excess of the guidelines who have self-reported calorie intakes within the specified goal ranges, recommendations for decreases in the calorie goals will be made; this is predicated on the assumption that the actual energy intake is higher than the self-reported intake and that lowering the goal for self-reported intake will achieve an intake level that supports appropriate GWG.

Exercise goals: Participants will be encouraged to engage in 150 minutes per week of moderate exercise. Fitness trackers will be issued with a hand receipt to participants as part of treatment to facilitate reaching their exercise goal. The fitness trackers are part of the treatment and not considered a form of compensation for participating in the study. After 21 months of use, the value of the fitness tracker will be near zero due to depreciation and advances in technology; therefore, participants will not be asked to return the fitness trackers. If the participant's obstetrician recommends limiting physical activity or complete bed rest, the exercise goal will be modified or halted.

<u>PPWL Intervention</u>: The PPWL intervention will begin at 6-weeks postpartum (when most women will be approved for weight loss and exercise by their obstetrician) for those participants randomized to the <u>PPWL-only</u> or the <u>GWG+PPWL</u> arms, and will continue until 12-months postpartum. The PPWL intervention will provide at least monthly individual, telephone-based sessions (20-30 minutes each), as detailed in <u>Table 2</u>, by trained interventionists. (The number of possible telephone sessions will depend on the level of support needed by each participant to meet her weight loss goals). Similar to the GWG intervention, the PPWL intervention will focus on self-monitoring; weight, dietary intake and exercise goals; and problem solving.

Table 2. Stepped-Care Postpartum Weight Loss Intervention

	Step 1	Step 2	Step 3
Trigger to Increase Intervention Intensity	<0.5-1 lb of weight loss per week at any monthly session	<0.5-1 lb of weight loss per week for 2 consecutive biweekly sessions	N/A
Contact Frequency	-Monthly 20-30 minute telephone sessions	-Biweekly 20-30 minute telephone sessions	-Weekly 20-30 minute telephone sessions -Weekly emailed materials
Dietary Recommendations	500 calorie deficit, tailored to breastfeeding status	Same as Step 1 with portion size measuring and daily dietary intake monitoring	↓ by 100-200 calorie per day until recommended weight loss achieved
Exercise	-↑ exercise to pregravid levels -Fitness tracker	-↑ exercise to pregravid levels -Fitness tracker	-↑ exercise to pregravid levels -Fitness tracker
Behavioral Strategies	-Weekly self monitoring of weight -Weekly emailed graph	-Daily self monitoring of weight, daily food intake & exercise -Weekly emailed graph -Goal setting and problem solving	-Daily self monitoring of weight, daily food intake & exercise -Weekly emailed graph -Goal setting & problem solving -Meal replacements & structured meal plans - Adapted Look AHEAD ILI materials -Toolbox resources
Trigger to Reduce Intervention Intensity	N/A	Return to weight loss within recommended range	Return to weight loss within recommended range

Failure to lose weight based on the expected trajectory (i.e., 1 lb per week until returning to their pregravid weight (for women who are in any pregravid weight category) or until they have achieved a 5% weight loss (for overweight and obese women, if they desire)) will trigger an increase in the intervention intensity (i.e., moving to the next step). That is, failure to lose weight based on the expected trajectory at any monthly session for those in Step 1 will trigger an increase in the intervention intensity (i.e., moving to Step 2) and any participant in Step 2 who is losing less than the expected trajectory for two consecutive biweekly sessions will trigger an increase in the intervention intensity (i.e., move to Step 3).

Weight goals: Weight loss from birth to 6-weeks postpartum is fairly standard—approximately 6 kilograms (or 13 pounds)—regardless of pregravid weight category and GWG [29]. For women with a normal pregravid BMI, the PPWL goal (initiated at 6-weeks postpartum) will be to return to the pregravid weight. For women who were overweight or obese pre-pregnancy, the PPWL goal (initiated at 6-weeks postpartum) will be to at least return to their pregravid weight and, if desired, lose up to an additional 5% of their pregravid weight. All participants will be advised to lose weight at a rate of approximately 1 pound per week, which has been shown to not have adverse effects on infant growth or breast milk production. All women will be given a tailored graph indicating the recommended PPWL trajectory. They will be prompted to weigh themselves at least weekly on the electronic scale provided at baseline (which will upload the weight automatically to a secure website). The electronic scale will be issued to the subject as part of treatment on a hand receipt. Due to depreciation of the scale over 21 months of use during the study, the scales would be valued at near zero, and therefore subjects will not be required to return them. The electronic scales are part of the treatment and not considered a form of compensation for participating in the study. These weights will be plotted on a graph and emailed to them weekly along

with personalized feedback from their interventionist about their weight trajectory. The graph will clearly identify weight losses that are both greater than recommended and below recommendations. Participants who are losing weight faster than expected will be instructed to increase their caloric intake and to monitor their weight daily. Participants who lose more weight than expected at 2 consecutive monthly intervention sessions will be referred to their obstetrician for guidance, but will be retained in the study.

Dietary goals: Calorie goals will be based on their baseline caloric intake and their current breastfeeding status. Women who are breastfeeding will be given a calorie goal that allows for the additional energy expenditure of breastfeeding (i.e., an extra 450-500 calories). While the primary emphasis will be to stay within the prescribed goal, participants will be also encouraged to eat a balanced diet in line with the current U.S. Dietary Guidelines. Among women who are not losing weight at the expected rate who have self-reported calorie intakes within the specified goal ranges, decreases in their calorie goal will be made; this is predicated on the assumption that the actual energy intake is higher than the self-reported intake and that lowering the goal for self-reported intake will achieve an intake level that supports appropriate weight loss.

Exercise goals: When approved by their obstetrician, participants will be encouraged to gradually resume their pregravid levels of exercise. Participants will be advised to set an initial exercise goal of 100 minutes per week and gradually increase the amount of moderate exercise that they perform. Fitness trackers will be issued with a hand receipt to participants as part of treatment to facilitate the exercise goal. After 21 months, the value of the fitness tracker will be near zero due to depreciation and advances in technology; therefore, participants will not be asked to return the fitness trackers. The electronic scales are part of the treatment and not considered a form of compensation for participating in the study. If the participant's obstetrician recommends limiting physical activity, the exercise goal will be modified or halted. Participants will also receive guidance about their ability to resume strength training (e.g., push-ups, sit-ups) at their first (i.e., 6-weeks) postpartum visit with their obstetrician, consistent with standard clinic practice.

Common Intervention Components for the GWG and the PPWL Interventions: In both interventions, participants will be taught behavioral techniques, as needed, to assist them in meeting their weight, calorie, and exercise goals.

- **Self-monitoring:** Self-monitoring will consist of recording weight, caloric intake, and/or exercise, using a website or app. depending upon the intervention step (see Tables 1 & 2), participants will be given appropriate self-monitoring targets. Weight monitoring (at least weekly) will be conducted at all levels of intervention.
- **Feedback:** Participants will be taught to use weight, calorie and/or exercise monitoring as an ongoing source of feedback. A major role of the interventionist will be to monitor and evaluate the progress of participants and provide positive reinforcement for behavior changes. The interventionist will encourage small steps toward behavior change and will elicit personalized behavioral goals.
- **Goal setting:** The interventionist will engage the participant in goal setting to achieve the behavioral goals (i.e., caloric intake, exercise) likely to realize the GWG recommendations and PPWL goals. They will also identify their personal reasons for striving for healthy GWG and/or PPWL as a strategy to develop and maintain motivation.
- **Problem solving:** Participants will be taught to use problem solving strategies to deal with situations that pose difficulties for changing their eating and exercise habits (e.g., vacations, spouse deployment, work stress).

Meal replacements: Meal replacements appropriate for pregnant and postpartum women will be offered to those women at the highest "step" or intensity of the interventions, as a method to achieve their weight and calorie goals as well as a strategy to control portions. With an eye toward sustainability, we will use commercially-available meal replacements (e.g., Slim Fast, Better Oats oatmeal, Healthy Choice frozen meals), like we have in our ongoing Fit Blue trial (FWH20130095H) at Lackland AFB. Meal replacements will be purchased through food vouchers and through actual food provided (e.g., oatmeal packets) and given, at no-cost, to participants who are struggling the most in their gestational weight gain or postpartum weight loss (step 3 of the intervention, after they have not met goals for two sessions in a row). The food vouchers and actual food will differ in value, depending on the size of the food item (e.g., a 10-pack of oatmeal that is expected to last 5 days). However, we will spend approximately $3.00 for two meal replacements per day for these participants. These are not considered gifts nor a form of compensation, and are part of the treatment, for those who are struggling with the weight goals the most.

Participants will be encouraged to replace 2 meals with meal replacements and will be advised to consume a third meal of conventional foods. We will select meal replacements that meet the nutritional needs of pregnant and postpartum women and will provide detailed meal plans that recommend conventional foods to be consumed, to ensure a balanced diet appropriate for pregnant and postpartum women. They will be advised to use the meal plans as guidance for their third conventional meal or for all meals, if they refuse meal replacements at any point. Dr. Harvey, as a registered dietician, will guide the meal replacement choices and the Look AHEAD meal plan adaptation.

- **Toolbox:** The toolbox will include additional treatment options (e.g., providing exercise videos, lower calorie cookbooks, arranging a session with an exercise physiologist/trainer) for participants who need assistance in meeting weight, calorie or exercise goals, or coping with challenges in meeting these goals. The toolbox items are not considered a form of compensation, and will be returned to the research team.
- **Additional behavioral strategies:** As appropriate, the interventionist will introduce other behavioral strategies using adapted Look AHEAD ILI lessons on topics such as stimulus control, social support, and combating negative thinking.
- **Trained Interventionists with Military Knowledge:** A critical part of any military intervention is the ability of the interventionist to understand the culture and the language of the participants. A sentence like, "I just got my PCS orders and have to go to the CSS to start paperwork, which will require an OPR that my OIC wants by COB Friday, but first I have to take my fitness test," is the norm. To civilians, this appears to be gibberish, but all military personnel know these acronyms because they are part of everyday life. Interventionist credibility is extremely important and if the interventionist does not understand the common vernacular of an active duty member, they lose credibility. We have addressed this with our research staff by ensuring that we have retired military staff available to educate and answer any questions our non-military staff might have, and we strive to retain our trained interventionists across research projects. Our interventionists have Bachelor's or Master's degrees in applicable areas (i.e., social work, counseling/psychology, child development, and nursing). As a result, we have highly trained interventionists who are very familiar with military culture and experienced in delivering behavioral interventions. An interventionist will be paired with a participant at randomization and will continue working with the participant throughout the entire intervention, to facilitate social support.
- **Treatment Fidelity:** Based on our previous experience with behavioral interventions, we will utilize the following quality procedures to help ensure treatment fidelity: 1) detailed intervention protocol development; 2) careful interventionist proficiency and ongoing re-training; 3) recording of 10% of intervention sessions to provide corrective feedback on protocol adherence; 4) electronic documentation of all intervention contacts in the study database to monitor participant exposure to

treatment; and 5) weekly study meetings to review participants' adherence to structured protocols (based on the process data collected). These study meetings (attended by all interventionists and investigators) will also include problem solving related to challenging cases and refining skills.

3.6.2. Data Collection and Processing:
Measures will be obtained by trained staff who are blinded to treatment assignment. In-person follow-up data collection visits will be scheduled at gestational Week 32 and Week 36, as well as at 6-weeks, 6-months, and 12-months postpartum. If a study participant has moved out of the local area after enrolling in the study and continues to be a Tricare beneficiary, with the participant's permission, research staff will collect weight data via the participant's Body Trace scale uploads and other data instruments through the use of paper questionnaires mailed to the participant. In addition, telephone interventions will continue as normal per protocol. Relevant incentives (e.g., actual diapers given to participants) will be used to obtain high retention at all follow-up data collection visits. Incentives will not exceed the maximum amount specified by military policy. The diapers are an incentive and would be provided to a participant who attends the following data collection visits:

Year 1 ($50 limit)	32 week visit	Choice of: $15 worth of diapers, baby ointment, or wet bag
	36 week visit	Choice of: $15 worth of diapers, baby ointment, or wet bag
	6 week post-partum visit	Handprint keepsake ($10)
Year 2 ($50 limit)	6 month post-partum visit	Choice of: $15 worth of diapers, baby ointment, or wet bag
	12 month post-partum visit	Choice of: $15 worth of diapers, baby ointment, or wet bag

3.6.3. Setting:
Subjects will complete pre-screening, consent and data collection in the OB clinics at WHASC and SAMMC. Interventions will be completed via telephone.

3.6.4. Date(s):
Participants will be involved in study related activities for twenty-one months from the time of enrollment.

3.6.5. Source of Research Material:

Source of Research Material per Participant (Procedures)	**# Routine Care**	**# Research Driven**	**# Total Procedures**
Research Project Medical Clearance	0	1	1
Screening Visit Interview Questions	0	1	1
Weight	12	7	19
Height	0	5	5
Abdominal Circumference	0	3	3
Contact information	0	7	7
Demographics	0	1	1
International Physical Activity Questionnaire	0	5	5
Breastfeeding Questions	0	2	2
EPDS Depression Screener	3	3	6
Military Fitness Test Scores	0	2	2
Program Evaluation	0	2	2
Modified Pregnancy-Unique Quantification of Emesis and Nausea Index	0	2	2
Weight Gain Recommendations	0	1	1

3.6.6. Subjects:
Study participants will be female, active duty military personnel stationed at Joint Base San Antonio.

3.6.7. Inclusion/Exclusion Criteria:
Inclusion:

- Participants will be female, DoD Tricare beneficiaries (Active Duty military, retirees and dependents) living in the San Antonio, Texas area receiving medical care at Joint Base San Antonio, and at least 18 years old.
- Participants must be less than 12 weeks gestation upon recruitment (based on the date of their last menstrual period and confirmed by first trimester ultrasound at the first prenatal visit).
- Participants must be within the normal, overweight, or obese BMI ranges upon Baseline measurement.
- Participants must plan to live in the San Antonio, Texas area for at least 1.5 years.

Exclusion:

- Participants who have any medical conditions that limit a participant's ability to engage in changes in dietary intake or increases in physical activity, based on the determination of physicians on the study team.
- Participants who have a high-risk pregnancy (i.e., Type I or II diabetes at conception or current multiple gestation), based on the determination of physicians on the study team.
- Participants who smoke at the time of conception (smoking cessation during pregnancy has significant benefits for fetal health, but the quitting process can be associated with weight gain and thus offers potential study confounds)

3.6.8. Instrumentation:

- Contact information
- Demographics: Participants will complete a questionnaire regarding their age, parity, race, and ethnicity.
- Physical Assessment:
  - Weight: At all measurement visits, weight will be recorded in kilograms. 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 pregravid weight (before the last menstrual period). 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.
  - Waist Circumference: As an indicator of subcutaneous and visceral abdominal fat, waist circumference will be measured (recorded in centimeters) using a non-distensible measuring tape and standard protocols for positioning.
  - Height: Height, using a wall-mounted stadiometer, will be recorded in centimeters. BMI will be calculated from measured weight and height.
- Physical Activity: We will assess physical activity, subjectively, using the International Physical Activity Questionnaire, as it has been used in other studies of gestational/postpartum weight management, has been validated against accelerometry, and has good test-retest reliability. We will also assess physical

activity objectively using the Actical accelerometer. Participants will be asked to wear the accelerometer for 7 days, including 2 weekend days and 3 weekdays.

- Weight Gain Recommendations: We will assess knowledge of weight gain recommendations at the Baseline visit, before randomization. One previous study has shown the gestational weight gain expectations, in a civilian population, predicted actual pregnancy weight gain; however, it is not certain whether this finding will replicate in a military population.
- Feeding Practices: Participants will be asked whether their child is being breastfed, partially breastfed (supplemented daily with formula or milk), or fully formula fed and whether solid foods are eaten daily. In addition, the duration of breastfeeding will be assessed. Breastfeeding status will also be used to calibrate postpartum calorie goals.
- Depression: Screening for depression at the first prenatal visit, 28 weeks gestation and at the 6-weeks postpartum visit is standard practice by the WHASC and SAMMC obstetric clinics using the Edinburgh Postnatal Depression Scale. We will obtain these scores from the participants' medical record. In addition, we will assess depression at the 6-weeks, 6-months and 12-months postpartum data collection visit, so we will be able to examine whether our results vary based on the presence of depression.
- Fitness Test Scores: We will obtain the final pregravid and the first postpartum fitness test score from active duty participants to be able to examine the impact of the interventions.
- Program Evaluation: Program satisfaction will be assessed to offer insight into program acceptability as well as barriers and facilitators to participation in each intervention arm. We will adapt the treatment satisfaction measure we are currently using in our "Fit Blue" study to evaluate acceptability and examine feedback on specific intervention aspects, which will inform program refinement and future implementation.
- Medical Outcomes and Health Care Utilization: Pregnancy-related medical outcomes will be obtained from the participant's medical record and will include: maternal (e.g., gestational diabetes, preeclampsia) and fetal conditions; type of delivery; Apgar score; gestational age at delivery; and birth weight and length of the infant. Length-for-age, weight-for-age and weight-for-length Z-scores will be calculated using the Center for Disease Control and Prevention (2000) reference data. Health care utilization (counts of ambulatory visits by type [physician, imaging, lab, other] and hospital/NICU admissions, hospital days) for mother and child will also be captured.

4.0. Human Subject Protection:

4.1. Recruitment:

Participants will be recruited through presentations from research staff and advertisements located in the OB clinics at WHASC and SAMMC as well as other appropriate areas of JBSA. Persons interested in learning more about the study may call the study phone number, or can request a call back or email through the website or in person event. We plan to use flyers, business cards, posters, newspaper, word-of-mouth, and electronic advertisements in base bulletins. Advertisements will include a phone number by which to reach study personnel for more information.

4.2. Consent Processes:

No study specific procedures will be performed without a written and signed informed consent document and HIPAA Authorization. Participants who do not demonstrate the ability to understand or the willingness to sign the written informed consent document will be excluded from study entry.

4.3 Participation Compensation:
Subjects will not be paid for participation in this study, however they will receive incentives, such as diapers, diaper ointment, wet bag, and a handprint keepsake for attending data collection visits as described in section 3.6.2.

4.4. Assent Process: N/A

4.5. Benefits:
Participants may increase their knowledge about healthy eating and physical activity. However, there is no guarantee or promise of direct benefit for subjects participating in the study.

4.6. Risks:
All study procedures involve only minimal risks to subjects. Since regular exercise will be encouraged, some people may experience some muscle soreness. There are no major risks associated with taking measurements (height, weight, and waist circumference), taking a health history or collecting questionnaire data. There is, however, the potential risk of loss of confidentiality. Although, we do not anticipate that any study related procedures would increase a participant's risk of suffering from emotional distress or having thoughts of suicide, study procedures are in place so that research staff can respond appropriately if this should occur (see section 4.9 for description of Study Procedures for Distressed Participants).

4.7. Costs: N/A

4.8. Safeguards for Protecting Information
The research consents and study related documents will be stored in a locked cabinet in a locked room. All research data including participant demographics will be kept in an electronic database, which will be encrypted, double password protected and the access will be restricted. The research database, consents, and study related documents will be securely maintained for six years after the closure of the study. The research data will not be utilized for further research activity beyond the protocol stipulations without additional IRB approval.

Identifiable research data will be entered electronically into a database housed at UTHSC via a secure connection using Cisco VPN client. The data will be encrypted, double password protected, and access will be restricted. The research database will be managed and maintained at UTHSC. Upon completion of the study protocol, UTHSC will destroy paper forms and links according to IRB procedures.

4.9. Safeguards for Protecting Subjects:
The principal investigator will be responsible for the protocol safety monitoring. The PI will make study documents readily available for inspection by the local IRB and oversight staff for confirmation of the study data.

Study procedures for distressed participants were developed for research staff to follow in the event that a participant is suffering from emotional distress or having thoughts of suicide.

Several precautions have been taken to both limit the likelihood of participants suffering from a significant psychological event and in the unlikely event that one occurs, we have established appropriate steps for the Counselor to follow in order to get the participant help.

A. PRESCREENING FOR DISTRESS

1. All prospective participants are pre-screened by a military medical provider who both screens the participants in person and reviews their electronic medical record. Specifically, all prospective participants are asked whether they have any "Emotional or psychiatric conditions (depression, schizophrenia)"asked on the HEALTHY PREGNANCY *Research Project Medical Clearance Form.*

2. Additionally, all patients (including the enrolled participants) at OB orientation and at 6-weeks postpartum are administered the 10-item Edinburgh Postnatal Depression Scale (EPDS) as a part of routine pregnancy care. Responses indicating an increased likelihood of depression are addressed by the prenatal care procedures at the medical facility. Please see attached SAMMC Standard Operating Procedure 36 and WHASC Operating Instruction 44-11.
    1. At 6-months and 12-months postpartum the research staff will administer the Edinburgh Postnatal Depression Scale during in-person data collection visits.
        a. If the participant scores a 10 to 12 on the EPDS, the participant is possibly experiencing depression.
        b. If the participant scores a 13 or greater on the EPDS, the participant is likely experiencing depression.
        c. Both these situations should be brought to the attention of a mental health professional.
            i. Participants will be referred to the Behavioral Health Optimization Program (BHOP) at the WHASC Family Health Clinic. BHOP can be reached by phone at 292-1159; same-day appointments are also offered.
            ii. The BHOP service is available to all active duty members. BHOP providers are authorized to document visits in AHLTA so that the encounter notes are available to other authorized users.
    2. If the following response is endorsed by the prospective/enrolled participant, the Counselor will probe briefly for more information about the circumstances of their distress, including potential suicidality.
        a. Critical responses are:
            i. Item 10 ("The thought of harming myself has occurred to me"): Responses 1 ("Yes, quite often") and 2 ("Sometimes").
        b. The Counselor will ask whether the participant has a plan to harm herself (to act on her suicidal thoughts) by asking:
            i. Do you have thoughts about suicide?
            ii. If yes, do you have a plan to hurt yourself?

A. STUDY PROCEDURES FOR PARTICIPANT DISTRESS, IN-CLINIC OR VIA TELEPHONE

1. **MILD TO MODERATE DISTRESS (NO THOUGHTS OR INTENT OF HARM TO SELF OR OTHERS)**
    a. During the in-clinic visits or via telephone, if the participant reports mild to moderate stress (but no suicidal thoughts or morbid ideations such as thoughts of wanting to be dead), the participant will be asked to make an appointment with primary obstetric provider or primary care provider. The patient will also be provided a listing of community resources and encouraged to seek help.
    b. Counselor will help the participant develop an action plan to be seen by a mental health professional should their distress persist over multiple sessions or worsen.
    c. Counselor will document the conversation and support materials provided.
    d. Continued distress without professional assistance and support can be a reason to temporarily or permanently withdraw the participant from the **GWG** or **PPWL** Intervention protocol. Due to safety concerns, notification of withdrawal from the study based on continued distress will result in formal notification of the participant's command.

2. **SEVERE DISTRESS AND THOUGHTS OR INTENT OF HARM TO SELF OR OTHERS WITH NO INTENT OR PLAN** Participant reports suicidal thoughts or thoughts of harming others but **no** intent or plan.
   a. Counselor will develop an action plan to get help from a mental health professional. This conversation with the participant and the action plan will be documented.
   b. Counselor will follow-up in two business days to ensure that the participant has an appointment with mental health scheduled.
   c. Counselor will also inform the participant that if their condition worsens the following emergency resources are available:
      1) Mental Health Clinic in WHASC (open for Walk-Ins during duty hours: 210-292-7361)
      2) SAMMC Emergency Department: 210-916-0808
      3) Crisis Hotline call: 1-800-273-TALK

3. **SEVERE DISTRESS AND PLANS OR CLEAR INTENT TO HARM SELF OR OTHERS**
   a. Participant reports suicidal thoughts or thoughts of harming others and intent or plan.
   b. Once a participant endorses suicidal intent the counselor will attempt to keep them on the phone.
   c. Whether the Counselor – Participant contact is by phone or in-person, the Counselor will attempt to maintain contact with the participant, identify the location of the Participant and maintain verbal contact until help arrives.
   d. Counselor will contact another staff member and indicate they have an emergency and direct them to call the appropriate emergency number (911; Lackland Command Post: 210-671-4225; Security Forces: 210-671-3030; Ambulance: 210-292-7331; SAMMC Police Duty Officer 210-916-4141) and provide an address.
   e. Counselor will document the conversation with the prospective participant and all actions taken.

B. DOCUMENTATION OF ADVERSE EVENTS

1. Incidences of EPDS scores greater than or equal to 10 may be documented as adverse events.
2. In the event of an adverse event, the participant should be followed to resolution of the event, or to its stabilization.

4.9.1. Minimizing Risks:

This study follows evidence-based lifestyle recommendations for weight management and improving health, including diet change and regular exercise. If followed according to program guidelines, no adverse medical conditions are expected to result from the research activities.

There are no major risks associated with taking measurements (i.e. height, weight, and waist circumference), taking a health history or collecting questionnaire data. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep participant information confidential as described in Section 4.8. In the event that questions asked make participants feel uncomfortable, they may refuse to answer and may take a break at any time during a study visit. However, we are not collecting any information that would in any way jeopardize participants' careers

Any significant new findings developed during the course of this research project, which may impact upon the safety and efficacy of the procedure or treatment under study and consequently influence participants' willingness to continue participation, will be provided to them.

4.9.2. Vulnerable Populations: Pregnant women

4.9.3. Clinical Care:
As all participants will be female active duty military members and DoD TRICARE beneficiaries, medical care (if needed) is provided at no cost through their Military Treatment Facility (MTF).

4.9.4. Injury Compensation: N/A

4.9.5. Data Safety Monitoring:
The trial will be conducted in compliance with this protocol, International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), and any applicable national and international regulatory requirements. The principal and associate investigators will be monitoring all aspects of the study in accordance with the appropriate regulations in order to:

1) Ensure protection of study subjects, compliance with the protocol, and accuracy and completeness of records.
2) Verify the prompt reporting of all data points, including reporting Serious Adverse Events (SAEs) and checking availability of signed informed consent,

Note: A Data Safety Monitoring Plan (DSMP) will be developed for this study and the Data Safety Monitoring Board (DSMB) will meet yearly to review participant safety.

5.0. Alternatives:
Alternatives include not participating in the study, consulting with their Primary Care Provider (PCP) or OB clinician to assist them with weight management efforts, or self-monitoring of dietary intake and physical activity to achieve weight management during pregnancy and postpartum. Meal replacements may also be bought at local stores.

6.0. Data Analysis:
We will analyze changes in weight and abdominal circumference, as well as data based on other measures from baseline, gestational Week 32 and Week 36, as well as at 6-weeks, 6-months, and 12-months postpartum.

6.1. Outcome Measures:
The primary study outcomes will be a comparison of GWG from baseline to the final gestational weight (either week 32 or week 36, depending on the delivery date) as well as a comparison of weight loss from 6-week postpartum to 12-months postpartum for the 3 intervention arms.

6.2. Sample size estimation/power analysis:
The study aims to enroll 755 (with the intent for 450 subjects completing the study) participants, 150 participants in each group. This distribution will provide a diverse representation within each intervention group and will provide the necessary information for data and power analysis.

6.3. Statistical Analysis:
All of the analyses will be performed with SASv9.4. Data will be examined for distributional normality and outliers prior to any analyses. Descriptive statistics will be generated for all variables of interest included in the analysis, overall and by treatment arm. Univariate comparisons will consist of t-test, chi-square test, ANOVA, and their respective non-parametric counterparts if needed, for continuous/categorical variables respectively. Primary analyses will be intention-to-treat, without regard to intervention adherence. We will use multivariable linear ANCOVA-like regression models for continuous outcomes, to model and compare

the GWG (Hypothesis 1) and PPWL (Hypothesis 2), in the 3 arms. Using these models, treatment effects will be estimated and tested by comparing change in group-specific means at the final prenatal visit and 12-months postpartum conservatively adjusting for baseline differences (which will be minimal by virtue of randomization) and in the case of hypothesis 2 for 6-weeks postpartum weight differences.
Randomization validity will be assessed by comparing arms on baseline measures using chi-square tests, ANOVAs and other appropriate tests. If imbalances are found, we will consider adjusting the between-group analyses for potential confounders.

6.4 Number of Subjects:

Number of subjects planned for WHASC/SAMMC	Enrolled in full study	755	to result in	450	completing the full study

TOTAL NUMBER OF SUBJECTS (nation-wide/study-wide):___755___

7. Duration of Study: Approximate duration of the study: 72 months

8. Local and External Support Services: A letter of support from the 59th MDW Commander is attached.

9. Intramural (GME) and Extramural Funding Support:
The National Institute of Diabetes and Digestive and Kidney Diseases provided extramural funding for this study.

10. Conflict of Interest:
If you or any investigator participating in the repository has, or anticipates having, any income from or financial interest in: the sponsor of the repository protocol, the supporting organization, or the company that owns/licenses the technology being studied, contact the WHASC IRB. A "Conflict of interest exists if an employee's position or authority may be used to influence or make decisions that lead to any form of financial or personal gain for that employee or for his or her family which includes spouse or dependent children." [NOTE: A conflict of interest or even the appearance of conflict calls into question the judgment or actions of the investigator in areas that affect the rights and welfare of research subjects and the integrity of the research process. At its worst, conflict of interest may endanger lives, e.g., not only those of the immediate research subjects under study, but those of future patients treated on the basis of biased research results.]

a. Financial Conflict of Interest: None
b. Personal Conflict of Interest: None
c. Current Off-Duty Employment: None

11. Use of an Investigational New Drug, use of a Drug for a non-FDA approved purpose, use of an investigative device or use of a placebo:

This research uses an Investigational New Drug	**[ ] YES [x] NO**
This research uses a FDA approved drug for a non-FDA approved purpose	**[ ] YES [x] NO**
This research uses an Investigational Device	**[ ] YES [x] NO**
This research uses a placebo.	**[ ] YES [x] NO**

12. Medical Research Area for the Study: (Pick as many as appropriate)

[] Analytical Chemistry	[] Anatomy	[] Anesthesiology	[] Biochemistry
[] Cardiovascular Surgery	[] Cardiology	[] Cell Biology	[] Dentistry
[] Dermatology	[] Dietetics	[] Electrophysiology	[] Endocrinology
[] Emergency medicine	[] Gastroenterology	[] General Surgery	[] Hematology
[] Histology	[] Immunology/Allergy	[] Infectious Disease	[] Microbiology
[] Molecular Biology	[] Neonatology	[] Neurology	[] Neurosurgery
[] Nursing	[x] OB/GYN	[] Occupational Medicine	[] Occupational Therapy
[] Oncology	[] Ophthalmology	[] Oral/Maxillofacial Surgery	[] Orthopedics
[] Pathology	[] Pediatrics	[] Pharmacology	[] Physical Therapy
[] Mental Health	[] Radiology/Imaging	[] Urology	[x] Wellness
[x] Other (state): Prevention, Behavioral			

13. Attachments:

1. Informed Consent Document
2. HIPAA Authorization Document
3. Letter of Support - 559 MDW/CC
4. Letter of Support- Fitness Center
5. Letter of Support- SAMMC Dept. of OB/GYN
6. Letter of Support- WHASC Women's Health Services
7. Extramural Funding Support Document
8. Medical Clearance Letter
9. Self-screener form
10. Screening Visit Interview Questions form
11. Contact information form
12. Demographics form
13. Physical Assessment Form (screening, baseline & follow-up visits)
14. International Physical Activity Questionnaire
15. Infant Feeding Questionnaire
16. Edinburgh Postnatal Depression Scale
17. Program Evaluation
18. Participant Lesson Outline
19. Recruitment electronic/newspaper advertisement
20. Data Safety Monitoring Plan (DSMP)
21. Form A-2
22. Form A signature sheet
23. Research Involving Pregnant Women, Human Fetuses, and/or Neonates Form
24. Modified-Pregnancy-Unique Quantification of Emesis and Nausea (Modified-PUQE)
25. Moms Fit2 Fight Pamphlet
26. Superheroes Flyer
27. Time is Running Out Flyer
28. Business Card
29. Weight Gain Recommendations