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Moms Fit 2 Fight: Rationale, Design, and Analysis Plan of a Behavioral Weight Management Intervention for Pregnant and Postpartum Women in the U.S. Military

Margaret C. Fahey, MA^a, G. Wayne Talcott, PhD^{b,c}, Callie M. Cox Bauer, DO, FACOG^d, Zoran Bursac, PhD^c, Leslie Gladney, MS^{b,c}, Marion E. Hare, MD, MS^{c,e}, Jean Harvey, PhD^f, Melissa Little, PhD, MPH^g, Deirdre McCullough, MD^d, Ann S. Hryshko-Mullen, PhD^h, Robert C. Klesges, PhD^{b,c}, Mehmet Kocak, PhD^c, Teresa M. Waters, PhD^c, and Rebecca A. Krukowski, PhD^c

^a Department of Psychology, The University of Memphis, Memphis, TN, USA

^b Department of Public Health Sciences, University of Virginia, School of Medicine, Charlottesville, VA, USA

^c Department of Preventive Medicine, University of Tennessee Health Science Center, Memphis, TN, USA

^d Department of Obstetrics and Gynecology, Brooke Army Medical Center, San Antonio, TX, USA

^e Department of Pediatrics, University of Tennessee Health Science Center, Memphis, TN, USA

^f Department of Nutrition and Food Sciences, The University of Vermont, Burlington, VT, USA

^g Center for Addition and Prevention Research, University of Virginia, School of Medicine, Charlottesville, VA, USA

^h Defense Institute for Medical Operations, Joint Base San Antonio-Lackland Air Force Base, San Antonio, TX, USA

The Department of Defense military health system (TRICARE), serving approximately 9.4 million individuals (i.e., active duty personnel, retirees, spouses, children), spends \$1 billion annually on excessive weight and co-morbidities [1–4]. Further, about 44% of TRICARE beneficiaries, similar to the general population, exceed gestational weight gain (GWG) guidelines [5–8].

Excessive GWG is a risk factor for perinatal and delivery complications (e.g., gestational diabetes) [9–12] and negative health outcomes for infants (e.g., childhood obesity) [11–17]. Increased GWG is associated with postpartum weight retention, placing the mother and fetus at risk for negative outcomes in subsequent pregnancies [13, 17–21], and increasing the likelihood that the mother will develop long-term overweight or obesity [22, 23]. Given that

Corresponding Author: 33 N Rembert Street #4 Memphis, TN 38104; mcfahay@memphis.edu.

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TRICARE spends more on pregnancy and childbirth-related hospital costs than any other type of hospital admission (\$782 million), excessive GWG burdens the national health care budget [1, 24].

Among active duty personnel, women have significantly lower fitness scores 6-months postpartum compared to pre-pregnancy [25, 26]. Personnel who fail a fitness test risk losing their career, health insurance, and pension if they have not served 20 years. Recruiting and training replacements is costly (\$50,000 or more per person) [2]. Thus, failure to maintain fitness standards negatively impacts military costs, women's military careers, and military readiness (the ability to mobilize quickly for national defense) [26, 27]. Thus, there is a critical need for interventions to support readiness for pregnant and postpartum personnel.

Fortunately, excessive GWG and postpartum weight retention are strongly influenced by health behaviors [10, 28–32]. Reviews have found that interventions promoting modifications in diet and exercise along with training and support for behavioral techniques (e.g., goal setting, problem solving), have been the most effective for healthy GWG and postpartum weight loss (PPWL) [33–43]. However, due to heterogeneous outcomes and settings across studies, the most efficacious treatment modalities, components, and intensity are undetermined [37, 40, 43].

Thus, this study implements a novel stepped-care behavioral program based on the Look AHEAD (Action for Health in Diabetes) intensive lifestyle intervention (ILI) [44–46]. Look AHEAD uses weight management strategies (e.g., diet and exercise modifications) consistent with effective GWG and PPWL interventions [47–49]. The stepped-care approach tailors the intervention intensity, thus, practically allocating resources to participants experiencing the most challenges. The current study also accommodates to the military lifestyle (e.g., managing stressors related to deployment, environmental facilitators such as fitness centers) [50]. Because face-to-face support is less feasible among military families [51], this study implements a telephone-based intervention supplemented by email and electronic-scales in order to reduce treatment barriers. Further, a telephone-based Look AHEAD ILI has previously been shown to effectively promote significant weight loss in a military setting [52].

This paper describes the design and analysis plan for an ongoing randomized clinical trial of a behavioral stepped-care GWG and PPWL intervention tailored to accommodate military culture. The study aims to determine if the GWG intervention, PPWL intervention, or a combination of the two interventions are effective in improving healthy GWG and PPWL, maternal and child health outcomes, and military readiness.

2. Material and Methods

2.1 Design Overview

The study design is a stepped-care gestational weight gain intervention and a postpartum weight loss intervention for active duty military personnel and other TRICARE beneficiaries. The study is randomizing participants to one of three conditions: a gestational weight gain intervention (GWG-only), a postpartum weight loss intervention (PPWL-only),

or a combined gestational weight gain and postpartum weight loss intervention (GWG + PPWL). This novel design allows the PPWL-only condition to be the comparison group for GWG (at the final pregnancy follow-up visit at 36-weeks gestation). The GWG-only condition is the comparison group for PPWL-only, and the GWG+PPWL condition will determine the combined effects of both conditions.

2.2 Study Aims and Hypotheses

The primary aim of the study is to determine if the GWG intervention, PPWL intervention, or a combination of the two interventions are effective in improving healthy GWG and PPWL. We hypothesize that participants randomized to the GWG-only and GWG + PPWL conditions will gain significantly less weight during pregnancy (i.e., screening to 36-weeks gestation) than those randomized to the PPWL-only condition. Secondly, we hypothesize that participants randomized to the GWG + PPWL and PPWL-only conditions will lose significantly more weight postpartum than those randomized to the GWG-only condition at 6-months postpartum. The secondary aim is to explore the impact of the interventions on pregnancy-related health outcomes and health care utilization. Additionally, fitness test outcomes (pre-pregnancy to 12-months postpartum) for those participants who are active duty military personnel will be examined. Finally, we will determine the impact of treatment-engagement (e.g., session participation, self-monitoring, and meal replacement adherence) on intervention outcome.

2.3 Participant eligibility and exclusions

Participants are TRICARE beneficiaries aged 18 years or older who reside in the San Antonio, Texas area. Active duty participants must have at least 1.5 years left in their current duty assignment to ensure the likelihood of completing in-person follow-up visits. Participants must be less than 12-weeks gestation (based on the date of their last menstrual period and physician report at first prenatal visit) upon screening and less than 13 weeks and 5 days gestation upon randomization [53]. Past research has shown that GWG interventions initiated prior to 12-weeks gestation were the most effective [40]. Sufficient recruitment in an underweight BMI category to allow for comparisons is unlikely, so these participants are excluded. Exclusion criteria include medical conditions that limit the ability to engage in dietary changes and increases in physical activity (e.g., uncontrolled congestive heart failure) or which may contribute to weight changes (e.g., uncontrolled thyroid disease). Additionally, current use of weight loss medication or medication affecting weight (as identified by each participant's physician), presence of unstable emotional or psychiatric conditions (e.g., depression, schizophrenia), and history of bariatric surgery or significant recent weight loss (> 4.5 kg in the past 3 months) are exclusion criteria. Participants with high-risk pregnancies before randomization (i.e., Type I or II diabetes or current multiple gestation) and those smoking regularly (i.e., more than 5 cigarettes per day) within the six months prior to conceiving the baby are also excluded. Smoking cessation creates significant fetal health benefits [54] but can also contribute to weight gain [55]; thus, women who report smoking at the screening visit are excluded. However, women who develop gestational diabetes after randomization are retained in the study. The total target sample size is 450 participants (See 2.12 Power Calculation and Statistical Analyses).

2.4 Recruitment, screening, and randomization

Materials at the Wilford Hall Ambulatory Surgical Center and the San Antonio Military Medical Center publicize the study (e.g., presented at the pregnancy orientation visits, posted in waiting rooms and exam rooms, listserv advertisements, referrals from health care providers, and posters in public areas). These materials direct interested individuals to complete a self-screener with a study staff member or to call the study telephone number to learn more and determine if they meet eligibility criteria. Participants can learn more about the study on the study website: <https://momsfit2fight.uthsc.edu/>. Those eligible are invited to schedule a screening visit. At this visit, eligibility is assessed, informed consent is obtained, and measures are administered. Participants are asked to complete a one-week dietary and exercise self-monitoring run-in as well as obtain medical clearance from their obstetrician. Following the screening visit and successful completion of the self-monitoring and the medical clearance, participants are randomized to one of the three conditions using a computerized randomization designed by the study statistician (ZB) blocked by baseline BMI category and parity status during the baseline visit. This randomization procedure ensures that participants are equally distributed to each condition with each BMI category and parity status. Assignment is revealed by the study database to the study staff, and participants are subsequently notified by non-blinded study staff with relevant intervention information.

2.5 Intervention Core Components

The stepped-care approach is designed to allow for the greatest tailoring of intervention intensity and resources to each individual (e.g., within obstetric practices, utilizing existing military resources like dietitians). The intervention is delivered telephonically in order to optimize its disseminability to military personnel. Difficulty in meeting the recommended weight gain/loss trajectory will trigger an increase in intervention intensity (i.e., moving to the next “step.”) (Table 1 and 2). However, when participants consistently meet the recommended weight gain trajectory, they experience a decrease in intervention intensity (Table 1 and 2). Participants meeting the weight goals early but having challenges meeting guidelines later in the intervention will trigger an increase in intervention intensity when this extra assistance is needed. Description of intervention steps are provided in Table 1 and 2.

Participants are taught behavioral techniques, as needed, to facilitate meeting weight, calorie and exercise goals consistent with those used in the Look AHEAD ILI [44]. Depending on the intervention step, participants are encouraged to meet self-monitoring targets (i.e., record weight, calorie intake, and exercise). However, regardless of intervention step, daily weight monitoring is promoted as an effective source of ongoing feedback for both the participant and interventionist. Dietary and physical activity self-monitoring are essential strategies used in other weight management interventions [56–60] and have been shown to prevent excessive GWG [42, 61, 62] and to promote PPWL [48, 62]. Thus, dietary and physical activity self-monitoring are encouraged for participants in Step 2 and 3 of the intervention (Table 1 and 2). The interventionist monitors and evaluates progress, provides positive reinforcement for behavior changes, and elicits personalized behavioral goals [63].

Goal setting is an important aspect of behavior change programs [64], and specifically, pregnancy-related weight management programs [65]. Thus, the interventionist encourages goal setting to achieve behavioral changes (i.e., calorie intake, exercise), as well as GWG and PPWL goals, with an emphasis on identifying these goals in Step 2 (Table 1 and 2). As a strategy to develop and maintain motivation, participants describe personal reasons for striving for healthy GWG and PPWL. Problem solving strategies [66, 67] help participants deal with situations that pose difficulties for changing their eating and exercise habits (e.g., vacations, deployment, work stress).

Participants at the highest “step” (i.e., Step 3, the highest intensity of the intervention) are offered meal replacements appropriate for the nutritional needs of pregnant and postpartum women [68] (Table 1 and 2). Previous research suggests that meal replacements enhance weight loss in general behavioral weight loss programs, on average, by approximately two kilograms (kg) [69]. This method helps achieve weight and calorie goals and is a strategy to control portions. To encourage sustainability after completion of the intervention, commercially available meal replacements are used (i.e., Better Oats™ oatmeal, Healthy Choice™ frozen meals), which are similar to those used in previous military-focused research [50]. Participants are encouraged to replace two meals with meal replacements and to consume a third meal of conventional foods. Detailed meal plans to ensure a balanced diet appropriate for pregnant and postpartum women offer guidance for the third conventional meal, or for all meals, if the participant refuses meal replacements at any point.

Participants who need further assistance in meeting weight, calorie, and exercise goals, or need help coping with these challenges receive a toolbox of additional treatment options (e.g., exercise videos, food scales, lower calorie cookbooks). The items can be checked out, but must be returned prior to the completion of the study (as the military limits the overall value of items provided to research participants). As appropriate, the interventionist will introduce other behavioral strategies using adapted Look AHEAD ILI lessons on topics such as managing restaurant eating, stimulus control, social support, and combating negative thinking.

2.6 GWG Intervention

Participants randomized into the GWG-only or the GWG + PPWL conditions receive individual telephone-based sessions (20–30 minutes each) by trained interventionists who encourage self-monitoring, clear goals (i.e., weight, dietary intake and exercise goals) and problem solving focused on gestational weight gain (Table 1). The number of telephone sessions depends on the gestational age at randomization and the level of support needed to meet Institute of Medicine (IOM) weight gain guidelines. Participants that gain weight above GWG recommendations for the gestational week increase the intervention intensity (i.e., move to the next step) (Table 1).

2.6.1. GWG weight goals.—The GWG weight goals for each participant are consistent with the 2009 IOM guidelines [27], based on screening weight. Weight gain goals are 11–16 kg for normal weight women (BMI 18.5–25.9 kg/m²), 7 to 11.5 kg for overweight women (BMI 25–29.9 kg/m²) and 5 to 9 kg for obese women (BMI 30–39.9 kg/m²). Weight self-

monitoring is a central feature of the intervention at all steps. Frequent self-weighing is a key component to weight management programs [70–73] and has been shown to be important in GWG-focused interventions as well [74]. Participants are encouraged to weigh themselves daily using the Body Trace™ e-scale, given to them at baseline. Each time a participant self-weighs, the e-scale uploads the weight automatically to a secure website, which can be accessed by the participant and the interventionist. In addition, the participant receives weekly emails from their interventionist with a weight graph tailored to their pre-pregnancy BMI, current weight trajectory, and personalized feedback. Those who gain less weight than the guidelines are instructed to increase their caloric intake and to monitor weight daily. Those who are 5 pounds below the guidelines for two consecutive weeks are referred to their obstetrician for guidance but are retained in the study.

2.6.2. GWG dietary goals.—Reflecting the IOM recommendations, it is recommended that participants consume the same number of calories in the first trimester as pre-pregnancy, based on their self-monitoring run-in diary. In the second and third trimester, the recommendation is to increase baseline intake, in order to meet their BMI-tailored GWG goal. Further, instructions are consistent with a healthy diet recommended for pregnant women (e.g., limiting large fish consumption to manage mercury intake) and emphasize the consumption of fruits, vegetables and whole grains [75]. Previous research suggests that individuals are often inaccurate in their assessment of caloric intake [76], thus instructions are given in food label reading and measuring to improve self-monitoring accuracy. At the randomization visit, participants in the GWG-only and GWG+PPWL conditions receive measuring cups and spoons to facilitate portion size estimates. Women who gain an excess of the guidelines, yet report calorie intake within the specified goal ranges, are recommended to decrease calorie goals. Decreasing calorie goals is based on the assumption that the actual energy intake is higher than self-reported intake; thus, lowering calorie goals will achieve an intake level that supports appropriate GWG.

2.6.3. GWG exercise goals.—Participants are encouraged to engage in 150 minutes per week of moderate exercise, consistent with the American College of Obstetrics and Gynecology [27, 77]. Research suggests this level of exercise during pregnancy reduces excessive GWG [28, 30]. Participants receive Fitbit Flex 2 activity trackers to facilitate reaching these goals. Previous research on GWG interventions suggests objective physical activity feedback is beneficial [47, 78, 79]. If the participant's obstetrician recommends limiting physical activity or complete bed rest, the exercise goal is modified or halted.

2.7 PPWL Intervention

Participants randomized into the PPWL-only or the GWG + PPWL conditions receive individual telephone-based sessions (20–30 minutes each) at least monthly by trained interventionists from 6-weeks postpartum until 12-months postpartum. The number of telephone sessions depends on the level of support needed to meet weight loss goals. Similar to the GWG intervention, the PPWL intervention focuses on self-monitoring, clear goals (i.e., weight, dietary intake and exercise goals), and problem solving. Failure to follow the recommended weight loss trajectory triggers an increase in intervention intensity (i.e., moving to the next step) (Table 2).

2.7.1. PPWL weight goals.—Standard weight loss from birth to 6-weeks postpartum is approximately 6 kg regardless of prepregnancy weight and GWG [80]. For women with normal pre-pregnancy BMI, the PPWL goal (initiated at 6-weeks postpartum) is to return to pre-pregnancy weight. For women with an overweight or obese prepregnancy BMI, the PPWL goal (initiated at 6-weeks postpartum) is to at least return to pre-pregnancy weight and, if desired, lose up to an additional 5% of pre-pregnancy weight. All participants are advised to lose weight at one pound or approximately 0.45 kg per week, which has been shown to not adversely affect infant growth [68, 81] or breast milk production [82]. Participants are encouraged to weigh themselves daily on the Body Trace™ e-scale, and weights are uploaded automatically to a secure website, which can be accessed by the participant and the interventionist. In addition, participants receive weekly emails from the interventionist of their personalized weight trajectories and feedback. Feedback emphasizes weight loss that is either greater or less than recommended. Participants who lose weight much faster than expected are instructed to increase caloric intake and to monitor weight daily. Those who lose more weight than expected for two consecutive weeks are referred to their obstetrician for guidance but retained in the study.

2.7.2. PPWL dietary goals.—Calorie goals are based on baseline caloric intake (from the self-monitoring run-in) and current breastfeeding status for the postpartum participants. Participants who are breastfeeding receive a calorie goal that allows for the additional energy expenditure of breastfeeding (i.e., an extra 300 calories) [83]. The primary emphasis is to stay within calorie goals and to eat a balanced diet in line with the current U.S. Dietary Guidelines [75]. Women who do not lose weight at the expected rate, yet report calorie intake within the specified goal, are asked to reduce calorie goals. Again, this strategy is based on the assumption that actual energy intake is higher than self-reported intake; thus, lowering calorie goals achieves an intake level that supports appropriate weight loss. At the 6-week data collection visit, participants in the PPWL-only condition receive measuring cups and spoons to facilitate portion size estimates (participants in the GWG+PPWL condition receive them at randomization).

2.7.3. PPWL exercise goals.—After obstetrician approval (typically 6-weeks postpartum), participants are encouraged to resume pre-pregnancy levels of exercise gradually [84] in order to promote PPWL [38, 39, 82, 85]. The initial exercise goal is 100 minutes per week followed by gradual increases back to the baseline level of physical activity or greater (if the participant wishes). Participants receive a Fitbit Flex 2 tracker to facilitate these exercise goals. Past research suggests that objective physical activity feedback aids PPWL [38, 86]. If the participant's obstetrician recommends limited physical activity, exercise goals are modified or halted. Participants receive guidance regarding their ability to resume strength training (e.g., push-ups, sit-ups) at their first (i.e., 6-week) postpartum visit with their obstetrician.

2.8 Interventionists and Treatment Fidelity

A critical part of any military intervention is the ability of the interventionist to understand the culture and language of the participants. This study ensures that retired military staff are available to educate and answer any questions from non-military staff. Further,

interventionists have Bachelor's or Master's degrees (e.g., social work, counseling/psychology, child development, and nursing) and are experienced in conducting behavioral interventions. Each interventionist is paired with a participant at randomization and continues working with that participant throughout the entire intervention to facilitate social support.

Several quality procedures are utilized to ensure treatment fidelity. Intervention protocol development is detailed and interventionist proficiency is monitored through ongoing re-training. If an interventionist is not meeting standards after intensive re-training, they would be removed as a counselor. All intervention contacts are electronically documented in the study database to monitor participant exposure to treatment. Further, 5 intervention sessions per participant are randomly selected and recorded to provide corrective feedback on protocol adherence. In biweekly meetings, interventionists review participants' adherence to structured protocols based on the process data collected, and investigators lead these meetings to focus on problem solving related to challenging cases and refining skills.

2.9 Measures

Trained staff obtain study measures at 7 visits: screening, baseline, gestational week 32 and 36, as well as 6-weeks, 6-months and 12-months postpartum (see Table 3). These measures include demographics, weight, height, waist circumference, self-reported physical activity, accelerometry, feeding practices, maternal and infant health outcomes, health care utilization, fitness test scores, and program satisfaction, as described in further detail below. Process measures (e.g., session participation, self-monitoring) are collected throughout the trial. Health outcomes and utilization are collected using the Armed Forces Health Longitudinal Technology Application, the military's electronic health record.

2.9.1. Demographic and physical measures.—Participants complete a questionnaire at screening regarding their age, parity, race, and ethnicity. Changes in body weight over pregnancy (i.e., screening to 36-weeks gestation) and postpartum period (i.e., 6-weeks to 6-months postpartum) are the primary study outcomes. At all visits, weight (kg) is measured using a calibrated digital scale without shoes and in light clothing. The measured screening visit weight is considered the official starting weight, upon which pre-pregnancy BMI is calculated from measured weight and height. Previous research has found that an early first trimester weight is a good proxy for pre-pregnancy BMI [7]. At the screening visit, mothers also report pre-pregnancy weight (before their last menstrual period). Strong concordance between self-reported pre-pregnancy weight and measured pre-pregnancy weight has been previously demonstrated [14]. Height (in centimeters) is measured at screening using a wall-mounted stadiometer. As an indicator of subcutaneous and visceral abdominal fat, waist circumference is measured using a non-distensible tape at screening, 6 week, 6months, and 12-months postpartum with standard protocols used for positioning [87].

Weight is measured at both gestational week 32 and 36 in order to capture the fullest extent of GWG. Weight at week 36 is the primary outcome except for mothers who deliver prior to week 36 (in which case week 32 weight is used). Thus, a final observation of GWG for all

participants is obtained regardless of whether delivery occurs earlier than 36-weeks. However, only approximately 11% of pregnant women deliver before 37 weeks [88], thus, data at week 36 is expected to be collected on most participants.

2.9.2. Physical Activity Measures.—Physical activity is measured using the International Physical Activity Questionnaire at screening, 32-weeks gestation, 6-weeks, 6-months, and 12-months postpartum. This self-report measure has been used in other studies of gestational and postpartum weight management [86, 89, 90] was validated against accelerometry, and has good test-retest reliability [91]. Objective physical activity at baseline, 32-weeks gestation, 6-weeks, 6-months, and 12-months postpartum is collected using the Actical accelerometer [92, 93]. Participants wear accelerometers for 7 days, including at least 2 weekend days and 3 weekdays.

2.9.3. Feeding Practices.—Breastfeeding has been associated with reduced postpartum weight retention in some studies [94–96], but not all [97], and is therefore measured. At 6-weeks, 6-month, and 12-months postpartum, mothers report if they are currently breastfeeding. If not currently breastfeeding, mothers are asked how many weeks old their baby was when they discontinued. Further, mothers are asked how many weeks old their baby was when they first introduced formula. Breastfeeding status is used to calibrate postpartum calorie goals.

2.9.4. Psychological measures.—Depression is assessed using the Edinburgh Postnatal Depression Scale at the screening visit, the 32-week visit, and at six-weeks, six-months, and twelve-months postpartum [98], in order to examine whether outcomes vary based on the presence of depressive symptoms.

2.9.5. Participant Safety.—Adverse event information is collected at all data collection visits and sessions with interventionists. A data safety monitoring plan was established prior to enrollment.

2.9.6. Health outcomes.—Because most participants deliver at the same hospital, we are able to obtain information on prenatal and perinatal health outcomes from electronic health records. These outcomes include maternal and fetal conditions (e.g., gestational diabetes, preeclampsia), type of delivery, “Appearance, Pulse, Grimace, Activity, Respiration” score, infant birth weight and length. Length-for-age, weight-for-age, and weight-for-length Z-scores are calculated using the Center for Disease Control and Prevention (2000) reference data. Health care utilization [i.e., counts of ambulatory visits by type (physician, imaging, lab, other), hospital admissions and hospital days] for mother and child are also collected from hospital management information systems at 4-weeks postpartum. If mother and/or child are still admitted at 4-weeks postpartum, assessment is repeated until discharge.

2.9.7. Fitness Outcomes.—At baseline, active duty military participants provide a printout of their most recent pre-pregnancy fitness test score. The first postpartum (i.e., 6-months or 12-months, depending on the branch of the military) fitness score is collected to examine the impact of the interventions. Fitness test scores are comprised of waist

circumference, a 1.5-mile timed run and one-minute timed number of sit-ups and push-ups for the U.S. Air Force. For the U.S. Army, fitness scores incorporate height and weight, body fat, a 2-mile timed run, and the number of 2-minute timed sit-ups and push-ups. Fitness scores are comprised of a medical screen, body composition assessment, a 1.5-mile timed run, and number of 2-minute timed curl-ups and push-ups for the U.S. Navy. Additionally, for the U.S. Marine Corps, the fitness test includes a 3-mile timed run, the number of 2-minute timed crunches, and sustained time maintaining flexed-arm hang. Finally, the fitness test is comprised of BMI, height, neck, hip, and waist circumference for the U.S. Coast Guard [24].

2.9.8. Process Data.—Process variables are critical to assure treatment fidelity and to inform intervention adjustments. Interventionists carefully monitor contact frequency and contact level to monitor implementation and capture intervention exposure (i.e., intervention “step”). Further, a consistent predictor of weight management success is treatment engagement [99–102]. Thus, we expect treatment engagement will also be important in GWG and PPWL interventions. Information on participation in intervention activities (i.e., weight, diet and exercise self-monitoring) as well as meal replacement adherence is collected on an ongoing basis.

2.9.9. Program satisfaction.—Program satisfaction is measured at 32-weeks gestation and 12-months postpartum to offer insight into program acceptability. This measure is adapted from the “Fit Blue” study [50] and identifies both barriers and facilitators to participation in each intervention.

2.10 Retention

To maximize retention, we offer flexible appointments for individuals, maintain current contact information, minimize barriers to assessment visits (e.g., bringing the scale to the workplace or a neutral location) and provide small but meaningful incentives for completing each follow-up visit. Regular study meetings, in which retention is a primary agenda item, are a component of this systematic and comprehensive approach. However, because participants are recruited at <12 weeks gestation (and miscarriage rates are highest in the first trimester), up to 15% of participants are expected to be lost due to miscarriage [102]. Because this is a highly mobile population (e.g., relocation based upon change of station for participant or spouse, separation from military within 12-months of delivery which can be requested under Air Force Institution code 36–3208), a 20% attrition at six-months postpartum is projected.

2.11 Data Management and Quality Control

Study staff directly enter study data into FileMaker Pro, a secure online data management system. Access is tightly controlled. All users are authenticated and all transactions are logged.

2.12 Power Calculation and Statistical Analyses

All power calculations were performed with PASS15 [103]. The primary study outcomes will be a comparison of GWG from screening to the final gestational weight (week 32 or 36,

depending on the delivery date) as well as a comparison of weight loss from screening to 6-months postpartum for all three conditions. In additional analyses, 6-week and 12-month postpartum weight will be compared to screening weight. GWG (without intervention) estimations are 14 kg, based on the national data [104] and TRICARE data generated for this application [7]. We powered this study under the assumption that the PPWL-only condition will gain 14 kg, similar to these previous data, and that the GWG-only and GWG + PPWL conditions will produce approximately 2.5 kg attenuation in total GWG, consistent with the previous data [7]. Group sample sizes of 150 (PPWL-only) and 300 (GWG-only and GWG+PPWL) achieve 81% power to detect a difference of 2.5 kg between the null hypothesis and alternative hypothesis. The null hypothesis posits that all group means are 14 kg and the alternative hypothesis posits that the mean of the GWG-only and GWG+PPWL combined is 11.5 kg with assumed group standard deviations of 8.9 and a significance level of 0.05 using a simple general linear model. Thus, with a sample size as proposed, we have 80% power to detect a small effect (0.28) [105].

Postpartum weight retention estimations are 1.7 kg at 6-months based on previous research [106]. We estimate that the GWG-only condition will experience postpartum weight retention similar to previous research and the PPWL-only and GWG+PPWL conditions will produce a 1.2 kg improvement in weight loss (i.e., weight retention of 0.5 kg), consistent with previous PPWL interventions [39]. With a proposed sample size of 150 in each of the three conditions, we can detect a difference between the group means as small as 0.4 kg, with 80% power, with assumed group standard deviations of 1.0 (medium effect) [107]. The postpartum weight retention in the PPWL-only and GWG+PPWL conditions is 1.7 kg in the null hypothesis and 0.5 kg in the alternative hypothesis. Therefore, the power to detect proposed change of 1.2 kg (a large effect) [105] is higher than 80% using a simple general linear model with the significance at 0.05. Consequently, the proposed study will enroll 450 participants and will have power of 80% or more, to detect hypothesized differences for both hypotheses.

All of the analyses will be performed with SAS/STATv14.24. Data are 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 condition. Univariate comparisons will consist of t-tests, chi-square tests, ANOVAs, and their respective non-parametric counterparts, if needed, for continuous or 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 GWG and PPWL in the three conditions. Using these models, treatment effects will be estimated and tested by comparing the change in group-specific means at the final prenatal visit and 6-months postpartum conservatively adjusting for baseline differences (which will be minimal by virtue of randomization) and for potential 6-weeks and 12-months postpartum weight differences. Randomization validity will be assessed by comparing conditions 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.

Due to the nature, design and population of the study, we cannot follow common practice in weight management studies and carry baseline weight forward with missing observations. To address this potential source of inferential error, we will use monotone regression based multiple random imputation of the GWG outcomes using SAS PROC MI, assuming missing at random (MAR) data mechanism. These imputations will help minimize any loss of power, resulting from attrition. We will use demographic covariates and prior weight measurements that are available in this predictive model. The analysis will then be carried out in multiple data sets, and the results combined using standard methods (SAS PROC MIANALYZE) to produce a summary effect and standard error estimates that incorporate the imputation error [107, 108]. As a sensitivity check, we will carry out a secondary analysis in SAS PROC MIXED without imputation; but will adjust for baseline covariates given treatment assignment, observed outcome values, and baseline predictors of outcome.

As most outcome measures for additional research questions are on a continuous scale, we are going to apply similar methods for those with adjustments for baseline differences and demographics as needed. In addition, we will model discrete outcomes (e.g., staying within guidelines, treatment adherence) by treatment condition using the logit or generalized logit models (logistic regression for nominal outcomes), with adjustments for demographic covariates. Health care utilization (count data) will be modeled using Poisson (or Negative Binomial) regression, with adjustments for baseline differences and demographics. We will also use the count data to construct an overall estimate of cost, using publicly available, national Medicare payment rates for similar services. Because costs are often highly skewed, we will use log transform to normalize it before using general linear modeling techniques to examine costs.

3. Discussion

This design implements a novel stepped-care gestational weight gain intervention and a postpartum weight loss intervention for active duty women and other TRICARE beneficiaries based on Look AHEAD ILI. The current study's behavioral interventions are designed to effectively promote healthy GWG and PPWL, military readiness (i.e., fitness test performance), maternal and child health, and reduce unnecessary health care utilization. Perhaps, because of unique stressors for military families (e.g., deployments, unit-reassignment, decreased or nonexistent family support), many interventions effective in civilian populations have shown limited or no efficacy in military population [24, 109, 110]. For this reason, it is important to develop interventions, specifically focused on GWG and PPWL, that address the usual strains on a military family and take into consideration the military culture and lifestyle. This trial aims to create an intervention that meets the critical needs of military personnel and family members, is feasible given the security and other constraints of the military, and is tailored to the unique military culture.

Despite unique stressors, there are also major facilitators for weight management in the U.S. military. Few professions have such stringent fitness and body shape requirements for postpartum women. The major concern of all military leaders is readiness, of which weight management and fitness are top priorities. Importantly, every branch of the military has similar, though not identical, body shape and fitness test requirements. Failing a fitness test

means personnel risk discharge from the military, loss of health insurance, and loss of financial stability. Clearly, the stakes are high for meeting fitness standards. As a result, pregnant active duty women are highly motivated to participate in an intervention that supports the achievement of long-term fitness goals and weight management. Further, personnel and other TRICARE beneficiaries have access to universal quality healthcare which can help promote weight management and a healthy lifestyle.

The current design is unique because it is the first randomized clinical trial addressing GWG and PPWL among TRICARE beneficiaries, a significantly understudied population. Given that both active duty personnel and other TRICARE beneficiaries are being recruited in the current study, it will be possible to measure potential differences in GWG and PPWL between these two groups. Further, military women, compared to the civilian population, have lower incomes and are racially and ethnically diverse (47% African American/Asian/Mixed/Other; 13% Hispanic) [111]. The marked racial, ethnic, and economic diversity of the military population will inform future interventions in both civilian and military settings. In addition, the military system provides unique opportunities to link research data with electronic medical records and fitness reports. Thus, this trial contributes a significant public health benefit because it targets a high-risk population and produces results that are potentially applicable to both military and civilian populations. Because this study is testing the efficacy of these intervention packages, it will not be possible to determine the specific components necessary for healthy GWG and PPWL perhaps possible in other designs. However, this trial will provide critical and previously unavailable information on health outcomes, health care utilization, and fitness effects associated with participation in a GWG and PPWL intervention.

3.1 Conclusion

The current design considers both military barriers and facilitators for appropriate GWG and effective PPWL in order to implement these interventions in both active duty women and other TRICARE beneficiaries. The current interventions are designed to impact the financial burden of the military health care system, as well as make a significant public health contribution to escalating obesity in this vulnerable and diverse population by improving health outcomes and reducing health care utilization. Further, these interventions aim to increase the likelihood that active duty women will be able to meet required fitness standards, which could have a significant impact on women's military careers and increase military readiness. If successful in promoting healthy GWG and PPWL, this treatment could be integrated into standard health care for pregnant and postpartum military personnel and TRICARE beneficiaries.

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Table 1.**Gestational Weight Gain (GWG) Intervention Stepped Approach**

	Step 1	Step 2	Step 3
Initiation of this step	• All participants who are not in Step 2 or Step 3	• If a participant is above the GWG guidelines during the weekly evaluation of the weight trajectory	• If this participant is above the GWG guidelines for the second consecutive week
Contact Frequency	• Monthly 20–30minute telephone session	• Biweekly 20–30minute telephone session	• Weekly 20–30-minute telephone sessions • Weekly emailed lesson materials
Dietary Recommendations	• Calorie goal is based on self-monitoring run-in at baseline	• Same as Step 1 with portion size measuring and daily dietary intake monitoring	• Decrease by 100–200 calories per day until appropriate GWG achieved
Exercise	• 150 minutes per week of moderate activity • Fitbit Flex 2 tracker	• Same as Step 1	• Same as Step 1
Behavioral Strategies	• Daily self-monitoring of weight • Weekly emailed graph and feedback	• Daily self-monitoring of weight, daily food intake & exercise • Weekly emailed graph • Goal setting & problem solving by phone and email	• Daily self-monitoring of weight, daily food intake & exercise • Goal setting & problem solving by phone and email • 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

Table 2.**Postpartum Weight Loss Intervention (PPWL) Stepped Approach**

	Step 1	Step 2	Step 3
Trigger to Increase Intervention Intensity	• All participants who are not in Step 2 or Step 3	• <0.5 lb weight loss for the week, if not already at goal weight	• <0.5 lbs weight loss per week for two consecutive weeks, if not already at goal weight
Contact Frequency	• Monthly 20–30minute telephone sessions	• Biweekly 20–30minute telephone sessions	• Weekly 20–30minute telephone sessions • Weekly emailed materials
Dietary Recommendations	• Calorie goal is based on self-monitoring run-in at baseline; tailored to breastfeeding status	• Same as Step 1 with portion size measuring and daily dietary intake monitoring	• Decrease by 100–200 calorie per day until recommended weight loss achieved
Exercise	• Gradually increase exercise to prepregnancy levels • Fitbit Flex 2 tracker	• Same as Step 1	• Same as Step 1
Behavioral Strategies	• Daily self-monitoring of weight • Weekly emailed graph and feedback	• Daily self-monitoring of weight, daily food intake & exercise • Weekly emailed graph • Goal setting and problem solving by phone and email	• Daily self-monitoring of weight, daily food intake, & exercise • Weekly emailed graph • Goal setting & problem solving by phone and email • 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

Table 3.

Study Measurements

Measures	Screening	Baseline	32-Weeks Gestation	36-Weeks Gestation	6-Weeks Postpartum	6-Months Postpartum	12-Months Postpartum
Demographics	X						
Weight	X	X	X	X	X	X	X
Height	X						
Demographics	X						
Waist Circumference	X				X	X	X
International Physical Activity Questionnaire	X		X		X	X	X
Accelerometer		X	X		X	X	X
Feeding Practices			X		X	X	X
Edinburgh Postnatal Depression Scale	X		X		X	X	X
Health Outcomes			X	X	X	X	X
Fitness Test Scores		X					
Process Data			X	X	X	X	X
Program Satisfaction			X				
Patient Safety	X	X	X	X	X	X	X