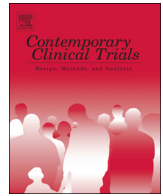




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# Moms fit 2 fight: Rationale, design, and analysis plan of a behavioral weight management intervention for pregnant and postpartum women in the U.S. military

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## 1. Introduction

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 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 yr. 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

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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 yr or older who reside in the San Antonio, Texas area. Active duty participants must have at least 1.5 yr left in their current duty assignment to ensure the likelihood of completing in-person follow-up visits. Participants must be < 12-weeks gestation (based on the date of their last menstrual period and physician report at first prenatal visit) upon screening and < 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 mo) 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., > 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 Section 2.12).

### 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.”) (Tables 1 and 2). However, when participants consistently meet the recommended weight gain trajectory, they experience a decrease in intervention intensity (Tables 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 Tables 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 (Tables 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

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