A Gestational Weight Gain Intervention in Active-Duty Military Personnel and Dependents: A Randomized Controlled Trial

Rosemary Estevez Burns[1]; Marion E. Hare[2]; Aline Andres[3]; Robert C. Klesges[4]; G. Wayne Talcott[1,4]; Karen LeRoy[1,4]; Melissa A. Little[4]; Ann Hyrshko-Mullen[1]; Teresa Waters[5]; Jean R. Harvey[6]; Zoran Bursac[7] & Rebecca A. Krukowski[2]

[1]Wilford Hall Ambulatory Surgical Center;[2]University of Tennessee Health Science Center, Department of Preventive Medicine; [3]University of Arkansas for Medical Sciences and Arkansas Children's Nutrition Center; [4]University of Virginia, Department of Public Health Sciences, University of Virginia Cancer Center ; [5]University of Kentucky, Department of Health Management and Policy; [6]University of Vermont, Department of Nutrition and Food Sciences; [7]Florida International University, Department of Biostatistics

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Clinical Trial Registration: The trial is registered on clinicaltrials.gov (NCT 03057808).

Contact Information: Rebecca A. Krukowski, Department of Preventive Medicine, University of Tennessee Health Science Center, 66 N. Pauline St., Memphis, TN 38105; 901-448-2426 (phone), rkrukows@uthsc.edu

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What is already known about this subject?

- Excessive gestational weight gain is associated with adverse pregnancy and delivery outcomes as well as postpartum weight retention.
- For active-duty personnel, failure to satisfactorily meet fitness standards can lead to administrative discharge, impacting women's careers and military readiness.

What are the new findings in your manuscript?

- Participants who received the intervention were significantly less likely to gain in excess of the National Academy of Medicine's gestational weight gain guidelines compared to those who did not receive the intervention.
- Active-duty personnel were more vulnerable to excessive gestational weight gain compared to military dependents.

How might your results change the direction of research or the focus of clinical practice?

- Should this intervention be found cost-effective, it may be sustainably integrated throughout the military prenatal care system and improve the health of women and their children.

Abstract

Objective: Excessive gestational weight gain (GWG) is associated with adverse pregnancy and delivery outcomes. Despite military fitness regulations, women in the military frequently experience overweight/obesity, excessive GWG and the postpartum implications. The Moms Fit 2 Fight study tested a stepped-care GWG intervention for TRICARE beneficiaries (i.e., active duty personnel and their dependents).

Method: Participants (N=430) were randomized to receive a GWG intervention, a postpartum weight loss intervention (PPWL-only), or a combined GWG + PPWL intervention. The sample was diverse (17% identified as Latina, 32% identified as an underrepresented racial minority, 47% were active-duty personnel).

Results: Outcome data were obtained from 91.2% of participants at 32-36 weeks gestation. Participants who received the GWG intervention gained significantly less weight compared to those who did not (M(SD)=9.9 (4.3) vs. 11.4 (5.3) kg, p=0.005). Participants who received the intervention were significantly less likely to exceed the GWG guidelines compared to those who did not (58.4% vs. 70.0%, *p*=0.03). Active-duty personnel had significantly greater odds of excessive GWG (OR: 1.67, 95% CI: 1.05, 2.65, p=0.03) compared to dependents.

Conclusions: The intervention successfully reduced excessive GWG. Should this intervention be found cost-effective, it may be sustainably integrated throughout the military prenatal care system.

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Introduction

Excessive gestational weight gain (GWG) is associated with multiple adverse pregnancy and delivery outcomes including preeclampsia, gestational diabetes, and cesarean delivery [1-5]. Further, excessive GWG is associated with adverse health outcomes for offspring across their lifetime [6-9]. Moreover, excessive GWG is associated with weight retention postpartum [10-13], which increases risk of maternal-child complications in subsequent pregnancies [14-16]. Excessive GWG is relatively common, making it a critical public health concern. In particular, 45% of women with obesity, 66% of women with overweight, and 19% of women with normal weight exceed the National Academy of Medicine's (NAM) GWG recommendations [17]. Pre-pregnancy BMI is strongly associated with GWG; women with overweight and obesity are most likely to gain weight excessively during pregnancy [18-20].

Contrary to common beliefs about the high level of health and fitness among military service members, women in the military are not protected from overweight/obesity [21], excessive GWG, and postpartum weight retention [22, 23]. Active-duty women, like their civilian counterparts, tend to exceed the GWG guidelines [24-26]. This is problematic as U.S. military women have only 12 months to meet fitness standards postpartum [27-30]. Failure to satisfactorily meet fitness standards can lead to administrative discharge [31], requiring the military to recruit and train replacements, at an estimated cost of $50,000 per person [32]. At an individual level, the inability to meet fitness standards may end a woman's military career and associated benefits. In 2006, healthcare costs associated with excess weight and obesity to the Department of Defense were estimated at 1.1 billion dollars [32]. Thus, it will be important to address excessive GWG in this population.

Fortunately, excessive GWG is a modifiable risk factor, through diet [33] and physical activity changes [19, 34-36]. This study implemented a novel stepped-care behavioral program based on the Look AHEAD (Action for Health in Diabetes) intensive lifestyle intervention [37, 38], to reduce the likelihood

of excessive GWG. The stepped-care approach was intended to allocate appropriate resources to participants who need either a higher or lower level of care, to potentially increase program sustainability. We hypothesized that participants randomized to Gestational Weight Gain-only (GWG-Only) and Gestational Weight Gain + Postpartum Weight Loss (GWG + PPWL) conditions would gain less weight than those randomized to the PPWL-only condition.

Methods

Our study tested the effect of a stepped-care GWG intervention or a postpartum weight loss intervention or both interventions on outcomes for TRICARE beneficiaries (i.e., active duty personnel and dependents). Participants were individually randomly assigned using a computerized block design based on baseline BMI category and parity status (i.e, no previous live birth, previous live birth) to one of the three intervention conditions (1:1:1 allocation) with allocation concealment, to assure balanced assignment to conditions throughout the study. Assignment was revealed by the study database, and staff notified the participant of the randomization assignment.

Participants were randomized to 1 of 3 study 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). The PPWL-only condition served as a comparison condition, as these participants did not receive treatment during the pregnancy period. Therefore, for this manuscript which is focusing on the GWG outcomes, we compared outcomes for participants in the two GWG intervention conditions with participants in the PPWL-only condition, who did not receive any treatment during their pregnancy. The protocol was approved by the Institutional Review Board (IRB) of the 59th Medical Wing and acknowledged by the University of Tennessee Health Science Center IRB. A detailed description of this study's methods and rationale has been published [39].

Participants

Participants were TRICARE beneficiaries who were 18 years and older. Initially, participants were required to be receiving obstetric care at either San Antonio Military Medical Center or Wilford Hall Ambulatory Surgical Center; however, in April 2020, we modified the study protocol to require only remote assessments due to the COVID-19 pandemic. With the obstetric clinic closure at Wilford Hall and the COVID-19 pandemic, recruitment was expanded to include obstetric clinics at Andrews and Wright Patterson Air Force Bases in July 2020. The active-duty personnel were initially eligible for our study if they had at least 1.5 years left in their current duty station to minimize chances of missing in-person follow-up visits, but this requirement was removed in April 2020 when remote assessments were approved.

At initial screening, participants were eligible if they were less than 12 weeks gestation (based on their last menstrual cycle date and physician confirmation at first prenatal visit) and less than 13 weeks and 5 days gestation at randomization. Underweight women were excluded given the infrequency of this BMI category in this population. Women with medical conditions that may make dietary and physical activity changes unsafe (e.g., congestive heart failure), or those that may impact weight (e.g., uncontrolled thyroid disease) were also excluded. Participants with a high-risk pregnancy (e.g., Type I or Type II diabetes or current multiple gestation) or those who regularly smoked within 6 months prior to conception were also excluded. Other exclusion criteria included use of medication affecting weight, unmanaged psychiatric conditions (e.g., depression, schizophrenia, eating disorders), recent substantial weight loss (i.e., > 4.5 kg in the past 3 months), or bariatric surgery.

Recruitment and screening

Interested individuals were recruited between February 2017 to October 2020 via posters, pregnancy orientation visits, listserv advertisements, referrals from health care providers, and word-of-mouth. Individuals could learn more about the study by phone or on the study website; a phone screener then determined likely eligibility. Potentially eligible participants presented for a screening visit where full eligibility was assessed, informed consent was obtained, and study measures were collected.

Participants were then asked to track their diet and exercise for one week with MyFitnessPal aand obtain their obstetrician's clearance for participation. Active duty personnel were also required to submit their fitness test scores for the year prior to study enrollment. Once participants completed these tasks, they were eligible to be randomized.

Intervention core components

The Moms Fit 2 Fight intervention was adapted from the Fit Blue intervention, which had adapted the Look AHEAD intensive lifestyle intervention for the military [40, 41]. The stepped-care approach adapted the intervention intensity level and access to resources based on each participant's GWG rate in comparison to the guidelines. The intervention was delivered via telephone to offer logistical flexibility to military personnel and dependents who are relatively mobile due to Temporary Duty assignments or Permanent Change of Stations. Telephone-based intervention was supplemented by other technology (e.g., email for interventionist feedback, MyFitnessPal for dietary and exercise self-monitoring, and BodyTrace electronic scales) to minimize treatment adherence barriers. Participants who received the GWG intervention had individual 20-30 minute telephone sessions with their interventionist. Telephone contact frequency was based on intervention step. Figure 1 details strategies used at each step and the contingencies that prompted an individual being moved to the next treatment level.

Participants were taught behavioral skills, consistent with the Look AHEAD intensive lifestyle intervention [37] to increase the likelihood the participant met their GWG, calorie, and exercise goals. All participants at all intervention steps were instructed to engage in daily self-weighing. The interventionist sent the participant a weekly email that included a weight trajectory graph. Interventionists used goal-setting principles to facilitate achievement of behavioral change (i.e., calorie intake, exercise) and GWG goals. Participants in Step 3 were offered a toolbox with supplemental treatment options (e.g., exercise videos, food scales, and healthy cookbooks). Lastly, interventionists facilitated behavioral skill-focused sessions in biweekly (Step 2) or weekly sessions (Step 3) on topics such as managing restaurant eating, stimulus control, social support, and fostering healthy mindsets.

Weight goals

GWG weight goals aligned with the 2009 NAM guidelines [42] based on screening weight. Women with normal weight were recommended to gain between 11 to 16 kg (BMI 18.5-25.9kg/m^2), women with overweight were recommended to gain between 7 to 11.5 kg (BMI 25-29.9kg/m^2), and women with obesity were recommended to gain between 5 to 9 kg (BMI >30). All participants were informed of the recommended GWG goal (tailored to BMI) at their baseline visit. Participants' e-scale weights were automatically uploaded to a secure website, which was accessible to both the interventionist and participant. If participants' GWG was below the recommendations for a given week, participants were directed to increase their caloric intake and continue with the self-monitoring strategies. Referrals to the obstetrician and documentation in their electronic medical record were made if a participant remained 5 pounds below the recommendations for two consecutive weeks; however, they remained eligible for study participation.

Dietary goals

Calorie goals were established at the baseline visit, based on the participant's caloric intake reported in the self-monitoring diary between the screening and baseline visits. In their first trimester, participants were encouraged to maintain the same caloric intake, consistent with the NAM recommendations. Once the participant entered their second and third trimester, she was recommended to increase caloric intake in order to achieve her BMI-tailored GWG goal. If participants exceeded their GWG goals, a decreased calorie goal was recommended. Interventionists advised participants to consume fruits, vegetables, and whole grains and avoid mercury intake, consistent with dietary guidelines for pregnancy [43]. At the randomization visit, those who received the GWG intervention were provided measuring cups and spoons to aid portion size estimates. Participants in Step 2 and 3 of the intervention were asked to use the MyFitnessPal app/website to self-monitor dietary intake and physical activity daily. Participants in the highest intervention intensity level (Step 3) were provided with meal replacements (i.e., Better Oats™ oatmeal, Healthy Choice™ frozen meals, and/or Slim Fast™) in alignment with the

nutritional needs of pregnant and postpartum women [44], to facilitate weight management and portion control. Participants in Step 3 were encouraged to substitute two meals with meal replacements, and eat conventional foods for the third meal of their day. Meal plans, including snack lists, were provided to participants in Step 3.

Exercise goals

Exercise goals were established at the baseline visit. At least 150 minutes of moderate exercise per week was encouraged [42, 45] unless pregnancy complications warranted physical activity restriction. To reinforce and facilitate adequate physical activity, participants who received the GWG intervention received Fitbit activity trackers at their baseline visit.

Interventionists and treatment fidelity

Interventionists had bachelor's or master's degree in an array of professional fields (e.g., social work, nursing) and were trained in conducting the behavioral intervention. An adequate understanding of the military culture (e.g., language, hierarchy/rank structure) was instrumental for our study interventionists. For this reason, we created consultation opportunities between non-military and retired military staff. Interventionists also received training in motivational interviewing and were required to meet MITI 3.1 proficiency standards. They were certified as counselors when they satisfactorily completed two mock sessions. At randomization, each interventionist was paired with a participant and, whenever possible, this unique therapeutic engagement remained until the intervention was complete. Both male and female interventionists were available, and participants were able to indicate their preference.

A written protocol and counselor guides were used to ensure treatment fidelity. Interventionists' proficiency and intervention fidelity was carefully monitored and bolstered by scheduled training sessions for content and MI. With participants' consent, five intervention sessions were randomly audio recorded to facilitate interventionist protocol adherence improvements. Further, biweekly meetings led by primary

investigators were held to offer consultation on challenging cases and identify additional strategies needed to ultimately improve participant adherence.

Outcome Measures

All measures were obtained by unblinded data collectors at baseline, 32-weeks gestation, and 36-weeks gestation unless otherwise indicated. Data were collected 2017-2021 in the obstetric clinic at San Antonio Military Medical Center or Wilford Hall Ambulatory Surgical Center (prior to April 2020) and remotely during the COVID-19 pandemic.

Sociodemographic characteristics.

Self-reported sociodemographic characteristics (i.e., age, race, ethnicity, education, marital status, military rank) were collected at baseline. Analyses were evaluated based on demographic categories of gender, military status (i.e., active duty, dependent), BMI category, ethnicity, and race (i.e., White, Black, or other)

Anthropometrics.

Weight change (kg) was the primary dependent measure. Weight was measured without shoes in light clothing, on a calibrated digital scale (Tanita BWB 800S) or on their Body Trace e-scale during the COVID-19 pandemic. Previous research has demonstrated the comparability between clinic and Body Trace e-scale weights [46]. The primary outcome was GWG at 36-weeks gestation. Per protocol, for those that did not have their GWG outcome measured at 36 weeks, the 32-week weight was used. Height was measured in centimeters using a stadiometer at baseline or self-reported during the COVID-19 pandemic. BMI was calculated using the standard formula.

In addition, we analyzed a discrete GWG outcome which was defined as being above 2009 NAM weekly GWG recommendations conditional on baseline BMI category, also referred to as excess GWG. To calculate average weekly gain, we divided the overall GWG for each participant by the number of

weeks between baseline and 36-week measures, or 32-week measures in those cases where 36-week measure was missing (see Figure 1 and Table 1 for missing data). Exact dates of measurements were used to calculate this duration. Four women with baseline weight measured at 14 weeks gestation due to protocol deviations (e.g., delayed scale delivery during the pandemic) had 0.45 kg (1 pound) subtracted from their weight for an estimate of their first-trimester baseline weight, consistent with previous research [47]. Excess GWG was defined as being above the upper limit of second and third trimester GWG for women with normal weight (>0.5 kg per week), overweight (>0.33 kg per week), and obesity (>0.27 kg per week) [47].

Statistical Analysis

All statistical analyses were performed with SAS/STATv14.2 (SAS Institute Inc., Cary, NC). Descriptive statistics including means, standard deviations, frequencies and proportions were generated for the combined GWG condition vs the PPWL-only condition at the 32-36-week time point. Comparisons between the conditions were conducted with the two-sample t-test, or chi-square test for continuous and/or discrete variables, respectively. The same analytical methods were applied for comparison of characteristics for those with complete versus missing outcome data at 32-36 weeks. We also calculated the intervention effect size expressed as the difference in means per one-unit standard deviation.

In order to test the GWG intervention effect at 32-36 weeks, we applied an analysis of covariance regression model (ANCOVA), adjusting for baseline weight, BMI category, demographics such as age, race, ethnicity, active-duty military status, gestation weeks at baseline, and parity. For the outcome of excessive GWG, we applied logistic regression model to estimate the relative odds of being above recommended NAM guidelines at 32-36 weeks as a function of the GWG intervention compared to the PPWL-only condition, while controlling for the same covariates as in the ANCOVA model. We used model-based multiple imputation of the missing outcome data as a sensitivity approach to completers analysis. First, we imputed observations to create a monotone missing data pattern at 32 and 36-week

time points. We then performed 25 imputations of the missing outcome values at the 32 and 36-weeks with the monotone regression method with SAS PROC MI, which included screening, baseline and 32-week weights, respectively, BMI category, age, race, ethnicity, active-duty status, gestation weeks at baseline, and parity. We analyzed each imputed data set using the same ANCOVA regression model as described above and generated combined parameter estimates and their standard errors with SAS PROC MIANYLIZE, to produce valid statistical inferences. Associations were considered significant at the alpha level of 0.05.

Results

Four hundred and thirty participants were randomized, representing 34.2% of those who initially indicated interest (Figure 2). Participant distribution across the BMI categories was 32.8% with normal weight, 40.0% with overweight, and 27.2% with obesity. Slightly under one-half (47.4%) of participants were active-duty personnel. Fifteen percent of participants identified as Black, 67.9% identified as white, and 17.2% of participants identified as another race group (5% mixed race, 3% Asian, 1% Native Hawaiian or other Pacific Islander, 0.5% American Indian/Alaska Native, and 8% other race groups). About seventeen percent of participants identified as Hispanic (Table 1). Most participants were affiliated with the Air Force (63%), followed by the Army (27%), the Navy (8%), the Marine Corps (2%), and finally the Coast Guard at 1%. Among active-duty participants, 70% were in the Air Force and 20% were in the Army, while among dependents, 56% were affiliated with the Air Force and 33% with the Army.

Approximately 9% of participants (N=38) did not have a weight outcome assessment at either 32 or 36-weeks gestation (Figure 1). There was no differential attrition between the conditions (p=0.25). Participants who did not complete the 32 or 36-week assessments were slightly younger (28.1 years vs. 30.9 years) and more likely to identify as Black (Table 2). A total of 57 (13.3%) randomized participants experienced a serious adverse event. There was no significant difference in the proportion of participants

experiencing a serious adverse event between the conditions (15.3% of those who received the GWG intervention and 9.2% in the PPWL group; p=0.0783).

Among completers of the 32-36 week assessment, using crude unadjusted estimates, GWG differed significantly between the conditions (GWG intervention: 9.87 kg [SD=4.33] vs. PPWL intervention 11.39 kg [SD=5.26], with the mean difference: 1.52 kg [SD=4.66]; effect size Cohen's d = 0.33; p=0.0048). Adjusted analyses controlling for baseline weight, BMI category, demographics such as age, race, ethnicity, active-duty status, gestation weeks at the baseline visit, and previous live birth status, showed similar findings. Participants in the GWG intervention group gained 9.31 kg (SE=0.32), on average, compared to the PPWL group that gained 10.87 kg (SE=0.43), for an intervention effect difference of 1.56 kg (SE=0.48; p=0.0012). There was a similar pattern of results for the intervention effect in sensitivity analyses with multiple imputations (mean difference = 1.45kg; SE=0.57; p=0.0061).

In addition, the proportion with excessive GWG differed significantly between the conditions. Among the participants who received the GWG intervention, 58.4% gained in excess of the guidelines, 26.3% gained within the guidelines, and 15.2% gained below the guidelines. Among the participants who received the PPWL intervention, 70.0% gained above the guidelines, 20.0% gained within the guidelines, and 10.0% gained below the guidelines. GWG intervention group, therefore, had significantly lower proportion of gaining in excess of the guidelines compared to PPWL (58.4% vs 70.0%; p=0.0257). Mean weekly average gain for those who received the GWG intervention was 0.42 kg (SD=0.19) while for PPWL group, it was significantly higher at 0.48 kg (SD=0.21) (p=0.0091).

In the multivariable logistic regression model, women who received the GWG intervention (Odds Ratio (OR)=0.54, 95% confidence interval (CI): 0.34, 0.88; p=0.0134) were associated with almost 50% lower odds of excessive GWG. Women with overweight (OR=5.26, 95% CI: 2.84, 9.76; p<0.0001) and obesity at baseline (OR=3.77, 95% CI: 1.49, 9.55; p=0.0052) had greater odds of excessive GWG compared to women with normal weight. In addition, active-duty personnel (OR=1.67, 95% CI: 1.05, 2.65; p=0.0301) had greater odds of excessive GWG compared to dependents. Those who identified as

Black (OR=0.35, 95% CI: 0.17, 0.68; p=0.0022) had lower odds of gaining in excess of the guidelines compared to white women (Table 3).

Discussion

In a diverse sample of women, we found those who received the GWG intervention gained significantly less weight than those who did not. In addition, fewer of the women exposed to the GWG intervention exceeded the guidelines in contrast to those unexposed to the intervention (58.4% vs 70.0%, respectively); In fact, the intervention decreased the odds of exceeding GWG recommendations by close to 50%. These results suggest that remotely delivered behavioral intervention can be effective in helping to faciliate healthy GWG among TRICARE beneficaries.

These findings are consistent with other randomized controlled trials with similar behavioral interventions among civilians [47-50]. In addition, the magnitude of the GWG difference observed in the current study was also similar to previous research [47, 51-53], although larger than the mean GWG difference found in a recent meta-analysis (0.7 kg) [54]. Consistent with the established literature on the relationship between BMI and excessive GWG [17], our study indicated women with overweight and obesity were at increased odds of exceeding GWG guidelines throughout their pregnancy. Interestingly, our study also found those who were active-duty had increased the risk of exceeding the guidelines. It is unclear what factors may contribute to this finding, as there is limited research in this area. One possible explanation is that active-duty women are required to maintain weight and fitness standards, except during pregnancy. Easing of fitness standards and unit exercise requirements during this period may lead to eating and exercise behavior changes among pregnant active-duty personnel that may not be comparable to dependents and may contribute to increased GWG for this population.

There is general recognition that active-duty women experience challenges returning to pregravid fitness levels and meeting physical fitness standards; specifically, in one study, fitness test failures increased by 21% at 6 months postpartum [23]. Furthermore, there were increased odds of fitness test

failure at 6 months postpartum among women who had been diagnosed with gestational diabetes [31]. Behavioral interventions aiming at increasing adherence to the GWG guidelines during gestation may improve postpartum fitness; these interventions may be particularly necessary in this population, given the high individual and systemic cost associated with a discharge from the military.

This study has notable strengths. First, the proportion of individuals randomized out of those who were screened for eligibility was much larger than in previous meta-analyses (34.2% vs. 4%) [47], suggesting that a GWG intervention is of interest to TRICARE beneficiaries. In addition, since prenatal care across the military healthcare systems is formally standardized by the Veteran's Affairs/Department of Defense Management of Pregnancy Clinical Practice Guideline, the participants in this sample likely received more similar prenatal care compared to the civilian health care system; for example, all women in this study were exposed to the same written language and pregnancy recommendations with the "Purple Book", a guide to healthy pregnancy published and distributed by the Veterans Affairs/Department of Defense [55]. Additional strengths of this study include its randomized design, high retention of participants, as well as the diversity of the sample, which included many individuals from racial and ethnic backgrounds who often are not included in research [56, 57]. Further, this intervention successfully utilized distance-based modalities (i.e., telephone and email) to treat participants, which is an essential characteristic of interventions for highly mobile populations such as the military. Additionally, use of these distance-based modalities may allow for greater disseminability during the COVID-19 pandemic as well as for other populations that may not be able to attend frequent in-person intervention visits (e.g., individuals with significant caregiving responsibilities, rural populations). Further, this stepped-care based behavioral intervention matched resources to clinical needs of the participant, thus likely reducing costs.

This study was not without limitations. We did not have a true no-treatment control group, due to military research guidelines that restrict no-treatment control groups; our PPWL-only served as a comparison group. For this reason, it is unclear if the magnitude of GWG difference between women who

received GWG intervention and those who did not, would have been greater or lesser if a no-treatment control group was included. Knowledge of upcoming treatment at postpartum may have served as a facilitating or hindering factor in GWG management. Moreover, 90% of the active-duty women in this study were associated with the Air Force and Army, limiting our ability to generalize our findings to other military branches.

In summary, our findings are encouraging. A telephone and email-based stepped-care, behavioral intervention mitigated against excessive GWG in a military population. Although promising, further research is needed to determine if this treatment approach could be extended across the Department of Defense and perhaps to civilian populations. Future research should examine whether a stepped-care based GWG intervention can minimize postpartum weight retention, increase adherence to active duty postpartum fitness standards, and meaningfully alleviate the financial burden of excessive GWG on the healthcare system.

Figure 1. Moms Fit 2 Fight Gestational Weight Gain Stepped Care Intervention Components

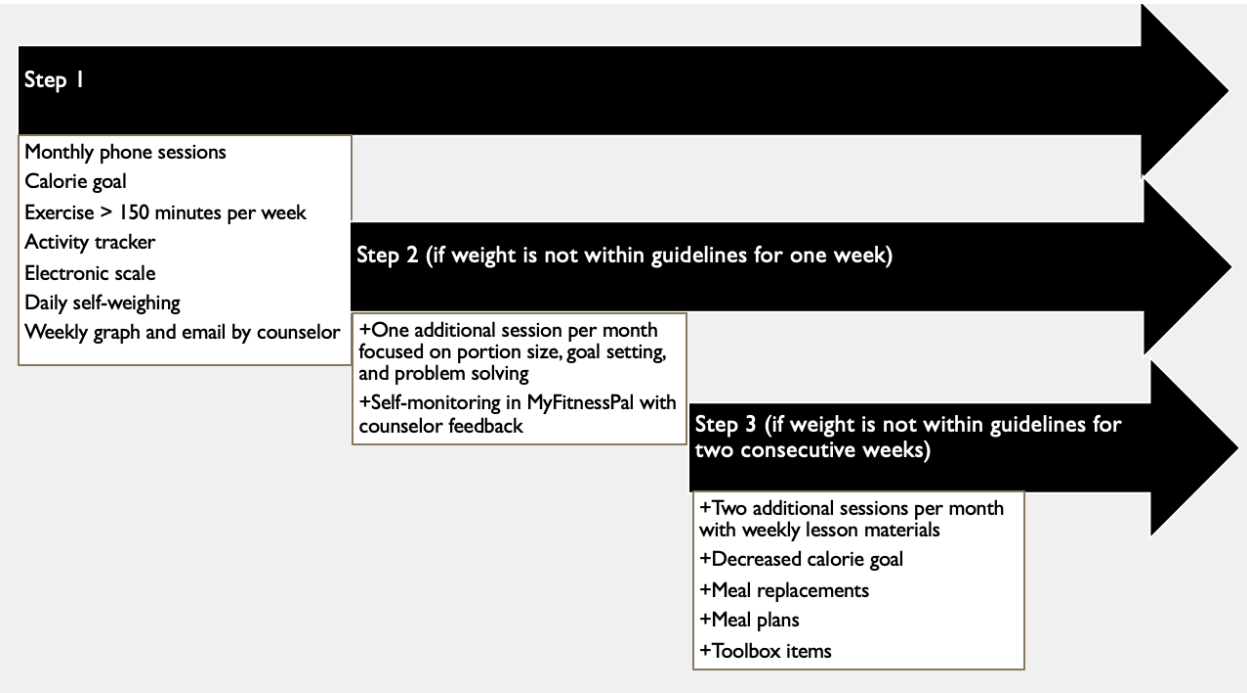
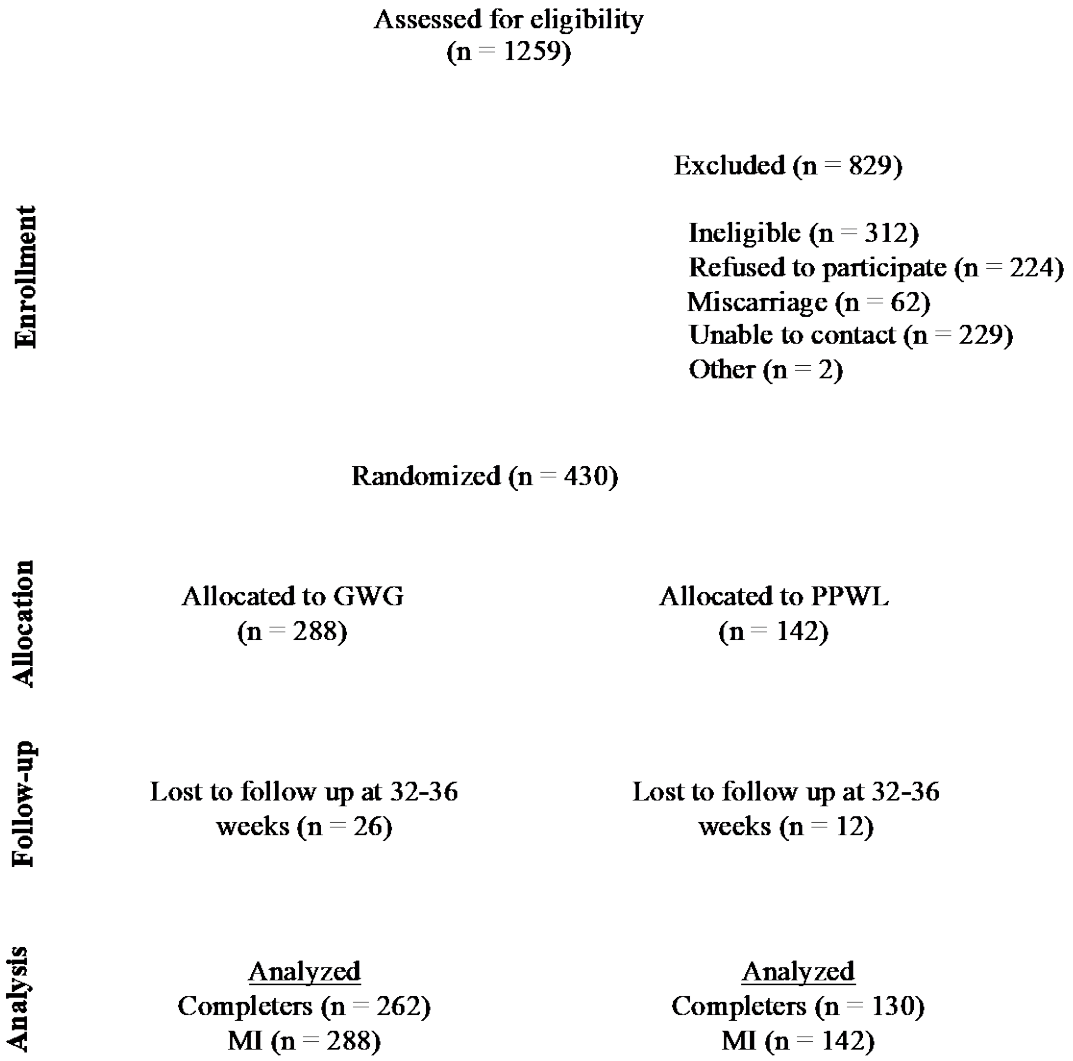


Figure 2. CONSORT Diagram



Note: GWG=gestational weight gain intervention; PPWL=postpartum weight loss intervention; MI=multiple imputation

Table 1. Baseline characteristics of Randomized Participants.

	Overall (N=430)	GWG (N=288)	PPWL (N=142)
Age (years)	30.6(4.9)	30.7(4.9)	30.4(4.8)
Body mass index (kg/m^2)	27.6(5.2)	27.6(5.1)	27.7(5.5)
Gestation week at baseline	11.7(1.1)	11.8(1.1)	11.6(1.2)
Weight – pre-pregnancy weight (self-reported) (kg)	73.0(14.9)	72.8(14.5)	73.4(15.7)
Weight – screening (kg)	74.2(15)	73.9(14.5)	74.9(15.8)
Weight – baseline (kg)	74.7(15)	74.4(14.6)	75.3(15.7)
BMI category (%)			
Normal	32.8	33.0	32.4
Overweight	40.0	39.9	40.1
Obese	27.2	27.1	27.5
Hispanic/Latino (%)	16.7	14.9	20.4
Race (%)			
White	67.9	67	69.7
Black	14.9	14.6	15.5
Other race groups	17.2	18.4	14.8
Active-duty (%)	47.4	48.6	45.1
Previous live birth (%)	55.6	55.6	55.6
Missing outcome data (%)			
32 weeks	10.0	10.1	9.9
36 weeks	14.2	15.3	12.0
32+36 weeks	8.8	9.0	8.5
Withdrew (%)	10.7	10.4	11.3

Mean(SD) or %

Table 2. Comparison of characteristics by missing outcome status at the 32/36-week follow-up.

32+36 WEEKS	Complete (N=392)	Missing (N=38)	p-value
Age (years)	30.9(4.8)	28.1(5.4)	0.0009
Body mass index (kg/m^2)	27.6(5.3)	27.9(4.5)	0.6668
Gestation week at baseline	11.8(1.1)	11.7(1.2)	0.6057
Weight – pre-pregnancy weight (self-reported) (kg)	72.8(15.1)	75.2(13.1)	0.3414
Weight – screening (kg)	74.1(15.1)	75.9(13.5)	0.4468
Weight – baseline (kg)	74.6(15.1)	76.5(14.1)	0.4402
BMI category (%)			0.2033
Normal	33.4	26.3	
Overweight	26.0	39.5	
Obese	40.6	34.1	
Hispanic/Latino (%)	17.6	7.9	0.126
Race			0.0003
White	69.1	55.3	
Black	12.8	36.8	
Other race groups	18.1	7.9	
Active duty (%)	47.7	44.7	0.9227
Previous live birth (%)	55.9	52.6	0.7015

Mean(SD) or %

Table 3. Characteristics associated with increased odds of gaining in excess of the guidelines

Variable	Odds Ratio	95% Confidence Limits		p-value
Study Arm (GWG vs. PPWL)	0.54	0.34	0.88	**0.0134**
Baseline weight	0.99	0.96	1.01	0.2544
BMI Category (Obese vs. Normal weight)	3.77	1.49	9.55	**0.0052**
BMI Category (Overweight vs. Normal weight)	5.26	2.84	9.76	**<.0001**
Age	0.97	0.92	1.02	0.2009
Gestation week at baseline	1.10	0.90	1.35	0.3676
Race (ref: White)				
Black	0.35	0.17	0.68	**0.0022**
Other race groups	1.00	0.55	1.84	0.991
Hispanic/Latino	0.66	0.35	1.22	0.1858
Active Duty	1.67	1.05	2.65	**0.0301**
Previous Live Birth	0.93	0.58	1.49	0.7662

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