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An interim analysis of a gestational weight gain intervention in military personnel and other TRICARE beneficiaries

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Abstract

Objective: Despite military fitness regulations, women in the military frequently experience overweight/obesity, excessive gestational weight gain (GWG), and the postpartum implications. This interim analysis of the Moms Fit 2 Fight study examines GWG outcomes among active-duty personnel and other TRICARE beneficiaries who received a stepped-care GWG intervention compared with those who did not receive a GWG intervention.

Method: Participants ($N = 430$; 32% identified with an underrepresented racial group, 47% were active duty) were randomized to receive a GWG intervention or the comparison condition, which did not receive a GWG intervention.

Results: Retention was 88% at 32 to 36 weeks' gestation. Participants who received the GWG intervention gained less weight compared with those who did not (mean [SD] = 10.38 [4.58] vs. 11.80 [4.87] kg, $p = 0.0056$). Participants who received the intervention were less likely to have excessive GWG compared with those who did not (54.6% vs. 66.7%, $p = 0.0241$). The intervention effects were significant for participants who identified as White, but not for those of other racial identities. There were no significant differences between the conditions in maternal/neonatal outcomes.

Conclusions: The intervention successfully reduced excessive GWG, particularly among participants who identified as White. Should this intervention be found cost-effective, it may be sustainably integrated throughout the military prenatal care system.

INTRODUCTION

Excessive gestational weight gain (GWG) is associated with multiple adverse pregnancy and delivery outcomes, including preeclampsia, gestational diabetes, and cesarean delivery [1]. Furthermore, excessive GWG is associated with adverse health outcomes for offspring across their lifetime [2, 3]. Moreover, excessive GWG is associated with postpartum weight retention [4, 5], which increases risk of maternal-child complications in subsequent pregnancies [6, 7]. Excessive GWG is 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 [8]. Prepregnancy body mass index (BMI) is strongly associated with GWG; women with overweight and obesity are most likely to gain weight excessively during pregnancy [9, 10].

Contrary to common beliefs about the health and fitness of military service members, women in the military are not protected from overweight/obesity [11], excessive GWG, or postpartum weight retention [12, 13]. Active-duty women, like their civilian counterparts, tend to exceed the GWG guidelines [14–16]. This is problematic, as United States military women have only 12 months to meet fitness standards after delivery [17–20]. Failure to satisfactorily meet fitness standards can lead to administrative discharge [21], requiring the military to recruit and train replacements, at an estimated cost of $50,000 per person [22]. At an individual level, the inability to meet fitness standards may end a woman's military career and associated benefits. In 2006, health care costs associated with excess weight and obesity to the Department of Defense were estimated at $1.1 billion [22]. Therefore, it will be important to address excessive GWG in this population.

Fortunately, excessive GWG is a modifiable risk factor through diet [23] and physical activity changes [10, 24]. This study implemented a novel stepped-care behavioral program, based on the Look AHEAD (Action for Health in Diabetes) intensive lifestyle intervention [25, 26], to reduce the likelihood of excessive GWG. The stepped-care approach was intended to allocate resources to participants who need either a higher or lower level of care in order to increase program sustainability. In this interim analysis, we hypothesized that participants randomized to receive the GWG intervention would gain less weight than those randomized to the comparison condition.

Study Importance

What is already known?

- 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 does this study add?

- 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 with those who did not receive the intervention.
- The intervention effects were significant for participants who identified as White, but not other racial identities.

How might these 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.

METHODS

The overall study is testing the effect of a stepped-care GWG intervention or a postpartum weight loss (PPWL) intervention or both interventions on outcomes for TRICARE beneficiaries (i.e., active-duty personnel, spouses, and children still covered under their parents' insurance), with the primary outcome focusing on postpartum weight retention. The protocol was approved by the Institutional Review Board of the 59th Medical Wing. A detailed description of this study's methods and rationale has been published [27].

Participants were randomized to one of three conditions: 1) a GWG intervention (GWG-only); 2) a PPWL intervention (PPWL-only); or 3) a combined GWG and PPWL intervention (GWG + PPWL). Interim analyses targeted GWG outcomes among participants in the two GWG intervention conditions compared with the PPWL-only condition, i.e., those who did not receive a GWG intervention during pregnancy (thereafter referred to as the "comparison condition"). Participants were individually, randomly assigned, using a computerized block design designed by the study biostatistician (Zoran Bursac) and based on screening BMI category and parity status (i.e., no previous live birth, previous live birth), to one of the three conditions (1:1:1 allocation), with allocation concealment, in order to assure balanced assignment to conditions. Assignment was revealed by the study database, and staff notified the participant of the randomization assignment.

Participants

Participants were TRICARE beneficiaries who were 18 years and older. Initially, participants were required to receive obstetric care at either San Antonio Military Medical Center or Wilford Hall Ambulatory Surgical Center in Texas; however, in April 2020, we modified the study protocol to require only remote assessments owing to the COVID-19 pandemic. With the obstetric clinic closure at Wilford Hall Ambulatory Surgical Center in October 2019 and the pandemic, recruitment was

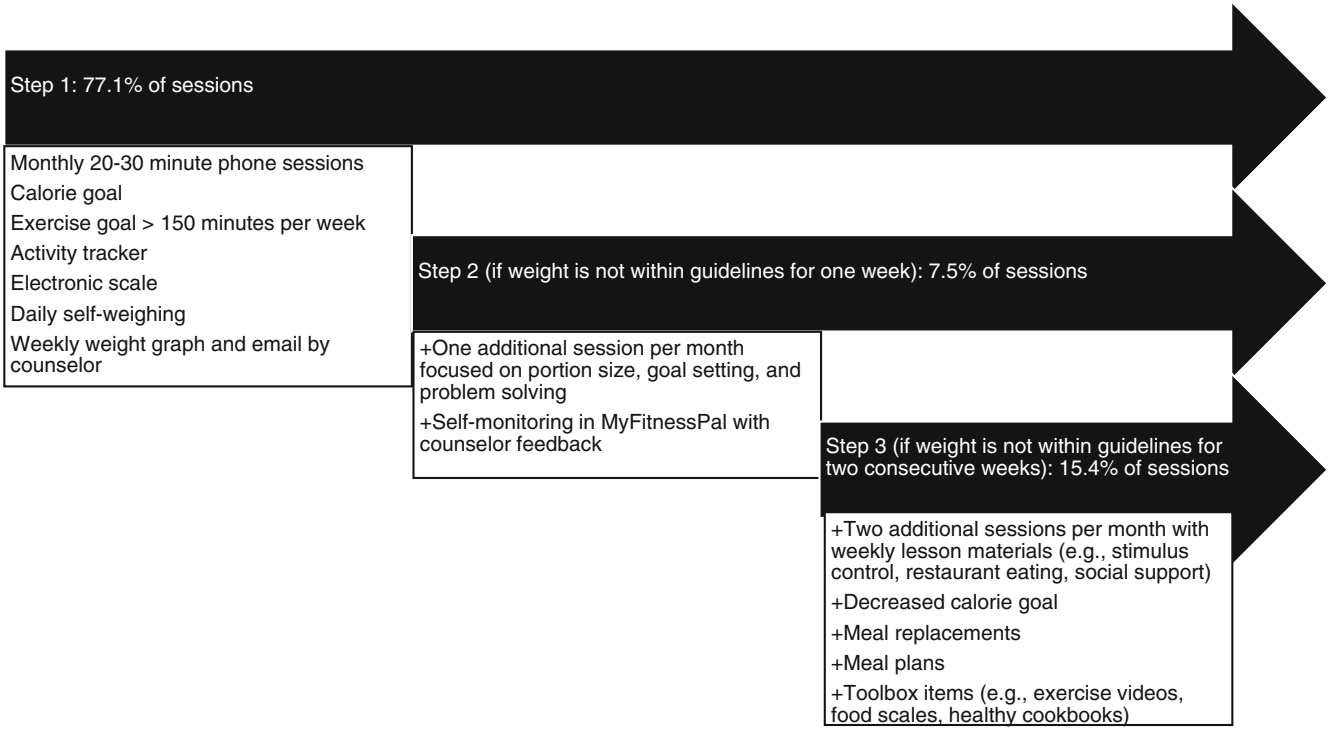

FIGURE 1 Moms Fit 2 Fight gestational weight gain stepped-care intervention components

expanded to include obstetric clinics at Andrews Air Force Base in Maryland and Wright-Patterson Air Force Base in Ohio 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 <12 weeks' gestation (based on their last menstrual cycle date and physician confirmation at first prenatal visit) and <13 weeks and 5 days' gestation at randomization. Individuals who have underweight are extremely rare in this population [28], and they were excluded, as it would be unlikely to recruit enough women in this BMI category to allow for comparisons. 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., diagnosis of type I or type II diabetes, 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 and October 2020 via posters, pregnancy orientation visits, email list 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 during which full eligibility was assessed, voluntary fully informed consent was obtained (as required by 32 CFR §219 and DODI 3216.02_AFI 40–402), and study measures were collected. Participants were then asked to track their diet and exercise for 1 week with MyFitnessPal (to experience a main component of the intervention before committing to participate) and 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 in order to facilitate comparisons with their postpartum fitness test scores (obtained at 12 months post partum). 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 was a military cultural adaptation of the Look AHEAD intensive lifestyle intervention [29, 30]. The stepped-care approach adapted the intervention intensity level and access to resources based on each participant's GWG rate in comparison with the guidelines. The intervention was delivered via telephone, supplemented by other technology (e.g., email for interventionist feedback, MyFitnessPal for dietary and exercise self-monitoring, BodyTrace electronic scales for self-weighing) to offer flexibility to military personnel and other TRICARE beneficiaries who are relatively mobile. 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 [25] to increase the likelihood that they met their GWG, calorie, and exercise goals.

Weight goals

GWG weight goals aligned with the 2009 NAM guidelines [31] based on screening weight. Women with normal weight were recommended to gain between 11 and 16 kg (BMI [kilograms per meter squared] = 18.5-25.9), women with overweight were recommended to gain between 7 and 11.5 kg (BMI = 25-29.9), and women with obesity were recommended to gain between 5 and 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 and plotted on a GWG graph tailored to their BMI category, 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 participants remained 5 lb below the recommendations for two consecutive weeks; however, they remained eligible for study participation.

Dietary goals

Calorie goals were established 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 participants entered their second and third trimester, they were recommended to increase caloric intake in order to achieve their BMI-tailored GWG goal. Interventionists advised participants to eat according to dietary guidelines for pregnancy [32]. 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. In Step 3, a decreased calorie goal was recommended. Participants in Step 3 were provided with two meal replacements per day (i.e., Better Oats oatmeal, Healthy Choice frozen meals, and/or SlimFast) in alignment with the nutritional needs of pregnant and postpartum women [33] to facilitate weight management and portion control. Meal plans, including snack lists, were provided to participants in Step 3.

Exercise goals

At least 150 minutes of moderate exercise per week was encouraged [31, 34] 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 baseline.

Interventionists and treatment fidelity

Interventionists ($N = 15$ over the course of the study) had bachelor's or master's degree in diverse fields (e.g., social work, nursing), and they 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; therefore, we created consultation opportunities between non-military and retired military staff. Interventionists also received training in motivational interviewing. 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 (20% men), and participants were able to indicate their preference. Interventionists were racially and ethnically diverse (20% Hispanic, 67% Black).

A written protocol and counselor guides were used to ensure treatment fidelity. Intervention fidelity was carefully monitored and bolstered by scheduled training sessions for content and motivational interviewing, and 15% of sessions were randomly selected to be audio-recorded. Constructive feedback was provided to the interventionists based on each session review. Furthermore, biweekly meetings led by the principal investigator were held to consult on challenging cases and identify strategies to improve adherence.

Outcome measures

All measures were obtained by unblinded data collectors at screening, baseline, 32 weeks' gestation, and 36 weeks' gestation, unless otherwise indicated. Data were collected between February 2017 and April 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 screening. Analyses were evaluated based on demographic categories of gender, military status (i.e., active duty, other TRICARE beneficiaries), BMI category, ethnicity, and race (i.e., White, Black, or other).

Anthropometrics

Weight change (kilograms) was the primary dependent measure. Weight was measured without shoes and in light clothing on a

TABLE 1 Characteristics of randomized participants

	Overall ($N = 430$)	GWG condition ($n = 288$)	Comparison condition ($n = 142$)
Age (y)	30.6 (4.9)	30.7 (4.9)	30.4 (4.8)
BMI (kg/m^2)	27.6 (5.2)	27.6 (5.1)	27.7 (5.5)
Gestational week at screening	11.7 (1.1)	11.8 (1.1)	11.6 (1.2)
Weight: prepregnancy 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 weight	32.8	33.0	32.4
Overweight	40.0	39.9	40.1
Obesity	27.2	27.1	27.5
Hispanic/Latino, %	16.7	14.9	20.4
Race, %			
White	67.9	67.0	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, %	12.1	13.5	9.2
Withdrew, %	10.7	10.4	11.3

Note: Data given as mean (SD) or percentage.
Abbreviation: GWG, gestational weight gain.

calibrated digital scale (Tanita BWB 800S) or on participants' Body Trace e-scale during the COVID-19 pandemic. Previous research has demonstrated the comparability between clinic and Body Trace e-scale weights [35]. The primary outcome was GWG at 36 weeks' gestation. Per protocol, the 32-week weight was used only for mothers who delivered prior to week 36. Height was measured in centimeters using a stadiometer at screening or was self-reported during the COVID-19 pandemic. BMI was calculated using the standard formula.

In addition, we analyzed excess GWG, defined as being above 2009 NAM weekly GWG recommendations conditional on screening BMI category. Average weekly gain was calculated for each participant by dividing, overall, GWG for each participant by the number of weeks between the screening visit and 36-week weight or 32-week weight for mothers who delivered prior to week 36 (see Figure 1 and Table 1 for missing data). Exact dates of measurements were used to calculate this duration. Excess GWG was defined as being above the upper limit of second and third trimester GWG for women with normal weight (>0.5 kg/wk), overweight (>0.33 kg/wk), and obesity (>0.27 kg/wk) [36].

Maternal and neonatal outcomes

For participants who delivered at a military hospital ($n = 348$), we were able to obtain maternal (i.e., preeclampsia, pregnancy-induced hypertension, gestational diabetes, cesarean delivery [elective and emergency], and preterm delivery [<37 weeks' gestation]) and neonatal outcomes (i.e., interuterine death, birth weight, 1- and 5-minute Appearance, Pulse, Grimace, Activity, and Respiration [APGAR] score, neonatal intensive care unit admission) from their electronic medical records. Infants whose birth weight was less than the 10th percentile (specific to sex) were categorized as small-for-gestational age, whereas infants whose birth weight was above the 90th percentile were categorized as large-for-gestational age [37].

Statistical analysis

The study was designed to detect a 2.5-kg difference between those who received GWG intervention conditions and participants in the comparison condition with assumed group standard deviations (SD) of 8.9, a significance level of 0.05%, and 80% power [27]. All statistical analyses were performed with SAS/STAT version 15.2 (SAS Institute). Descriptive statistics compared the means, SD, frequencies, and proportions for the GWG condition and the comparison condition. Descriptive comparisons between the conditions were conducted with the two-sample t test or χ^2 test for continuous and/or discrete variables, respectively, by the originally assigned group. The same analytical methods were applied for comparison of characteristics for those with complete versus missing outcome data at 32 to 36 weeks. We also calculated the intervention effect size expressed as the difference in means per one-unit SD.

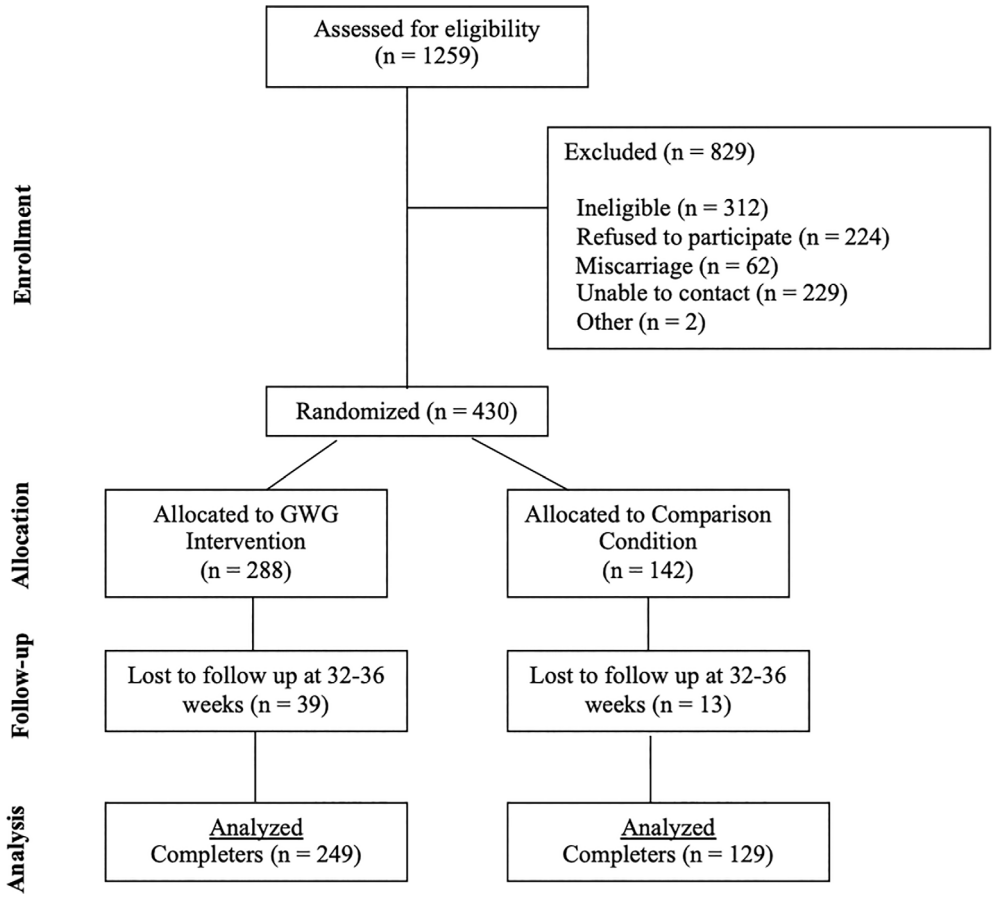

FIGURE 2 CONSORT (Consolidated Standards for Reporting Trials) diagram

TABLE 2 Comparison of characteristics by missing outcome status at the 32- to 36-week follow-up

	Complete ($n = 378$)	Missing ($n = 52$)	*p* value
Age (y)	30.9 (4.7)	28.7 (5.5)	0.0021
BMI (kg/m^2)	27.6 (5.4)	27.8 (4.2)	0.792
Gestational week at screening	11.8 (1.1)	11.6 (1.2)	0.4374
Weight: prepregnancy weight (self-reported) (kg)	72.8 (15.2)	74.2 (12.7)	0.5234
Weight: screening (kg)	74.0 (15.2)	75.5 (13.5)	0.5118
Weight: baseline (kg)	74.5 (15.1)	76.2 (13.7)	0.4543
BMI category, %			0.3968
Normal weight	33.6	26.9	
Overweight	40.2	38.5	
Obesity	26.2	34.6	
Hispanic/Latino, %	17.7	9.6	0.142
Race, %			0.0001
White	69.8	53.9	
Black	12.2	34.6	
Other race groups	18	11.5	
Active duty, %	47.6	46.2	0.8427
Previous live birth, %	56.4	50.0	0.3876

Note: Data given as mean (SD) or percentage.

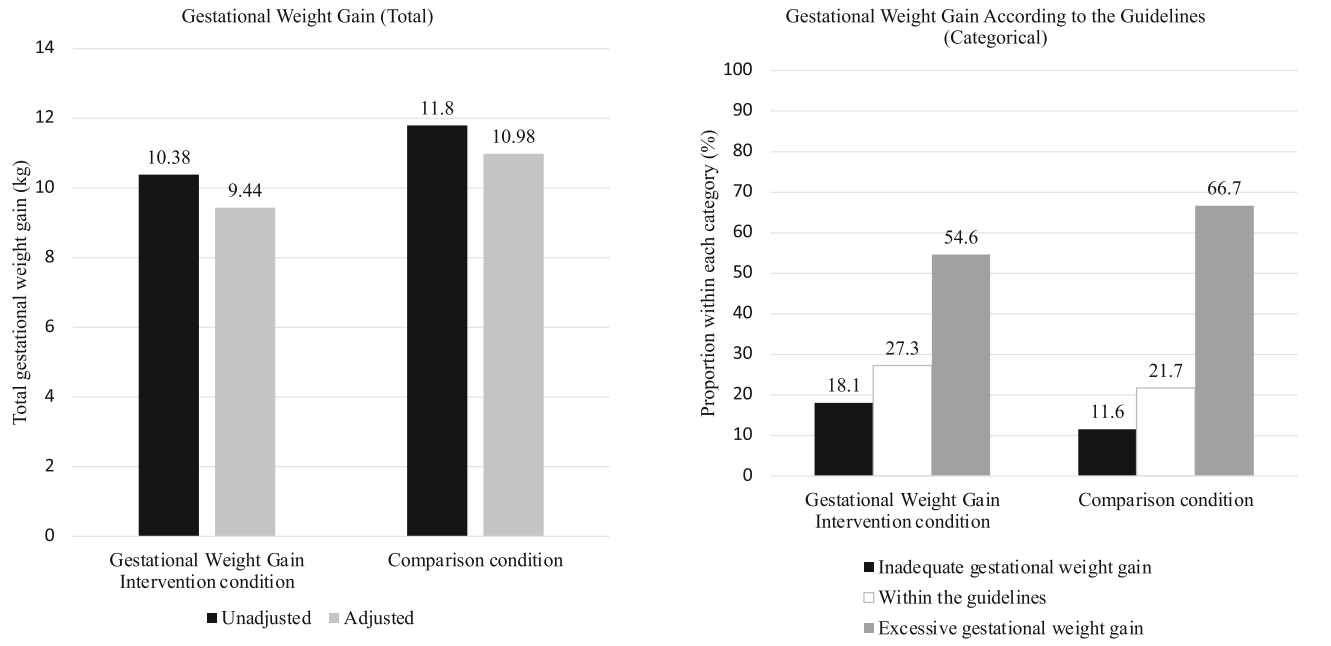

FIGURE 3 Gestational weight gain differences by condition

TABLE 3 Multivariable model examining characteristics associated with GWG

	β	SE	*p*
Study arm (GWG vs. comparison)	−1.54	0.48	0.0015
Screening weight	0.99	0.02	<0.0001
BMI category (obesity vs. normal weight)	−3.40	0.99	0.0007
BMI category (overweight vs. normal weight)	−1.29	0.63	0.04
Age	−0.01	0.05	0.7795
Gestation week at screening	0.19	0.21	0.3776
Race (ref: White)			
Black	−1.74	0.72	0.0155
Other race groups	−0.30	0.63	0.6285
Hispanic/Latino (ref: non-Hispanic)	−1.17	0.64	0.0689
Active duty (ref: not active duty)	1.14	0.47	0.0164
Previous live birth (ref: no previous live birth)	−0.25	0.48	0.6041

Note: Bolded text indicates a statistically significant finding. β is a parameter estimate based on the regression model. SE is a standard error of the parameter estimate.
Abbreviations: GWG, gestational weight gain; ref, reference.

To test the GWG intervention effect at 32 to 36 weeks, we applied an analysis of covariance regression model (ANCOVA), adjusting for screening weight, BMI category, age, race, ethnicity, active-duty military status, gestation weeks at screening, and parity. For the outcome of excessive GWG, we applied a logistic regression model to estimate the relative odds of being above recommended NAM guidelines at 32 to 36 weeks, as a function of the GWG intervention compared with the comparison condition, while controlling for the same covariates as those in the ANCOVA model. In both models, we tested the heterogeneity of treatment effect by including interaction terms between intervention condition, BMI category, race, ethnicity, and active-duty status to determine whether there were any differential effects. Associations were considered significant at the alpha level of 0.05 in combination with other evidence such as effect sizes, magnitude of the association, and confidence levels.

RESULTS

A total of 430 participants were randomized, representing 34.2% of those who initially indicated interest (Figure 2). Participant distribution across the BMI categories and demographic characteristics of the

TABLE 4 Maternal and neonatal outcomes based on intervention condition

	GWG condition	Comparison condition	*p* value
Maternal outcomes			
Preeclampsia, *n* (%)	22/232 (9.5%)	13/114 (11.4%)	0.5776
Pregnancy-induced hypertension, *n* (%)	35/232 (15.1%)	26/115 (22.6%)	0.0831
Gestational diabetes, *n* (%)	17/230 (7.4%)	13/114 (11.4%)	0.2144
Cesarean delivery (elective), *n* (%)	36/232 (15.5%)	18/114 (15.8%)	0.9477
Cesarean delivery (emergency), *n* (%)	39/233 (16.7%)	14/114 (12.3%)	0.2783
Preterm delivery (<37 weeks), *n* (%)	14/231 (6.1%)	7/115 (6.1%)	0.9923
Fetal/neonatal outcomes			
Intrauterine death, *n* (%)	0/232 (0%)	1/113 (0.9%)	0.3295[a]
Birth weight (g), M (SD)	3363.5 (529.1)	3365.3 (545.8)	0.9781
Small-for-gestational age (<10th percentile), *n* (%)	15/217 (6.9%)	7/102 (6.9%)	0.9997
Large-for-gestational age (≥90th percentile), *n* (%)	19/217 (8.8%)	9/102 (8.8%)	
APGAR score (1 minute), M (SD)	7.7 (1.2)	7.6 (1.5)	0.5744
APGAR score (5 minutes), M (SD)	8.8 (0.6)	8.7 (1.0)	0.2260
Neonatal intensive care unit admission, *n* (%)	19/233 (8.2%)	12/115 (10.4%)	0.4828

Abbreviations: APGAR, Appearance, Pulse, Grimace, Activity, and Respiration; GWG, gestational weight gain; M, mean.
[a]Fisher exact test.

TABLE 5 Characteristics associated with increased/decreased odds of gaining in excess of the guidelines

	Odds ratio	95% confidence limits		*p* value
Study arm (GWG vs. comparison)	0.54	0.34	0.88	**0.0125**
Screening weight	1.00	0.98	1.02	0.9498
BMI category (obesity vs. normal)	2.42	0.95	6.19	0.0653
BMI category (overweight vs. normal)	4.17	2.26	7.70	**<0.0001**
Age	0.99	0.94	1.03	0.453
Gestation week at screening	1.22	0.99	1.50	0.0566
Race (ref: White)				
Black	0.40	0.20	0.80	**0.0098**
Other race groups	0.92	0.51	1.68	0.7908
Hispanic/Latino (ref: non-Hispanic)	0.69	0.38	1.28	0.2406
Active duty (ref: other TRICARE beneficiaries)	1.26	0.80	2.00	0.3204
Previous live birth (ref: no previous live birth)	0.92	0.58	1.48	0.7411

Note: Bolded text indicates a statistically significant finding.
Abbreviations: GWG, gestational weight gain; ref, reference.

sample are presented in 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 (1%). Among active-duty participants, 70% were in the Air Force and 20% were in the Army, whereas, among other TRICARE beneficiaries, 56% were affiliated with the Air Force and 33% with the Army.

Approximately 12% of participants ($n = 52$) did not have a weight outcome assessment (Figure 2). There was no differential attrition between the conditions (GWG intervention = 13.5% vs. comparison group = 9.2%; $p = 0.1895$). Participants who did not complete the outcome assessment were slightly younger (28.7 vs. 30.9 years) and were more likely to identify as Black (Table 2). A total of 57 (13.3%) randomized participants experienced a serious adverse event (defined as "any undesirable experience either associated or not associated with participation in the study that results in death, risk of death, hospitalization, disability or permanent damage, or congenital anomaly or birth defect and requires intervention to prevent permanent impairment or damage"). 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 comparison group; $p = 0.0783$).

Among completers of the 32- to 36-week assessment ($n = 378$), using crude unadjusted estimates, GWG differed significantly between the conditions (GWG intervention: 10.38 kg [SD = 4.58] vs. comparison condition: 11.80 kg [SD = 4.87], with the mean difference: 1.42 kg [SD = 4.68]; effect size Cohen $d = 0.3$; $p = 0.0056$; Figure 3). Adjusted analyses controlling for screening weight, BMI category, age, race, ethnicity, active-duty military status, gestation weeks at screening, and parity showed similar findings. Participants in the GWG intervention group gained 9.44 kg (standard error [SE] = 0.40), on average, compared with the comparison condition that gained 10.98 kg (SE = 0.46), for an intervention effect difference of 1.54 kg (SE = 0.48; $p = 0.0015$; Table 3). Active-duty personnel gained 1.14 kg more than other TRICARE beneficiaries ($p = 0.0164$).

In addition, the GWG condition had a significantly lower proportion gaining in excess of the guidelines compared with the comparison condition (54.6% vs. 66.7%; $p = 0.0241$; Figure 3). Mean weekly average gain for those who received the GWG intervention was 0.40 kg (SD = 0.18), whereas, for the comparison condition, it was significantly higher (0.46 kg; SD = 0.18; $p = 0.0061$). However, there were no significant differences between the conditions in maternal or neonatal outcomes (Table 4).

In the multivariable logistic regression model, the GWG intervention was associated with almost 50% lower odds of excessive GWG (Table 5). Women with overweight or obesity had greater odds of excessive GWG compared with women with normal weight. Those who identified as Black had 60% lower odds of gaining in excess of the guidelines compared with White women. Overall, 60.6% of White women, 47.8% of the women who identified as Black, and 58.8% of the women who identified with other racial groups had excessive GWG.

In both linear and logistic models, we found significant differential effects of intervention by race. Effects were significant for White women but not for Black women or women identifying with other racial groups. Among White women, GWG was significantly lower (2.4 kg; $p < 0.0001$) for those in the GWG intervention relative to the comparison condition, with the odds of excessive GWG being 65% lower (odds ratio = 0.36, 95% CI: 0.20-0.65; $p = 0.0007$). For Black women or women identifying with other race groups, GWG was not significantly different between the intervention arms; specifically, GWG was 1.16 kg lower for those who received the GWG intervention among Black women ($p = 0.4901$), and GWG was 1.23 kg higher for those who received the GWG intervention among women of other racial groups ($p = 0.2533$).

Among those who received the GWG intervention, there were a total of 1373 sessions completed; on average, 4.2 sessions per participant (Figure 1). Among participants who received the GWG intervention, 25.9% of participants had at least one Step 2 session and 23.7% had at least one Step 3 session. Among those who had at least one Step 2 session, 93.6% exceeded the recommended GWG guidelines, and 96.5% exceeded the recommended GWG guidelines among those who had at least one Step 3 session.

DISCUSSION

In a diverse sample of women, we found that those who received the stepped-care-based GWG intervention gained significantly less weight than those who received usual care during pregnancy. In addition, women exposed to the GWG intervention were less likely to exceed the GWG guidelines (54.6% vs. 66.7%, respectively); in fact, the intervention decreased the odds of exceeding GWG recommendations by close to 50%. These results suggest that a remotely delivered behavioral intervention can be effective in facilitating healthy GWG among TRICARE beneficiaries.

Observed reductions in the prevalence of excessive GWG are consistent with other randomized controlled trials with similar behavioral interventions among civilians [36, 38, 39]. Additionally, the magnitude of the observed GWG difference is also similar to previous research [36, 40–42], although it is larger than the mean GWG difference found in recent meta-analyses (0.7 kg and 1 kg) [43, 44]. Notably, these outcomes were achieved with 4.2 sessions, on average, provided to each participant and using the stepped-care approach, which is substantially less than the 12 or more sessions that were associated with similar outcomes in the systematic review conducted by the US Preventive Services Task Force [44]. Nonetheless, this attenuation in GWG was not sufficient to significantly reduce negative maternal and neonatal health outcomes in the participants who received the intervention, consistent with previous analyses with larger samples [36]. Consistent with the established literature on the relationship between BMI and excessive GWG [8], our study indicated women with overweight and obesity were at increased odds of exceeding GWG guidelines throughout their pregnancy. Furthermore, the GWG intervention appeared to have differential effects by race; specifically, effects were only significantly different for White women. These findings may be explained by previous research indicating that White women exceed the GWG guidelines more frequently than women identifying with other racial groups [45, 46]; therefore, there may be more room for improvement in reducing excessive GWG among White women.

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%) [36], suggesting that a GWG intervention is of interest to TRICARE beneficiaries. Additionally, because prenatal care across the military health care 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 with 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 [47]. Additional strengths of this study include its randomized design, high retention rate, and diverse sample, which included individuals from racial and ethnic backgrounds who are often absent in research [48, 49]. Furthermore, this intervention successfully used 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). Furthermore, this stepped-care intervention matched resources to clinical needs of the participant, thereby likely reducing costs.

This study was not without limitations. We did not have a true no-treatment control group, owing to military research guidelines that restrict no-treatment control groups; our delayed intervention served as a comparison group. Knowledge of upcoming treatment at postpartum may have served as a facilitating or hindering factor in GWG management. Despite the two GWG arms being combined for the analyses, sensitivity testing showed no significant difference between GWG and GWG + PPWL arms in either model. In addition, although we intended to blind the assessor to the randomized condition, staff turnover prevented us from blinding the assessor in every instance. Furthermore, although a total of 450 participants was the original enrollment goal, only 430 participants were randomized because of slower-than-expected recruitment during specific study periods (e.g., the pandemic, closure of one obstetric clinic). 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, particularly among White women. Further research is needed to determine whether this approach could be extended across the Department of Defense and perhaps to civilian populations, particularly with fewer sessions, on average, per participant in this stepped-care intervention than in other previous interventions [44]. Given the new US Preventive Services Task Force recommendation to broadly provide behavioral counseling to achieve healthy GWG [44], this intervention could be integrated into the military prenatal care system using centralized call centers with trained interventionists who are responding to the needs of pregnant patients based on data collected from connected devices (e.g., smart scales). Future research should examine the cost-effectiveness of this intervention as well as 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 health care system.

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CONFLICT OF INTEREST

The authors declared no conflict of interest.

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