A Postpartum Weight Loss-Focused Stepped-Care Intervention in a Military Population: A Randomized Controlled Trial

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Author Note

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Abstract

Objective: Postpartum weight retention is associated with adverse health and career-related outcomes among both civilian and military women. The current study evaluated a stepped-care weight management intervention (Moms Fit 2 Fight) adapted for use in a pregnant military population.

Method: Active-duty women and other TRICARE beneficiaries ($N = 430$) were randomized to one of three conditions: gestational weight gain only (GWG-only) intervention ($n = 144$), postpartum weight loss (PPWL)-only intervention ($n = 142$), or a combined GWG+PPWL intervention ($n = 144$). Those participants who received the PPWL intervention were compared to those who participants who did not receive this intervention in the primary analyses. Primary outcome data (i.e., postpartum weight retention) was obtained at 6-months postpartum.

Results: Participants who received the PPWL intervention retained less weight (1.3 kg) compared to participants that received the GWG-only intervention (2.4 kg).

Conclusions: A behavioral intervention targeting diet and physical activity during the postpartum period reduced postpartum weight retention and was associated with an increased likelihood of returning to baseline BMI.

Keywords: postpartum weight loss, behavioral intervention, clinical trial, weight management, postpartum women, military health

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Meeting military standards for weight-to-height ratio (including body mass index (BMI)) is an entry-level requirement as well as a contractual requirement throughout military service that can be impacted by both lifestyle (e.g., diet, activity level) and life event (e.g., medical condition, injury, pregnancy)-related changes (Tanofsky- Kraff et al., 2010). Pregnancy, in particular, is frequently associated with weight increases (Fraser et al., 2011; Mannan & Mamun, 2013; Nartea et al., 2019), and the risks and potential consequences of which are increased among active-duty or military women (Chauhan et al., 2013; Spieker et al., 2015; Maciejewski et al., 2018; Krukowski et al., 2018; Bookwalter et al., 2019; Rogers et al., 2020). In a previous longitudinal research study, women, on average, retained approximately 1.7 kg at 6 months postpartum (Rooney & Schauberger, 2002), although anywhere from 14-20% of women retain a substantial amount of weight (more than 5 kilograms; Gunderson, 1999). In military populations, a study evaluating weight in active duty Navy women found that only half (49%) met weight standards and 32% met BMI standards (< 25 kg/m^2) at 6 months postpartum, compared to 68% meeting weight standards and 53% meeting BMI standards pre-pregnancy (Chauhan et al., 2013). In more recent research, active duty women in the Navy who became pregnant were at greater risk of failing to meet fitness test and BMI requirements at one year postpartum and up to 2.5 years postpartum, compared to women who did not become pregnant (Rogers et al., 2020).

In addition, postpartum weight retention is associated with increased risk for obesity and other weight-related morbidity (Chauhan et al., 2013), as well as increased medical costs. The Department of Defense (DoD) Military Health System exceeds $1 billion in preventive and treatment costs associated with overweight, obesity, and related comorbidities (Tanofsky- Kraff et al., 2010; Dall et al., 2007). Fortunately, a meta-analysis of 27 trials found that interventions targeting both diet and activity level were generally associated with reduced postpartum weight retention (Dodd et al., 2018).

A recent adaptation of the Look AHEAD ILI (Action for Health in Diabetes, Intensive Lifestyle Intervention) program (Look AHEAD Research Group, 2006, 2007, and 2013) for non-pregnant active duty personnel was successful at inducing clinically significant weight loss (Krukowski et al., 2018). In addition, a stepped-care adaptation of this intervention was successful at reducing gestational weight gain (GWG) among pregnant active duty personnel and other TRICARE beneficiaries (Estevez Burns, under review). The current study examines the postpartum weight loss phase of this intervention among pregnant and post-partum active duty women and TRICARE beneficiaries (e.g., spouses and/or other dependents of active duty personnel). As such, the purpose of this study is to evaluate and compare the efficacy of a gestational weight gain (GWG)-only intervention, postpartum weight loss (PPWL)-only intervention, or combined (GWG+PPWL) intervention in promoting postpartum weight loss. For the purpose of this study, postpartum weight loss is defined as the loss of weight gained during pregnancy (i.e., the difference between screening weight and weight at 6 months postpartum). We hypothesized that participants randomized to either the GWG+PPWL and PPWL-only intervention would lose significantly more weight at 6-months postpartum than participants randomized to the GWG-only intervention.

Materials & Methods

Design

The study design reflects an unblinded randomized controlled trial (RCT) of a stepped-care intervention for postpartum weight loss within a military population, including both active duty military personnel and TRICARE beneficiaries. Individuals were recruited from two Department of Defense (DoD) outpatient medical centers located in Texas (USA), Wilford Hall Ambulatory Surgical Center and San Antonio Military Medical Center. With the closure of the Wilford Hall obstetric clinic and the COVID-19 pandemic, two additional military bases, Andrews Air Force Base and Wright Patterson Air Force Base, were added as recruitment sites starting in July 2020. Participants were recruited via advertisements and healthcare provider referrals. Interested individuals meeting initial eligibility criteria were scheduled for a screening visit. During the screening visit, study personnel assessed eligibility, administered initial screening measures, and obtained informed consent. Following the screening visit, participants were asked to self-monitor dietary and exercise information for one week as well as to obtain medical clearance to participate in the study. In the case of active duty status, fitness test scores from one year prior to study enrollment were obtained to compare pre-pregnancy and postpartum fitness test scores. Upon successful completion of these procedures, participants were randomized to one of three intervention conditions (GWG-only, PPWL-only, or combined GWG+PPWL). Participants were individually randomly assigned using a computerized block design designed by a study biostatistician, 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 study staff notified participants of the randomization assignment.

There were no changes to the study outcomes once the study began. Planned analyses were conducted related to the effect of the GWG intervention (Estevez Burns, under review), but no other interim analyses were conducted. Study recruitment ended in October 2020 with 430 randomized participants to allow for follow-up to 12 months postpartum within the grant period, with no further sample size-related stopping guidelines applied. Thus, this study reports the primary study outcomes—postpartum weight retention at 6-months postpartum. 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.

Participants

Recruitment for this study began in February 2017 and ended in October 2020. Eligible participants included individuals aged 18 years or older that were either active duty personnel or other TRICARE beneficiaries (e.g., spouses). Participants were eligible if they were < 13 weeks and 5 days gestation upon randomization, consistent with previous research (Redman et al., 2017). Active-duty personnel were initially eligible for our study if they had at least 1.5 years left in their current duty station; this requirement was in place to minimize chances of missing in-person follow-up visits, but was removed in April 2020 when the study moved to remote assessments due to the COVID-19 pandemic. Other exclusion criteria included the presence of medical and psychiatric conditions that may limit full participation in the intervention, history of bariatric surgery or recent weight loss, and the use of medications that may contribute to changes in weight. Individuals with conditions contributing to high-risk pregnancy (including those who reported smoking cigarettes, as well as those with diabetes or multiple gestation) and those with underweight were also excluded from participation in this study.

A total of 430 participants were randomized to one of three intervention conditions: Gestational weight gain intervention (GWG; n = 144), postpartum weight loss intervention

(PPWL; *n* = 142), and combined intervention (GWG+PPWL; *n* = 144). Consistent with the pre-registered protocol (Fahey et al., 2018), the GWG intervention was compared to a combined PPWL and GWG+PPWL group in order to compare postpartum weight retention between groups that received the PPWL intervention (*n* = 286) and those that did not *n* = 144).

Interventions

The interventions implemented in this study reflected a stepped-care behavioral approach designed to either increase or decrease the intensity of the intervention depending on individual participant's progress in meeting established weight gain and weight loss recommendations. Additional details can be found in the study protocol (Fahey et al., 2018) and the main GWG outcome paper (Estevez Burns, under review), including details of the GWG intervention.

Post-Partum Weight Loss (PPWL) Intervention

The PPWL intervention consisted of remote (telephone) sessions (20 – 30 minutes) delivered individually by trained study interventionists from 6-weeks to 12-months postpartum, although the primary outcome and the focus of this paper is on the first 6 months postpartum. Contact occurred monthly, biweekly, or weekly in accordance with the stepped-care approach. The PPWL intervention included self-monitoring, goal-setting, and problem solving for weight, diet, and physical activity. Interventions were delivered by trained interventionists. Randomly selected intervention sessions were audio-recorded (with participant permission), and feedback on adherence to the protocol was provided to the interventionist. Interventionists were re-trained periodically to ensure treatment fidelity.

Weight. Weight loss goals for women were generally divided into two pre-pregnancy BMI categories: weight goals for women within a normal pre-pregnancy BMI were to return to pre-pregnancy weight, whereas weight loss goals for women within an overweight or obese pre-pregnancy BMI were to return to pre-pregnancy weight or to lose up-to an additional 5% of pre-pregnancy weight, if desired. Irrespective of BMI, women were advised to follow a weight loss trajectory of approximately one pound (0.45 kg) per week. Participants were encouraged to engage in daily weight monitoring using a Body Trace™ e-scale; data from the scale, including the date and time of weigh-ins, were accessible to both participants and interventionists via a secure and personalized website. Participants received weekly feedback from an interventionist regarding their weight loss trajectory via email (including the weight graph).

Diet. All participants received measuring utensils to assist with portion size estimates; participants received these tools at baseline if they received the GWG intervention and at 6 weeks postpartum if they received the PPWL-only intervention. Caloric intake goals were based on baseline reports, breastfeeding status, and U.S. Dietary guidelines (myplate.gov). Women who were breastfeeding received a caloric intake goal that was 300 kcal greater than women who were not breastfeeding. Caloric intake goals were periodically adjusted as needed, based on individual weight loss trajectories. Participants not meeting weekly weight loss goals received additional support. Specifically, as part of the stepped-care approach (Step 2 and 3), participants were encouraged to self-monitor their dietary intake and physical activity using MyFitnessPal. Step 3 included the addition of meal replacements and meal planning.

Physical Activity. Participants received a wrist-worn activity tracker (e.g., Fitbit) to promote and monitor physical activity goals; participants received these tools at baseline if they received the GWG intervention and at 6 weeks postpartum if they received the PPWL-only intervention. Following medical clearance at approximately 6-weeks postpartum, participants were encouraged to gradually return to pre-pregnancy levels of physical activity. Physical activity was reduced or halted in accordance with medical recommendations.

Measures

Data were collected across 6 visits: screening, baseline, gestational weeks 32 and 36, 6-weeks postpartum, and 6-months postpartum. Self-reported sociodemographic characteristics (i.e., age, race, ethnicity, education, marital status, military rank) were collected at the screening visit. Changes in body weight (kg) from screening to the 6-months postpartum period was the primary study outcome. Weight was measured, collected, and stored using a research-grade digital scale within the obstetric clinic (prior to March 2020) and using the participants' assigned Body Trace™ e-scale during the COVID-19 pandemic. Baseline BMI was calculated during the initial screening visit using the standard formula. Height was measured in centimeters using a stadiometer at screening, or self-reported during the COVID-19 pandemic. Consistent with previous research, weight retention was defined by three categories: < 0.9 kg, 0.9 – 4.99 kg, and ≥ 5 kg (Phelan et al., 2014; Phelan et al., 2017).

Analysis

A-priori power calculations were conducted using PASS15 (see Fahey et al., 2018). Based on previous research, postpartum weight retention estimations without intervention are 1.7 kg at 6-months postpartum (Rooney & Schauberger). Further, our a-priori hypothesis was that the GWG+PPWL and PPWL-only conditions would result in weight loss improvements of 1.2 kg, or 0.5 kg postpartum weight retention in the intervention group (Joi et al., 2013). A sample size of 150 participants per condition was determined to detect between-group mean differences of 0.4 kg (assumed group standard deviations of 1.0), with 80% power and a medium effect size (Little & Rubin, 1987). Given the population characteristics (e.g., the mobility of the military population, a pregnant population with the possibility of miscarriage), a 20% attrition rate at 6-months follow-up was estimated.

Statistical analyses were conducted using SAS/STATv15.2. Descriptive statistics including the means, standard deviations, frequencies and proportions were generated overall and for the GWG/PPWL conditions. Two-sample t-test or chi-square test for continuous and/or discrete variables, respectively, were applied for comparison of characteristics for those with complete versus missing outcome data at six months post-partum. Primary analyses for testing the PPWL intervention effect at six months post-partum was based on analysis of covariance linear regression model (ANCOVA), adjusting for screening weight, BMI category, age, race, ethnicity, active-duty military status, gestation weeks at screening, and parity, using an intent-to-treat approach. Shifts in BMI category between screening and six months post-partum were tested using chi-square symmetry test with weighted kappa coefficient. Comparison of weight retention group proportions between conditions was performed with a chi-square test. 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

Across groups, 47.4% of participants classified as active-duty personnel, whereas 52.6% of participants classified as other TRICARE beneficiaries. Overall, a majority of participants were affiliated with the Air Force (63%), with fewer participants affiliated with the Army (27%), Navy (8%), Marine Corps (2%), and Coast Guard (1%). A majority of active-duty and other TRICARE beneficiaries were affiliated with the Air Force (70% and 56%, respectively), and fewer were affiliated with the Army (20% and 33%, respectively). Close to 12% of participants ($N = 50$) did not have a weight outcome assessment at 6 months postpartum (Figure 2 and Table

2). There was no significant differential attrition between the conditions (PPWL condition 13.3% vs. GWG condition 8.3%; $p = 0.1305$). Participants who did not complete the outcome assessment were slightly younger and were more likely to identify as Black (Table 3). There was no significant difference in the proportion of participants experiencing a serious adverse event between the conditions (11.9% of those who received the PPWL condition and 16.0% in the GWG condition; $p = 0.2389$).

Results demonstrated a weight retention of 2.39 kg for the GWG-only arm (95% CI 0.98, 3.80; $p < 0.0001$), 1.25 kg for PPWL arm (95% CI -0.22, 2.72; $p = 0.1905$) and 1.36 kg for the combined GWG+PPWL arm (95% CI -0.08, 2.78; $p = 0.0808$). As previously mentioned, planned comparisons for this analysis involved comparing the GWG-only intervention to interventions including a PPWL component (PPWL-only and GWG+PPWL). Results indicated that weight retention among PPWL-only and GWG+PPWL was similar among both intervention groups (1.25 kg and 1.36 kg, respectively). Thus, results reported here reflect the planned analyses. These results showed similar weight retention of 2.39 kg for the GWG arm (2.39 kg), and 1.31 kg for the arms involving a PPWL component (95% CI 0.38, 2.23, $p = 0.0012$). After the adjustment for other covariates, the ANCOVA model showed similar findings with adjusted weight retention of 2.09 kg for the GWG-only condition and 1.02 kg for arms involving a PPWL condition. Weight retention was therefore 1.07 kg lower for the PPWL condition (95% CI -2.25, 0.1; $p = 0.0728$) compared to those who received only the GWG intervention. There were no significant differences in demographic predictors of postpartum weight retention (Table 4).

For the GWG arm, 75% of the participants remained in the same BMI category at 6 months postpartum, 6.1% moved to a lower BMI category, and 19% moved to a higher BMI category. For those who received the PPWL component, 78.6% of the participants remained in the same BMI category, 6% moved to a lower BMI category, and 15.4% moved to a higher BMI category. Data showed a slightly larger, but non-significant shift toward higher BMI categories for the GWG-only arm (19%), compared to higher BMI category shift for interventions that included a PPWL component (15.4%).

When weight retention was examined categorically, 48.1% participants receiving a PPWL intervention returned to their preconception weight (i.e., <0.9 kg weight retention), and 43.4% of women who received the GWG-only intervention returned to their preconception weight. In contrast, 23.7% of participants who received the PPWL intervention had 5 kg of postpartum weight retention or greater, and 28.8% of participants in the GWG-only intervention retained at least 5 kg. Despite lower total weight retention in PPWL condition, there was, however, not a statistically significant difference between two conditions in returning to their preconception weight ($p = 0.5374$).

Discussion

Using a stepped-care approach, this study found that a weight management intervention targeting the postpartum period resulted in approximately 1 kg lower weight retention than an intervention that included only a gestational weight gain component. Those participants who did not have the postpartum weight loss intervention retained about 2.3 kg while those who received the postpartum intervention retained about 1.3 kg. Overall, results supported the hypothesis that conditions with a PPWL intervention were more effective at reducing postpartum weight retention than a GWG-only intervention.

The results of this study are consistent with those of other behavioral intervention trials targeting or evaluating postpartum weight outcomes (Phelan et al., 2014; Phelan et al., 2017; Phelan et al., 2020). Results from the LIFE-Moms consortium (Clifton et al., 2016) similarly

support the effectiveness of lifestyle interventions focusing on diet and activity level delivered during the pregnancy period (Peaceman et al., 2018), and in the postpartum period (Phelan et al., 2020). In sum, the LIFE Moms interventions indicated a 1.6 kg difference in weight retention at 12 months postpartum compared to standard care. Additionally, a recent meta-analysis found that multi-component eHealth interventions targeting both diet and physical activity during the postpartum period were associated with significant postpartum weight reduction (-2.55 kg; Sherifali et al., 2017). The use of remote communication, delivery, and tracking methods (email, text messaging, phone calls) in the current study contributes to knowledge in novel eHealth approaches to PPWL interventions.

Across the entire sample, participants tended to remain in the same BMI category postpartum that they were early in their first trimester (77.4%). Results did, however, demonstrate a slightly larger, but non-significant shift toward higher BMI categories for the intervention including only a gestational weight gain component (19%) compared to interventions including a postpartum weight loss component (15%). In addition, a modestly (albeit non-significantly) greater proportion of individuals receiving an intervention that included a PPWL component (48.1%) returned to their preconception weight compared to individuals receiving an intervention that included only a GWG component (43.4%), based on the definition used in previous research (>0.9 kg; Phelan et al., 2014; Phelan et al., 2017). These results are consistent with previous research in the proportion returning to pre-conception weight with a PPWL intervention (45.3%) (Phelan et al., 2014).

The stepped-care intervention approach employed in this study provides support for individualized interventions during the postpartum period. In addition, the intervention was well-received, indicated by approximately 25% of participants randomized out of 1259 individuals who initially indicated interest. Further, there was a good retention of participants at 6 months postpartum (88.4%). However, the study was not without limitations. First, there was not a no-treatment control group, so it is not clear how much postpartum weight retention would have occurred in the absence of any intervention; however, typical postpartum weight retention is 1.7 kg among civilians (Rooney & Schauberger, 2002), but may be higher in a military population since those participants who received only the GWG intervention had 2.4 kg of weight retention. It is also possible that the approximately 25% of the participants with 5 kg or greater weight retention postpartum may have required an even more intensive intervention than the highest step of the current intervention. A potential further limitation is that 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. Furthermore, generalizability to civilian populations is unknown. Additionally, measured weight at 6 months postpartum was not possible to obtain in the majority of the sample due to the COVID-19 pandemic; however, previous research (e.g., Pebley et al., 2019) indicates strong concordance between weights on Body Trace™ e-scales and clinic weights. Finally, although we intended to blind the assessor to the randomized condition, staff turnover prevented us from blinding the assessor in every instance.

In conclusion, the results of this study suggest that a remote, diet and physical activity stepped-care behavioral intervention delivered during the postpartum period is effective at reducing weight retention in a diverse sample of women affiliated with the military. Future research should investigate the cost-effectiveness and potential dissemination of stepped-care interventions, as well as investigate the efficacy of a similar stepped-care postpartum intervention in civilian populations.

Table 1. Postpartum Weight Loss (PPWL): Stepped-care Intervention

	Step 1 Beginning	Step 2 < 0.5 lbs./ week weight loss	Step 3 < 0.5 lbs./ week for two weeks
Contact	20-30-min. monthly phone sessions	20-30-min. biweekly phone sessions	20-30-min. weekly phone sessions and resources
Dietary recommendations	Calorie goal based on baseline self-monitoring and breastfeeding status	Step 1 with addition of: monitoring portion size and dietary intake	Calorie intake reduced by 100-200 calories/ day
Physical activity level recommendations	Activity goal gradually increased to pre-pregnancy levels, monitored using wrist-worn activity tracker (Fitbit)	Step 1	Step 1
Behavioral strategies	Daily self-monitoring and weekly feedback regarding weight	Step 1 with addition of: monitoring food intake and exercise, and goal setting and problem solving strategies (via email and phone)	Step 2 with addition of: meal replacements, meal plans, toolbox resources, and additional resources (adapted Look AHEAD ILI material)
Conditions for decreasing level of intervention	All participants (beginning)	Return to recommended weight loss trajectory	Return to recommended weight loss trajectory

Table 2. Sample Characteristics, Overall and by Condition.

	Total (N = 430)	GWG (N = 144)	PPWL (N = 286)
Age (years)	30.6(4.9)	30.9(5)	30.5(4.8)
Body mass index (kg/m^2)	27.6(5.2)	27.6(5.3)	27.7(5.2)
Gestation week at screening (weeks)	11.7(1.1)	11.8(1.1)	11.7(1.1)
Weight – self-reported pre-pregnancy weight (kg)	73.0(14.9)	72.3(14.6)	73.3(15.1)
Weight – screening (kg)	74.2(15)	73.6(14.4)	74.5(15.2)
Weight – 6 months postpartum (kg)	74.7(15)	76.2(15.4)	75(15.7)
BMI category (%)			
Normal weight	32.8	33.3	32.5
Overweight	40	40.3	39.9
Obesity	32.5	26.4	27.6
Hispanic/Latino (%)	16.7	15.3	17.5
Race (%)			
White	67.9	70.1	66.8
Black	14.9	13.9	15.4
Other race groups	17.2	16	17.8
Active-duty (%)	47.4	48.6	46.9
Previous live birth (%)	55.6		
Missing primary outcome data at 6 months postpartum (%)	11.6	8.3	13.3
Withdrew (%)	10.7	7.6	12.2

Mean (SD) or %

Table 3. Comparison of characteristics by missing outcome status at the 6-month postpartum follow-up.

	Complete (N=380)	Missing (N=50)	p-value
Age (years)	30.9(4.7)	28.1(5.3)	0.0001
Body mass index (kg/m^2)	27.6(5.3)	27.8(4.6)	0.8350
Gestational week at screening	11.8(1.1)	11.6(1.2)	0.3905
Weight – pre-pregnancy weight (self-reported) (kg)	72.7(15.2)	75.0(12.6)	0.3170
Weight – screening (kg)	74.0(15.2)	75.6(13.3)	0.4958
Weight – baseline (kg)	74.6(15.1)	75.9(13.9)	0.5680
BMI category (%)			0.6462
Normal weight	33.4	28	
Overweight	40	40	
Obesity	26.6	32	
Hispanic/Latino (%)	16.8	16	0.8808
Race			0.014
White	68.7	62	
Black	13.2	28	
Other race groups	18.2	10	
Active duty (%)	48.4	40	0.2623
Previous live birth (%)	55.8	54	0.8108

Mean(SD) or %

Table 4. Multivariable linear regression model examining characteristics associated with postpartum weight retention.

Variable	β	SE	p-value
Study Arm (PPWL vs. GWG)	-1.074	0.597	0.0728
Screening weight	0.01	0.03	0.7366
BMI Category (Obesity vs. Normal weight)	-1.579	1.211	0.1931
BMI Category (Overweight vs. Normal weight)	-0.556	0.78	0.4766
Age	-0.086	0.062	0.1659
Gestation Week at Screening	-0.002	0.264	0.9948
Race (ref: White)			
Black	0.078	0.877	0.9291
Other race groups	-0.035	0.778	0.9644
Hispanic /Latino (ref: Non-Hispanic)	-0.677	0.813	0.4055
Active Duty (ref: Not Active Duty)	0.427	0.595	0.4739
Previous Live Birth (ref: No Previous Live Birth)	0.309	0.601	0.6067

Bolded text indicates a statistically significant finding

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