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Effects of a behavioral intervention on physical activity, diet, and health-related quality of life in postpartum women with elevated weight: results of the HIPP randomized controlled trial

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Abstract

Background Approaches to improve physical activity (PA), diet, and health-related quality of life (HRQOL) during postpartum in diverse women with elevated weight are needed.

Methods Health In Pregnancy and Postpartum (HIPP) was a randomized controlled trial that followed African American and white women with overweight or obesity from pregnancy through 12 months postpartum. Participants were randomized to a behavioral intervention grounded in social cognitive theory ($n=112$) or standard care ($n=107$). From enrollment (≤ 18 weeks gestation) through 6 months postpartum, the intervention group received two in-depth counseling sessions (one each during pregnancy and postpartum), counseling calls, behavioral podcasts, and access to a private Facebook group, while the standard care group received monthly mailings and podcasts focused on healthy pregnancy and infant development. PA (SenseWear armband), diet (ASA24), and HRQOL (SF-12) measurements were obtained from blinded assessors at baseline and 6- and 12-months postpartum. Linear or quantile regression models, depending on conformity to normality assumptions, were used to test differences between behavioral intervention and standard groups in PA outcomes (minutes/day of total PA, light PA, and moderate-to-vigorous intensity PA (MVPA), and total steps/day), dietary outcomes (diet quality and six measures of dietary intake), and HRQOL at 6- and 12-months postpartum, controlling for baseline values, race, parity, weight status, education, maternal age, gestational age, and caloric intake (for most diet models).

Results There were no statistically significant differences by group for any PA, diet, or HRQOL outcomes at 6 or 12 months postpartum. Irrespective of group assignment, all PA outcomes improved from pregnancy to postpartum, as did kcals and the mental component of HRQOL. Furthermore, while not statistically significant, virtually all PA outcomes, except MVPA at 12 months, and several dietary outcomes, including diet quality, had patterns favoring the intervention group but with small effect sizes.

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Conclusions Postpartum PA, diet, and HRQOL did not differ significantly between women in the behavioral intervention group and those in the standard care group. Given the increased responsibilities and stress that women face during the postpartum period, this appears to be a challenging time to make lifestyle changes.

Trial registration This trial was registered at ClinicalTrials.gov on 10/09/2014. Identifier: NCT02260518.

Keywords Postpartum, Maternal health, Health behaviors, Behavior change, Physical activity, Nutrition, Diet quality, Quality of life

Background

The life stage of pregnancy through the postpartum period is critical for women's health and well-being and offers an opportunity to implement healthy lifestyle changes [1–4]. Indeed, several professional, federal, and global organizations recommend physical activity (PA) and dietary changes during pregnancy and postpartum to reduce the risk of adverse maternal and child health outcomes [5–11]. There is substantial evidence that PA and dietary interventions during pregnancy reduce gestational weight gain and lower the risk of adverse maternal and neonatal outcomes relative to standard care [12], and these benefits are observed in those with normal weight status as well as overweight/obese weight status [13]. Reducing excessive gestational weight gain is also important because of its association with maternal and infant outcomes [14, 15], future obesity in offspring [16], and subsequent obesity among women [17]. Furthermore, PA during pregnancy is associated with a reduced risk of prenatal [18–20] and postpartum [21, 22] depression.

Fewer studies have examined the impact of PA and dietary interventions during the postpartum period. Several literature reviews have concluded that pregnancy and postpartum lifestyle interventions reduce postpartum weight retention [2, 23–25], including up to two years after delivery [26], but inconsistencies have been noted. While Farpour-Lambert et al.'s review (2018) found that diet and PA interventions reduced postpartum weight retention among women with normal weight as well as among those with overweight/obesity, Michel et al.'s review [27] did not find significant intervention effects for those with overweight/obesity.

The Health in Pregnancy and Postpartum (HIPP) study was a randomized controlled trial of a behavioral lifestyle intervention program delivered from early/mid pregnancy (< 18 weeks gestation) through 6 months postpartum in women with overweight and obesity. It was designed to test whether a behavioral lifestyle intervention reduced excessive gestational weight gain (primary outcome) and promoted postpartum weight loss as well as improved PA and dietary changes during pregnancy and postpartum (secondary outcomes) in African American and white women [28]. A unique aspect of this study was that women received the intervention from early pregnancy through 6 months postpartum and were followed through 12 months postpartum. The behavioral intervention resulted in reduced gestational weight gain in African American participants who were overweight (but not obese) but had no impact on weight gain in white women [29]. Notably, women in the behavioral intervention group (regardless of race or weight status) had less weight retention at 6 and 12 months than those in standard care [30]. The behavioral intervention also improved several dietary outcomes during pregnancy but only modestly affected prenatal PA and health-related quality of life (HRQOL). This paper aimed to examine the impact of the behavioral intervention (versus standard care) on PA, dietary outcomes, and HRQOL at 6 and 12 months postpartum. We hypothesized that those receiving the behavioral intervention would be more physically active and less sedentary, have lower caloric intake and more favorable dietary behaviors, and have better HRQOL.

The HIPP study was responsive to several gaps identified in the literature. First, studies have lacked diversity by race/ethnicity and weight status [13, 27]. African American/Black women retain substantially more weight postpartum than Latino and white women [31]. Furthermore, women with overweight/obesity are at increased risk for adverse maternal and child health outcomes [15], and in addition, they are at increased risk for excessive gestational weight gain [32]. Second, very few studies have intervened from pregnancy through the postpartum period [23], thus missing an opportunity to support women during this critical life transition. Third, several reviews graded the quality of evidence in this area as moderate or low [23, 25, 27], often because details regarding the intervention were not adequately reported [23, 24, 33]. We have published an extensive process evaluation paper on intervention fidelity in the HIPP trial [34]. Fourth, most intervention studies do not follow participants after the intervention ends. For example, in Michel et al.'s (2019) review of 14 lifestyle intervention studies, only 3 followed women to 12 months postpartum. Fifth, while postpartum depression is a commonly studied outcome [35, 36], few studies have examined the impact of lifestyle interventions on HRQOL during postpartum, especially among women with overweight and obesity. Last, this literature rarely includes data on the

behavioral targets of PA and diet that theoretically underlie weight changes. The HIPP study used state-of-the-art measures of diet and PA to address this gap.

Methods

Study design and participants

The CONSORT and TiDieR Checklists are included in Additional Files 1 and 2. We recruited participants primarily through 13 obstetrics and gynecology clinics in South Carolina [37]. The study design is described in detail elsewhere [28]. The Institutional Review Boards of three participating healthcare centers and one university approved the study protocol. All participants signed a written informed consent form. Participants completed four measurement visits. This paper used prerandomization baseline data collected during early pregnancy (< 18 weeks gestation; February 2015-January 2019) along with data collected at 6 months (April 2016-January 2020) and 12 months (September 2016-August 2020) postpartum. We did not use data collected in late pregnancy. The measurement staff were blinded to the study assignments. Most (90.4%) baseline measurements were conducted at the university, but this percentage decreased to 54.0% at 6 months and 46.2% at 12 months due to increased home visits and a small percentage of visits at other sites (e.g., library, clinic). The eligibility inclusion criteria were 18–44 years of age, white or Black/African American, able to read and speak English, no plan to move from the area in the next 18 months, ≤ 16 weeks gestation, pre-pregnancy body mass index ≥ 25 kg/m^2, prepregnancy weight ≤ 370 pounds (scale limitation), regular access to a telephone, and willingness to participate in weekly calls. The exclusion criteria were uncontrolled blood pressure (> 160 systolic or > 100 diastolic), insulin use, uncontrolled or untreated thyroid disease, hospitalization for mental health or substance abuse disorders in the past 6 months, multiple gestation, persistent bleeding in the first trimester, physical disabilities that prevent exercise, physician advice to not exercise during pregnancy, and a history of > 3 miscarriages, eating disorders or malnutrition, or incompetent cervix. The sample size was determined from a power analysis that indicated that 400 participants were needed to detect small (d = 0.28) intervention effects for the primary outcome (gestational weight gain) with assumed retention of 80% of participants at 6 months and 70% of participants at 12 months [28]. Due to recruitment challenges described elsewhere [37], we did not meet our recruitment goal.

Randomization

We used a stratified randomization procedure with blocking by delivery hospital site and racial/ethnic group. The allocation ratio was 1:1 such that within each of the eight strata (i.e., four delivery sites x two racial/ethnic groups), for every four participants, two were randomized to the behavioral intervention group and two to the standard care group. The statistician generated a randomization list. The study coordinator randomized the participants and shared the group assignment with the intervention staff.

Behavioral Intervention

The behavioral intervention components and our process evaluation results are described elsewhere [28, 34]. In brief, the intervention was guided by social cognitive theory [38] and focused on improving diet, increasing PA, gaining healthy gestational weight, and losing weight in postpartum through evidence-based strategies (e.g., self-monitoring, goal setting). The behavioral intervention was delivered by master's level staff with training in public health and behavior change, with additional training from the study PI (SW), using semistructured scripts. The intervention components during pregnancy included an initial in-depth counseling session (within the first 18 weeks of gestation) followed by brief telephone counseling calls until delivery, 10 behavioral podcasts (average duration of 21 min each), and access to a private Facebook group. Participants received a pedometer, scale, and weight gain chart (with upper and lower recommended bounds) to facilitate self-monitoring, a key evidence-based behavioral strategy in general populations [39–41] and in the postpartum period [42].

After delivery, participants received brief weekly check-in calls until the in-depth postpartum counseling session was delivered. These supportive calls were intended to last only a few minutes and included no weight, PA, or diet discussion. At 6 to 8 weeks postpartum, the interventionist provided an in-depth counseling session (~ 60 min). Nearly half of the sessions were conducted at the university (48.3%), 36.8% at the participants' homes, and 14.9% by phone. This session focused on setting goals for resuming PA (after being cleared by their health care provider), meeting nutritional needs postpartum (including for those who were breastfeeding), setting a weight loss goal, and discussing strategies for losing one to three pounds per week. MyPlate, tailored to breastfeeding status, guided the postpartum nutritional content [43]. All participants received a personalized weight loss tracking graph with the upper (three pounds per week) and lower (one pound per week) bounds of recommended weight loss over time for six months (adjusted to not go below a healthy BMI).

After the in-depth postpartum counseling session, and through 6 months postpartum, the intervention staff delivered biweekly telephone counseling calls. Each call began with an assessment of whether there were any

health-related changes. Participants were asked to report their weight and plot it on their weight loss graph (the interventionist did the same), which led to a discussion of how their weight loss compared to their goals. Each call emphasized behavioral strategies deemed most relevant to assisting them in improving their diet, increasing their PA, and losing weight. Calls ended by setting a weekly PA and healthy eating goal.

Beginning at 4 weeks postpartum, participants received a link to their first of 16 weekly podcasts that followed the 16 core Diabetes Prevention Program sessions and focused on gradual weight loss (1–3 pounds per week) [26]. They were tailored as needed for the postpartum period. The format of the podcasts was based on previous work that demonstrated their efficacy for weight loss in nonpregnant adults [25]. Podcasts featured scripted character narratives for two postpartum women attempting healthy lifestyle changes and weight loss. Two voice actors, one African American and one white woman, portrayed the main characters. The podcast recordings also included a narrator to guide the storyline and connect module content. Podcasts averaged 20 min in duration. Participants were required to enter their study ID and initials to download each podcast so that downloads could be tracked. We sent reminder emails to participants who had not downloaded the podcast. We provided a CD with that week's podcast if participants did not have a device to access the podcast.

Participants remained in the Facebook pregnancy group until 6 to 8 weeks postpartum and then transitioned to the postpartum group, which continued through 6 months postpartum. The intervention staff used Hootsuite to schedule one Facebook post per day (Monday through Friday) that, during postpartum, reinforced behavioral skills, modest weight loss in postpartum, PA (including exercise videos), and diet (including links to recipes). Due to the rolling enrollment of participants, the content for the Facebook group was posted on a continuous cycle, but with enough content to prevent anything from being repeated for a given participant (i.e., 24 weeks × 5 posts/week = 120 posts for postpartum). Participants could respond to posts from study staff and post content to the group directly as a group member (i.e., peer-to-peer posting was enabled), with staff monitoring of posts.

Standard care

Participants assigned to the standard care group attended regularly scheduled clinic visits with their healthcare provider. To enhance retention and participant engagement, we also sent standard care participants study mailings of publicly available educational materials and podcasts. During pregnancy, the six study mailings (one per month) focused on tips for a healthy pregnancy and fetal development. During the postpartum period, the six study mailings (one per month) focused on infant development. We sent standard care participants a link to 10 weekly podcasts during pregnancy and 16 weekly podcasts during postpartum. Their timing corresponded to the delivery of the behavioral intervention podcasts. Pregnancy podcasts averaged 28 min, and postpartum podcasts 22 min in duration. Pregnancy podcasts focused on having a healthy pregnancy and fetal development. Postpartum podcasts focused on infant development and parenting. Podcasts avoided content related to nutrition, PA, and weight.

Measures

Physical activity

Participants wore the SenseWear Armband, which contains a 2-axis accelerometer and four sensors at all study visits. It has been used as a criterion measure for PA during pregnancy [44]. Although the armband overestimates energy expenditure during pregnancy (9% in one study and 22% in another study), it is highly related to the gold standards of portable oxygen analyzer (ICC = 0.85) and indirect calorimetry (mean $r = 0.93$) [45, 46]. At all study visits, we asked participants to wear the device for the next 8 days and return it by mail in a prepaid envelope. If participants did not meet the wear criteria (≥ 5 days, ≥ 1 weekend day, ≥ 21 h/day), or if there was equipment failure, they were allowed to wear the monitor again. The proprietary algorithms classified the intensity of activity by metabolic equivalents (METS). For this study, we used five continuous PA outcomes: minutes/day spent in total PA (> 1.5 METS), light-intensity PA (LPA; 1.6 to 2.9 METS), moderate- to vigorous-intensity PA (MVPA; ≥ 3 METS), sedentary behavior (≤ 1.5 METS), and total steps/day.

Dietary intake

Participants completed two unannounced dietary recalls at each study visit using the validated Automated Self-Administered 24-h dietary recall (ASA24) [47, 48]. One recall was conducted for a weekday, and one was conducted for a weekend (Friday, Saturday, or Sunday). After a brief training, the first dietary recall was completed at the measurement visit. The second recall was scheduled within the next seven days and completed on the participant's own based on a request from study staff (randomly selected day). If the participant could not be reached, another randomly selected day was chosen. The two dietary recalls were scored using the National Cancer Institute's Healthy Eating Index-2015 (HEI-2015) algorithm [49]. The HEI-2015 includes 13 components determining diet quality relative to the 2015–2019 Dietary Guidelines

for Americans [50, 51]. Nine are adequacy components (e.g., total vegetables) that need to be increased, whereas four are moderation components (e.g., refined grains) that need to be reduced. The component scores are summed to create a total score with a maximum of 100 points, with higher scores indicating more favorable diet quality. Corresponding to academic grades in the US, Krebs-Smith and colleagues [50] suggested that scores of 90–100 be graded as A, 80–89 as B, 70–79 as C, 60–69 as D, and 0–59 as F (i.e., failing). In addition to HEI-2015, we also reported changes in dietary intake for six outcomes that were emphasized in the intervention: fruit and vegetable intake (cups/day), percentage of grains that were whole grains, percentage of energy from added sugar, percentage energy from saturated fat, and total energy intake (kcals).

Health-related quality of life

The 12-item Short Form (SF-12) measures HRQOL [52]. This widely used measure, including during pregnancy [52] and postpartum [53], assessed eight areas over the past four weeks: physical functioning, role physical, bodily pain, general health perceptions, vitality, social functioning, role emotional, and mental health. Physical and mental component summary scores can range from 0 to 100, with higher scores indicating better perceived physical and mental health.

Demographic and pregnancy-related variables

Participants provided demographic and pregnancy-related information at baseline. These characteristics were used to describe the sample and, as appropriate, were used as covariates in the statistical analyses.

Statistical analyses

We used both linear and quantile regression models to examine the effect of the behavioral intervention (versus standard care) on PA, diet, and HRQOL outcomes. All models were examined for violations of linear regression assumptions, including normality and constant variance. When linear regression assumptions were met, we used linear regression models (minutes/day spent in total PA, LPA, and sedentary activity; diet quality and percentage of energy from saturated fat). When these assumptions were violated, we used quantile regression models (minutes/day spent in MVPA, total steps/day, fruit and vegetable intake (cups/day), percentage of grains that were whole grains, percentage of energy from added sugar, total energy intake (kcals), and both HRQOL measures).

We conducted separate models for each outcome of interest at 6 and 12 months postpartum. All models were adjusted for the baseline (prerandomization) pregnancy value of that outcome along with race (African American versus white), parity (nulliparous versus not nulliparous), weight status (overweight versus obese), education (college graduate versus not college graduate), maternal age at baseline in years, and gestational age at baseline in weeks. All diet models, except caloric intake and HEI-2015, were also adjusted for caloric intake at 6 or 12 months [54].

For the linear regression models using adjusted least squares means, we also computed the effect size of the intervention effect, calculated as Cohen's d = [(behavioral intervention mean) – (standard care mean)] / (pooled baseline standard deviation) [55].

Quantile regression models were fitted for the 50th percentile (median) of the outcome variables distribution. As described by McGreevy et al. [56], we centered continuous variables and computed adjusted medians (analogous to adjusted least square means in linear regression) for the intervention effect. We evaluated whether the adjusted median values differed significantly between the behavioral intervention and the standard care group for each outcome. There is no consensus regarding how to compute an effect size for medians. We estimated an effect size for the difference between adjusted medians by creating a measure that reflects the relative difference between these medians in a standardized way. To do this, we (1) calculated the difference between adjusted medians, (2) standardized the difference by dividing it by a measure of spread from the data, specifically the interquartile range, which is a robust measure of spread for median-based statistics, and (3) calculated the effect size as effect size = [(behavioral intervention median) – (standard care median)] / (interquartile range).

All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC) for linear regression models and R version 4.0.3 (R Core Team, 2020) for quantile regression models. Statistical significance was tested at the 0.05 level.

Results

Sample

As reported elsewhere [29, 30] and shown in Fig. 1, 228 participants were randomized. Nine participants were withdrawn by research staff because they became ineligible, resulting in a sample of 219 (112 intervention, 107 standard care). Baseline dietary and HRQOL data were available for all participants. The second baseline dietary recall was completed, on average, 4.4 ± 2.6 days after the first dietary recall (range: 1 to 17 days). Thirteen women at baseline reported nickel allergies and could not wear the SenseWear armband, and data could not be located for an additional participant. At 6 months postpartum, 174 participants (79.4%) completed the measurement visit; of these, 173

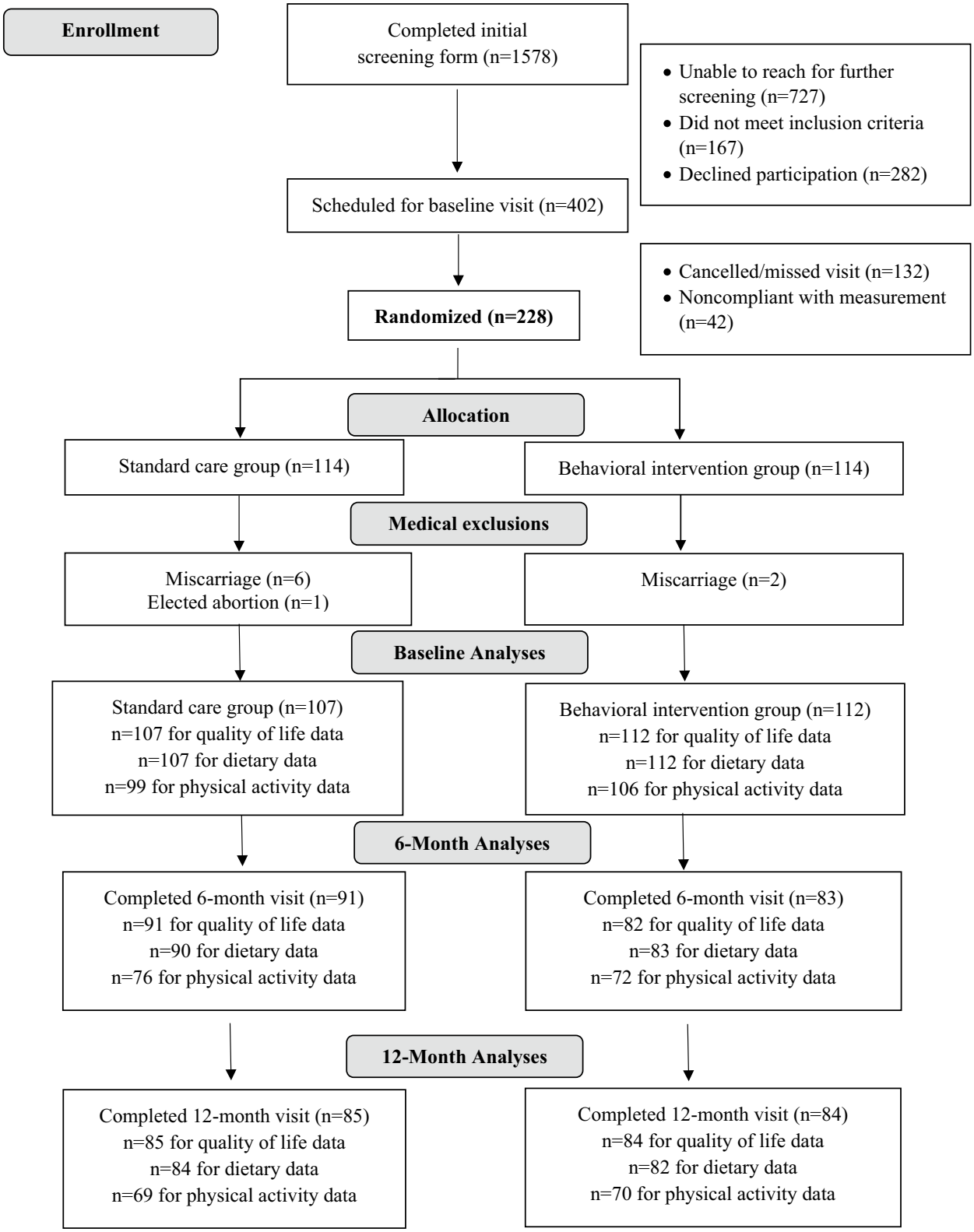

Fig. 1 Recruitment and retention of study participants

completed the dietary and HRQOL measures, and 148 wore the SenseWear armband. The second 6-month dietary recall was completed, on average, 5.4 ± 4.2 days after the first dietary recall (range: 1 to 31 days). At 12 months postpartum, 169 participants (77.2%) completed the measurement visit; of these, all completed the HRQOL measure, 166 completed the dietary measure, and 139 wore the SenseWear armband. The second 12-month dietary recall was completed, on average, 4.5 ± 3.42 days after the first dietary recall (range: 1 to 25 days). Adverse events during pregnancy ($n = 24$; 11 behavioral intervention, 13 standard care) and postpartum ($n = 18$; 12 behavioral intervention, 6 standard care) were reported elsewhere [30], with all pregnancy events unrelated to the intervention. In postpartum, 17 adverse events were deemed unrelated to the intervention, and 1 was unknown. The number of adverse events did not differ by group; all were mild or moderate in severity.

Table 1 reports the baseline demographic, behavioral, and HRQOL variables. Nearly half of the sample participants were African American (44.3%) and nulliparous (42.9%), and just over half were college graduates (59.4%). Over half were married (67.1%) and employed full-time (61.2%). At baseline, participants averaged 30 years of age and were at the end of the first trimester of their pregnancy. Participants were evenly split between overweight and obese weight categories.

Treatment effects on physical activity

The behavioral intervention did not have a significant impact ($p > 0.05$) on minutes/day of total PA, LPA, MVPA, or sedentary behavior at 6 or 12 months postpartum (see Tables 2 and 3). It also did not significantly impact the number of steps/day at either time

Table 1 Baseline characteristics of the study participants ($N = 219$), by randomization assignment

	Behavioral Intervention ($n = 112$)		**Standard Care ($n = 107$)**	
Characteristic	**%**	**n**	**%**	**n**
Race				
Black/African American	42.0	47	46.7	50
White	58.0	65	53.3	57
Married	75.0	84	58.9	63
College graduate	59.2	67	58.9	63
Employed full time	61.6	69	60.8	65
Nulliparous	43.8	49	42.1	45
Overweight	50.0	56	53.3	57
Obese	50.0	56	46.7	50
	Mean (SD)	**Median**	**Mean (SD)**	**Median**
Age, years	30.4 (5.2)	31.0	29.1 (4.8)	30.0
Gestation at baseline, weeks	12.6 (2.4)	12.6	12.6 (2.3)	12.6
Prepregnancy BMI, kg/m^2	33.0 (6.6)	31.2	33.9 (6.1)	33.5
Total PA, minutes/day	256.2 (95.4)	276.1	235.2 (93.0)	229.2
Light PA, minutes/day	218.2 (83.5)	220.6	200.1 (77.1)	191.1
MVPA, minutes/day	38.0 (21.4)	34.7	35.2 (23.4)	32.8
Sedentary minutes/day	1148.6 (98.5)	1142.6	1169.4 (95.0)	1187.5
Steps/day	5560.7 (2021.5)	5446.8	5145.1 (2296.6)	4727.1
Diet quality (HEI-2015)	53.1 (13.0)	53.2	50.9 (10.4)	51.3
Kcals/day	1857.0 (489.6)	1854.6	2013.5 (729.5)	1941.2
Fruit, cup equivalents/day	1.2 (1.1)	1.0	1.0 (1.2)	0.7
Vegetables, cup equivalents/day	1.6 (1.0)	1.4	1.7 (1.2)	1.4
% Whole grains	12.4 (14.6)	6.8	11.5 (14.2)	7.1
Added sugar, % of kcals	12.3 (8.2)	10.9	11.4 (7.0)	10.8
Saturated fat, % of kcals	11.7 (2.9)	11.7	12.6 (2.9)	12.2
HRQOL – mental component	51.0 (7.6)	52.5	49.6 (6.8)	52.2
HRQOL – physical component	47.7 (7.5)	48.6	47.6 (6.8)	48.4

Kg kilogram, *M* meters, *BMI* body mass index, *PA* physical activity, *LPA* light-intensity physical activity, *MVPA* moderate- to vigorous-intensity physical activity, *Kcals* kilocalories, *HEI-2015* Healthy Eating Index 2015, *HRQOL* health-related quality of life, *SD* standard deviation

Table 2 Differences between behavioral intervention and standard care participants at 6 months postpartum

Outcomes	Intervention	Standard care	Btwn Grp Diff	d	*p*
	[a]**Adjusted Means**				
Total PA minutes/day	303.04	284.39	18.65	0.18	0.11
Light PA minutes/day	258.46	245.15	13.31	0.16	0.18
Sedentary minutes/day	1099.46	1117.51	-18.05	-0.17	0.13
HEI-2015 total score	53.77	51.90	1.87	0.14	0.33
Saturated fat, % of kcals	11.40	11.52	-0.12	-0.04	0.81
	[a]**Adjusted Medians**				
MVPA minutes/day	49.35	44.19	5.16	0.14	0.26
Steps/day	6819.69	6421.28	398.41	0.13	0.32
Kcals/day	1618.58	1801.83	-183.25	-0.19	0.21
Fruit, cup equiv/day	0.78	0.75	0.03	0.03	0.86
Vegetables, cup equiv/day	1.51	1.39	0.12	0.09	0.50
% whole grains	9.52	9.30	0.21	0.01	0.95
Added sugar, % of kcals	9.90	11.45	-1.54	-0.18	0.15
HRQOL—mental	52.32	52.52	-0.20	-0.02	0.87
HRQOL—physical	53.85	51.78	2.07	0.23	0.15

PA physical activity, *HEI-2015* Healthy Eating Index 2015, *MVPA* moderate- to vigorous-intensity physical activity, *HRQOL* health-related quality of life

[a] Adjusted for baseline value of outcome, race, parity, weight status, education, gestational age, and participant age. Dietary outcomes, except HEI-2015 and kcals/day were also adjusted for kcals at 6 months postpartum

Table 3 Differences between behavioral intervention and standard care participants at 12 months postpartum

Outcomes	Intervention	Standard Care	Btwn Grp Diff	d	*p*
	[a]**Adjusted Means**				
Total PA minutes/day	330.13	322.57	7.55	0.07	0.60
Light PA minutes/day	272.78	269.86	2.92	0.03	0.79
Sedentary minutes/day	1075.60	1082.93	-7.33	-0.06	0.62
HEI-2015 total score	51.28	48.64	2.64	0.24	0.10
Saturated fat, % of kcals	11.97	12.23	-0.25	-0.08	0.60
	[a]**Adjusted Medians**				
MVPA minutes/day	52.94	53.79	-0.85	-0.02	0.87
Steps/day	7066.56	6772.58	293.99	0.08	0.51
Kcals/day	1623.63	1647.92	-24.29	-0.03	0.86
Fruit, cup equiv/day	0.58	0.50	0.08	0.09	0.51
Vegetables, cup equiv/day	1.39	1.46	-0.07	-0.06	0.68
% whole grains	5.45	1.65	3.80	0.19	0.16
Added sugar, % of kcals	9.77	10.76	-0.99	-0.13	0.52
HRQOL—mental	54.53	54.96	-0.73	-0.07	0.62
HRQOL—physical	53.82	52.86	0.96	0.12	0.41

PA physical activity, *HEI-2015* Healthy Eating Index 2015, *MVPA* moderate- to vigorous-intensity physical activity, *HRQOL* = health-related quality of life

[a] Adjusted for baseline value of outcome, race, parity, weight status, education, gestational age, and participant age. Dietary outcomes, except HEI-2015 and kcals/day were also adjusted for kcals at 6 months postpartum

point. Nonetheless, for all variables, except MVPA at 12 months, values were more favorable in the behavioral intervention group than in the standard care group, with effect sizes ranging from d = |0.02| to |0.18|.

Treatment effects on diet

The behavioral intervention did not have a significant impact ($p > 0.05$) on diet quality or dietary intake at 6 or 12 months postpartum (see Tables 2 and 3). Nonetheless,

for all variables, except for cups/day of vegetables at 12 months, values were more favorable in the behavioral intervention than in the standard care group, with effect sizes ranging from d=|0.01| to |0.19|. It is noteworthy that servings per day of fruits and vegetables were low for all participants, and the percentage of grains from whole grains was well below the dietary recommendation of 50%.

Treatment effects on HRQOL

The behavioral intervention did not have a significant impact ($p>0.05$) on either component of HRQOL at 6 or 12 months postpartum (see Tables 2 and 3). The effect sizes ranged from d=|0.02| to |0.23|. The largest effect size was at 6 months postpartum, when the behavioral intervention participants had higher (more favorable) scores than did the standard care participants ($p=0.15$, d=0.23).

Discussion

The main findings from this study were that PA, diet, and HRQOL at 6- and 12-months postpartum did not differ significantly between participants who received a behavioral intervention that spanned pregnancy to 6 months postpartum and those who received standard care. The HIPP randomized trial recruited an important but understudied group, Black/African American and white women who entered pregnancy with overweight or obesity. Furthermore, the trial used device-assessed PA, intervened from pregnancy through 6 months postpartum with a theoretically grounded approach, and followed women to 12 months postpartum.

We hypothesized that the behavioral intervention would result in more favorable PA, diet, and HRQOL at postpartum among participants randomized to the behavioral intervention group than among those randomized to usual care. Indeed, in this study, we previously reported significantly lower weight retention at 6 and 12 months postpartum among the behavioral intervention participants than among those receiving standard care [30], consistent with the larger body of literature on lifestyle interventions conducted during postpartum [13, 24]. Notably, after controlling for baseline caloric intake and other covariates, participants in the behavioral intervention group consumed 183 fewer kcals per day than did those in the standard care group at 6 months, and 24 fewer kcals were consumed at 12 months postpartum. Although these differences were not statistically significant, perhaps due to the error variance inherent in self-reported dietary intake [54, 57–59], these differences may have been large enough to explain the more favorable weight retention patterns we observed in the behavioral intervention group in our previous paper [30]. Other aspects of diet, notably diet quality, percentage of whole grains, and added sugar, were more favorable in the behavioral intervention group but with small effect sizes. Similarly, for all PA outcomes (except MVPA at 12 months), the behavioral intervention group had more favorable but not significantly different postpartum scores than did the standard care group. Finally, irrespective of group assignment, all PA outcomes improved from pregnancy to postpartum, as did kcals and the mental component of HRQOL. This pattern of MVPA reduction during early and mid-pregnancy, followed by increases in postpartum, is consistent with other research [60]. Given the overall improvements, regardless of group assignment, we may not have been adequately powered to detect group differences. Nonetheless, our study was still moderately large; in comparison, a recent review of postpartum exercise interventions reported that the median sample size was 66, ranging from 20 to 130 [61].

Women report many barriers to healthy eating and PA during the postpartum period, spanning individual-level factors such as emotional eating (diet), physical limitations related to childbirth (PA), and lack of partner/spousal support (diet); environmental factors such as the availability of unhealthy foods in the home (diet), childcare needs (PA), and lack of access to structured programs (PA and diet); and social and cultural norms including time constraints (PA and diet) and prioritization of maternal responsibilities (PA and diet) [62]. These barriers make it difficult to change behaviors, even with the support of a structured program. In our previously reported process evaluation of the HIPP trial, we found that fidelity to the intervention was greater during pregnancy than during the postpartum period, likely due to these barriers [34]. However, in contrast, a recent systematic review and meta-analysis of PA and healthy eating interventions delivered within the first two years postpartum reported that behavioral lifestyle interventions improved weight and PA but not energy intake [63]. Furthermore, although this review did not identify behavioral strategies associated with PA outcomes, they identified strategies associated with a greater reduction in energy intake, many of which were targeted in our study, including problem-solving, goal setting, and self-monitoring. Participants in our study who were overweight or obese before pregnancy and were recruited during pregnancy and followed postpartum, so it is difficult to make direct comparisons with this review. Another review of interventions ($n=11$) that used telemonitoring and telecoaching, an approach more similar to ours, concluded that these interventions show promise for optimizing gestational weight gain and postpartum weight retention, but the effects on PA and diet were inconsistent [64]. Our findings of no group differences are also consistent with

other studies, including one that intervened from pregnancy and followed women postpartum [65], one that recruited during the postpartum period and intervened on PA [66], one that recruited women with a history of depression during the postpartum period and intervened on PA [67], and two that enrolled postpartum women with overweight or obesity and intervened on PA and/or diet [68, 69].

With regard to HRQOL, an earlier paper from our study reported that in both groups, the mental component increased, whereas the physical component decreased from early to late pregnancy, consistent with a systematic review of observational studies [52]. Few intervention studies have examined the impact of diet and/or PA on HRQOL during pregnancy or postpartum, and the results have not been consistent [70–73]. In the present study, the physical component increased from early pregnancy to postpartum in both groups, but the mental component was similar at both time points. More intervention studies that include measures of HRQOL in addition to commonly assessed psychological outcomes such as depression [22, 35, 36] are needed.

This study has several limitations. Perhaps most significantly, we did not meet our recruitment goal despite recruiting from 13 clinics over a 4-year period. We have described our recruitment challenges in a previous paper [37], and other groups have noted similar challenges. For example, in the LIFE-Moms trials [74], a consortium of seven independent but collaborative clinical trials focused on excessive gestational weight in women with overweight or obesity, recruitment at three of the seven sites was stopped early by the funder given the unlikelihood of reaching their target recruitment goal over the three-year recruitment period. Multiple effect sizes near d=|0.20| were not found to be statistically significant. While small, these effect sizes were mostly in the direction favoring the intervention group. Our inclusion of effect sizes provides valuable information for others to consider the clinical meaningfulness of our outcomes. We also had lower adherence to the components of our intervention in the postpartum period than in the pregnancy period [34]. Greater adherence might have fostered larger changes in our behavioral intervention group. Another limitation is that we recruited entirely from one state; this focus may limit generalizability to other areas of the U.S. and beyond. Finally, despite using a randomized design, we had a higher percentage of participants who were married in the intervention as compared to the standard care group.

A major strength of the study is that we used an objective measure of PA at multiple time points. Our intervention also spanned from pregnancy to postpartum, which is fairly rare despite the potential value of assisting women during this transition. Other strengths include that nearly half of the participants were Black/African American women, all participants were overweight or obese, and we tested a comprehensive, theory-based intervention.

Conclusions

Overall, this study demonstrated that changes in PA, diet, and HRQOL, while overall favoring the behavioral intervention group, did not differ significantly by group. Given the increased responsibilities and stress that women face during the postpartum period, this appears to be a challenging time to make lifestyle changes. Although participants described the program favorably in process evaluation surveys [34], finding time to talk was cited as a barrier to the telephone calls and podcast duration (too long) as a barrier to the podcasts during postpartum. Similarly, competing responsibilities and lack of time were cited as factors that limited program participation overall. During postpartum, interventions may need to be modified to be more realistic or simplified (e.g., more limited behavior change goals), and adaptive or stepped care designs might merit investigation. Given the physical and mental health benefits of PA and a healthy diet in postpartum, interventions that are feasible and help women integrate these changes into their lives are critical.

Abbreviations

ASA24	Automated Self-Administered 24-h dietary recall
HEI-2015	Healthy Eating Index-2015
HRQOL	Health-related quality of life
LPA	Light-intensity physical activity
MET	Metabolic equivalent
MPA	Moderate-intensity physical activity
MVPA	Moderate- to vigorous-intensity physical activity
PA	Physical activity

Supplementary Information

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Additional file 1.

Additional file 2.

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Authors' contributions

S.W. and J.L. were responsible for the study design. S.W., J.L., and G.T.M. were responsible for seeking and receiving funding for the work. S.W., J.L., and G.T.M. were responsible for selecting the study measures. J.L. oversaw study recruitment and retention activities. S.W. oversaw delivery of the intervention. M.S. conducted the statistical analyses, interpreted the analyses, and drafted the statistical analysis section, in consultation with S.W. and J.L. S.W. drafted the manuscript with assistance from J.P.B. S.W., J.L, M.S., J.P.B., and G.T.M. read, revised, and approved the final manuscript.

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Data availability
The data are not included in a repository but are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
The Institutional Review Boards of three participating healthcare centers (Palmetto Health, Lexington Medical Center, and Medical University of South Carolina) and one university (University of South Carolina) approved the study protocol. All participants provided written informed consent before participating. All methods were carried out in accordance with the Declaration of Helsinki and with the Institutional Review Boards that approved the study.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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