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A randomized controlled trial to prevent excessive gestational weight gain and promote postpartum weight loss in overweight and obese women: Health In Pregnancy and Postpartum (HIPP)

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ABSTRACT

Background: Interventions to prevent excessive gestational weight gain and promote postpartum weight loss have yielded modest results, particularly in overweight and obese women.
Objectives: To examine the impact of a theory-based lifestyle intervention on gestational weight gain, postpartum weight loss, and related maternal and child outcomes and to examine race differences in these outcomes.
Design: A randomized controlled trial (target $N = 400$; 200 intervention, 200 standard care; 200 African American, 200 white).
Methods: Overweight and obese African American and white women ≤ 16 weeks gestation are recruited from obstetrics and gynecology clinics in South Carolina. Intervention participants receive two in-depth counseling sessions (early pregnancy and postpartum), telephone counseling, behavioral podcasts, and social media support that target weight self-monitoring and increasing physical activity and healthy dietary behavior practices, guided by Social Cognitive Theory. Standard care participants receive monthly mailings and a matched number of podcasts on non-weight related topics. All intervention activities last from ≤ 18 weeks gestation to 6 months after delivery. Gestational weight gain is the primary outcome. Secondary outcomes are meeting gestational weight gain guidelines (inadequate, adequate, excessive), weekly rate of gestational weight gain, postpartum weight retention, physical activity and dietary behaviors, health-related quality of life, and offspring adiposity. Participants are assessed at baseline (≤ 16 weeks gestation), 32 weeks gestation, and 6 and 12 months postpartum, and offspring are assessed at 6 and 12 months.
Summary: HIPP is an innovative study that addresses significant gaps in the literature. Primary outcome results are expected in 2019.

1. Introduction

Excessive gestational weight gain (GWG) is a significant clinical and public health problem due to its high prevalence and deleterious effects on maternal and offspring health [1]. Estimates from the United States are that nearly half (47.2%) of all pregnant women exceed the Institute of Medicine (IOM) GWG guidelines [2,3]. Women who enter pregnancy overweight or obese are at even greater risk for excessive GWG with nearly two-thirds exceeding recommendations [2]. These numbers are important when considering the majority of women in the United States aged 20–39 years are overweight or obese, and the prevalence is notably higher among African American women [4,5].

Excessive GWG is a consistent risk factor for postpartum weight retention [6–9], even up to 15 and 21 years postpartum [7]. Furthermore, excessive GWG increases a woman's risk for gestational diabetes [10], pregnancy-associated hypertension [11], and adverse birth

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outcomes such as cesarean delivery and large for gestational age infants [1,11]. Accumulating observational studies also show that higher GWG is associated with higher offspring weight and obesity [6,12,13].

Although pregnancy and postpartum are high-risk periods for the development of overweight and obesity [14,15], they are also times that afford unique opportunities for lifestyle behavior change due to women's frequent contact with health care providers and concern for their offspring's health. Behavioral interventions can increase the chance of achieving a healthy weight over the life course of both mother and child. Indeed, a recent Cochrane review concluded that diet, exercise, or combined interventions reduce the risk of excessive GWG and may reduce the risk of cesarean delivery, macrosomia, and neonatal respiratory morbidity [16]. Despite this positive review, notable gaps exist in the literature. Relatively few studies target GWG in overweight and obese pregnant women, and results are inconsistent [17–19]. Few intervention studies span both pregnancy and postpartum and include measures of offspring [20–22]. Evidence-based behavior change strategies are often not used. Few studies are adequately powered to test intervention effects within racial and ethnic minorities or to examine differences in outcomes [23,24]. Finally, mean GWG differences between intervention and control groups tend to show relatively modest differences, ranging from around 1.0 kg [25,26] to 2.0 kg [19,27]. These differences may not translate into meeting IOM GWG recommendations [20].

In response to the gaps in literature, the Health In Pregnancy and Postpartum (HIPP) study is a randomized controlled trial designed to examine the efficacy of a behavioral lifestyle intervention to reduce excessive GWG and promote postpartum weight loss among women who enter pregnancy overweight or obese as compared to a standard care intervention. The primary study outcome is GWG and the secondary outcomes are postpartum weight retention, physical activity (PA), dietary intake, health-related quality of life, and offspring adiposity. This paper provides an overview of the study design, theoretical framework, intervention protocol, outcome evaluation, program evaluation, and statistical considerations for the HIPP study.

2. Methods

This study was funded by the National Institutes of Health (R01HD078407) and is registered in clinicaltrials.gov (NCT02260518). Institutional Review Boards at Palmetto Health, the University of South Carolina, Lexington Medical Center, and the Medical University of South Carolina approved the study protocol. CONSORT reporting guidelines were followed [28].

2.1. Study aims

The HIPP study has four specific aims: (1) examine the impact of a lifestyle intervention on GWG and postpartum weight loss in overweight and obese women, (2) examine the impact of the intervention on PA, dietary intake, and health-related quality of life, (3) examine race differences in total GWG, PA, dietary intake, and health-related quality of life; and (4) examine the impact of the intervention on offspring adiposity.

2.2. Setting and recruitment

This study is being conducted in South Carolina, a state known for its poor maternal and child health indicators, high prevalence of obesity, high proportion of African Americans, and racial disparities in health [29–32]. Based on data from the 2009 SC Pregnancy Risk Assessment Monitoring Surveillance (PRAMS), 46.5% of South Carolinian mothers gained excessive weight during pregnancy (48.9% of white women, 44.0% of African American women) [33].

Participants are recruited primarily through obstetrics and gynecology (OB/GYN) clinics, although self-referrals also occur in response to community-wide and social media advertisements. A total of 13 OB/GYN clinics were targeted for recruitment, 9 in the greater Columbia, SC area, 2 in Sumter, SC, 1 in Winnsboro, SC, and 1 in Charleston, SC. In these OB/GYN clinics, study advertisements are posted in waiting rooms and other highly-trafficked areas and trained research assistants, nursing staff, or reception staff ask participants to complete a one-page, 7-item screening form that assesses initial eligibility and provides permission for study staff to contact the participant. Initial eligibility criteria are that the participant is 18–44 years of age, is white or Black/African American, can read and speak English, has no plan to move outside of the geographic area in next 18 months, is within first 16 weeks of pregnancy, and has a prepregnancy body mass index (BMI) $\geq 25\ kg/m^2$ and a prepregnancy weight ≤ 370 pounds. In addition to OB/GYN clinics, flyers are posted in other locations in the greater Columbia, SC area, including a large pediatric clinic, university bulletin boards, local grocery stores, childcare centers, Women, Infants, and Children (WIC) offices, Healthy Start offices, and other businesses commonly frequented by pregnant women. Study advertisements are also distributed through Craig's list, social media sites, such as Facebook, local parenting magazines, some of the participating clinics' websites, and some local events that are mainly targeting pregnant women or mothers with young infants. Interested women can complete the screening form on the study website or by telephone with study staff.

Study staff attempt to contact all women who are initially eligible, based on the initial screening form responses, for a more comprehensive telephone screening. The main purpose of the telephone screening is to identify and exclude women with contraindications to exercise [34,35] and women who have substantial barriers that would preclude participation in the trial. Medical exclusions include uncontrolled blood pressure ($>$ 160 systolic or $>$ 100 diastolic), use of insulin for diabetes, uncontrolled or untreated thyroid disease, hospitalization for a mental health or substance-abuse disorder in the past 6 months, multiple gestation, persistent bleeding in first trimester, history of $>$ 3 miscarriages, history of eating disorder or malnutrition, history of incompetent cervix, physical disabilities that prevent exercise, and physician advice to not exercise during pregnancy. Intervention-related exclusions are irregular or inconsistent access to a telephone and unwillingness to take part in weekly telephone calls.

Modeled after Goldberg and Kiernan [36], women who remain eligible based on the telephone screening are also guided through an interview in which they explore the pros and cons of the two study arms, barriers to participation in each study arm, and potential solutions to barriers regarding participating in the two study arms of the trial. The purposes of this interview, based on principles of motivational interviewing, are to ensure that participants are fully informed about the two study arms and what they entail, have an opportunity to think through challenges they may experience related to participation, determine whether these challenges can be overcome, and explore any ambivalence they might have about participating. Women who remain eligible and interested after the telephone screening and motivational interview are scheduled for a baseline visit.

The study enrolls women relatively early in pregnancy, and their health and pregnancy status may change as the pregnancy progresses. Therefore, at each measurement visit (two during pregnancy and two during postpartum), all participants are systematically screened for new symptoms or conditions since starting the program or since the participant's last study visit. In addition, if participants (irrespective of randomization group assignment) report a change in their health status at any other contacts besides measurement visits (e.g., phone calls, emails, letter to the study), a symptoms questionnaire is administered. Participants are withdrawn from the study if any of the following conditions occur: miscarriage, fetal loss, still birth, discovery of pregnancy with multiples after randomization, sudden death of newborn, or delivery before 32 weeks gestation. With approval of the principal investigators (PI), participants who develop a condition that necessitates