

PROTOCOL SYNOPSIS “HEALTHY BEGINNINGS”

Principal Investigator(s)/ Institution(s):

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Objective: To determine the efficacy of a multi-component lifestyle intervention that incorporates a partial meal replacement program into a comprehensive and nutritionally sound behavioral program to promote healthy gestational weight gain in multiethnic obese women.

Primary Hypothesis: The rate of gestational weight gain will be reduced among participants assigned to a multi-component lifestyle intervention with partial meal replacement (LS-PMR) program relative to standard care.

Description of intervention: The Healthy Beginnings treatment incorporates partial meal replacement (PMR) into a comprehensive behavioral program delivered in-person during pregnancy (2 visits/month until 20 weeks gestation; then, 1/month until delivery). Participants are taught to follow the 2009 IOM guidelines for healthy weight gain during pregnancy. The PMR plan provides a caloric prescription of ~20 kcal/kg of body weight. Participants receive a free supply of meal replacement shakes and/or bars, and encouraged to increase physical activity with a goal of 30 minutes of activity on most days of the week. Behavioral strategies (e.g., daily recording of food intake, activity, and weight; stimulus control techniques, problem-solving skills) and home environmental strategies (e.g., cabinet “cleanouts”, placement of visual cues) are also encouraged. Weight graphs are provided to women at each visit. In addition, women receive weekly educational tips via mail that are designed to reinforce healthy eating, physical activity, and behavioral recommendations.

Design Summary: In this two-site trial, 260 obese women will be randomly assigned within site and ethnicity/race to one of the two treatment conditions: 1) standard care or 2) LS-PMR. Maternal assessment/outcomes visits will be conducted at baseline (9-15), 24-27 and 35-36 weeks of gestation, and 26 and 52 weeks post delivery. Infant visits will occur at birth, 26 weeks and 52 weeks of age.

Primary Outcome: Gestational weight gain per week

Secondary Outcomes:

Mother:

- Gestational weight gain above IOM guidelines
- Postpartum weight retention
- Physical activity and dietary intake
- Pregnancy complications: preeclampsia, gestational diabetes, cesarean delivery, and infant complications
- Quality of Life, depressive symptoms, dietary restraint and disinhibition, unsafe dieting practices and frequency of self-weighing
- Blood pressure, glucose, insulin, and HOMA

Offspring:

- Weight-for-length z-scores
- Dietary intake, television viewing, infant feeding styles, and breast feeding
- Home eating and physical activity environment

Study Population and Eligibility Criteria: All race/ethnicities will be eligible for this study. Target enrollment is 50% Hispanic and 50% non-Hispanic women within each site.

*Inclusion criteria for Healthy Beginnings that are **not LIFE-Moms core:*** NONE

*Exclusion criteria for Healthy Beginnings that are **not LIFE-Moms core:*** Untreated psychiatric illness

Clinicaltrials.gov: NCT01545934