"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: Behavioral lifestyle intervention with a structured partial meal replacement plan includes behavioral counseling sessions by study interventionists (2/month until 20 weeks gestation; then, 1/month until delivery; meal replacement product provided at these visits); weekly educational/behavior change materials; and weight graphing with feedback (2/month until 20 weeks gestation; then, 1/month until delivery).

Design Summary: In this two-site trial, 350 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**:* Smoking / quit within last 6 months; untreated psychiatric illness

Clinicaltrials.gov: NCT01545934