"EXPECTING SUCCESS: Personalized Management of Body Weight During Pregnancy"

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Objective: To test whether personalized gestational weight management delivered in-person or via a Smartphone can reduce the proportion of overweight and obese pregnant women who exceed the 2009 IOM guidelines for gestational weight gain.

Primary Hypothesis: The proportion of pregnant women in the SmartMoms-Clinic and SmartMoms-Phone groups exceeding 2009 IOM guidelines for gestational weight gain will be significantly lower compared to the Physician Directed control group (usual prenatal care), and the proportion of women exceeding the 2009 IOM guidelines for gestational weight gain will not significantly differ between a clinic-based intervention, SmartMoms-Clinic, and an electronically-administered intervention, SmartMoms-Phone groups.

Description of intervention: The two intervention groups will receive a structured intervention with a defined calorie prescription and nutritional and exercise advice. The lifestyle intervention is adapted for pregnant women from DPP, Look AHEAD, and CALERIE. The SmartMoms Clinic participants will have in-person individual and group sessions, while all but the first and last interactions for the SmartMoms-Phone group will be via the multimedia functions of a smartphone.

Design Summary: This parallel arm, single blind RCT will randomize 306 overweight and obese pregnant women to the Control (usual care), in-person personalized weight management (SmartMoms Clinic), or remote personalized weight management (SmartMoms Phone) groups. The intervention will be implemented from 13 weeks gestation and continue until delivery. Maternal assessment/outcome visits will be conducted at baseline (9-12), 25-27 and 35-36 weeks gestation, and 4-8, 24, and 52 weeks post delivery. Infant visits will occur at birth and 4-8, 24, and 52 weeks of age.

Primary Outcome: Proportion with gestational weight gain exceeding 2009 IOM recommendations

Secondary Outcomes:
Mother:
- Gestational diabetes
- Body composition (by skin fold thicknesses and air displacement plethysmography)
- Energy intake and physical activity level
- Postpartum weight retention
- Quality of life, mood and body image, eating behavior

Offspring:
- Birth weight, length, head circumference
- Body composition (by skin fold thicknesses and air displacement plethysmography)
- Food intake (by nutritive sucking behavior)

Study Population and Eligibility Criteria*:* Participants will be recruited from the diverse population of pregnant women receiving prenatal care at Woman's Hospital in Baton Rouge where 45% of births are paid for by Medicaid programs.

Inclusion criteria for Expecting Success that are <u>not LIFE-Moms core criteria</u>*: Gestational age at randomization upper cutoff (12 weeks 6 days),* BMI upper cutoff (<40), age upper cutoff (40), fluent in English language, medically cleared from primary care OB and the study physician;
Exclusion criteria for Expecting Success that are <u>not LIFE-Moms core criteria</u>: Not willing to avoid pregnancy for 12 months following delivery; recent history of or currently smoking; recent history of or current alcohol or drug abuse ; history or current psychotic disorder or diagnosis of a current major depressive episode or bipolar disorder; HIV.

Clinicaltrials.gov: NCT01610752