

“PREGNANCY AND EARLY LIFESTYLE IMPROVEMENT STUDY (PEARLS)”

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Objective: To investigate whether a lifestyle intervention (nutrition and physical activity) delivered within an empowerment framework in overweight and obese pregnant women results in a greater percent of women who gain the appropriate amount of body weight during pregnancy, and in lower infant BMI Z-scores at 52 weeks.

Primary Hypothesis: A lifestyle intervention incorporating nutritional, physical activity and empowerment components, compared to standard care will increase the percent of pregnant women with appropriate gestational weight gain, as defined by the 2009 IOM guidelines.

Description of intervention: The intervention will be delivered during pregnancy through group sessions, with individual counseling as needed, emphasizing improving diet and physical activity behaviors, using an empowerment framework focusing on the behavioral and psychosocial factors needed to achieve and sustain positive health outcomes. In the postpartum period, mothers and infants will attend together, focusing on breastfeeding, physical activity, quality of the diet, and feeding practices through the first year.

Design Summary: 400 overweight and obese women will be randomized to either the control or the lifestyle intervention group. The control group will receive phone calls and will have 2 pre-partum and 1 postpartum group session to promote bonding and enhance retention. Maternal assessment/outcomes visits will be conducted at baseline (9-15), 24-27 and 35-36 weeks of gestation, and 5, 20, and 52 weeks post delivery. Infant assessments will occur around birth and 5, 20, and 52 weeks of age.

Primary Outcome: Percent with gestational weight gain within 2009 IOM guidelines

Secondary Outcomes:

Mother:

- Estimates of beta-cell function and insulin action using data obtained from a frequently sampled 75g OGTT.
- Blood pressure during pregnancy (pre-eclampsia) and post-partum
- Postpartum weight retention
- Pregnancy and delivery complications
- Body circumferences
- Sleep quality and duration

Offspring:

- Infant BMI Z-score at 12 months derived using *WHO standards* (the major secondary outcome)
- Fetal and neonatal outcomes: neonatal morbidity and mortality, congenital anomalies, preterm birth, NICU admission rate, hypoglycemia and hyperbilirubinemia
- Blood pressure
- Anthropometric and growth measures, including body circumferences and skinfold measures (infant adiposity)
- Insulin and glucose levels
- Physical activity and nutrition
- Breastfeeding duration, age at start of solid foods, diet quality
- Sleep quality and duration

Study Population and Eligibility Criteria: Participants will be recruited from pregnant women receiving prenatal care at the University of Puerto Rico Hospital in San Juan. Almost all are expected to be Hispanic with the majority living below the poverty level.

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

*Exclusion criteria for PEARLS that are **not LIFE-Moms core**:* Past or current intravenous drug use, HIV infection, inability to functionally participate in group sessions and other study requirements on a regular basis for the duration of the study, non-Spanish speaking, plan on giving up infant for adoption