

“LIFESTYLE INTERVENTIONS FOR EXPECTANT MOMS (LIFE-MOMS) – PHOENIX”

Principal Investigator(s)/Institutions(s):

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Objective: To implement an intensive lifestyle intervention (ILI) in overweight and obese pregnant women aimed at controlling gestational weight gain and maternal hyperglycemia, promoting post-partum weight loss, and achieving appropriate infant growth.

Primary Hypothesis: An intensive lifestyle intervention, compared with enhanced standard care, will result in lower gestational weight gain.

Description of intervention: Participants in the ILI group will receive instruction and management, adapted from the Diabetes Prevention Program, aimed at controlling excessive gestational weight gain through diet and physical activity counseling using structured group and individualized counseling delivered by trained lifestyle interventionists. The goal of ILI is to encourage managed weight gain with targets based on a modification of the 2009 Institute of Medicine guidelines.

Design Summary: Two hundred overweight and obese pregnant women without pre-gestational diabetes will be randomly assigned to either an enhanced standard of care group or an ILI intervention group, stratified by the initial OGTT results (non-diabetic or diagnosed gestational diabetes). The intervention will continue until delivery. Maternal assessment/outcomes visits will be conducted at baseline (9-15), 24-27, and 35-36 weeks gestation, and 52 weeks post delivery. Infant assessment visits will occur at birth, 6-12 weeks and 52 weeks of age.

Primary Outcome: Gestational weight gain

Secondary Outcomes:

Mother:

- Gestational weight gain above goals
- Glycemia and gestational diabetes
- Serum lipids
- Kidney function
- Physical activity
- Genetics and epigenetic analyses

Offspring:

- Birth weight, complications
- Body size (length and weight)
- Body composition (by skin fold thicknesses and air displacement plethysmography)
- Glucose, insulin, and c-peptide in cord blood
- Motor development
- Breastfeeding and infant feeding

Study Population and Eligibility Criteria: Participants will be recruited from pregnant women receiving prenatal care at the Phoenix Indian Medical Center (PIMC). Almost all women or their fetuses will be of American Indian heritage.

*Inclusion criteria for LIFE-Moms-Phoenix that are **not LIFE-Moms core**:* Able to have an OGTT prior to 16 weeks gestation; able to complete run-in screening visits

*Exclusion criteria for LIFE-Moms-Phoenix that are **not LIFE-Moms core**:* Need for follow-up at specialty care clinics outside of PIMC; not fluent in English, unwilling to provide consent for abstraction of data from prenatal and delivery records; any condition that in the opinion of the investigators would interfere with consent, treatment, or follow-up.