Lifestyle Interventions for Expectant Moms (LIFE-Moms)

Clinical Centers:
California Polytechnic Institute State University & Brown University
Columbia University & Mt. Sinai-Roosevelt Hospital
University of Puerto Rico
Northwestern University
Washington University in St. Louis
Pennington Biomedical Research Center
NIDDK-Phoenix Indian Medical Center

Research Coordinating Unit (RCU):
The George Washington University Biostatistics Center

Funding Institutes:
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Heart, Lung, and Blood Institute (NHLBI)
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
National Center for Complementary and Integrative Health (NCCIH)
Office of Research on Women's Health (ORWH)
Office of Behavioral and Social Science Research (OBSSR)

Summary:
The Consortium is a collaboration between the seven clinical centers, the Research Coordinating Unit and the funding Institutes and Centers of the NIH. The overall goal of the Consortium is to identify effective behavioral and lifestyle interventions that will improve weight, glycemic control and other-pregnancy-related outcomes in obese and overweight pregnant women, and determine whether these interventions reduce obesity and metabolic abnormalities in their children. Although each clinical center is conducting a separate trial, the objective of the collaboration is to maximize the value of the individual trials by identifying core measures collected across all studies and ensuring consistency of procedures, certain eligibility criteria, definitions and data collection.

Core Inclusion Criteria:
- Singleton viable pregnancy
- Gestational age at randomization no earlier than 9 weeks 0 days and no later than 15 weeks 6 days
- Body mass index (BMI) based on first trimester measured weight and height of 25 kg/m^2 or higher (other BMI criteria are site specific)

Core Exclusion Criteria:
- Maternal age of less than 18 years
- Diabetes prior to pregnancy
- Fetal anomaly
- Planned termination of pregnancy
- History of 3 or more consecutive first trimester miscarriages
- Past history of anorexia/bulimia
- Current eating disorder
- Actively suicidal
- Prior or planned bariatric surgery

- Current use of exclusionary medications (i.e., metformin, systemic steroids, antipsychotic agents, anti-seizure medications or mood stabilizers that would be expected to have a significant impact on body weight, medications for ADHD including amphetamines and methylphenidate)
- Continued use of weight loss medication
- Contraindications to aerobic exercise in pregnancy
- Participation in another interventional study that influences weight control
- Enrollment in this trial in a previous pregnancy
- Intention to deliver outside a LIFE-Moms consortium hospital
- Unwillingness/inability to commit to a 1 year follow-up

Core Measures:

- Maternal
    - Baseline (9-15 weeks gestation)
        - Maternal and paternal demographics, medical, obstetrical and social history
        - Weight, height, blood pressure
        - Maternal physical activity assessed by the Actigraph GT3X+
        - Fasting blood and urine
        - Questionnaires: Beck Depression Inventory (BDI-II), Eating Disorder Examination, Self weight, Sedentary behavior, Sleep, SF-12
    - 24-27 weeks gestation
        - Weight, blood pressure
        - Assessment of contraindications to moderate/high intensity physical activity assessment
        - 2 hour Oral Glucose Tolerance Test (OGTT)
        - Questionnaires: Self weight, Sedentary behavior
    - 35-36 weeks gestation
        - Maternal medications
        - Weight, blood pressure
        - Assessment of contraindications to moderate/high intensity physical activity assessment
        - Maternal physical activity assessed by the Actigraph GT3X+
        - Fasting blood and urine
        - Questionnaires: Self weight, Sedentary behavior, Sleep
    - Delivery
        - Pregnancy complications, maternal and neonatal delivery outcomes (chart abstraction)
    - 48-56 weeks post delivery
        - Maternal social history
        - Medical history and medications
        - Weight, blood pressure
        - Fasting blood and urine
        - Questionnaires: Breastfeeding, Self weight, Sedentary behavior, Sleep, SF-12
- Infant
    - Birth
        - Weight, length, head circumference, skinfold thickness
        - Cord blood
    - 48-56 weeks of age
        - Weight, length, skinfold thickness

Core Analyses:
Primary and secondary analyses will utilize core data and samples collected from the seven centers. The Consortium primary outcome is gestational weight gain per week (difference between the maternal weight measured at the 35-36 week visit and the baseline visit divided by time elapsed in weeks) above the IOM guidelines for weight gain per week in the second/third trimester among overweight and obese women.

Super Shared Measures (4 or more sites):

- Maternal
  - Baseline (9-15 weeks gestation)
    - 2 hour Oral Glucose Tolerance Test (UPR, WU, PBRC, PIMC)
    - Maternal circumferences (CPB, CU, UPR, PBRC)
    - Questionnaires
      - LM02 Baseline Questionnaire
        - Family history of high blood pressure or diabetes (CU, UPR, NW, PBRC, PIMC)
        - Supplemental food sources (CPB, CU, UPR, NW, PBRC, PIMC)
        - Control of food budget (CU, UPR, NW, PBRC, PIMC)
        - Family routines (CU, UPR, NW, PBRC, PIMC)
        - Fast food restaurants frequency (CPB, CU, UPR, NW, PBRC, PIMC)
        - Meals together as a family (CPB, CU, UPR, NW, PBRC, PIMC)
        - Plans to breastfeed (CPB, CU, UPR, NW, PBRC, PIMC)
      - LM25 PANES (CPB, CU, UPR, NW, WU)
        - Questions 2, 3, 4, 6, and 7 are common to all 5 sites
      - LM27 NHS Physical Activity Questionnaire (CPB, CU, UPR, PIMC)
      - ASA-24 completed by participant/interview (CPB, CU, NW, PIMC)
  - 35-36 weeks gestation
    - 2 hour Oral Glucose Tolerance Test (UPR, WU, PBRC, PIMC)
    - Maternal circumferences (CPB, CU, UPR, PBRC)
    - Questionnaires
      - LM20 BDI-II (CPB, CU, NW, PBRC, PIMC)
      - LM24 SF-12 (CPB, CU, UPR, NW, WU, PBRC)
      - LM27 NHS Physical Activity Questionnaire (CPB, CU, UPR, PIMC)
      - LM28 Infant Feeding Styles Questionnaire
        - 16 items (CPB,WU, PBRC, PIMC)
        - 22 items (CU, UPR, NW)
  - Delivery
    - Placenta (CPB, CU, UPR, NW, PBRC)
  - 48-56 weeks post delivery
    - 2 hour Oral Glucose Tolerance Test (UPR, WU, PBRC, PIMC)
    - Maternal circumferences (CPB, CU, UPR, PBRC)
    - BOD POD (CU, NW, WU, PBRC)
    - Maternal physical activity assessed by the Actigraph GT3X+ (CPB, CU, UPR, NW, WU, PIMC)
    - Questionnaires:
      - LM11 Infant Follow-up Questionnaire optional questions
        - Infant milestones (CPB, CU, UPR, NW, WU, PIMC)

        - Infant daycare, TV viewing, & TV in bedroom (CPB, CU, UPR, NW, WU, PBRC, PIMC)
    - LM14 Accelerometry Log (CPB, CU, UPR, NW, WU, PIMC)
    - LM20 BDI-II (CPB, CU, NW, PBRC, PIMC)
    - LM25 PANES (CPB, CU, UPR, NW, WU)
    - LM27 NHS Physical Activity Questionnaire (CPB, CU, UPR, PIMC)
    - LM28 Infant Feeding Styles Questionnaire
        - 16 items (CPB,WU, PBRC, PIMC)
        - 22 items (CU, UPR, NW)
    - LM29 Infant Consumption Questionnaire (CPB, CU, UPR, NW, PIMC)
    - ASA-24 completed by participant/interview (CPB, CU, NW, PIMC)

- Infant
    - Birth
        - PeaPod (CU, NW, WU, PIMC)