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)

PROTOCOL SYNOPSIS
"HEALTHY BEGINNINGS"

Principal Investigator(s)/ Institution(s):
Suzanne Phelan, PhD, California Polytechnic State University, San Luis Obispo CA
Rena Wing, PhD, Brown Medical School/Miriam Hospital, Providence RI

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: The Healthy Beginnings treatment incorporates partial meal replacement (PMR) into a comprehensive behavioral program delivered in-person during pregnancy (2 visits/month until 20 weeks gestation; then, 1/month until delivery). Participants are taught to follow the 2009 IOM guidelines for healthy weight gain during pregnancy. The PMR plan provides a caloric prescription of ~20 kcal/kg of body weight. Participants receive a free supply of meal replacement shakes and/or bars, and encouraged to increase physical activity with a goal of 30 minutes of activity on most days of the week. Behavioral strategies (e.g., daily recording of food intake, activity, and weight; stimulus control techniques, problem-solving skills) and home environmental strategies (e.g., cabinet "cleanouts", placement of visual cues) are also encouraged. Weight graphs are provided to women at each visit. In addition, women receive weekly educational tips via mail that are designed to reinforce healthy eating, physical activity, and behavioral recommendations.

Design Summary: In this two-site trial, 260 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**:* Untreated psychiatric illness
Clinicaltrials.gov: NCT01545934

PROTOCOL SYNOPSIS

"Lifestyle Intervention for Two (LIFT)"

Principal Investigator(s) / Institution(s):
F. Xavier Pi-Sunyer, MD, Columbia University, New York, NY
Dympna Gallagher, EdD, Columbia University, New York, NY

Objective: To compare the effect of an intensive lifestyle intervention (ILI) vs. usual care (UC) on prevention of excess gestational weight gain in overweight and obese pregnant women.

Primary Hypothesis: The percent body fat of the infant at birth will be significantly less in offspring from ILI mothers than UC mothers.

Description of intervention: *Pregnancy***:** Multiple component lifestyle intervention using specific curriculum for diet modification and physical activity, along with behavioral support strategies and social support via weekly individual counseling sessions. Two additional phone or email contacts per week for support; *Postpartum:* Group classes every 8 weeks, along with individual, telephone and e-mail/internet support.

LIFT STUDY – SUMMARY of INTERVENTION (ILI): Eligible participants will be randomized into one of the two groups of the study**:** the Usual Care (UC) Group or to the Intensive Lifestyle Intervention (ILI) Group. The importance of balanced nutrition, activity (based on ACOG guidelines) and controlled weight gain -based on the 2009 IOM recommendations - are emphasized for both groups.

INTENSIVE LIFESTYLE INTERVENTION (ILI): We utilize a multi-component approach to intervention (including nutrition counseling, behavior modification, physical activity and social support), and ongoing regular contact throughout the follow-up period. The Intervention curriculum is adapted from both the DPP and LA (Look AHEAD Study). The curriculum was designed to be appropriate for individuals of different backgrounds. Toolbox approaches such as gifts and financial support for joining the local YMCA for exercise are available.

ILI Intervention Phase I: Prenatal: *Individual Visits*: The first session is a 60-minute "Intro" (or Introduction). Participants are seen bimonthly (every other week) for approximately 30 minute sessions. The individual sessions allow tailoring of the intervention to individual needs. These sessions are scheduled so that adherence to the Lifestyle Intervention is optimum. Between visits patients are asked to self-monitor their diet and exercise (food/exercise diaries). The patient is weighed and food/exercise logs are reviewed at every visit, with appropriate recommendations made as needed. LIFT has designed a curriculum that can be easily tailored to each meet each participant's needs. It includes "modules" (with handouts) for each session including: nutrition, eating out, cooking, problem-solving, mindfulness, goal-setting, relapse prevention, positive self-talk, and exercise. We use *www.choosemyplate.gov*, the website of the USDA's Center for Nutrition and Policy Promotion, to develop an individualized meal plan for each ILI participant. We will also utilize nutrition guidelines from the Academy of Nutrition and Dietetics: *www.nutritioncaremanual.org*.
Follow-up contacts: These are done by telephone, email or texting with each participant 1-2 times/week. These contacts provide support and can reinforce the work of the past individual sessions
Groups: Voluntary group sessions are offered approximately every eight weeks during pregnancy. Topics include breastfeeding (taught by a lactation consultant) and a variety of other subjects related to health and pregnancy.

Phase II: **Postpartum:** Voluntary group sessions are offered every 8 weeks through week 52, to encourage retention, provide support, promote a return to pre-pregnancy weight and reinforce a healthy lifestyle.

USUAL CARE (UC): UC participants receive one 20-30-minute individual "Intro" after randomization and are then invited to group sessions: once every 2 months during pregnancy; once every 4 months for Phase II – postpartum.

Design Summary: The study will enroll 210 overweight and obese pregnant women and randomize them to either an ILI intervention or UC using allocation ratio (1:1). The goal for the ILI group is to achieve a gestational weight gain as recommended by the IOM Guidelines, based on BMI. Maternal assessment/outcomes visits will be performed at baseline (9-15), 24-27 and 35-36 weeks gestation, and 14 and 52 weeks post-delivery. Infant visits will occur at birth and 14 and 52 weeks of age.

Primary Outcome: Newborn percent body fat by air displacement plethysmography

Secondary Outcomes:
Mother:
- Gestational weight gain
- Weight and adipose tissue assessed by MRI as percent of total weight
- Subcutaneous, visceral, and intramuscular fat assessed by MRI
- Glucose control and gestational diabetes

Offspring:
- Weight, percent body fat (by air displacement plethysmography) at 14 weeks of age.

Study Population and Eligibility Criteria*:* All race/ethnicities will be eligible for this study. Target enrollment is 30% minority participants.

*Inclusion criteria for LIFT that are **not LIFE-Moms core**:* BMI upper cutoff (≤35) for participants who elect to have an MRI performed.

*Exclusion criteria for LIFT that are **not LIFE-Moms core**:* Self-reported history of asthma, use of medications, or ER or PCP visits within last year for asthma; smoking; history of drug and/or alcohol addiction; chronic health problems known to prohibit regular exercise or to influence body composition; other chronic disease as determined by the investigators; current binge-eating disorder; claustrophobia (in participants who elected to have an MRI performed); implanted metal objects that render MRI unsafe (in participants who elected to have an MRI performed); lack of support from primary health care provider or family members; another member of the household is a study participant or staff member in the study; any other medical, psychiatric, social, or behavioral factors that in the judgment of the Principal Investigators may interfere with study participation or ability to follow the intervention protocol.

Clinicaltrials.gov: NCT01616147

"PREGNANCY AND EARLY LIFESTYLE IMPROVEMENT STUDY (PEARLS)"

Principal Investigator(s) /Institution(s): Kaumudi Joshipura, ScD, University of Puerto Rico Medical Sciences Campus, San Juan PR; Harvard School of Public Health and Paul W. Franks, PhD, Lund University Diabetes Center, Malmo, Sweden; Harvard School of Public Health

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 stand*ards (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

Clinicaltrials.gov: NCT01771133

PROTOCOL SYNOPSIS

"MATERNAL-OFFSPRING METABOLICS: FAMILY INTERVENTION TRIAL (MOMFIT)"

Principal Investigator(s)/ Institution(s):
Alan Peaceman, MD, Northwestern University Feinberg School of Medicine, Chicago IL
Linda Van Horn, PhD, Northwestern University Feinberg School of Medicine, Chicago IL

Objective: To test, in 300 ethnically diverse overweight /obese pregnant women, a behavioral intervention aimed at controlling gestational weigh gain through recommended diet, activity and lifestyle changes delivered during pregnancy and the post-partum period.

Primary Hypothesis: Gestational weight gain will be reduced in the Intervention Group vs. Usual Care (control) group.

Description of intervention: The MOMFIT intervention will use the modified DASH diet and moderate physical activity delivered within individual visits and group coaching sessions. Electronic self-monitoring will be implemented via smartphone and Internet access, along with ongoing feedback from a lifestyle coach.

Design Summary: Three hundred overweight and obese ethnically diverse pregnant women will be randomly assigned to the MOMFIT intervention group or Usual Care control group. The intervention will be initiated more intensively in the first and second trimester with continued support and telephone coaching through one year post-partum. Maternal assessment/outcomes visits will be conducted at baseline (9-15), 24-27 and 35-36 weeks of gestation, and 6 and 52 weeks post delivery. Infant visits will occur at birth, 6 and 52 weeks of age.

Primary Outcome: Gestational weight gain

Secondary Outcomes:
Mother:
- Postpartum weight control
- Metabolic profile
- Pregnancy complications: preeclampsia, gestational diabetes, cesarean delivery, shoulder dystocia
- Adiposity (percent body fat), BP
- Diet quality and physical activity
- Metabolomic differences related to dietary intake
- Epigenetic analyses
- Sleep quality and duration, depression and stress, self-efficacy and mindfulness in diet, breast feeding, and physical activity

Offspring:
- Birth weight, length
- Metabolic profile (based on cord blood)
- Breastfeeding duration, age at start of solid foods, diet quality, physical activity
- Adiposity (percent body fat)
- Epigenetic analyses (based on cord blood)

Study Population and Eligibility Criteria*:* Participants will be recruited from racially, ethnically and socio-economically diverse population of pregnant women receiving prenatal care at Prentice Women's Hospital, Chicago IL.

*Inclusion criteria for MOMFIT that are **not LIFE-Moms core**:* BMI upper cutoff (<40); age upper cutoff (45)
*Exclusion criteria for MOMFIT that are **not LIFE-Moms core**:* IVF conception/ovulation induction w/ gonadotropins, weight gain of >15 pounds from reported pre-pregnancy weight, current smoker, enrollment in a weight loss program within 3 months of conception, history of alcohol or drug abuse within 5 years, no access to internet and / or smartphone, unable to attend intervention/follow-up visits, unwilling/unable to commit to self-monitoring data collection, unable to complete intervention program, presence of any condition that limits walking or following diet recommendations, not fluent in English

Clinicaltrials.gov: NCT01631747

PROTOCOL SYNOPSIS

Weight Management in Obese Pregnant Underserved African American Women

Principal Investigator(s)/Institution(s):
Samuel Klein, MD, Washington University in St. Louis, St. Louis MO
Alison Cahill, MD, Washington University in St. Louis, St. Louis MO
Debra Haire-Joshu, PhD, Washington University in St. Louis, St. Louis MO

Objective: To test the effect of a lifestyle intervention delivered by parent educators on control of gestational weight gain and reduction of post-partum weight retention, compared to a control condition. Both the intervention and control program will be delivered through Parents as Teachers (PAT™), a national, non-profit home visiting program focused on parenting and child development for high-needs women through pregnancy and post-partum until their children reach kindergarten.

Primary Hypothesis: Compared with the control condition (PAT), a lower percentage of women randomized to the intervention (PAT+) will exceed IOM recommendations for gestational weight gain.

Description of intervention: The intervention (PAT+) is an integrated diet and exercise lifestyle program, delivered through home visits, with a goal of controlling gestational weight gain and promoting post-partum weight loss. The control condition will be the standard PAT curriculum. For both PAT+ and the control condition, the visit schedule will be as follows: the prenatal phase will be delivered in 10 weekly and bi-weekly home visits, while the post-partum phase will include 18 monthly home visits. In addition, for *PAT+*, when possible, the parent educator will do a check-in visit at the hospital, after the baby is born.

Design Summary: 266 overweight or obese, socioeconomically-disadvantaged, African American pregnant women will be randomized to the standard PAT home visiting curriculum or to the PAT+ program. Both PAT and PAT+ will be delivered for 6 months prenatally and 18 months postpartum. Maternal assessment/outcomes visits will be conducted at baseline (9-15), 24-27 and 35-36 weeks of gestation, and 52 weeks post delivery (and weight at 18 months post delivery). Infant visits will occur at birth, and 52 weeks and 18 months of age.

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

Secondary Outcomes:
Mother:
- Postpartum weight retention
- Body Composition
- Insulin sensitivity (2-hour OGTT)
- Lipids and suppression of plasma free fatty acids concentrations after an oral glucose load
- Aerobic exercise capacity (by 6-minute walk test)
- Breastfeeding

Offspring:
- Birth weight, birth length, and overweight status at 12 months of age
- Infant body fatness (by skin fold thicknesses and air displacement plethysmography)
- Infant insulin sensitivity (HOMA-IR) and lipids
- Neurodevelopmental status at 18 months of age (Bayley Scales of Infant Development, third edition [BSID-III])

Translation potential: Will programmatic evaluation of the PAT+ intervention demonstrate applicability based on reach, implementation, fidelity, acceptability, and sustainability?

Study Population and Eligibility Criteria: Participants will be recruited from the Women's Health Clinic (WHC) at Washington University, where more than half of the deliveries are by mothers who are overweight/obese, African American, and socioeconomically disadvantaged and from Grace Hill, a community health center with similar demographics as WHC.

*Inclusion criteria that are **not LIFE-Moms core**:* BMI (≥25 & ≤45); age upper cutoff (45), African American, socioeconomically disadvantaged (i.e. on Medicaid, uninsured, live in zip codes with median income below the poverty level, or use our clinic for their obstetric care)
*Exclusion criteria that are **not LIFE-Moms core**:* Prior unexplained spontaneous preterm birth (before 34 weeks), current use of any medications/products known to have metabolic effects

Clinicaltrials.gov: NCT01768793

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

Principal Investigator(s)/Institution(s):
Leanne M. Redman, PhD, Pennington Biomedical Research Center, Baton Rouge, LA
Corby K. Martin, PhD, Pennington Biomedical Research Center, Baton Rouge, LA

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

"LIFESTYLE INTERVENTIONS FOR EXPECTANT MOMS (LIFE-MOMS) – PHOENIX"

Principal Investigator(s)/Institutions(s):
William C. Knowler, MD, DrPH, Diabetes and Epidemiology Research Section (NIDDK)/Phoenix Indian Medical Center (PIMC), Phoenix, AZ

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.

Clinicaltrials.gov: NCT01812694