PROTOCOL SYNOPSIS

"Lifestyle Intervention for Two (LIFT)"

Principal Investigator(s) / Institution(s):
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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