

## PROTOCOL SYNOPSIS

### “MATERNAL-OFFSPRING METABOLICS: FAMILY INTERVENTION TRIAL (MOMFIT)”

**Principal Investigator(s)/ Institution(s):**

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**Objective:** To test, in 300 ethnically diverse overweight /obese pregnant women, a behavioral intervention aimed at controlling gestational weight 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