

PROTOCOL SYNOPSIS

Weight Management in Obese Pregnant Underserved African American Women

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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