



# Delta Healthy Sprouts: A randomized comparative effectiveness trial to promote maternal weight control and reduce childhood obesity in the Mississippi Delta

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## ABSTRACT

**Introduction:** Excessive and inadequate gestational weight gain can complicate a woman's pregnancy and put her and her child at risk for poor delivery and birth outcomes. Further, feeding and activity habits established early in life can significantly impact the development of childhood obesity.

**Methods:** The on-going Delta Healthy Sprouts Project is a randomized, controlled, comparative trial testing the efficacy of two Maternal, Infant, and Early Childhood Home Visiting programs on weight status and health behaviors of 150 mothers and their infants residing in the rural Mississippi Delta region of the United States. Women are enrolled in their second trimester of pregnancy and randomized to one of two treatment arms. The control arm curriculum is based on Parents as Teachers, an evidence based approach to increase parental knowledge of child development and improve parenting practices. The experimental arm, labeled Parents as Teachers Enhanced, builds upon the control curriculum by including culturally tailored nutrition and physical activity components specifically designed for the gestational and postnatal periods. We hypothesize that, as compared to the control arm, the experimental arm will be more effective in preventing inappropriate gestational weight gain, reducing postnatal weight retention, and decreasing infant obesity rates. We also will evaluate mother and child dietary and physical activity outcomes, breastfeeding initiation and continuation, and child feeding practices.

**Conclusion:** The Delta Healthy Sprouts Project tests a novel, combined approach to maternal weight management and childhood obesity prevention in pregnant women and their children at high risk for obesity and chronic disease.

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## 1. Introduction

Inappropriate gestational weight gain (GWG) can complicate pregnancy placing women and their children at risk for poor delivery and birth outcomes. Pregnancy complications associated with excessive GWG include gestational diabetes

and hypertension, and preeclampsia [1–3]. Associated delivery complications include operative vaginal delivery and cesarean section [1,4]. Further, many of these adverse outcomes for the mother can affect her infant as well. For example, adult obesity has been associated with birth by cesarean section as compared to vaginal delivery [5], while gestational diabetes has been associated with congenital malformations [6] and later metabolic dysfunction [7]. Neonatal complications associated with excessive GWG include macrosomia [1,8] which can increase a newborn's risk for birth trauma, respiratory distress syndrome, hypoglycemia, hyperbilirubinemia, and admission to the neonatal intensive care unit as compared to newborns of an

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appropriate weight [9]. Inadequate GWG is associated with increased odds of infant death, for which the concomitant increased risk of low birth weight is only a partial mediator [10]. Neonatal complications associated with inadequate GWG include preterm birth, small for gestational age birth weight, and failure to initiate breastfeeding [11].

Exacerbating risks associated with inappropriate GWG, women who begin pregnancy obese are at increased risk for the same adverse pregnancy [12,13], delivery [14,15], and birth complications [15] as women who have excessive GWG. Additional pregnancy complications associated with maternal obesity include miscarriage [16], while additional neonatal complications include fetal distress and perinatal morbidity and mortality [17], still birth [18], and birth defects [19,20]. Further, excessive GWG and maternal obesity are associated with increased risks of postnatal weight retention and long term obesity in mothers [21,22], and greater risk for obesity, diabetes, and cardiovascular disease in their children [23,24].

Some of the strongest risk factors for childhood obesity include rapid infant weight gain [25–27], and type and duration of infant feeding [23]. Breastfeeding has been associated with less rapid infant weight gain as compared to formula-feeding [28,29], as well as risk reductions for childhood obesity and type 1 and 2 diabetes [30,31]. Likewise, positive associations with weight-for-age at 12 months have been reported for juice consumption in the first year of life and introduction to solid foods prior to 4 months of age [32–35]. Hence, feeding and activity habits established early in life can substantially impact the development of obesity in children.

Fortunately, obesity and its comorbidities are largely preventable. Learned behaviors disseminated from mother to child serve as the basis for development of lifelong health behaviors. Established at a young age, good nutrition (beginning with breastfeeding), adequate physical activity, and reduced sedentary behavior can prevent childhood obesity and its related comorbidities [23]. Thus, interventions designed to optimize GWG and promote postnatal and early childhood weight management have the potential to significantly impact the health of mothers and their children [36]. Such interventions are particularly needed in areas of the United States (US) that suffer from disproportionately high rates of obesity, diabetes, and hypertension, such as the Mississippi Delta region [37].

## 2. Materials and methods

### 2.1. Study aims and hypotheses

The objective of the Delta Healthy Sprouts Project is to test the comparative effectiveness of two Maternal, Infant, and Early Childhood Home Visiting (MIECHV) programs on weight status (primary aim), dietary intake (secondary aim), and health behaviors (secondary aim) of mothers and their infants residing in the rural Mississippi Delta region of the US. We hypothesize that, as compared to mothers in the Parents as Teachers (PaT) control arm, mothers in the Parents as Teachers Enhanced (PaTE) experimental arm will have: (1) appropriate GWG (based on pre-pregnancy body mass index [BMI] and Institute of Medicine [IOM] guidelines); (2) less pregnancy weight retention at 12 months postnatal; (3) larger improvements in diet quality at 9 months gestation and 12 months

postnatal; (4) greater physical activity levels at 9 months gestation and 12 months postnatal; (5) initiated breastfeeding; (6) breastfeed longer at 12 months postnatal; and (7) increased knowledge regarding infant and toddler feeding. Further, we hypothesize that as compared to infants in the PaT arm, infants in the PaTE arm will have: (1) lower rates of weight-for-length exceeding the 95th percentile (based on the World Health Organization [WHO] reference growth curves for age and sex) from birth to 12 months of age; (2) greater compliance with the American Academy of Pediatrics (AAP) feeding recommendations for the first 12 months of age; and (3) less sedentary behavior (e.g., time spent confined in car/infant seat) during the first 12 months of age.

### 2.2. Study design

The Delta Healthy Sprouts Project is an 18-month, randomized, controlled, comparative effectiveness trial. Participants are randomly assigned to one of two treatment arms (75 participants per arm) – PaT or PaTE. Participants in both the control and experimental arms receive the monthly PaT lessons and materials. Only participants in the experimental arm receive the PaTE supplemental nutrition and physical activity lessons and materials.

### 2.3. Research ethics approval and sponsors

The Delta Healthy Sprouts Project has been approved by the Institutional Review Board of the Delta State University. Informed written consent is obtained from all study participants. The project is funded by the Agricultural Research Service (ARS) of the US Department of Agriculture (USDA) in collaboration with the Delta Health Alliance. Delta Healthy Sprouts is registered at clinicaltrials.gov (NCT01746394).

### 2.4. Participant recruitment and eligibility screening

Study inclusion criteria include: female; at least 18 years of age; less than 19 weeks pregnant with first, second or third child; and resident of Washington, Bolivar, or Humphreys County, Mississippi, US. While some women are recruited in their first trimester of pregnancy, the first (enrollment) visit takes place between 14 and 18 weeks gestation. Additionally, because too many potential participants were ineligible due to the original single parity criterion, it was relaxed to include multi-parity. Women expecting more than one child are excluded. Further, while the intervention is targeted toward African American women, race/ethnicity is not an inclusion or exclusion criterion. The majority of study participants reside in Washington County. Hence demographic characteristics of Washington County in comparison to the state of Mississippi and the US are presented in Table 1. Washington County, with 71% non-white residents [38], has an adult obesity rate of 38%, exceeding both the state and national rates of 35% and 28%, respectively [39,40]. Additionally, percentages of low birth weight infants and preterm births, 13% and 19%, respectively, in Washington County also exceed national rates of 8% and 12%, respectively [41,42]. Further, the County has overall and child poverty rates of 36% and 51%, respectively, more than double the national rates (14% and 20%, respectively) [43].

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