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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.

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].

Table 1
Demographic characteristics of Washington County Mississippi, state of Mississippi, and United States populations.

	Washington County			Mississippi (MS)			United States (US)		
Characteristic (%)	Total	White	AA/NW	Total	White	AA/NW	Total	White	AA/NW
Race[a]		27.0	71.3		59.1	37.0		72.4	12.6
Poverty rate[b]	36.0	15.5	44.3	21.6	12.8	35.7	14.3	11.6	25.8
Child poverty rate[b]	50.9	25.5	57.8	30.9	16.3	48.2	20.0	15.5	36.1
Births to unmarried women[c]	79.5	39.3	90.5	54.7	34.6	79.5	40.8	29.0	72.5
Low birth weight infants[c]	12.8	6.5	14.5	11.6	8.2	15.9	8.1	7.1	13.2
Preterm births[c]	18.6	14.3	19.8	16.9	14.1	20.3	12.0	11.1	16.9
Adult obesity[d]	38.0	NA	NA	34.6	30.2	43.2	28.1	26.4	36.6
Youth obesity[e]	NA	NA	NA	21.7	19.8	23.5	15.7	12.1	23.1

AA/NW, African American or non-white; NA, estimate not available.

[a] 51,137 population estimate for Washington County and race percentages obtained from US Census Bureau, 2010 Census [available from: https://www.census.gov/2010census/data/].

[b] Estimates obtained from US Census Bureau, 2007–2011 American Community Survey [available from: https://www.census.gov/acs/www/data_documentation/data_main/]. Child defined as <18 years of age.

[c] County and state 2012 estimates obtained from MS State Department of Health, Vital Statistics [available from: http://msdh.ms.gov/phs/statisti.htm]. US estimates obtained from Centers for Disease Control and Prevention (CDC), National Vital Statistics System, Births: Final Data for 2010. National Vital Statistics Reports 2012;61(1) [available from: http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_01.pdf]. Low birth weight defined as <2500 g. Preterm birth defined as <37 weeks gestation.

[d] US and state 2012 estimates obtained from CDC Behavioral Risk Factor Surveillance System, Prevalence and Trends Data [available from: http://apps.nccd.cdc.gov/brfss/]. County 2009 estimate obtained from Robert Wood Johnson Foundation, County Health Rankings & Road Maps [available from: http://www.countyhealthrankings.org/app/home]. Adult obesity defined as BMI ≥ 30 kg/m^2.

[e] Estimates for 2011–2012 obtained from Data Resource Center for Child & Adolescent Health [available from: http://www.childhealthdata.org/browse/survey]. Youth (10–17 years of age) obesity defined as age- and sex-specific BMI ≥ 95th percentile.

Study staff began recruitment activities in January 2013 by contacting and informing Washington County community partners about the research project. Community partners include: obstetricians/gynecologists; health clinics and departments; Women, Infant, and Children (WIC) sites; social services; faith based and other community organizations; and schools, colleges and universities. Study participants are recruited using a variety of methods which include: obtaining referrals from the community partners and current study participants; posting study flyers and brochures throughout the targeted communities; attending local health fairs; and using local print, radio, and television media. Referrals are contacted via telephone, email, or in person to determine interest and screen for eligibility. Upon determination of interest and eligibility, individuals are randomly assigned to one of the two treatment arms — PaT or PaTE. Random assignment is accomplished using a statistical program with a random number generator. Enrollment is on a rolling basis and is expected to encompass approximately 24 months.

2.5. Interventions: Parents as Teachers (PaT) and Parents as Teachers Enhanced (PaTE)

The control arm of the intervention utilizes the PaT curriculum. Parents as Teachers is a nationally recognized, evidence based MIECHV program that includes one-on-one home visits, monthly group meetings, developmental screenings, and a resource network for families. Through these activities, PaT seeks to increase parental knowledge of child development, improve parenting practices, provide early detection of developmental delays, prevent child abuse, and increase school readiness [44]. Home visitation is the key component of the PaT model where Parent Educators provide parents with research based information and activities. Materials are tailored to the age of the child and responsive to parental information requests.

Parents as Teachers Enhanced, delivered to participants randomized to the experimental arm, builds upon the MIECHV program, PaT, by adding culturally tailored, maternal weight management and early childhood obesity prevention components. These features are based upon foundational elements from the Diabetes Prevention Program (DPP) and the Infant Feeding Activity and Nutrition Trial (InFANT). In the seminal paper reporting the results of DPP, the authors concluded that while both lifestyle changes and treatment with metformin were effective in reducing the incidence of diabetes, the lifestyle intervention was more effective [45]. Elements based upon DPP principles include a flexible, culturally sensitive, individualized educational curriculum taught on a one-to-one basis [45]. InFANT is a 16-month, early childhood intervention designed to prevent childhood obesity in Australia [46]. The intervention was designed using the anticipatory guidance theory and parenting support theory. Anticipatory guidance, as used in pediatric healthcare, is the process of providing practical, developmentally appropriate, child health information to parents in anticipation of significant physical, emotional, and psychological milestones [47]. Therefore, it is likely that messages presented to parents may be preferentially received if delivered at key times during their child's development [46]. The parenting support theory emphasizes children's psychological and behavioral goals, logical and natural consequences, mutual respect, and encouragement techniques [48]. Results from InFANT provided evidence that sweet snack consumption and television viewing time in young children can be reduced by a relatively low-dose, group-level intervention focused on parent knowledge and skills [49].

For PaTE, emphasis is placed on educating mothers about the ways in which they can facilitate the development of appropriate eating, physical activity, and other health behaviors in their children, including modeling these behaviors themselves. Intervention components of the PaTE arm include healthy weight gain during pregnancy and weight management after pregnancy, nutrition and physical activity in the gestational (mother) and postnatal (mother and infant) periods, breastfeeding, appropriate introduction of solid foods, and parental modeling of positive nutrition and physical activity behaviors. Lessons include hands-on activities, instructional digital versatile discs (DVD), and goal-setting for both diet and exercise. In both the gestational and postnatal periods, participants are provided with an individualized USDA MyPlate daily eating plan [50], as well as tracking sheets to record what they eat and drink. Additionally, at each monthly visit, participants are given weight gain and loss charts for the gestational and postnatal periods, respectively. These charts, which contain reference ranges for IOM gestational weight gain recommendations and targeted (5%) postnatal weight loss are updated monthly with the participants' current weight.

Both arms of the intervention are delivered in the home to women beginning in their early second trimester of pregnancy by community based, trained Parent Educators. These visits occur monthly for both intervention arms and are approximately 60–90 min in length for the PaT lessons, and approximately 90–120 min for the PaTE lessons. The lesson plan outlines for PaT and PaTE are presented in Table 2.

2.6. Data collection procedures

Baseline data are collected from the participants at the first home visit prior to implementation of any educational lessons. Other data are collected at designated time points throughout the 18-month intervention. Data are collected on the infants starting at the first home visit after birth and continuing until the infant is one year (12 months) of age. The data collection schedule and instruments are presented in Table 3.

2.7. Parent Educator training and monitoring

Parent Educators are trained to implement both arms of the intervention. Training by PaT National Center staff includes three days of foundational training in parent–child interactions, development-centered parenting, and family well-being, and two days of model implementation training in quality assurance guidelines and implementation strategies [44]. Additionally, Parent Educators complete annual, competency based training in a variety of topics (e.g., cardiopulmonary resuscitation and first aid). Training for PaTE includes bimonthly sessions with a nutritionist/registered dietitian covering the 16 nutrition and physical activity lessons as well as general nutrition topics (e.g., fruit and vegetable consumption, meal planning, and weight control).

Parent Educators also are trained to collect survey data using computer-assisted personal interviewing via Snap Surveys® software [51] installed on Windows based ultrabook laptop computers. Survey data are collected in the participants' homes and subsequently stored and maintained on an online encrypted Snap WebHost server. Additionally, Parent Educators are trained by certified master trainers to conduct and analyze 24-hour dietary recalls using the Nutrition Data System for Research (NDSR) software [52]. Training for NDSR includes approximately six months of weekly 24-hour dietary recalls with a certified master trainer/dietitian followed by monthly recalls to ensure skill levels remain high. In addition to this skill level monitoring, quality assurance of the dietary recalls is performed by certified master trainers. Further, quality assurance of both control and experimental home visits is conducted by the Project Manager with each Parent Educator a minimum of two times per year. Finally, Parent Educators complete a yearly self-assessment survey to identify areas in which they may need further training, knowledge, or skills.

Because Parent Educators implement both arms of the intervention, strategies to reduce contamination are used.

Table 2
Delta Healthy Sprouts lesson plan outlines.

Visit	Parents as Teachers	Parents as Teachers Enhanced[a]
GM4	None	None
GM5	FVP1: Introduction to program	Healthy weight gain during pregnancy (nutrition and physical activity)
GM6	FVP2: Child development	Nutrition basics I: reading the food label
GM7	FVP3: Parenting behaviors	Nutrition basics II: portion sizes and staying active and healthy snacking
GM8	FVP4: Developmental topics	Breastfeeding
GM9	FVP5: Brain development	Healthy mom and healthy baby
PM1	FVP2: Child development[b]	Weight management for mom and baby hunger cues
PM2	FVP3: Parenting behaviors	Tummy time/confinement time and weight management for mom
PM3	FVP4: Developmental topics	Introduction to solid foods for baby I
PM4	FVP5: Brain development	Introduction to solid foods for baby II
PM5	FVP6: Family culture and perspectives	Beverage basics
PM6	FVP7: Family supports	Healthy habits: family play time and decrease TV time
PM7	FVP8: Planning as partners	Healthy meal planning, shopping, and cooking
PM8	Individualized for family	Toddler feeding
PM9	Individualized for family	Modeling positive nutrition and physical activity behaviors
PM10	Individualized for family	Healthy, toddler friendly meals and managing toddler food rejection and demands
PM11	Individualized for family	Creating and maintaining a healthy home

FVP, foundational visit plan; GM, gestational month; PM, postnatal month.
[a] Visits GM5, GM6, GM8, PM2, PM3, PM5, PM7, PM8, PM10, and PM11 include an instructional DVD to reinforce lesson topic.
[b] Parents as Teachers curriculum requires that the foundational lessons given in the gestational period be repeated in the postnatal period with the exception of the first lesson.

Table 3
Delta Healthy Sprouts data collection schedule and instruments.

	Gestational month[a]						Postnatal month											
Survey instrument	4	5	6	7	8	9	1	2	3	4	5	6	7	8	9	10	11	12
Enrollment, demographics & health history record	x																	
Mother supplement — G[b]		x	x	x	x	x												
24 hour dietary recall — mother	x		x		x		x			x		x		x				x
Physical activity Q	x		x		x		x					x						x
Perceived Stress Scale	x						x											x
CES-D	x						x											x
Breastfeeding Q — G	x					x												
Child feeding & activity knowledge Q	x																	x
Diet & PA: beliefs and practices survey		x					x											x
Birth & infant outcome survey							x											
Mother & child supplement — PN[c]							x	x	x	x	x	x	x	x	x	x	x	x
24 hour dietary recall — child							x	x	x	x	x	x	x	x	x	x	x	x
Milestones[d]							x		x		x	x	x	x	x		x	x
ASQ-3								x		x						x		
ASQ:SE										x						x		
Child health record											x							
Survey of parenting practice												x						
Parent satisfaction survey						x												x
Family personal visit record — G[e]	x	x	x	x	x	x												
Family personal visit record — PN[e]							x	x	x	x	x	x	x	x	x	x	x	x
Life skills progression		x						x						x				
Visit activities	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

G, gestational; Q, questionnaire; CES-D, Center for Epidemiologic Studies Depression Scale; ASQ-3, Ages and Stages Q (version 3); ASQ-SE, Ages and Stages: Social–Emotional Q; PN, postnatal.
[a] Month 4 = weeks 14–18; month 5 = weeks 19–23; month 6 = weeks 24–27; month 7 = weeks 28–31; month 8 = 32–35; and month 9 = weeks 36–39.
[b] Collected data includes prenatal care, gestational diabetes and hypertension, preeclampsia, and weight.
[c] Collected data includes breastfeeding, mother weight, infant illnesses, and infant length and weight.
[d] Questionnaires appropriate for child's age (birth to 1.5 months, 1.5 to 3.5 months, 3.5 to 5.5 months, 5.5 to 8 months, and 8 to 12 months).
[e] Collected data includes education, discussion, and intervention-related components.

These strategies include color coding of participant files based on intervention arm assignment, use of separate checklists for materials and handouts given during each home visit based on intervention arm assignment, and double-checking of intervention arm assignment prior to home visiting. Additionally, in the rare case where participants are directly related (e.g., sisters) or cohabitate, both participants are assigned to the same intervention arm.

2.8. Primary outcome measures

2.8.1. Mothers

Appropriate GWG (based on pre-pregnancy BMI and IOM guidelines) and weight loss at 12 months postnatal are the primary outcomes for the mothers in the gestational and postnatal periods, respectively. These primary outcomes are based upon the mothers' anthropometric measures, including height, weight, and BMI. Height is measured at baseline, in duplicate using a portable stadiometer (model seca 217, seca, Birmingham, UK). Weight is measured at each monthly visit using a digital scale (model SR241, SR Instruments, Tonawanda, NY). Both measures are performed without shoes or heavy clothing. Pre-pregnancy weight is self-reported. Body mass index is calculated as weight (kg) divided by height (m) squared.

2.8.2. Infants

Weight-for-length meeting or exceeding the 95th percentile (based on WHO reference growth curves for age and sex) from birth to 12 months of age is the primary outcome for the infants. Infants are classified as obese if they meet or exceed the 95th percentile of WHO reference growth curves for age and sex at any time point during their first 12 months of life. This primary outcome is based upon the infants' anthropometric measures, including length, weight, and infant BMI z-score. Length and weight are measured at each monthly visit, in duplicate, in the postnatal period using an infantometer (model seca 416, seca, Birmingham, UK) for length and the digital scale for weight. Infant BMI is calculated as defined previously and BMI z-score is derived using WHO reference growth curves for age and sex [53].

2.9. Secondary outcome measures and demographic characteristics

2.9.1. Diet

Dietary data is collected via multiple pass 24-hour dietary recall using NDSR software. NDSR is a Windows-based dietary analysis program that allows for calculation of nutrients per ingredient, food, meal, and day in report and analysis formats [54]. The software also includes a dietary supplement assessment module so nutrient intake from supplemental sources can be captured and quantified [55]. While the 24-hour dietary recalls are conducted in the participants' homes using laptop computers, the dietary data is subsequently stored on a password protected desktop computer that is backed up on a regular basis.

Dietary recalls are collected on the mothers at baseline and two additional time points in the gestational period, as well as at five time points during the postnatal period. Dietary recalls are collected from the mothers on their infant's intake at each monthly visit in the postnatal period. The dietary intake reports created by the NDSR system are used to counsel experimental participants on modifications to improve their diet (e.g., increase consumption of fruits and vegetables, decrease consumption of processed meats). Additionally, both the mother and infant dietary datasets are used to test for changes in specific components of participants' and their infants' diets as well as their diet quality.

2.9.2. Diet quality

The Healthy Eating Index-2010 (HEI-2010) [56], which measures adherence to the 2010 Dietary Guidelines for Americans (DGA) [57], is used as the diet quality index. The HEI-2010 includes 12 components summed to create a total score of 100. The 12 components include: total fruit, whole fruit, total vegetables, greens and beans, whole grains, dairy, total protein foods, seafood and plant proteins, fatty acids, refined grains, sodium, and empty calories. For each component, higher scores reflect greater adherence to the 2010 DGA recommendations.

2.9.3. Physical activity

Physical activity is collected on the mothers using a modified version of the Pregnancy Physical Activity Questionnaire [58] for both the gestational and postnatal periods. Modifications include small wording changes (e.g., driving or riding in a car vs. driving or riding in a car or bus) and time frame adjustment (during this month vs. during this trimester) to make the instrument more relevant to this population of southern, rural women and our study design. This 26-item instrument allows for calculation of both duration and intensity of physical activity, as well as calculation for specific activity type (i.e., sedentary, light-intensity, moderate-intensity, vigorous-intensity, household/care-giving, occupational, and sports/exercise) and total activity. Additionally, data is collected from the mothers on their infant's daily activities (i.e. time spent sleeping [day and night], confined [infant seat, car seat], and unconfined [play mat, play pen, walker]) at each monthly home visit in the postnatal period. Time spent confined is used as a measure of infant sedentary behavior.

2.9.4. Knowledge, beliefs, and practices

Additional constructs that may relate to obesity also are assessed. Participants complete questionnaires pertaining to breastfeeding knowledge and beliefs (19 items) [59,60], child feeding (15 items) and activity (4 items) knowledge and beliefs, diet and physical activity beliefs and practices [61–64], and parenting practices [65]. The diet and physical activity beliefs and practices questionnaire contains sections measuring attitude (5 items), healthy eating expectations (4 items), regular physical activity/exercise expectations (5 items), barriers (15 items), neighborhood characteristics (6 healthy eating and 3 physical activity items), social support from family and friends (17 items each), self-efficacy (11 healthy eating and 5 physical activity/exercise items), and food practices (6 items). The two questionnaires measuring breastfeeding knowledge and beliefs, and diet and physical activity beliefs and practices use questions from validated instruments, but are modifications of these original instruments. Hence they will be validated during the course of this study. The questionnaire measuring child feeding and activity knowledge was created by the investigators for this study and is based upon professional knowledge and guidelines from the American Academy of Pediatrics [66–68]. It also will be validated during the course of this study. The Survey of Parenting Practice is designed to measure how participants feel the PaT program has changed the knowledge and skills they have as a parent [65].

2.9.5. Stress, depression, and life skills

Stress is measured using the Cohen 14-item Perceived Stress Scale [69]. Questions are framed during the last month and higher scores indicate higher perceived stress. Depression is measured using the Center for Epidemiologic Studies Depression (CES-D) Scale [70]. This 20-item scale is a quick test which measures depressive feelings and behaviors during the past week. It is used as a screening tool for mild to moderate and possible major depression [70]. The Life Skills Progression questionnaire is an outcome and intervention planning instrument for use with families at risk [71]. This 43-item tool contains scales for relationships (family and friends, child[ren], and supportive resources), education and employment, health and medical care, mental health and substance use/abuse, basic essentials, and child development.

2.9.6. Infant development

Additional data collected on the infants include milestones (language, intellectual, socio-emotional, and motor) [72], developmental monitoring of skills (communication, gross and fine motor, problem solving, and personal–social) [73], and social and emotional behavioral development [74]. The milestones surveys, created by PaT, are simple checklists of activities and behaviors based on the infant's age. The Ages & Stages Questionnaires® (third edition and social–emotional), used to monitor the infants' development, are scored to identify areas in which age-appropriate intervention activities or referrals to special services may be required [73,74].

2.9.7. Demographics, health history, and breastfeeding

Participants also provide information regarding demographic characteristics (e.g., age, marital status, household size, education, employment, household income, insurance, prenatal care), health history and current health conditions (mother and infant), delivery and infant birth outcomes (e.g., infant's birth weight and length, delivery method, problems during labor or delivery, infant's race and gender), and breastfeeding initiation and continuation.

2.10. Process evaluation measures

The conduction of a process evaluation based on the RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) framework [75] aids in understanding relationships between specific program elements and outcomes [76]. Reach is assessed using county estimates of births by race (vital statistics for Mississippi), number of recruitment activities conducted (contacts with referral sources and participation in community events), and number of referrals (both eligible and non-eligible) received. Effectiveness is assessed as described in the following Sample size, power calculations, and data analysis section. Adoption, the proportion and representativeness of settings and of individuals who implement the program, is not assessed because settings are the participants' homes (setting thus equates to participant) and the program is implemented by research staff hired specifically for the purpose of conducting this study. Implementation is assessed utilizing the percentage of home visits conducted vs. scheduled (fidelity), the number of activities conducted and materials/handouts given according to the PaT and PaTE lesson plans (dose delivered; Table 2), the number of diet and exercise goals set and achieved (dose received or participant engagement), and participant satisfaction (anonymous surveys). Maintenance, the long-term adoption and implementation of the intervention, is assessed through interactions with services in the area (e.g., PaT program alone) and a community advisory board (requirement of PaT program) whose focus is to identify sources of funding for continuation of the program.

2.11. Sample size, power calculations, and data analysis

All statistical analyses are performed using SAS® software, version 9.4 (SAS Institute Inc., Cary, NC). Enrolling 75 participants per arm and assuming a 20% attrition rate achieve a final sample size of 60 participants per arm. The PaT national program reports an average attrition rate of 21% (Dr. Guskin, Director of Research & Quality Improvement, oral communication, 2014). Assuming that 37% of participants in the control arm have GWG within IOM recommendations [77], a sample size of 120 participants allows for detection of a 22% difference in percentages of GWG within IOM recommendations between the two arms. Others have reported group differences ranging from 11% to 22% for GWG within IOM recommendations [78,79]. Additionally, assuming an average 12-month postnatal weight loss of 1.5 kg in the control arm (SD = 4.7 and 5.4 kg in control and intervention arms, respectively) [80], a sample size of 120 participants allows for detection of a 3.8 kg difference in 12-month postnatal weight loss between the two arms. Others have reported group differences ranging from 4.2 to 5.1 kg for postnatal weight loss [81,82]. Finally, assuming that 15% of infants in the control arm are classified as obese in their first year of life [83], a sample size of 120 participants allows for detection of a 12% difference in percentages of infants classified as obese during the first year of life. Others have reported a group difference of 23% between children of participants with and without risk factors [84]. All sample size calculations are based upon one-sided significance tests at 80% power with a type I error rate (α) of 0.05. One-sided tests are used because the “unworthiness” of the enhanced nutrition and physical activity components is the same for the case in which the outcomes are no different between the experimental and control arms as for the case in which the outcomes are worse for the experimental arm as compared to the control arm.

The primary objective is to determine the comparative effectiveness of the two MIECHV programs, PaT and PaTE on appropriate GWG (mothers), weight loss at 12 months postnatal (mothers), and weight-for-length meeting or exceeding the 95th percentile (based on WHO reference growth curves for age and sex) from birth to 12 months of age (infants). Analyses are conducted both with and without adjustment for baseline characteristics such as age and pre-pregnancy BMI, as well as other covariates that are related to the outcomes of interest (e.g., baseline dietary intake and physical activity level, delivery and birth outcomes, breastfeeding initiation and length). Significance is assessed at $\alpha = 0.05$.

Analyses are based on the intention to treat principle where all randomized participants, including dropouts, are included in the analysis based upon their randomized intervention group [85]. Given that participants vary in adherence (fidelity) to the intervention (e.g., only keep some of their scheduled monthly home visits), dose response analyses also are conducted where dose corresponds to the number of monthly home visits conducted and group sessions attended. Additionally, generalized linear mixed models, utilizing maximum likelihood estimation, are used to test for outcome differences between treatment arms. Maximum likelihood estimation is an approach for handling missing data in repeated measures [86]. Finally, process data on recruitment, retention, participant engagement in the intervention, participant satisfaction, and implementation (dose delivered) are analyzed using descriptive and qualitative methods. These analyses will inform ongoing and future implementations of MIECHV programs, such as PaT, and allow for more effective dissemination of study findings.

3. Discussion

The gestational and postnatal periods may be the most opportune times to target behavior change that will reduce the risk of obesity and its comorbidities in both mother and child for several reasons. First, women appear particularly amenable to modifying their behavior during these periods to benefit their children. Second, given the frequent routine medical care that pregnant women and infants receive, interventions involving improved health care delivery have great potential. Third, these periods are relatively brief, and behavior change interventions are often most successful short term. Fourth, if effective interventions begun during pregnancy are maintained after birth, they will reduce the risk of maternal obesity for future pregnancies and thus help to interrupt the intergenerational cycle [36].

These unique characteristics of the gestational and postnatal periods notwithstanding, results from interventions designed to optimize GWG have been mixed. In a low glycemic index diet intervention and a supervised exercise intervention, both designed to prevent excessive GWG, the intervention groups were less likely to gain weight above IOM recommendations as compared to the control groups [87,88]. Unfortunately, no follow-up was provided for offspring outcomes in either study. Further, in a cluster randomized, controlled intervention trial conducted in eight gynecological practices and consisting of individually delivered counseling sessions focusing on diet, physical activity, and weight monitoring, not only did the intervention result in a lower proportion of women exceeding IOM guidelines for GWG, but women in the intervention group also were less likely to show substantial weight retention (>5 kg) at four months postpartum than women in the control group [78]. Again, no follow-up was reported for offspring outcomes.

Conversely, in a nonrandomized, controlled, pragmatic trial aiming to prevent childhood obesity, neither GWG nor infant weight gain from 0 to 12 months of age differed significantly between intervention and historic control groups [89].

However, the Lifestyle in Pregnancy (LiP) study, a randomized controlled trial with lifestyle intervention in obese pregnant women, resulted in significantly lower GWG in intervention participants as compared to control participants [79]. The follow-up study, Lifestyle in Pregnancy and Offspring (LiPO) assessed the effect of the pregnancy intervention on body composition of offspring of women recruited to the LiP study. In LiPO, no differences were seen in mean BMI z-scores in children from the intervention group as compared to children from the control group at 2.8 years of age [90]. Of note, the LiP study only intervened in the gestational period, and over one-third of the intervention group exceeded IOM recommendations for GWG [90]. While we are aware of several other randomized, controlled trials specifically targeting excessive GWG in an effort to prevent childhood obesity, results have not yet been reported in the literature.

In terms of weight loss in the postnatal period, results are more promising. In a systematic review of lifestyle interventions designed to reduce postpartum weight retention, seven of 11 identified studies were effective at decreasing postpartum weight retention [91]. The authors concluded that the inclusion of both diet and physical activity components as well as individualized support is more likely to be successful in promoting healthy postpartum weight. However, many uncertainties concerning the most effective approach for inducing weight loss during this period in a women's life stage remain, including timing of intervention initiation, intervention setting, and use of mobile technology [91].

The present study, Delta Healthy Sprouts is unique in several aspects. First, the intervention spans both the gestational and postnatal periods and targets both mother and child. Second, the MIECHV program creates a foundation for acquiring essential parenting skills and building solid support and service bases necessary for raising healthy, developmentally sound children. Third, the MIECHV program is enhanced with culturally tailored, nutrition and physical activity components for both mother (gestational and postnatal periods) and infant that are designed to reduce inappropriate GWG, postnatal weight retention, and rapid infant weight gain. Included in these enhancements are provision of information on the consequences of behavior and self-monitoring of behavior (i.e. tracking dietary intake) — behavior change techniques proven effective in GWG interventions [92]. Further, the primary mode of contact between Parent Educators and participants, outside of home visits and including confirmation of home visit dates and times and reminders about upcoming meetings and events, is through text messaging. We have found that the majority of Delta Healthy Sprouts participants prefer this method of contact versus traditional telephone calls or email.

Despite the many strengths of this study, there are some limitations that bear mentioning. Data collection is not blinded and therefore a potential source of bias. However, because the data is collected in the participants' homes, it is not practically, logistically, or financially feasible to have a second set of blinded research staff whose purpose is simply to collect data. The PaTE home visits are generally longer in duration than the PaT visits, thus introducing a potentially confounding factor of contact length with participants. However, the frequency of home visits is the same between the two intervention arms. Additionally, the potential for socially desirable responses for survey questions and dietary recalls cannot be discounted. To reduce the potential for such bias, Parent Educators are trained to not ask leading questions and to maintain neutral facial expressions, particularly when conducting dietary recalls. Further, because the study is being conducted in a southern, primarily African American population, the results may not be generalizable to other US populations. Nonetheless, the health disparate Mississippi Delta arguably needs such interventions more than other regions of the nation.

The Delta Healthy Sprouts Project tests a novel, combined approach to maternal weight management and childhood obesity prevention. By building upon the foundational structures provided through the MIECHV program, Delta Healthy Sprouts aims to improve the health and well-being of mothers and their infants in the Mississippi Delta region of the US, and potentially break the intergenerational cycle of obesity in this health disparate population.

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