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Family-based Obesity Prevention for Infants: Design of the “Mothers & Others” Randomized Trial

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Abstract

OBJECTIVE—Our goal is to test the efficacy of a family-based, multi-component intervention focused on infants of African-American (AA) mothers and families, a minority population at elevated risk for pediatric obesity, versus a child safety attention-control group to promote healthy weight gain patterns during the first two years of life.

DESIGN, PARTICIPANTS, AND METHODS—The design is a two-group randomized controlled trial among 468 AA pregnant women in central North Carolina. Mothers and study partners in the intervention group receive anticipatory guidance on breastfeeding, responsive feeding, use of non-food soothing techniques for infant crying, appropriate timing and quality of

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complementary feeding, age-appropriate infant sleep, and minimization of TV/media. The primary delivery channel is 6 home visits by a peer educator, 4 interim newsletters and twice-weekly text messaging. Intervention families also receive 2 home visits from an International Board Certified Lactation Consultant. Assessments occur at 28 and 37 weeks gestation and when infants are 1, 3, 6, 9, 12, and 15 months of age.

RESULTS—The primary outcome is infant/toddler growth and likelihood of overweight at 15 months. Differences between groups are expected to be achieved through uptake of the targeted infant feeding and care behaviors (secondary outcomes) and change in caregivers' modifiable risk factors (mediators) underpinning the intervention.

CONCLUSIONS—If successful in promoting healthy infant growth and enhancing caregiver behaviors, “Mothers and Others” will have high public health relevance for future obesity-prevention efforts aimed at children younger than 2 years, including interventional research and federal, state, and community health programs.

Keywords

infancy; obesity; breastfeeding; complementary feeding; television; social support

BACKGROUND

There has been an approximate 60% increase in overweight among infants and toddlers in the past few decades.^{1,2} This is concerning given research suggesting obesity is intractable; both large infant size and rapid postnatal growth are associated with subsequent child and adult overweight^{3,4} and future co-morbidities, including hypertension, cardiovascular disease, and Type 2 diabetes.^{5,6}

Research into the causes of large infant size and rapid growth has steadily increased.^{3,7,8} Promising behavioral determinants include short durations of exclusive or any breastfeeding,⁹ introduction of complementary foods (CF) before 4 months,¹⁰ shorter sleep duration among older infants and young children,^{11,12} early emergence of obesogenic diets (i.e., low fruit and vegetable intake; high intake of fatty/sugary snack foods, fast foods, juice, and sugar-sweetened beverages [SSBs]),^{13–18} and higher levels of television (TV)/media time.^{19–21} Importantly, there is growing evidence on the modifiable factors associated with these early life feeding and care behaviors, providing insight into potential avenues for intervention.

Modifiable factors include psychosocial constructs from health behavior theories (attitude, intention, and self-efficacy),^{22–25} parental feeding styles (responsive feeding),^{26–33} and interpretation of infant fussiness.^{34–39} Specific to breastfeeding, substantial evidence shows that more positive attitudes, greater levels of social support, and greater breastfeeding self-efficacy are each associated with higher rates of breastfeeding initiation and/or longer durations of exclusive or partial breastfeeding.^{22–25}

Similarly, feeding styles are latent constructs characterizing caregivers based on their beliefs and behaviors.²⁶ Research over the last three decades has culminated in a comprehensive set of caregiver feeding styles,²⁷ including those our team has adapted and validated for use

with caregivers of infants and toddlers (Table 1).²⁸ Notably, each of the less responsive feeding styles (i.e., controlling, pressuring, indulgent, and laissez-faire) has been associated with one or more outcomes among preschoolers as well as infants and toddlers, including dysregulation of appetite and higher energy intakes,^{29–31} lower intake of fruits and vegetables,³² higher intake of junk-type foods,³³ and greater adiposity.³³

The importance of parental perception of infant temperament on early feeding behaviors has become increasingly clear. Multiple studies show caregivers use infant fussing and crying as a cue an infant is hungry and/or it is time to introduce CF,^{34–37} and the use of food to soothe infant/toddler distress has been associated with higher child weight status.^{38,39} Among toddlers, internalized negative emotionality, being sad/fearful/anxious, and externalized negative emotionality, being defiant/aggressive, have each been associated with feeding of sweet foods, sweet drinks, and night-time caloric drinks.⁴⁰

While interventions targeting the first two years of life have increased dramatically over the last decade,^{41,42} critical gaps remain. First, most interventions begin after three or more months of infant age, missing an important opportunity to promote breastfeeding, responsive feeding, and healthy infant sleep behaviors in the early postpartum period. Pregnancy is also a teachable moment, a “naturally occurring life transition or health event thought to motivate individuals to spontaneously adopt risk-reducing health behaviors” (p.156).⁴³ Second, there is limited engagement of non-maternal caregivers in interventions. Nearly half of all infants and toddlers are in regular non-maternal care, most frequently by relatives,⁴⁴ who are actively involved in feeding.⁴⁵ The influence of fathers and grandmothers on infant feeding and care decisions has been well-documented,^{34,46–49} making it essential to involve other caregivers in early life obesity prevention efforts. Third, few interventions have directly targeted infant behavior, an important limitation given research on caregivers’ use of suboptimal feeding practices, including early cessation of breastfeeding and adding infant cereal in the bottle.^{34–37,40}

One priority population for intervention is African-American (AA) families, as AA infants, compared to white infants, have a higher prevalence of obesity² and are twice as likely to experience rapid weight gain in the first six months of life.⁵⁰ AA mothers have lower rates of breastfeeding across all nationally reported indicators,⁵¹ and our preliminary work with AA mothers has documented a normative pattern of feeding CF as early as 7–10 days postpartum,⁵² a common practice of feeding cereal in the bottle,^{37,52} and a predominant feeding pattern of formula, solids, and juice by 3 months of age.^{8,37} AA infants are also significantly more likely than white infants to have a daily sleep duration of < 12 hours, to have a TV in the bedroom, and to consume SSBs and fast food.^{50,53}

Conceptual framework

The conceptual framework underpinning the design of this study (Figure 1) is informed by the aforementioned literature, preliminary data from an observational, longitudinal study,^{8,21,28,31,37,45} and a transdisciplinary set of theoretical frameworks. From developmental psychology, we include parental feeding styles, which are feeding domain-specific parenting styles similar to those developed by Birch and Johnson (1995)²⁶ for older children and based on the seminal work of Baumrind (1971) and Maccoby and Martin

(1983) that defined general parenting styles and their relationships to child development outcomes.^{54,55} From biomedicine, we incorporate anticipatory guidance (AG), information given to families about what to expect in their child's development and how to promote it;⁵⁶ which has been associated with improved parental knowledge of child development,^{57,58} higher quality parent-child interactions,^{59–61} and better infant sleep patterns.^{62–64} Additionally, two recently completed randomized controlled trials (RCTs) aimed at early life obesity prevention utilized AG,^{65,66} each documenting improvements in parental responsive feeding practices,^{67–69} infant preference for fruit,⁶⁸ and decreased intake of SSBs and snacks.^{68,70} From health behavior and health education, we build on behavioral constructs from Social Cognitive Theory⁷¹ and the theory of Social Networks and Social Support⁷² that are associated with better infant care and feeding outcomes, including outcome expectations/attitudes,^{22,73,74} self-efficacy,^{22,46,75,76} and social support.^{46,47,77}

Aims and hypotheses

The aim of this study is to compare the effect of a home-based, multi-component intervention for AA pregnant women and families, versus an attention-control, on: infant size and growth (primary outcomes); infant diet, sleep and TV/media (secondary outcomes); and, caregiver behavioral and psychosocial constructs (mediators). Pregnant AA women are randomized to one of two study groups:

- Early life obesity prevention consisting of home visits delivered by a trained peer educator (PE), newsletters, reinforcing text messages, and identification of a study partner, who receives study materials and is encouraged to actively participate in the study alongside the mother;
- Attention-control group on child safety also consisting of PE-delivered home visits, newsletters, reinforcing text messages, and identification of a study partner, who only completes study assessments.

We hypothesize that, relative to the attention control:

- Infants of families in the intervention group will display significantly healthier growth outcomes, including: 1) lower mean weight-for-length z-score (WLZ) at 15 months; 2) smaller change in WLZ between 0–15 months; and, 3) lower likelihood of overweight (WLZ ≥ 95th percentile) at 15 months.
- Intervention caregivers will report significantly greater achievement of the targeted health behaviors: breastfeeding, appropriate timing and quality of CF, fewer reports of infant sleep problems, and lower levels of infant TV/media.
- Intervention caregivers will have improved diet, physical activity, and TV/media behaviors, more positive breastfeeding attitudes and higher maternal breastfeeding self-efficacy, greater knowledge of intervention messages, more responsive feeding styles, and diminished perceptions of infant fussiness.
- Intervention mothers will report higher levels of perceived social support from family.

DESIGN AND METHODS

Overall study design

The study design is a two-group RCT with an attention-control child safety group and a targeted sample of 468 AA pregnant women and families living in central North Carolina. Figure 2 illustrates the intervention and assessment activities by study arm. The study begins when women are 28 weeks gestation (baseline) and has a final assessment when infants are 15-months-old, with interim assessments at 37 weeks gestation and when infants are 1, 3, 6, 9, and 12 months of age. The primary delivery channel is home visits, supplemented by newsletters and twice-weekly text messaging. Funding for this 5-year project comes from the National Institute of Child Health and Human Development (R01HD073237). Institutional review board approval has been granted by the University of North Carolina, Office of Human Research Ethics.

Participants and recruitment

Pregnant AA women planning to deliver at three local hospitals are primarily recruited by trained recruitment specialists in prenatal clinics. These efforts are supplemented with flyers posted in community-based locations (e.g. churches, libraries) and announcements to parenting listservs. Eligible women are ages 18–39 years, have a singleton pregnancy, speak English, are <28 weeks gestation, are planning to stay in the area, and can identify a study partner. Exclusion-criteria include premature birth (<36 weeks), the mother or infant having a hospital stay after delivery >7 days, birthweight <2500 grams, or diagnosis of a congenital anomaly or condition significantly affecting feeding or growth (e.g., Down's syndrome, cleft lip or palate).

Sample size

The sample size of 468 families is based on power analyses showing a minimum of 354 mother-infant pairs (177 per group) allows detection of an effect size of 0.30 in infant WLZ at 15 months. This is based on an estimated mean WLZ of 0.34 and a standard deviation of 1.04 from our preliminary observational cohort study in a similar population.^{8,21,28,31,37,45} To achieve the minimum sample size of 354 infants at study end, we have incorporated a 12% loss of mothers, who may become ineligible to participate after enrollment due to meeting one or more birth-related exclusion criteria, as well as a sample attrition rate of 20%.

Randomization

Due to the influence of hospital practices on breastfeeding outcomes,⁷⁸ randomization is stratified by hospital using a computer generated sequence and block size of 50. Allocation concealment is used to prevent the PEs and participants from knowing which group families will be assigned. The project director, who has no direct contact with study participants, is responsible for generating the random number table and uploading it to REDCap,⁷⁹ a secure, online database maintained by the Center for Translational and Clinical Sciences Institute at UNC (1UL1TR001111 from the Clinical and Translational Science Award program of the Division of Research Resources, National Institutes of Health [NIH]). All baseline

assessments are conducted in the home by one of the trained PEs, after informed consent is given. At the completion of the baseline assessment, the PE randomizes the participant using the randomization functionality in REDCap. Blinding is not maintained for PEs and participants after allocation as participants are made aware of the intervention groups during the consent process and PEs deliver the differing intervention content. After randomization, participants complete all surveys online or via mail-based paper surveys prior to each educational home visit. PEs only collect objective, anthropometric data. Dietary recall data collectors are blinded to intervention group. All study data is maintained in REDCap.⁷⁹

Intervention group

Intervention participants receive 8 home visits, an information toolkit, 4 newsletters and twice-weekly text messages designed to provide AG and support for enactment of the 6 targeted infant feeding and care behaviors: breastfeeding; adoption of a responsive feeding style; use of non-food soothing techniques for infant crying; appropriate timing and quality of CF; minimization of TV/media; and, promotion of normal infant sleep. To increase social support for the targeted behaviors, study partners are encouraged to attend all home visits, are provided their own informational toolkit and series of newsletters, and are encouraged to sign up for reinforcing text messages. Mothers are given the opportunity to change their study partner at three time points over the course of the intervention: 3, 6, and 9 months postpartum.

Delivery channels—The primary delivery channel is home visitation. Six home visits are delivered by a PE at 30 and 34 weeks gestation and 3, 6, 9, and 12 months postpartum. The PE is an AA mother, who breastfed her own children and received over 100 hours of training in breastfeeding, CF, and infant behavior during the first 6 months of study preparation. Participants are offered enhanced lactation support services, consisting of up to 2 additional home visits by an International Board Certified Lactation Consultant after hospital discharge.

Home visits are reinforced through an informational toolkit provided to mothers and study partners at the first prenatal home visit. The toolkit is titled “My Guide to Growing [NAME OF INDEX CHILD] Healthy” and is organized according to the home visitation schedule. Each section contains a bullet-pointed summary of key messages covered during the home visit and a combination of supplementary resources carefully selected or developed by our team of experts. Prior to each postpartum home visit, mothers and study partners also receive a newsletter focused on CF. The series of 4 newsletters, titled “My Great Eating Adventure,” is organized around key developmental stages: head up (less than 6 months), learning to sit (6–8 months), learning to crawl (8–10 months), and learning to walk (10–12 months). One-way text messages reinforce content delivered through home visits and newsletters.

Curriculum content—The AG curriculum and text messages for the current study were informed by several expert resources, including the Baby Behavior program,⁸⁰ Ages & Stages Learning Activities,⁸¹ the Start Healthy Feeding Guidelines⁸² and the American Academy of Pediatrics (AAP) Nutrition Handbook.⁸³ Baby Behavior is a curriculum and

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programmatically developed to address the growing evidence that caregivers implement suboptimal feeding practices in response to infant behavioral traits (crying/fussing) or to achieve a desired outcome (extending infant nocturnal sleep).³⁵ Organized around three topic areas (cues, crying, and sleep), Baby Behavior teaches caregivers: how to recognize and respond appropriately to infant hunger and fullness cues and signs of engagement (when an infant wants to play) and disengagement (when an infant needs a break); typical patterns of infant sleep and how to recognize and respond appropriately to different phases of infant sleep (active and dreaming versus light and easy-to-waken); and the variety of reasons for which an infant might cry and how to recognize and respond appropriately to infant crying that is not related to hunger.

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The importance of minimizing TV/media is embedded within the Baby Behavior program. Caregivers are encouraged to keep TV/media out of the infant's bedroom and to reduce infant exposure to screen time as a tool for promoting normal, healthy sleep. Caregivers are encouraged to turn off TV/media during meals and snacks to minimize distractions for both the caregiver and infant, providing an environment in which modeling, mealtime learning, and recognition of hunger and fullness cues is more likely to occur. Caregivers are shown vignettes of parents interacting with infants and promoting activity in easy ways, including eye contact, conversation, and mat play. The Ages & Stages Learning Activities, created by developmental experts to promote parent-child interactions across five developmental domains (communication, gross motor, fine motor, problem solving, and personal-social) provide additional ideas for engaging with infants to promote development. The activities utilize safe and age-appropriate materials that are common in most households.

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The Start Healthy Feeding Guidelines and the AAP Nutrition Handbook informed the curriculum on CF, particularly the new types of foods and textures that are appropriate and safe at each developmental stage. Caregivers are encouraged to begin with small amounts (teaspoons) of CF and to use their infant's cues to decide to feed a smaller or greater amount. Iron-rich foods are encouraged first, followed by a gradual introduction, in no particular order, of healthy foods, such as modified whole fruits and vegetables. Caregivers are encouraged early in the postpartum period to make healthful changes to their own diet, as infants are likely to be exposed to and fed the types of foods commonly consumed by the family. Areas of focus include: increasing fruits and vegetables, decreasing sugar-sweetened beverages, choosing lean protein foods, making healthier choices when eating out, and choosing healthy snacks. Participants set small goals and are provided a goal setting and tracking calendar. Goal progress is assessed at each subsequent postpartum home visit and new goals are set accordingly. A similar process is followed for family physical activity, TV/media, and family meals. An overview of the curriculum for all home visits, by study arm, is presented in Table 2, with more detailed examples of the curriculum in the supplementary file.

Control group

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Content for the attention-control group is based on the child safety and injury prevention AG published in AAP Bright Futures.⁸⁴ The PE for the control group is AA, has previous experience in the supervision of young children, and received over 100 hours of training

during the study preparation phase in the prevention of Sudden Infant Death Syndrome, proper installation of infant car safety seats, and household injury prevention measures. Mothers in the attention-control group receive the same number of home visits, newsletters and text messages. While mothers in the control group also identify a study partner, they only complete study assessments: they are not encouraged to attend home visits or given the opportunity to sign up for text messages.

Measures

Study measures are outlined in Table 3. Primary outcomes include lower WLZ at 15 months, smaller change in WLZ between 0–15 months, and lower likelihood of overweight (WLZ 95th percentile) at 15 months. WLZ scores are calculated using the World Health Organization 2006 international growth standards.⁸⁵ Infant birth weight and length are self-reported by mothers, with a subset abstracted from hospital records to verify accuracy. Anthropometrics at subsequent time points are directly measured by the PEs, who are trained according to guidelines used in the existing National Health and Nutrition Examination Survey.⁸⁶

Secondary outcomes include infant diet, TV/media exposure, and sleep. All measures are self-reported by mothers and study partners via online surveys taken prior to each postpartum home visit and at study end. Mothers also complete a survey at 1 month postpartum to assess hospital experiences and early feeding and care practices. Infant diet outcomes include exclusive breastfeeding until 3 and 6 months, duration of any breastfeeding, timing of introduction of CF, and intake of select CF at 15 months (fruits and vegetables, desserts and sweets, chips and salty snacks). Infant dietary intake is measured in two ways: an infant diet history adapted after the Infant Feeding Practices II Study⁸⁷ and, at 15 months, a series of two 24-hour dietary recalls^{88,89} administered by the UNC Diet, Physical Activity and Body Composition Core (NIH grant DK56350). Infant TV/media exposure is measured using questions from previous studies associating TV/media with infant diet and size,^{90–95} and infant sleep is assessed by the Brief Infant Sleep Questionnaire.^{96–98}

Mediating variables related to caregiver psychosocial and behavioral determinants are collected via online surveys occurring at each data collection time point. Process measures capturing intervention fidelity and participant satisfaction are completed by home visitors and mothers at the end of each home visit. Study partners in the intervention arm also complete process measures.

Statistical analysis plan

A detailed analysis plan has been developed. While randomization should equalize important baseline characteristics across groups, we will begin analyses by testing for differences between groups and adjust for these variables in subsequent analyses as appropriate. The primary efficacy analysis will be a linear mixed model (LMM) on an intention-to-treat dataset with WLZ score at birth, 3, 6, 9, 12, and 18 months as the dependent variable and treatment group, age and their interaction term as the independent variables. LMM will be used to assess the effect of treatment group on change in WLZ and a

generalized linear mixed model (GLMM) for likelihood of overweight. Secondary analyses will use LMM and GLMM to determine the effect of treatment group on continuous and categorical targeted health behaviors, respectively. For health behaviors found significantly different between groups, an additional set of mixed models will determine their impact on WLZ. Mediation analyses as described by Baron and Kenny (1986) and MacKinnon, Krull and Lockwood (2000) will determine the extent to which underlying psychosocial and behavioral determinants mediate the relationship between treatment group and targeted health behaviors.

Conclusion

“Mothers and Others” is an efficacy trial of a multi-component, home-based intervention focused on infants of AA mothers and families, a minority population at elevated risk for pediatric obesity. “Mothers and Others” advances the field by addressing critical gaps in family-based interventions aimed at early life obesity prevention, namely beginning during pregnancy, a “teachable moment,” increasing maternal social support for the enactment of healthy infant feeding and care behaviors through the engagement of a study partner, and incorporating a unique curriculum on infant behavior and responsive feeding that is grounded in developmental science. If successful in promoting healthy infant growth and enhancing caregiver health behaviors, “Mothers and Others” will have high public health relevance for future obesity-prevention efforts aimed at children less than two years, including interventional research and federal, state, and community health programs.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations

AA	African-American
CF	complementary feeding/foods
SSB	sugar-sweetened beverage
TV	television
AG	anticipatory guidance
PE	peer educator
WLZ	weight-for-length z-score
RCT	randomized controlled trial
NIH	National Institutes of Health

AAP American Academy of Pediatrics

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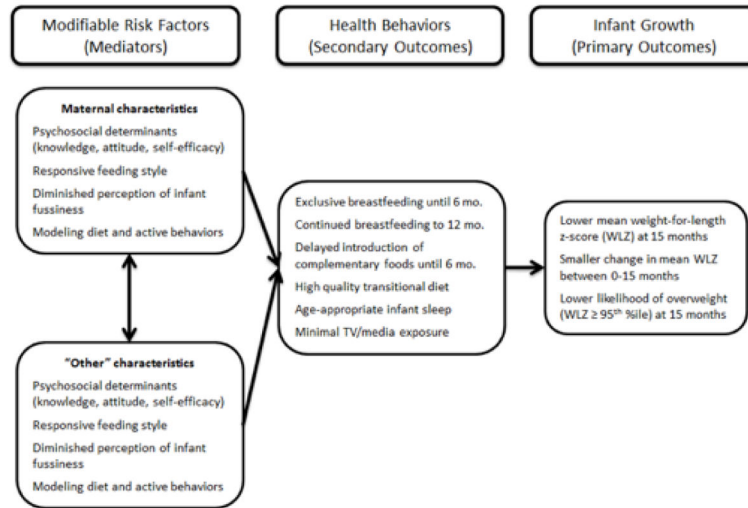


Figure 1. Conceptual framework underpinning the “Mothers & Others” intervention.

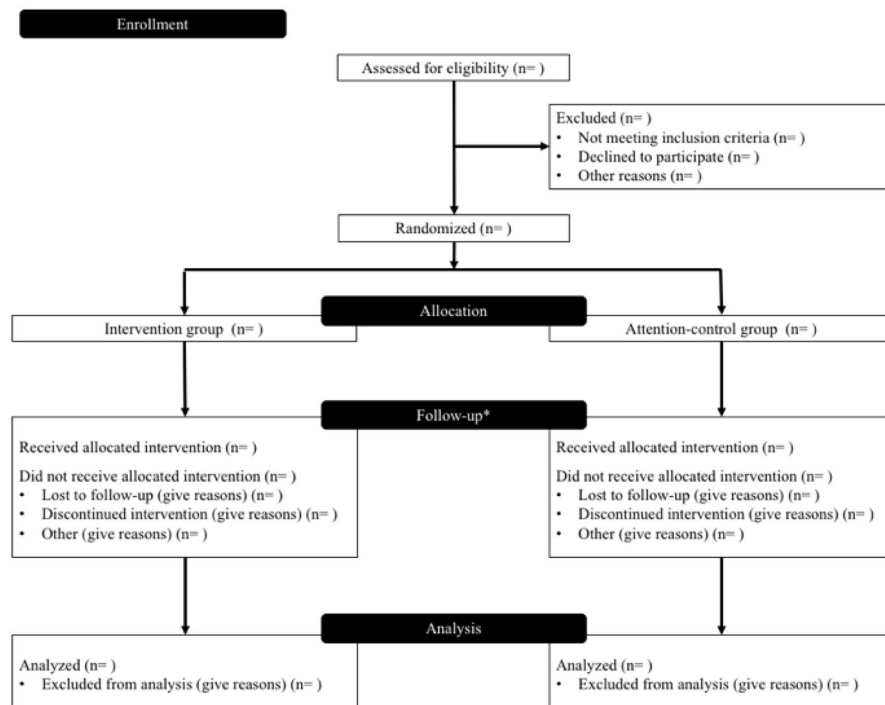


Figure 2. CONSORT flow diagram of intervention and assessment activities by study arm

Table 1Caregiver feeding styles and definitions from the Infant Feeding Styles Questionnaire (IFSQ)²⁸

Feeding Style	Definition
Responsive	Caregiver is attentive to child's hunger and satiety cues and monitors the quality of the child's diet.
Restrictive (Controlling)	Caregiver limits the infant to healthful foods and limits the quantity of food consumed.
Restrictive (Pressuring)	Caregiver is concerned with increasing the amount of food the infant consumes and uses food to soothe the infant.
Indulgent	Caregiver does not set limits on the quantity or quality of food consumed.
Laissez-Faire	Caregiver does not limit the infant's diet quality or quantity and shows little interaction with the infant during feeding.

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Table 2

Intervention content for home visits, by timing of delivery and study arm

Home Visit (<i>Timing</i>)	Obesity Prevention Group (<i>Intervention Arm</i>)	Injury Prevention Group (<i>Attention Control Arm</i>)
PRENATAL		
Home Visit 1 (30 weeks)	<p>Baby behavior (cues, crying, and sleep) 0–6 months</p> <ul style="list-style-type: none"> Information on infant behavioral cues, common reasons for crying, distinguishing hunger-related crying, non-food strategies for soothing a crying baby, typical sleep patterns, and promoting healthy sleep. <p>Building our village: identifying needs and support</p> <ul style="list-style-type: none"> Tools and tips for mobilizing social support from family and friends to help with the transition of bringing home a new baby. <p>Introducing you to your toolkit: finding more information</p> <ul style="list-style-type: none"> Reputable resources for finding more information, organized according to the home visitation schedule^a 	<p>Preventing SIDS and accidental suffocation</p> <p>Tips for selecting a crib</p> <p>Introducing you to your toolkit: finding more information</p>
Home Visit 2 (34 weeks)	<p>Baby behavior: the first 72 hours</p> <ul style="list-style-type: none"> Information on typical behavior in the first few days, including an initial alertness, followed by a period of sleepiness, and then an increase in alertness in which the baby will want to eat more often. <p>Feeding your baby: myths and reality</p> <ul style="list-style-type: none"> Discussion of common myths related to breastfeeding, including those associated with infant behavior (crying and sleep), racial identity (e.g. few African-American women breastfeed), and over-swaddling. <p>Using your B.R.A.I.N.: a tool for making decisions that are right for you</p> <ul style="list-style-type: none"> Tools and tips for making an informed infant feeding decision, including an assessment of the Benefits, Risks, Alternatives, Intuition, and Need for time to continue thinking it through. 	<p>Choosing and using a safe car seat</p> <p>Safety in and around the car</p> <p>Keeping baby safe in a stroller</p>
POSTNATAL		
Home Visit 3 (3 months)	<p>Let's catch up!</p> <ul style="list-style-type: none"> Check-in on baby behavior and social support. Are cues getting easier to read? Sleep getting longer? Did you have the help you needed after delivery? Now? Do you want or need to change your "other"? <p>Let's review: your 2-month newsletter</p> <ul style="list-style-type: none"> Check-in on infant feeding topics in newsletter, including overview of feeding for the first year of life, organized by developmental stage, and an emphasis on feeding only breast milk (or formula) until 6 months. <p>Healthy eating: it's all in the family</p> <ul style="list-style-type: none"> Tools and tips for improving family eating habits with emphasis on increasing fruits, vegetables and lean protein foods; choosing water instead of sugar-sweetened beverages, and making smart snack choices. 	<p>Let's catch up! safe sleep and safety-on-the-go</p> <p>Top safety tips for 1–6 months: the "head up" stage</p> <p>Getting ahead on safety: childproofing your home for the "independent sitter" stage</p>
Home Visit 4 (6 months)	<p>Let's review: your 5-month newsletter (learning to sit)</p> <ul style="list-style-type: none"> Check-in on infant feeding topics in newsletter, including signs of readiness for solid food, iron-rich first food choices, beginning with small amounts, hunger and fullness cues for older babies, and limiting juice. <p>Your growing baby: baby behavior for older babies</p> <ul style="list-style-type: none"> Reinforce and praise mothers' and others' understanding of their infants' cues and provide new information related to hunger and fullness cues, reasons for crying and sleep patterns for older infants. 	<p>Let's review: top safety tips for the "independent sitter" stage</p> <p>Getting ahead on safety: childproofing your home for the "crawler" stage</p> <p>Home fire safety: prepare, practice, prevent the unthinkable</p>

Home Visit (<i>Timing</i>)	Obesity Prevention Group (Intervention Arm)	Injury Prevention Group (Attention Control Arm)
	<p>Being active: it's all in the family</p> <ul style="list-style-type: none"> Information on the benefits of physical activity for adults and babies, the importance of modeling active versus inactive behaviors, and how to minimize TV and screen time for everyone in the family. <p>Planning for change (family physical activity and TV/media behaviors)</p> <ul style="list-style-type: none"> Goal setting tips and tools and refrigerator calendar for monitoring. 	
Home Visit 5 (9 months)	<p>Healthy eating and being active: it's all in the family (checking in)</p> <ul style="list-style-type: none"> Review goals set at previous visit, discuss progress, barriers and facilitators, and assist with setting new goals in the same area or additional areas, depending on progress. <p>Your 7-month materials: let's review what was mailed to you</p> <ul style="list-style-type: none"> Check-in on infant feeding topics in newsletter, including new eating skills (pincer grasp), healthy ideas for finger foods, establishing mealtime routines, and best practices for bottles and "sippy" cups. <p>Baby behavior: tantrums and food refusal</p> <ul style="list-style-type: none"> Information on infant behavior related to tantrums and food refusal, including new reasons for infant crying, non-food soothing strategies, importance of routines, and the difference between routines and schedules. 	<p>Let's review: top safety tips for the "crawler" stage</p> <p>Getting ahead on safety: childproofing your home for the "learning to walk" stage</p> <p>Preventing TV tip-overs: what every parent should know</p>
Home Visit 6 (12 months)	<p>Healthy eating and being active: it's all in the family (checking in)</p> <ul style="list-style-type: none"> Review goals set at previous visit, discuss progress, barriers and facilitators, and assist with setting new goals in the same area or additional areas, depending on progress. <p>Your 10-month materials: let's review what was mailed to you</p> <ul style="list-style-type: none"> Check-in on infant feeding topics in newsletter, including sample menu, strategies for minimizing food struggles, tips for transitioning from bottles to cups, and best practices for "sippy" cups. <p>Family meals: food, togetherness, and fun</p> <ul style="list-style-type: none"> Information on the health and psychosocial benefits of family meals for children, tips for increasing family meals to 3 times/week, and for improving quality of family meals by turning off TV and media. <p>Planning for change (family meals)</p> <ul style="list-style-type: none"> Goal setting tips and tools for improving the quantity and quality of family meals. 	<p>Let's review: childproofing your home</p> <p>Splish-splash: Staying safe around water</p> <p>Bye-bye boo-boos: staying safe on the playground</p>

Table 3

Study measures and assessment timetable

Measure	Source/Instrument (where applicable)	Assessment Time Point																		
		Prenatal (weeks)					Postnatal (months)													
		28	30	34	37	1	3	6	9	12	15									
Background information ^d		X																		
Primary outcome																				
Infant weight-for-length	Direct measurement of anthropometrics ^{85,86}					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Secondary outcomes																				
Infant dietary intake	Infant Feeding Practices Study-II ⁸⁷					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X ^b
Infant TV and electronic media exposure	Questions from previous studies ⁹⁰⁻⁹⁵						X	X	X	X	X	X	X	X	X	X	X	X	X	X
Infant sleep	Brief Infant Sleep Questionnaire ⁹⁶⁻⁹⁸					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Mediators																				
Maternal infant feeding intentions	Infant Feeding Intentions Scale ¹⁰¹					X				X										
Caregiver breastfeeding attitude ^c	Iowa Infant Feeding Attitudes Scale ¹⁰²					X				X										
Maternal breastfeeding self-efficacy	Breastfeeding Self-Efficacy-Short Form ¹⁰³														X					
Maternal parenting self-efficacy	Parenting Self-Efficacy Scale ^{104,105}																			
Caregiver feeding responsiveness ^c	Infant Feeding Styles Questionnaire ⁸																			
	Responsiveness to Child Feeding Cues Scale ¹⁰⁶					X ^d				X ^d	X ^e	X	X ^e	X	X ^e	X	X ^e	X	X ^e	X ^e
Caregiver perception of infant temperament ^c	Infant Behavior Questionnaire-Revised ¹⁰⁷														X	X	X	X	X	X
Maternal perceived social support	Perceived Social Support from Family ¹⁰⁸									X					X					X
Caregiver KAB of intervention messages ^{c,f}						X				X	X	X	X	X	X	X	X	X	X	X
Caregiver dietary intake ^c	Starting the Conversation ¹⁰⁹					X									X					X
Caregiver physical activity ^c	International Physical Activity Questionnaire ¹¹⁰					X														X
Additional measures:																				

Measure	Source/Instrument (where applicable)	Assessment Time Point														
		Prenatal (weeks)							Postnatal (months)							
		28	30	34	37	1	3	6	9	12	15					
Caregiver body mass index ^c	Direct measurement of anthropometrics ⁸⁵	X		X		X		X		X		X		X		X
Caregiver depression ^c	Center for Epidemiological Studies-Depression ¹¹¹	X				X		X		X		X		X		X
Process measures:																
Treatment fidelity (adherence, exposure) ^d			X	X				X	X	X	X	X	X	X		X
Participant satisfaction ^d			X	X				X	X	X	X	X	X	X		X

^aDemographics, household composition, food security, employment history, available maternal leave, health history, current health status and paternal self-reported height and weight

^bTwo 24-hour dietary recalls will also be collected at study end (15 months)^{88,89}

^cThe assessment for the study partner, in both intervention arms, also contains this measure, except for anthropometrics; study partners self-report height and weight

^dDuring pregnancy, the assessment only includes items on infant feeding beliefs

^eIncludes video observation of a feeding episode and analysis using the Responsiveness to Child Feeding Cues Scale¹⁰⁶

^fKAB = knowledge, attitudes, beliefs

^gIncludes an assessment by the home visitor as to whether or not the study partner was in attendance

^hStudy partners in the intervention arm, but not the attention-control arm, also complete a satisfaction survey