



## Family-based obesity prevention for infants: Design of the “Mothers & Others” randomized trial



Heather M. Wasser<sup>a,\*</sup>, Amanda L. Thompson<sup>a,2</sup>, Chirayath M. Suchindran<sup>a,3</sup>, Eric A. Hodges<sup>a,4</sup>, Barbara D. Goldman<sup>a,5</sup>, Eliana M. Perrin<sup>e,6</sup>, Myles S. Faith<sup>b,7</sup>, Cynthia M. Bulik<sup>a,c,8</sup>, M. Jane Heinig<sup>d,9</sup>, Margaret E. Bentley<sup>a,10</sup>

<sup>a</sup> University of North Carolina, Chapel Hill, NC, United States

<sup>b</sup> University at Buffalo, Buffalo, NY, United States

<sup>c</sup> Karolinska Institutet, Stockholm, Sweden

<sup>d</sup> University of California, Davis, CA, United States

<sup>e</sup> 3643 N. Roxboro Street, Duke University, Durham, NC 27704, United States

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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 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

**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

\* Corresponding author at: Nutrition Department, Gillings School of Global Public Health, University of North Carolina, 135 Dauer Drive, 245 Rosenau Hall, CB# 7461, Chapel Hill, NC 27599-7461, United States.

**E-mail addresses:** [wasser@email.unc.edu](mailto:wasser@email.unc.edu) (H.M. Wasser), [althomps@email.unc.edu](mailto:althomps@email.unc.edu) (A.L. Thompson), [suchindran@unc.edu](mailto:suchindran@unc.edu) (C.M. Suchindran), [eahodges@email.unc.edu](mailto:eahodges@email.unc.edu) (E.A. Hodges), [barbara\\_goldman@unc.edu](mailto:barbara_goldman@unc.edu) (B.D. Goldman), [eliana\\_perrin@med.unc.edu](mailto:eliana_perrin@med.unc.edu) (E.M. Perrin), [mfaith@buffalo.edu](mailto:mfaith@buffalo.edu) (M.S. Faith), [cynthia\\_bulik@med.unc.edu](mailto:cynthia_bulik@med.unc.edu) (C.M. Bulik), [mjheinig@ucdavis.edu](mailto:mjheinig@ucdavis.edu) (M.J. Heinig), [pbentley@unc.edu](mailto:pbentley@unc.edu) (M.E. Bentley).

<sup>1</sup> 104B Market Street, CB# 7521, University of North Carolina, Chapel Hill, NC 27599-7521, United States.

<sup>2</sup> 209-A Alumni Bldg, CB# 3115, University of North Carolina, Chapel Hill, NC 27599-3115, United States.

<sup>3</sup> 3103-A McGavran-Greenberg HI, CB# 7420 University of North Carolina, Chapel Hill, NC 27599-7420, United States.

<sup>4</sup> 5110 Carrington Hall, CB# 7460, University of North Carolina, Chapel Hill, NC 27599-7460, United States.

<sup>5</sup> 105 Smith Level Rd., CB# 8180, University of North Carolina, Chapel Hill, NC 27599-8180, United States.

<sup>6</sup> 231 MacNider, 333 South Columbia St, CB# 7225, University of North Carolina, Chapel Hill, NC 27599-7225, United States.

<sup>7</sup> 420 Baldy Hall, University at Buffalo, Buffalo, NY 14260-1000, United States.

<sup>8</sup> 10505 Neurosciences Hosp, CB# 7160 University of North Carolina, Chapel Hill, NC 27599-7160; and Karolinska Institutet, Stockholm, Sweden.

<sup>9</sup> 1283D Academic Surge, One Shields Avenue, University of California, Davis, CA 95616, United States.

<sup>10</sup> 130 Rosenau Hall, CB# 7400 University of North Carolina, Chapel Hill, NC 27599-7400, United States.

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than 2 years, including interventional research and federal, state, and community health programs.  
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## 1. 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 obesity [2] 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 h, to have a TV in the bedroom, and to consume SSBs and fast food [50,53].

### 1.1. Conceptual framework

The conceptual framework underpinning the design of this study (Fig. 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 [26] for older children and based on the seminal work of Baumrind and Maccoby and Martin 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

**Table 1**  
 Caregiver 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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