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# A Community-Based Intervention to Prevent Obesity Beginning at Birth among American Indian Children: Study Design and Rationale for the PTOTS study

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# Abstract

Eating and physical activity behaviors associated with adult obesity have early antecedents, yet few studies have focused on obesity prevention interventions targeting very young children. Efforts to prevent obesity beginning at birth seem particularly important in populations at risk for early-onset obesity. National estimates indicate that American Indian (AI) children have higher rates of overweight and obesity than children of other races/ethnicities. The Prevention of Toddler Obesity and Teeth Health Study (PTOTS) is a community-partnered randomized controlled trial designed to prevent obesity beginning at birth in AI children. PTOTS was developed to test the effectiveness of a multi-component intervention designed to: promote breastfeeding, reduce sugar-sweetened beverage consumption, appropriately time the introduction of healthy solid foods, and counsel parents to reduce sedentary lifestyles in their children. A birth cohort of 577 children from five AI tribes is randomized by tribe to either the intervention (three tribes) or the comparison condition (two tribes). The strengths and weaknesses of PTOTS include a focus on a critical growth phase, placement in the community, and intervention at many levels, using a variety of approaches.

# Keywords

Primary Obesity Prevention; Infants; Toddlers; American Indians

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# Introduction

Overweight (body mass index [BMI] 25) and obesity (BMI 30) in the general U.S. population are expected to rise to 75% and 41%, respectively, by 2015 (Wang & Beydoun, 2007). American Indian (AI) adults are already close to these levels, with 69.2 of AI adults 18 years or older being overweight or obese (Schiller et al, 2012). AI children have a similarly higher risk of obesity compared to children of other races/ethnicities. The age-adjusted prevalence of obesity and overweight (BMI 85th percentile) among AI school-aged children (5–17 years of age) is approximately 47% (Zephier et al., 2006), compared with 33.6% among school-aged children of other races/ethnicities (Caballero et al., 2003; Eisenmann et al., 2000; Jackson, 1993; Potvin et al., 1999).

Antecedents for adult obesity may begin at birth in AI children. Research has shown that Pima Indian infants gain weight more rapidly in the first 6 months of life compared with age- and gender-matched reference populations (Lindsay et al., 2002; Salbe et al., 2002). According to the Pediatric Nutrition Surveillance System (PedNSS; Polhamus et al., 2007), 12.6% of AI infants (0–11 months) and 24% of AI toddlers (12–23 months) are obese (weight 95th percentile), compared with 10.9% and 17% of infants and toddlers of other races/ethnicities, respectively. Moreover, among preschoolers (24–60 months), 40% of AI children are overweight or obese, compared with 31.2% of children of other races/ethnicities (Polhamus et al., 2007). Similar data have been reported by Anderson and Whitaker (2009) among 4-year-olds in the Early Childhood Longitudinal Study birth cohort.

Childhood obesity can lead to an earlier onset of adult obesity, its sequelae, including type 2 diabetes mellitus, escalation of cardiovascular disease risk factors, cardiovascular disease itself, cancer, and asthma, as well as increase obesity-associated costs (Must & Strauss, 1999; Srinivasan et al., 1996; Wang & Dietz, 2002; Renehan et al., 2008).

Efforts to prevent obesity beginning at birth seem particularly important in populations at risk for early-onset obesity, such as AI populations. This article provides an overview of the rationale for and the intervention design of PTOTS, which was developed to test the hypothesis that obesity prevention beginning at birth reduces overweight at age 2 years in AI children.

# Methods

#### **Design Overview**

PTOTS is a cluster randomized controlled trial. In this trial, a birth cohort of 577 children from five AI tribes is randomized by tribe to either the intervention (three tribes) or the comparison condition (two tribes). The intervention includes nutrition and physical activity (PA) goals, and consists of a community-wide component coupled with an individualized family-counseling component to improve nutrition and PA in infants and toddlers. The nutrition goals are presented in four modules: (1) breastfeeding, (2) curtailment of sugar-sweetened beverage (SSB) consumption, (3) introduction of healthy solid foods, and (4) parental management of feeding behaviors. The PA goal are: (1) to reduce sedentary behaviors, including reducing amount of television viewing and minimizing use of tools that may be used for safety, but which also limit children's ability to move (e.g., strollers, high chairs, playpens); and (2) to promote the development of motor and movement skills in infants and toddlers by creating safe spaces for structured and unstructured play. We are following the guidelines of the National Association for Sports and Physical Education (NASPE), which recommends at least 30 minutes of structured play and 60 minutes of

unstructured play daily for toddlers (NASPE, 2009). Intervention goals are the same in the community-wide component and the family-counseling component.

#### Study Population, Recruitment, and Screening

PTOTS is targeting AI infants and toddlers aged 0–2 years. Recruitment, consent, and screening goals are similar across all tribes, but each tribe designs its own screening procedures for enrolling children born of uncomplicated pregnancies and their parents in the study. Expectant mothers in their second or third trimester are approached by Maternal Child Health (MCH) clinic staff, including staff in the Women, Infants, and Children (WIC) program. WIC is a federally funded supplemental food program for low-income families offered to pregnant mothers and their children aged 5 years or younger (Oliveira et al., 2002). Interested mothers consent to receiving the intervention and/or provide their own data and those of their unborn child. The Portland Area Indian Health Service institutional review board approved the PTOTS study, and each tribe has approved the study and access to the local PedNSS longitudinal data. AI individuals are defined as tribal members who are eligible to receive health care services at tribal health clinics, based on each tribe's ancestry rules (Thornton, 1996).

#### **Comparison Communities**

Parents and guardians in the comparison tribes consent to provide study data for their children. We offer non-diagnostic dental screenings to children aged 1–5 years as a service to the comparison communities. The extent of early childhood caries is high in AI communities, and dental services are sparse (Maupomé et al., 2010). The choice of dental screenings is, therefore, based on need. Dental hygienists are trained to conduct the screenings once a year. Any child in the community, whether they are enrolled in the PTOTS study or not, receives the screening using a separate consent form. Those children found to have early childhood caries are referred for further evaluation and appropriate treatment. Incentives to attend measurement and intervention visits include gas coupons, discount coupons for child merchandise, and raffles for specific items such as family meals at local restaurants.

#### **Rationale for the Target Population**

A substantial body of research indicates that infancy is a critical period for the development of obesity (Stettler, 2007). Children who grow rapidly in infancy may have an earlier BMI rebound (Cole, 2004; Rolland-Cachera et al., 1987), which, in turn, may increase their risk of overweight/obesity in childhood and obesity in adulthood.

At the same time, the development of food preferences is thought to occur during a narrow window between 2 and 5 years of age (Fieldhouse, 1996; Birch, 1999). During this time period, parents transfer their values about where, with whom, when, how, and how much food should be eaten (Sepp, 2002). Children's PA patterns may be similarly transferred through parental modeling (Fogelholm et al., 1999; Sallis et al., 1992).

These data suggest the need for early intervention to prevent imprinting of obesogenic behaviors in infants and toddlers. However, only 6% of the programs on obesity prevention among children target preschoolers (Flynn et al., 2006; Campbell et al., 2002). To our knowledge, only three studies have explored prevention of overweight in children beginning at birth (Costom & Shore, 1983; Karanja et al., 2010, Paul et al., 2011). Costom and Shore (1983) reported a reduction in adiposity in 182 infants whose parents received individualized feeding advice. Our research team (Karanja et al. 2010) reported an attenuation of BMI increase with an intervention structure similar to the one we propose here, but focusing only on promoting breastfeeding and curtailing SSBs. In their study, Paul

et al. (2011) found lower weight-for-length percentiles in children of mothers who received two home visits to assist them in dealing with infant fussiness and introduction of complementary foods.

The PTOTS study combines elements of these three previous studies by customizing the intervention to tribe and family, but it expands the intervention to include more nutrition and PA components. This study also addresses the lack of available interventions to prevent obesity during the time when most lifestyle habits become entrenched.

#### Theoretical Basis of the Intervention and Rationale for Placing the Intervention in the Community Setting

**Theoretical basis of the intervention**—The intervention design is based on the socialecological model of behavior change, which impacts the child by targeting the expectant mother, her family networks, and community institutions that serve and interact with mothers and their children (Booth et al., 2001; Green et al., 1996). By targeting the extended family, we recognize that childrearing is a shared responsibility within the structure of AI families (Clarke, 1991). Engaging Community Health Workers (CHWs) from tribal communities to deliver the interventions ensures that they are translated in a manner consistent with tribal values.

The PTOTS study follows the general tenets of participatory research (King et al., 2002; Tones et al., 1990; Wallerstein & Bernstein, 1998; Stokols, 2000; Airhihenbuwa, 1994; Freire, 1972, 1973; Hooks, 1994). Tribal representatives provide input to both study design and implementation through their participation as project staff and interventionists. The community-wide intervention is carefully defined in terms of goals and strategies, but it is tailored to fit the specific needs of each tribal community.

CHWs are trained to use behavioral self-management principles and motivational interviewing to deliver the intervention (Miltenberger, 2008; Miller & Rollnick, 2002). These techniques support autonomy in behavioral change by helping participants set reasonable short-term goals, formulate action plans, and develop behavioral reinforcements and social support to achieve their goals. The techniques also help participants find self-management tools to assess progress and regularly evaluate and modify plans using these tools. CHWs are taught to apply outreach principles to manage home visits and to connect participants with social and intervention-related services, such as lactation support (Forest & Palmer-House, 2003).

**Rationale for placing the intervention in the community and the home**—In AI communities, research programs that are delivered at multiple levels using community institutions that are likely to sustain these programs are more successful (Gittelsohn & Rowan, 2011). The family and the community in which these programs are implemented represent such institutions. Families can create environments that are conducive to poor food choices, excess calorie consumption, and sedentary lifestyles. Families can also reinforce and support healthy food and activity habits (Birch & Davison, 2001; Wilson, 2002). Despite the central role of the family in shaping health, and the family's importance in the social-ecological model (Stokols, 1992; King et al., 2002; Stokols, 2000; Sallis et al., 1998), few studies have placed interventions in a family setting. Healthy family behaviors can be supported or undermined by community design, structure, and norms. In their gap analyses of interventions to prevent obesity in children, Flynn et al. (2006) noted the paucity of such interventions conducted in the home or the community.

#### Intervention Goals and Rationale for the Chosen Interventions

The scarcity of overweight prevention studies in infants under 1 year of age may result from concerns that such interventions may harm children. These concerns are valid given that obesity prevention interventions, if not carried out appropriately, may result in non-organic failure to thrive (Pugliese et al., 1987) and psychological harm (Zametkin et al., 2004; O'Dea, 2005; McCullough et al., 2009). Thus, overweight prevention interventions targeting infants must do no harm, and they must be both consistent with health promotion and not conflict with other aspects of child health (O'Dea, 2005).

**Nutrition goals and rationale for their choice**—The nutrition goal has four modules designed to: (1) promote breastfeeding, (2) reduce SSB consumption, (3) appropriately time the introduction of healthy solid foods, and (4) provide guidance on parental management of feeding behaviors.

Breastfeeding appears to be an important component of interventions to prevent obesity in children (Dewey, 2003; Grummer-Strawn & Mei, 2004; Costom & Shore, 1983; Karanja et al., 2010; Paul et al., 2011), so it is the first component of the intervention. The breastfeeding sub-module has four goals: (1) promoting breastfeeding as a cultural value; (2) preparing mothers who anticipate breastfeeding during the prenatal period; (3) creating community breastfeeding support in the early weeks after delivery; and (4) addressing barriers and policies that interfere with initiating and maintaining lactation (Butte et al., 2004; Story et al., 2002; American Academy of Pediatrics Committee on Nutrition, 2001).

The second component is reducing SSB consumption. SSBs increase energy intake (Harnack et al., 1999; Wilson, 2000; Frary et al., 2004), and their curtailment has been shown to reduce BMI in school-aged children (Ebbeling et al., 2006; Albala et al., 2008). Thus, curtailing the consumption of SSBs may have a role in preventing obesity in the very young (Karanja et al., 2010), but more empirical evidence showing the effectiveness of this strategy in younger children is needed. The SSB sub-module increases parental awareness of the links between children's consumption of SSBs and overweight/underweight, tooth decay, and chronic diseases, as well as provides guidance to parents in developing their own strategies to follow the American Academy of Pediatrics Beverage Consumption Guidelines (Fox et al., 2004).

It is currently unknown whether delaying the introduction of solid foods and socializing children to the taste of healthful foods, such as vegetables, fruits, and water, early in life attenuates BMI acceleration. In a survey of how parents feed children called the "Feeding Infants and Children" (FITS) study, 94% of the population surveyed reported that they introduced solid foods before 6 months of age (Dwyer et al., 2004); FITS participants also reported that they introduced energy-dense, nutrient-poor foods at about 15 months, and that the consumption of fruits and vegetables fell dramatically at the same time (Briefel et al., 2004; Fox et al., 2004). Retrospective studies examining the association between delaying solid foods and child BMI have yielded inconsistent results (Burdette et al., 2006; Wilson et al., 1998; Agras et al., 1990), and the only prospective study found no association between these two variables (Mehta et al., 1998). The FITS data suggest that interventions targeting the overall eating patterns of families—combined with guidelines for feeding infants and toddlers—are likely to improve the diets of very young children, as children adopt family eating patterns fairly early in life (Butte et al., 2004).

The third component, therefore, focuses on solid food introduction. The sub-module addresses the *timing* of introducing solid foods (6 months), *what* solid foods are appropriate (nutrient-dense, hypoallergenic foods of varied textures and colors), and *how* to introduce

foods to infants/toddlers. Training sub-modules covering these topics are introduced when the infant is 4 months old.

The fourth component applies to both nutrition and physical activity and is described under physical activity below.

**PA goals and rationale for their choice**—Car seats, high chairs, and playpens which are used to keep infants and children safe can also be used to confine them in ways that limit movement and spontaneous play. This, combined with television viewing (Certain & Kahn, 2002), can limit the development of a wide range of motor activities needed for children to remain active as they mature (NASPE, 2009). Given that children will move more in the absence of cues to remain sedentary (Certain & Kahn 2002), interventions to reduce sedentary behaviors are as important as those that actively promote movement.

There are two PA sub-modules. The first sub-module focuses on reducing sedentary behaviors, including television viewing; creating safe spaces for structured and unstructured play; and minimizing use of strollers and high chairs. The second sub-module integrates the NASPE guidelines, which focus on developing motor and movement skills in infants and toddlers, and recommend at least 30 minutes of structured play and 60 minutes of unstructured play daily (NASPE, 2009).

Parenting is also a critical part of any intervention to prevent obesity, so it is woven into the PA and nutrition components of the intervention. Parents can model both food/beverage consumption (Wardle et al., 2003; Lederman et al., 2004) and PA behaviors. Excess control over what a child eats, as well as lack of structure and unregulated eating, may promote overweight by overriding the children's natural appetite regulation mechanisms (McConahy et al., 2002; Birch et al., 2001; Birch & Ventura, 2009; Wardle et al., 2002; Rolls et al., 2000). The curriculum contains information on how to manage the home environment to make healthy eating easier by buying and preparing healthy foods; *increasing triggers* for healthy food/beverage consumption and PA; *modeling* healthy eating and PA behaviors to children; and *using supportive parenting skills* (patience, structure, autonomy, confidence building, etc.) to encourage healthy eating and PA behaviors in children.

#### **Operationalizing Intervention Goals**

**Community-wide intervention**—Table 1 shows a prototypical community-wide intervention plan. These plans contain activities addressing study goals to be executed over successive 6-month periods. Plans are similar across tribes, but they are customized to fit the specific needs of each tribe. For example, a tribe with a pre-existing prenatal breastfeeding program might create a breastfeeding room in a tribally owned casino, whereas a tribe without a strong prenatal breastfeeding program might decide to make a culturally appropriate breastfeeding, but the specific strategies they choose are tailored to the tribe's needs. Community plans were intended to:

- Raise awareness about a targeted goal (e.g., low breastfeeding duration)
- Deliver public health education to the community at large (e.g., create posters, billboards, and public service announcements promoting the benefits of breastfeeding)
- Alter policies and the environment to promote a targeted goal (e.g., allow mothers to breastfeed while at work)
- Augment public health practice (e.g., facilitate formation of breastfeeding support groups)

Change community and individual behavior (e.g., increase the number of women who choose to breastfeed)

**Family-counseling intervention**—The family is used as an additional social-ecological channel to increase intervention dose (Booth et al., 2001; Green et al., 1996). The family-counseling intervention is delivered in 15 visit clusters as shown in Table 2. Each visit cluster consists of 1–3 contacts, one of which occurs in the participant's home. Thus, families could receive 15–45 contacts during the 3-year follow-up period. The actual number of visits depends on the varying needs of different families. For example, a mother who has breastfed successfully before, and is breastfeeding a second child, might need fewer visits in the early weeks than a mother who is breastfeeding for the first time.

Clusters 1 and 2 occur before the baby is born, and are intended to establish rapport and contact guidelines between participants and their CHWs. The CHW collects baseline data needed to plan the family's intervention approach, and encourages mothers to choose breastfeeding.

Clusters 3 and 4 occur around the time of the baby's birth, and include visits to the hospital, when necessary. These visits provide support for breastfeeding mothers, and connect them to community resources offering infant services, such as car-seat programs.

Clusters 5 and 6 occur around the time that working mothers return to work (2–6 months) and widen their circle of childcare providers. These counseling sessions reinforce WIC/ MCH counseling guidelines by helping families create plans for sustaining full or partial breastfeeding.

Clusters 7–15 occur when the child is 6–30 months old. These sessions address the introduction of solid food, parenting around feeding of older infants and toddlers, SSB and water consumption, and introduce PA topics.

As shown in Table 2, each counseling session follows a similar pattern, and consists of a check-in; an information-sharing session on a given topic, such as SSBs and health; a demonstration to support the session's informational content; a goal-setting segment; and action plans for the subsequent weeks.

#### **Outcomes and Measures**

Table 3 shows the study measures and schedule of collection for intervention and comparison tribes. The primary outcome is BMI Z-scores at ages 24 months. PedNSS data, collected over the preceding 2 years, are used to adjust for potential differences in BMI at baseline between the two groups of tribes. Secondary outcomes include: BMI at 0, 6, 12, and 18 months of age; breastfeeding initiation and duration rates; and parental knowledge, attitudes, beliefs, and practices about child feeding and PA. Process measures include home visit completion rates and community-wide intervention completion plans.

#### **Statistical Analysis Plan**

Community-level interventions can only be delivered to communities, not to individuals within communities. This precludes a trial randomized at the individual level, and thus dictates a cluster randomized trial. It is well known that cluster-randomized trials exact a price in terms of sample size or statistical power that is disproportionately large in relation to the within-cluster correlation of outcomes (Donner & Klar, 2005). To address this statistical issue, a double-matching procedure similar to that described by Economos et al. (2007) will be used in the statistical analysis of PTOTS. First, the communities will be paired based on characteristics that are believed to potentially affect the outcomes. Communities will be

randomized within pairs. Second, pairs of infants will be matched across the paired communities based on individual characteristics believed to affect the outcomes. The analyses will then be based on differences between the paired children analyzed in the context of a model that includes random effects for communities. This strategy is based on two observations: (a) the reason for the sample size penalty is the effect that a positive within-community correlation has on the standard deviation (SD) of a sample mean; and (b) a positive correlation induced across paired communities and across paired individuals reduces the SD of a within-pair difference score, and hence tends to counteract the undesirable effect of the within-community correlation. Theoretical calculations show that the doubly matched design has statistical power and sample size characteristics much closer to a completely individual-randomized design than to a cluster-randomized design conventionally analyzed for reasonable assumptions about the two-level matching. The effect of matching is very difficult to predict, so the success or failure of this strategy will only be known at the end of the study.

# Discussion

The PTOTS study has several distinctive features that include: focus on the very young child; a comprehensive, multi-component intervention; intervening at multiple levels using the child's social ecology; involving the community in the study design; using community members as interventionists; and tailoring the intervention to community and individual family needs. These features constitute both the strengths and weaknesses of this study.

First, the focus on the very young child is a strength of the study design in that it allows us to investigate the effect of early intervention on the development of early excess adiposity. However, it is possible that the rapid growth associated with this age may overshadow any intervention effect, so we may not detect a change in BMI within the timeframe of the study.

A second strength is the multi-component approach to preventing obesity, which appears to be well supported by the published, albeit limited, literature (Costom & Shore, 1983; Karanja et al., 2010; Paul et al., 2011). This approach recognizes that lifestyle changes to prevent or treat obesity are ultimately about attaining energy balance, which is influenced by a multiplicity of behaviors. However, the multi-component approach has some limitations. For example, none of the chosen intervention strategies—except breastfeeding and SSB curtailment—have been evaluated for their effectiveness in preventing obesity either alone or in combination with other strategies. A related potential limitation is the inability to ascribe any outcomes to a single intervention strategy. Another potential limitation is that the intervention might become too diffuse, and difficult to implement, because of the sheer number of strategies delivered. We are attempting to mitigate these potential weaknesses by staging the intervention to the individual infant's growth phase, such that any individual family receives discrete messages depending on the age of the infant/toddler. This means that all strategies are not applied at the same time to the same child.

A third strength is the use of the social ecology of the child to deliver the intervention by targeting the individual parent, the family network, and the community at large. This may be an efficient way of increasing intervention dose, as messages are repeated across these levels. A more comprehensive social ecology of the child would include daycare centers, which are not directly targeted by our intervention. Excluding daycare centers may be considered a weakness in our intervention design. We are attempting to overcome this potential weakness by counseling parents to use assertiveness skills to let daycare providers know and implement their wishes regarding food, beverage, and PA preferences.

A fourth strength is employing principles of community engagement (Centers for Disease Control and Prevention, 1997), which include collaborative design and implementation of the intervention; using community-dwellers as interventionists; and tailoring the intervention to fit the specific needs of the community. The study also uses principles of outreach and tailoring to intervene at the family level (Forest & Palmer-House, 2003), while keeping a common protocol, intervention goals, and general implementation approaches. These community design elements-engaging community institutions, leveraging community expertise and resources, and including the cultural knowledge of the CHWs (Gittelsohn & Rowan, 2011)—increase the potential for sustainability of the program were the intervention found to be effective. These same design elements, however, may also weaken the study. For example, tailoring the intervention to community and family reduces standardization across study sites. While not uncommon in lifestyle change trials, lack of standardization may cause differences in intervention dose and outcomes in different tribes and/or families, posing a potential risk to internal validity of the study. A related potential weakness is the delivery of the curriculum by CHWs. CHWs bring a unique knowledge to the study, and are trained to deliver the intervention, but not all of them have received traditional counseling education and may not completely implement the curriculum as intended.

In summary, the PTOTS study was developed to test the effectiveness of a multi-component intervention to prevent obesity beginning at birth in AI children. It utilizes a community-based approach that engages the community at various levels. The study design has a number of weaknesses that are outweighed by the numerous strengths of increased community participation and potential for sustainability, in the event that the intervention is found to be effective.

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Item	Approach	Action	Collaborators	Issues to be addressed
Focus of intervention	Focus of intervention Intervention framework What is to be done	What is to be done	People involved	(Choose the one that community) fits your
Water consumption	Public health practice	Work with tribal program staff to offer water at tribal functions.	Site coordinator Health director	Kids drink soda pop when they are away from home Soda pop is everywhere
Breastfeeding	Environment	Set up breastfeeding area in office and casino for moms to pump or feed baby. Provide rocking chair, shade, and comfortable surroundings.	Site coordinator Casino manager	Poor continuation
Feeding practice	Behavior change	Offer bag lunches at community events with tips inside on how to pack bag lunches/how to negotiate practices with childcare providers.	Caregivers/parents	Childcare providers do not always provide healthy meals or snacks
Water consumption	Awareness	Invite a tribal elder to "Baby and Me" group to speak on the culture (storytelling) of water.	Tribal Elders Program	Tribal Elders Program Loss of cultural tradition in drinking water
Physical activity	Education	Create handouts that give physical activities that are family-oriented such as walking, bike riding, and swimming, and post around community.	Site coordinator	Sedentary families

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Table 1

	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Session 7	Session 8	Session 9	Session 10	Session 11	Session 12	Session 13	Session 14	Session 15
1 Timing	Prenatal	Prenatal	Newborn (0-2 weeks)	Young infant (2-4 weeks)	Young infant (1–2 months)	2-5 months	5-7 months	7–9 months	9-12 months	12-15 months	15-18 months	18-21 months	21–24 months	2430 months	30-36 months
2 Purpose/Objective	Establish rapport Conduct assessments	Determine feeding intention: breast or bottle?	Provide early breastfeeding support	Moher's faigue and stress as contributors to breatfeeding success	Infant sleeping issues or fussines in relation to feeding	Continue to promote breastfeeding	How to introduce solid foods at 6 months	Adding new solid foods	Self-feeding	Delay introduction of super- super-sweetened bycenges Encourage drinking water	Parent model healby sating behaviors burent provides access to healthy food provide structure for meals and structure for meals and	Discourage sedentary behavior Encourage physical activity	Parent models physical activity incorporates into duily routine Parent delays the introduction of TV viewing Importance of family meals	Parents learn about bealthy snacking Parents working with daycare to provide daycare to provide opportunities for safe active play	Parent provides healthy "away from home" meals Parent seeks safe outside play spaces
3 Check-in	Question list	Question list	Question list	Question list	Question list	Question list	Question list	Question list	Question list	Question list	Question list	Question list	Question list	Question list	Question list
4 Information/Discussion	Another introduction to the study	Infam feeding principles	Reassure mother Help for breast discomfort Infant feeding cues	Reassure mother Crying and colic	How to read baby's hunger and fullness cues Delaying solid foods	Baby's need for touch and security	It takes time for baby to learn to accept solid foods	Avoiding sugar-sweetened beverages and jutces	Self-feeding	Assess beverage consumption Define sugar- sweetened beverages and their health effects	Parent's role in feeding child	Benefits of physical activity How to encounge physical activity Harmful effects of sedentury behavior	Parent as role model Creating family activities	Snacks and competitive foods Talking to daycare staff about snacks and play	Planning for meals outside the home Safe and enjoyable meals at restaurants
4 a Nutrition	Maternal	Matemal	Feeding frequency	Feeding frequency	Feeding frequency	Reasons for delaying solid foods to 6 months	Continued breastfeeding Infant cereals	Continued breastfeeding Infant cereals Adding fruits and vegetables	Breast milk, cereal, fruits, and vegetables Adding meats, beans, grains, etc.	Introduction to 100% fruit juice Water as a beverage Health effects of sugar-sweetened beverages	Parent provides variety of healthy foods Child chooses own portions	TV viewing and obesity	What and how to serve family meals How to introduce new foods	Healthy snacks Giving children opportunities to choose what they eat	Parent decides what healthy foods and bevenges to serve and what serving sizes
4 b Physical activity	Mother's rest and exercise	Mother's rest and exercise	Burping Feeding positions	Beginning baby exercise	Baby stretches	Passive stretches	Seated fun and water play	Crawling fun	Standing fun			Discourage introduction of TV viewing until 2 years of age Steps, obstacle course, too stands, backward	Modeling physical activity Age-appropriate activities: hide and seek, tag, etc.	Parents play active games with child: hide and seek, tag, etc.	Ruming, climbing, and playing in group activities
5 Activity/Discussion	Concerns of mother	Breastfeeding advantages Breastfeeding as a cultural value Safe bottle feeding alternative	Support and information for concerns of mother Practice breastfeeding (or bottle feeding, if not breastfeeding)	Support and information for concerns of mother Avoid use of water, juice, or solid foods for baby	Support and information for concerns of mother Calm and tender feeding	Misuse of feeding Solid foods will not help babies sleep No bottle in bed	Feeding technique May prætice mixing cereal	Avoiding allergic reactions	Bite-size finger foods Avoiding foods that can cause choking	Demonstration of sugar content and nutrient differences of sugar-sweetened beverages	The food pyramid Pyramid portion sizes for toddlers	Non-sedentary activities children enjoys Recommendations for physical activity and TV viewing	Family playtime activities	Tips for toys and toy safety	"Fast Food Without the Guilt" Chart
6 Behavior	Setting expectations	Mother chooses feeding method	Plans for rest. fluids, and healthy food for mother	Plans for rest, fluids, and healthy food for mother	Responding to huby's feeding cues though the during the during feedings, no propped bottle	Respond to huby's feeding cues	Patient and calm feeding	Patience while halty learns to accept new foods	Include child at family meals	Parents purchase healthy foods for child	Model beauthy eating behaviors Provide a variety of healthy foods Choose healthy portion size for child	Encourage physical activity viewing Limit TV viewing	Model physical activity Play as a family Create family meals	Parent recognizes healthy snack options and behaviours Parent works as partner with daycare staff to assure healthy snacking and sufe play activities	Parents momitor outdoor play safety Encourage physical activity Make healthy choice in restaurants
7 Supporting materials	General breastfeeding information	Preparing to breastfeed	Breast care help resources	Colic help resources	Signs baby is hungry or full	Safe exercise Signs báby is ready for solid foods	Signs buby is full	Baby-proofing house Foods to avoid	Safety issues while encouraging movement	Background information on 100% fruit juice	Handouts. "My Pyramid for Preschoolers." "Knowing Portions for Toddlers." "Peeding Tips." and "Sale Snæcks"	Handout: "How to Encourage Physical Activity and Suggested Play Activities for Toddlers 18-21 months old"	Handont: 'How to Encourage Negresian Activity and Suggested Play Activities for Toddlers 21-24 months off"	Handout: "How to Encourage Physical Activity and Suggested Phy Activities for Toddlers 24–30 months old"	Handout: "How to Encourage Physical Activity and Suggested Play Activities for Activities for Toddlers 30–36 months old"

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Table 2

Outline of 15 sessions to be delivered to Healthy Beginnings participants by community health workers

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Table 3

Measurement collection schedule

			Ąg	e of inf	Age of infant/child	p		
Measures	Prenatal 0 M 2 M 4 M 6 M 12 M 18 M 24 M	0 M	2 M	4 M	6 M	12 M	18 M	24 M
Demographics (mother)	х							
KAB questionnaire <sup>a</sup>	Х					Х		х
Child weight, height/length		x	х	X	Х	х	х	х
Child feeding and activity questionnaire $^{b}$		×	x	x	х	х	×	X
Home visit completion				Continuous	snont			
Community-wide intervention plan completion				Continuous	snont			

 $^a\mathrm{Knowledge},$  attitudes, and beliefs (KAB) about child feeding and physical activity

 $\boldsymbol{b}_{\text{Separate question$ naires for 2, 4, 12, and 24, months of age