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# Healthy Habits, Happy Homes: Methods and baseline data of a randomized controlled trial to improve household routines for obesity prevention

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#### ABSTRACT

*Objective.* To develop a home-based intervention for parents of 2–5 year old children to promote household routines to prevent overweight/obesity.

Methods. We recruited 121 children from health centers in Boston between 2011 and 2012 and randomized 62 to intervention and 59 to the control condition. The 6-month intervention included 1) motivational coaching at home and by phone with a health educator, 2) mailed educational materials, and 3) weekly text messages. The intervention promoted three household routines: eating meals as a family, obtaining adequate sleep, and limiting screen time.

*Results.* Of the 121 children, mean (SD) age was 4.0 (1.1) years; 52% were Hispanic, 34% Black, and 14% White/Other. Nearly 60% of the sample had annual household incomes ≤\$20,000. Approximately 64% of families reported eating together  $\geq$ 7 times per week, however, many meals were eaten in front of a TV. Over half of the children slept less than the recommended 11 h/night and 78% viewed  $\geq$ 2 h/day of screen time.

Conclusions. Household routines that increase obesity risk were prevalent among low-income families in this study. If proven to be effective, promotion of household routines related to family meals, sleep, and screen time may prevent young children from becoming overweight/obese. Clinical Trials Registration Number: NCT01565161.

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#### Introduction

While childhood obesity rates may have plateaued in some US population subgroups, (Ogden et al., 2012) such as whites and those of higher socioeconomic status, overall rates of obesity remain stubbornly high and racial/ethnic and socioeconomic disparities appear to be widening (Ogden et al., 2012). Among the most promising approaches for childhood overweight and obesity prevention and management are interventions that begin early in life (Dixon et al., 2012) and that support change at the individual and community levels (Huang et al., 2009; Swinburn et al., 1999). To be maximally effective in reducing racial/ethnic and socioeconomic disparities, it is clear that such early childhood interventions must be structured, culturally appropriate, and extend to settings where children and families spend most of their time, chiefly, their homes.

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Research has shown that racial/ethnic and socioeconomic disparities exist across most known risk factors for childhood overweight and obesity early in life (Taveras et al., 2010). For example, in early childhood, Black and Hispanic children have higher levels of TV viewing, higher prevalence of televisions in bedrooms,(Dennison et al., 2002) higher consumption of sugar sweetened beverages, (Wang et al., 2008; Welsh et al., 2005) increased fast food consumption,(Piernas and Popkin, 2011) lower levels of physical activity,(Whitt-Glover et al., 2009) and get fewer hours of sleep (Nevarez et al., 2010) compared to white children. Thus, interventions to reduce overweight and obesity-related risk factors in early childhood might help stunt the rising prevalence of overweight and obesity.

One potential approach for promoting early childhood overweight and obesity prevention is to target the adoption of household routines that appear to be protective of overweight and obesity. Anderson and Whitaker (2010) have found that among US preschool-aged children, exposure to 3 household routines, e.g. regularly eating the evening meal as a family, obtaining adequate nighttime sleep, and having limited screen-viewing time was associated with an approximately 40% lower prevalence of obesity than those exposed to none of these routines. It is possible that stealth interventions (Robinson and Sirard, 2005) that

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provide support to families to adopt household routines related to bedtime, mealtime, learning, and playtime could have beneficial effects on overweight and obesity prevention.

The goal of the proposed study was to develop and test an intervention delivered to racial/ethnic minority and low socioeconomic status parents of 2–5 year old children in their homes, designed to promote adoption of household routines and parenting strategies that are preventive of overweight and obesity. In this paper we describe the development and baseline assessments of the *Healthy Habits*, *Happy Homes* intervention.

#### Methods

#### Overview of study design

We recruited families from 4 federally-qualified community health centers in the greater Boston area to participate in an individual-level randomized controlled trial. Our partner community health centers were the Roxbury Comprehensive Community Health Center, the Dimock Community Health Center, and the Cambridge and Somerville pediatric offices of the Cambridge Health Alliance (CHA). The intervention is 6-months in duration and the main outcomes are adoption of 3 targeted household routines: regularly eating meals together as a family, obtaining adequate sleep, and limiting screen-viewing time. The intervention also included promotion of a healthful diet and physical activity behaviors, and parenting strategies such as limit setting and role modeling.

#### Participants, recruitment, and randomization

We enrolled children who received their annual routine well child care visit at the 4 urban community health centers serving largely low-income and minority populations, and who were seen for a well child care visit within the three months prior to the recruitment period. Recruitment took place from June, 2011 to February, 2012. Parent–child dyads were considered eligible if: 1) at least one parent was over the age of 18 years; 2) the index child was between the age of 2 and 5 years old; 3) the index child had a television in the room where s/he sleeps; 4) the family was not planning to move from the Boston area within the study time frame; 5) the child did not have a physical or mental health condition requiring chronic care; and 6) at least one parent was comfortable responding to interviews and reading in English or Spanish. If there was more than one child meeting the eligibility requirements, we chose the index child as he/she who had the most recent birthday. Because this is a prevention-focused intervention, we accepted all children regardless of their weight status.

We worked with each health center to identify children who were potentially eligible and identified a total of 1467 children. After obtaining permission from the Pediatric staff, we mailed a letter on the Pediatrician's behalf to each parent introducing the study and encouraging participation. The letter included an opt-out telephone number to call if the family did not want to participate. We telephoned those parents who did not refuse additional contact beginning 7 days after mailing the letter. Research assistants attempted telephone contact with 1148 families. During the telephone calls, we further described the study, screened for eligibility, obtained verbal consent, collected contact information, and scheduled a home visit. Study staff collected all baseline data and obtained written consent at the home visit. Duration of the home visit was between 40 min to 1 h. Participants received \$40 for completing the baseline research assessments.

We used a stratified block randomization scheme to assign participants to the intervention or control condition. Strata were recruitment site and child gender; condition was assigned by blocks of four in each strata. A biostatistician used a pseudo-random number generator in SAS to generate each random allocation sequence. Assignments were implemented through sealed sequentially numbered individual envelopes, and research assistant opened the envelopes following completion of baseline assessments. Participants were then informed if they would be receiving regular educational materials by mail regarding child development (control) or individualized coaching on improving their household routines (intervention). All study activities were approved by the human subjects committee at Harvard Pilgrim Health Care.

#### Intervention arms

#### Control

Participants randomized to the control group received mailed educational materials on reaching developmental milestones during early childhood. The materials covered four primary domains: motor, language, cognitive and social/emotional. We developed monthly mailed packages each focusing thematically on a particular developmental domain. The educational materials were adapted from the CDC's "Positive Parenting Tips for Healthy Child Development". (Anderson and Whitaker, 2010) We chose age-appropriate, low cost materials and mailed to families activities to reinforce the concepts presented in the educational materials and support behavior change. For example, along with materials highlighting healthy motor development, we sent parents a ball and mitt set to encourage active play.

#### Intervention

Studies based on a sound theoretical framework, with adequate attention to the social context in which families live have been shown to substantially increase the likelihood that an intervention will be effective. (Sorensen et al., 2003) The overarching framework for the Healthy Habits, Happy Homes intervention was the social contextual framework (Sorensen et al., 2003) that integrates multiple perspectives following a social ecological model (Breslow, 1996; Stokols et al., 1996) and posits that, to be effective, interventions must take into account the social context in which participants live as well as the key psychosocial constructs that influence behavior. In addition to the intervention being home-based, health educators specifically tailored their counseling based on information from the baseline assessment on the home and media environment and social supports, barriers, and facilitators to behavior change reported by the parent. Major components of the intervention included 1) motivational coaching by a health educator during home visits and telephone calls, 2) mailed educational materials coupled with behavior change activities and tools, and 3) weekly text messages on adoption of household routines and behavior change strategies (Fig. 1).

We trained bachelors and masters level staff to be the key intervening health educators, using motivational interviewing (MI) during four, 60 min, in-person, home visits and four, 20 minute telephone calls during the 6-month intervention. MI is a communication technique that enhances self-efficacy, increases recognition of inconsistencies between actual and desired behaviors, teaches skills for reduction of this dissonance, and enhances motivation for change (Emmons and Rollnick, 2001; Miller and Rollnick, 2002; Rollnick and Butler, 1999; Rollnick et al., 2008). At each home visit, health educators reviewed focus group-tested educational handouts, used MI to encourage and support behavior change, and gave participants materials and activities to catalyze and support behavior change. These included, for example, reading books to improve bedtime sleeping routines; plate and cup sets to encourage family meals and healthy portion sizes, and arts and craft sets to replace TV viewing. Each health coach visit included, 1) a check-in to review progress and set-backs to behavior change, 2) discussion of educational materials and motivational interviewing, and 3) deciding on a concrete activity or tool the parent could use at home to support behavior change. Examples included creation of a "bedtime routine clock" to engage child in bedtime, "fitness dice" to get children engaged in physical activity and replace screen-time, and a "sometimes/anytime" food game to increase awareness about healthy eating as a family. During the monthly coaching calls, health educators assessed participants' progress on making changes to their routines, provided support for challenges that arose, and reinforced the study messages.

To encourage reduction of TV viewing, we selected a random sample of 30 intervention participants to receive a TV monitoring device (TV Allowance; Mindmaster Inc., Miami, Florida), that our research staff attached only to the television used most often by the child. The TV Allowance is an automated device that controls and monitors the use of the TV it is attached to. To turn on the TV, we instructed parents to select a 4-digit code for the child. During the home visits, health coaches would review the TV Allowance summary of the child's TV viewing and assist parents with goal setting to reduce the total viewing time.

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