Contemporary Clinical Trials 38 (2014) 59–68

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

The Healthy Home Offerings via the Mealtime Environment (HOME) Plus study: Design and methods ☆

Jayne A. Fulkerson [a,*], Dianne Neumark-Sztainer [b], Mary Story [b], Olga Gurvich [a], Martha Y. Kubik [a], Ann Garwick [a], Bonnie Dudovitz [c]

[a] School of Nursing, University of Minnesota, United States
[b] Division of Epidemiology and Community Health, University of Minnesota, United States
[c] Minneapolis, MN, United States

ARTICLE INFO

Article history:
Received 6 November 2013
Revised 17 January 2014
Accepted 20 January 2014
Available online 27 January 2014

Keywords:
Obesity prevention
Randomized controlled trial
Family meals
Intervention
Snacks
Families

ABSTRACT

Background: Informed and engaged parents and healthful home environments are essential for the health of youth. Although research has shown health benefits associated with family meals, to date, no randomized controlled trial (RCT) has been developed to examine the impact of a family meals intervention on behavioral and health outcomes.
Methods/design: The Healthy Home Offerings via the Mealtime Environment (HOME) Plus study is a two-arm (intervention versus attention-only control) RCT being conducted in Minneapolis/St. Paul. Built on previous pilot research, HOME Plus aims to increase the frequency and healthfulness of family meals and snacks and reduce children's sedentary behavior, particularly screen time, to promote healthier eating and activity behaviors and prevent obesity. HOME Plus is delivered to families in community settings. The program includes 10 monthly sessions focused on nutrition and activity education, meal planning and preparation skill development. In addition, five motivational goal-setting phone calls are conducted with parents. The primary outcome measure is age- and gender-adjusted child BMI-z score at post-intervention by treatment group. Secondary household-level outcomes include family meal frequency, home availability of healthful foods (fruits/vegetables) and unhealthful foods (high-fat/sugary snacks) and beverages (sugar-sweetened beverages), and the quality of foods served at meals and snacks. Secondary child outcomes include dietary intake of corresponding foods and beverages and screen time.
Conclusions: The HOME Plus RCT actively engages whole families of 8–12 year old children to promote healthier eating and activity behaviors and prevent obesity through promotion of family meals and snacks and limited media use.

1. Introduction

Few children in the United States meet dietary [1,2] and activity recommendations [3,4] and childhood obesity is a major health concern [5–7]. The Institute of Medicine recommendations to address these issues include policy and environmental change that support a decrease in sedentary behavior and an increase in physical activity and healthful food consumption as well as individual- and family-level behavior change [8]. Researchers [9–12], professional organizations [13], and NIH Institutes [14] indicate that efforts, especially family-based programs, are needed to increase healthful behaviors and reduce childhood obesity. Yet, few childhood obesity prevention studies have significantly engaged parents with a focus on the home environment, which is essential to promote healthful behaviors at home and establish lifelong healthful habits. Parents are primary role models for healthful eating and activity and gatekeepers

☆ ClinicalTrials.gov Identifier: NCT01538615.

* Corresponding author at: School of Nursing, University of Minnesota, 5-160 Weaver-Densford Hall, 308 Harvard Street, SE, Minneapolis, MN 55455, United States. Tel.: +1 612 624 4823; fax: +1 612 626 6606.
E-mail address: fulke001@umn.edu (J.A. Fulkerson).

1551-7144/$ – see front matter © 2014 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.cct.2014.01.006

for food and beverage availability and degree of inactivity at home [11]. Moreover, almost 70% of daily total calories and 80% of snacks consumed by 6–11 year old children are eaten in the home [15]. Foods consumed in the home provide the greatest amount of calories from low-nutrient, energy-dense foods [16]. The home is also where most sedentary behavior occurs, particularly screen time [17] (e.g., television, computer, video games). In addition to the importance of home availability of media and healthful foods, children's participation in family meals has been shown to be significantly and positively associated with nutrient intakes and fruit and vegetable intake among youth [18–25], and inversely associated with consumption of soft drinks and high-fat foods [18,20], as well as overweight/obesity in some studies [19,26–28]. However, no randomized controlled trials (RCT) have been developed to examine the impact of a family-focused program that includes improving the home food and activity environment, by focusing on family meals and sedentary activity, to promote healthful eating and prevent obesity.

2. Objectives of the HOME Plus study

The HOME Plus study focuses on increasing family meal frequency, improving the home food environment, and decreasing sedentary activity, particularly media-related activity. The HOME Plus study was funded by a grant from the National Institute of Diabetes, and Digestive and Kidney Diseases (NIDDK). It builds on extensive family meals and obesity prevention research and capitalizes on the lessons learned in our pilot study (2006–2008; NIH R21-DK0072997) in which the feasibility and acceptability of the HOME program were tested. The development and implementation of the pilot program were successful and participant recruitment, retention and program satisfaction ratings were excellent [29].

The HOME Plus study is designed as a two-group RCT (intervention and attention-only control) to promote healthier eating and activity behaviors and prevent obesity among 8–12 year old children. It is based on Social Cognitive Theory [30] and a socio-ecological framework [31] as it addresses the role of families in the initiation, support, and reinforcement of healthy food and beverage consumption, and the reduction of sedentary behavior, particularly screen time, within the home. The HOME Plus study is innovative because it was developed as a family-focused program that promotes healthful behaviors through an active and experiential (i.e., cooking) promotion of regular and healthful family meals and snacks. It includes home food environmental components shown to be successful in our pilot work [29] and integrates successful strategies from our previous research [32,33] and those described in the literature to decrease screen time [34]. The primary aim of the study is to test the efficacy of the HOME Plus program by assessing differences in children's standardized body mass index (i.e., BMI z-score) between the intervention and the attention-only control groups. Additional study aims include examining the effects of the intervention on: 1) the frequency of weekly family meals and number of healthful foods and beverages available in the home and served at family meals and snacks, 2) children's daily intakes of healthful foods and beverages, and 3) children's minutes of sedentary behavior per week, particularly screen time (television viewing, video and computer game playing).

3. Study design

3.1. Overview

Participants include 160 families (8–12 year old child (one target child per family) and the primary meal-preparing parent/guardian) in the Minneapolis/St. Paul, Minnesota metropolitan area. A staggered cohort design is used in which two cohorts of families are recruited and randomized to study group one year apart (see Fig. 1). Families are assigned to either a 10-month family-focused, community-based intervention program or an attention-only control group that receives monthly newsletters. The staggered design allows for more contact with families by intervention staff, increased monitoring and control of the intervention, and decreased staff costs. Data from target parents and children are collected by research staff at baseline prior to randomization, at post-intervention (10-months post-randomization) to assess the impact of the intervention, and at follow-up (19-months post-randomization) to assess the sustainability of the intervention. At study initiation, we formed an Advisory Group that includes University of Minnesota (UMN) Extension Service faculty and staff and administrative staff from Minneapolis Park and Recreation to assist with program refinement to facilitate delivery, translation and sustainability.

3.2. Lessons learned from the HOME pilot study

We learned several lessons by testing the RCT design and intervention program in our HOME pilot [29] and made requisite changes in the full-scale HOME Plus study. In our pilot study, we delivered the intervention program in five sessions over ten weeks to assess feasibility and acceptability and concluded that a larger trial should be longer in duration to encourage greater behavior change. Also, a review of effective obesity prevention programs for children recommended longer program durations [35]. Thus, we expanded the content of our pilot trial into a 10-month intervention program for the large-scale HOME Plus trial.

Additionally, although we had 100% compliance with data collection activities in the HOME pilot among families in both control and intervention conditions, with the longer time frame of the larger trial, we concluded that retention may be more difficult and that a non-active control group might be less desirable to families. Thus, the HOME Plus trial uses an attention-only control group that receives monthly newsletters (and all written session materials at the conclusion of the study) rather than a non-active control group.

3.3. Formative research

The HOME Plus study began with a formative phase in which focus groups were conducted with parents of ethnically/racially-diverse families with 8–12 year old children to guide recruitment and retention and ensure the intervention's relevance to families from diverse backgrounds. Three focus groups were held with African American parents ($n = 24$) and two focus groups were held with Latino parents using a bilingual