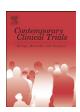
FI SEVIER

Contents lists available at ScienceDirect

Contemporary Clinical Trials

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



NET-Works: Linking families, communities and primary care to prevent obesity in preschool-age children **,****



Nancy E. Sherwood ^{a,*}, Simone A. French ^{b,1}, Sara Veblen-Mortenson ^{b,1}, A. Lauren Crain ^{a,2}, Jerica Berge ^{c,3}, Alicia Kunin-Batson ^{a,2}, Nathan Mitchell ^{b,1}, Meghan Senso ^{a,b,1,2}

- ^a HealthPartners Institute for Education and Research, 8170 33rd Ave. S., Mail stop 21111R, PO Box 1524, Bloomington, MN 55440-1524, USA
- ^b Division of Epidemiology and Community Health, School of Public Health, University of Minnesota, West Bank Office Building, 1300 South Second St., Suite 300, Minneapolis, MN 55454, USA
- ^c Department of Family Medicine and Community Health, University of Minnesota, 717 Delaware St SE, Ste 454, Minneapolis, MN 55414, USA

ARTICLE INFO

Article history: Received 11 June 2013 Received in revised form 24 September 2013 Accepted 26 September 2013 Available online 9 October 2013

Keywords:
Obesity prevention
Parent
Family
Community
Dietary intake
Physical activity

ABSTRACT

Obesity prevention in children offers a unique window of opportunity to establish healthful eating and physical activity behaviors to maintain a healthful body weight and avoid the adverse proximal and distal long-term health consequences of obesity. Given that obesity is the result of a complex interaction between biological, behavioral, family-based, and community environmental factors, intervention at multiple levels and across multiple settings is critical for both short- and long-term effectiveness. The Minnesota NET-Works (Now Everybody Together for Amazing and Healthful Kids) study is one of four obesity prevention and/or treatment trials that are part of the Childhood Obesity Prevention and Treatment (COPTR) Consortium. The goal of the NET-Works study is to evaluate an intervention that integrates home, community, primary care and neighborhood strategies to promote healthful eating, activity patterns, and body weight among low income, racially/ethnically diverse preschool-age children. Critical to the success of this intervention is the creation of linkages among the settings to support parents in making home environment and parenting behavior changes to foster healthful child growth. Five hundred racially/ethnically diverse, two-four year old children and their parent or primary caregiver will be randomized to the multi-component intervention or to a usual care comparison group for a three-year period. This paper describes the study design, measurement and intervention protocols, and statistical analysis plan for the NET-Works trial.

© 2013 Elsevier Inc. All rights reserved.

status children are at even greater risk for obesity [2]. The preschool years provide a unique window of opportunity to

establish healthful eating and physical activity behaviors [3].

Given the complex etiology of childhood obesity, multi-level, multi-setting interventions are critical for effectiveness [4].

to the development of interventions with high potential for

1. Introduction

Nearly one-third of preschool-age children are overweight or obese [1]. Racial/ethnic minority and lower socioeconomic

E-mail address: nancy.e.sherwood@healthpartners.com (N.E. Sherwood).

Interventions that directly engage parents and impact the home environment are needed given that the largest obesity prevention interventions have been school-based with limited parental involvement [5–9]. One strategy to more effectively engage parents in obesity prevention efforts is to consider the types of organizations and community-based programmatic initiatives utilized and valued by parents. Integrating strategies that promote healthy eating and activity patterns into settings where parents already spend their time could lead

[☆] ClinicalTrials.gov Identifier: NCT01606891.

^{☆☆} This study is supported by a grant from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (U01HD068990).

^{*} Corresponding author at: HealthPartners Institute for Education and Research, 8170 33rd Ave. S., Mail stop 21111R, Bloomington, MN 55425, USA. Tel.: ± 1 952 967 7303.

¹ Tel.: +1 612 626 8594.

² Tel.: +1 952 967 7303.

³ Tel.: +1 612 626 3693.

dissemination and sustainability. Three examples include public health nurse home-visiting, community-based parenting classes, and pediatric primary care.

Public health nurse home-visiting programs provide health and psychosocial-related services to at-risk pregnant women and young mothers [10–15]. National early child-hood parent education programs also offer home-visiting models [16,17]. Recently, the nurse home-visiting model was evaluated for obesity prevention in infants in a randomized controlled trial [18,19]. The Parents As Teachers Program also evaluated a parent-targeted home-based intervention to increase child fruit and vegetable intake [20]. Results suggest home-visiting holds promise for obesity prevention.

Community parenting classes are also widely available and appeal to parents of preschool-age children from diverse backgrounds. Parenting classes promote child school readiness through building parenting skills and social support networks. Healthful food choices, active play, and screen time topics align well with parenting class curriculum and could be readily incorporated into existing parent-focused community-based programs.

Primary care is a third important setting through which parents of preschool-aged children may be reached [21]. Primary care providers are influential sources of health information who can help parents promote and reinforce child behaviors related to healthful eating, activity patterns, and body weight. The primary care setting represents a unique intervention opportunity for direct, parent-focused child obesity prevention [21].

In addition to these well-established systems, the neighborhood environment provides resources that can enhance or detract from parent efforts to support optimal child growth [22–26]. Without access to these resources, parents face significant barriers to adopting eating and activity-related behavioral intervention messages. Thus, obesity prevention interventions need to identify and connect parents to existing neighborhood resources.

The goal of the Minnesota NET-Works (Now Everybody Together for Amazing and Healthful Kids) study is to integrate home, community, primary care and neighborhood intervention strategies to prevent obesity among ethnically diverse preschool-age children. The NET-Works trial is one of two unique prevention trials that are part of the Childhood Obesity Prevention and Treatment Research (COPTR) consortium, a National Heart, Lung, and Blood Institute (NHLBI)and National Institute of Child Health and Human Development (NICHD)-sponsored collaborative effort to develop and test novel approaches to prevent or treat childhood obesity. Each field center is testing distinct interventions with unique populations and eligibility criteria, but share a core set of common measures and protocols. This paper describes the NET-Works trial study design, measurement and intervention protocols, and statistical analysis plan.

2. Materials and methods

2.1. Trial design overview

NET-Works is a two-arm, randomized controlled trial to test the efficacy of a multi-setting, multi-component intervention approach to preventing obesity among racially/

ethnically diverse preschool age children. The NET-Works intervention includes four main components: 1) a pediatric primary care brief counseling intervention; 2) a home-based intervention delivered by NET-Works family connectors to support parents in making changes in the home environment and parenting practices to promote healthful eating and activity patterns; 3) community-based parenting classes designed to parallel the home-based intervention curriculum and provide social support to participating parents; and 4) linkages to neighborhood and community resources to support parents in promoting healthful eating and activity patterns for their children. Five hundred parent/child dyads will be randomized to either the NET-Works intervention or a usual care comparison condition and followed for three years. Participants will be assessed at baseline and annually. The primary hypothesis is that children randomized to the NET-Works intervention will have lower BMI at two and three years post-randomization relative to usual care comparison group children. BMI is the primary outcome across all four COPTR trials. Recruitment for the trial began in July 2012 and will be completed in December 2013, with the final three year follow-up data collected in December 2016.

2.2. Study setting and population

The target population for NET-Works is racially/ethnically diverse preschool children and their parent or primary caregiver. To reach the intended population, NET-Works has partnered with 12 primary care clinics and three managed health care systems that serve diverse populations with respect to race, ethnicity and income. Over 18 months, 500 families will be recruited, enrolled and randomized to the intervention or to the usual care comparison group. Administrative databases and centralized electronic scheduling systems at the partner clinics provide data needed to target recruitment efforts on two-to-four year old children residing in certain zip code areas. The clinics have recent data from preventive care visits available for calculation of child body mass index (BMI) percentile to focus recruitment efforts on children who are potentially BMI-eligible for the study.

2.3. Eligibility criteria and exclusions

Eligibility criteria are assessed on a telephone screening call and confirmed in person at the first data collection home visit. A child and his or her parent or primary caregiver are eligible for the study if: 1) the child is between ages of two and four years of age; 2) the child has no medical problems that would preclude study participation as determined by the primary care physician; 3) does not use any medications that would affect the child's growth; 4) the child's BMI is greater than or equal to the 50th percentile according to CDC age and sex reference standards with no upper limit [27]; 5) the family's income is below \$65,000 per year; 6) the child's parent agrees to participate in the study and does not plan to move out of the state in the next three years; 7) the parent or primary caregiver is willing and able to complete the evaluation measures and participate in intervention activities if assigned to the active intervention group; and 8) the parent or primary caregiver speaks either English or Spanish.

Download English Version:

https://daneshyari.com/en/article/6151288

Download Persian Version:

https://daneshyari.com/article/6151288

<u>Daneshyari.com</u>