Contemporary Clinical Trials 36 (2013) 574–586

Contents lists available at ScienceDirect

Contemporary Clinical Trials

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

IMPACT: A multi-level family and school intervention targeting obesity in urban youth ☆

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ARTICLE INFO

Article history:
Received 7 June 2013
Revised 21 August 2013
Accepted 24 August 2013
Available online 2 September 2013

Keywords:
Obesity
Children
Multi-level intervention trial
Community-based research

ABSTRACT

IMPACT (Ideas Moving Parents and Adolescents to Change Together) is a 3-group randomized, multi-level trial comparing the efficacy of two distinct behavioral interventions and a control condition on body mass index (BMI) in middle school urban youth who are overweight/obese. Interventions include: (1) SystemCHANGE™ (SC), a promising new behavior change approach that focuses on system redesign of the family environment and daily routines; (2) HealthyCHANGE (HC), a cognitive–behavioral and Motivational Interviewing (MI)-consistent approach to behavior change that focuses on increasing intrinsic motivation, self-monitoring, goal setting, and problem solving; and (3) diet and physical education counseling (attention control). In addition, about half of the participants are enrolled in a K-8 public school that offers an innovative community-sponsored fitness program, augmented by study-supported navigators. In addition to the primary interventions effects, the study assesses the moderating effect of the school environment on BMI, blood pressure, cardiovascular risk factors, and quality of life.

The sample consists of 360 children entering 6th grade from a large urban school district in the Midwest, identified through an existing BMI screening program. The intervention period is 36 months, and measures are obtained at baseline, 12, 24, and 36 months. Using intent-to-treat analyses across the 36-month intervention window, we hypothesize that both SC and HC will have a greater impact on BMI and other health outcomes compared to health education alone, and that the enriched school environment will enhance these effects. This manuscript describes IMPACT's study design and methods.

☆ Funding acknowledgement: Research reported in this publication was supported by the National Heart, Lung, and Blood Institute of the National Institutes of Health under Award Number HL103622. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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http://dx.doi.org/10.1016/j.cct.2013.08.009

1. Introduction

1.1. Background

Despite the epidemic of childhood obesity [1,2], effective and sustainable intervention approaches to help children lose weight or maintain their weight as they grow remain elusive. With one in three children today being overweight or obese, it is critical to identify effective methods for weight management in these children to reduce their risk for future health problems [3–5]. Several clinical and individualized approaches for weight reduction in children have been developed and some show promise [6–23]. However, few approaches have shown substantial and/or sustained benefits in children [5]. Further, many previous studies have involved non-representative samples of economically disadvantaged children, wide age ranges, absence of stratification by risk, and short follow-up periods — limiting their generalizability [24].

Childhood obesity is of great concern for both the current health of the child and the increased risk of developing more severe health problems as these children mature. There is significant evidence of associated co-morbidities with obesity in childhood, including hypertension, insulin resistance, diabetes, lipid abnormalities, and sleep-disordered breathing [16,25–27]. Moreover, children who are overweight are significantly more likely to have coronary heart disease and resulting earlier mortality when they reach adulthood [28–32]. Treatment of these obesity-related co-morbidities has been estimated to have direct medical costs of $147 billion annually in the US [33].

In addition to biological contributors to obesity, there is strong evidence identifying several behavioral, contextual, and environmental factors as critical underpinnings of the growing prevalence of pediatric obesity [34–45]. Family, school, peers, community, and policy provide the environmental contexts that shape children's energy intake and expenditure — and therefore together influence the development of obesity and its co-morbidities [46]. Viewing childhood obesity from this socio-ecological perspective [43,47–49] suggests that to gain traction in treating obesity, it is important to target more than one level of environmental influence. Interventions that target multiple environments (e.g., home, school, neighborhood) are likely to be more powerful in reducing obesity than interventions addressing only one. This may be particularly true for young adolescents [50–52], who are increasingly influenced by peers and environments outside the home.

2. Study aims

The primary aim of this study is to compare the effects of three distinct behavioral obesity management interventions on BMI in overweight/obese middle school, urban youth. This study also assesses the additive effect of an enriched school-based intervention on BMI. Secondary aims are to: (a) assess the effects of the interventions on cardiovascular risk factors (blood pressure, insulin sensitivity, lipids, C-reactive protein [CRP], body composition, biomarkers, fitness); (b) examine the effects of the interventions on participants' diet, physical activity, sedentary behavior, sleep, and quality of life; and (c) explore whether the impact of the interventions on relevant outcomes is influenced by selected socioeconomic and demographic factors, environmental (home, school, neighborhood) factors, peer norms, and personal and psychosocial characteristics of the child and parent(s)/guardians.

3. Materials and methods

3.1. Trial design

IMPACT (Ideas Moving Parents and Adolescents to Change Together) is a randomized control trial with three intervention arms (SystemCHANGE [SC], HealthyCHANGE [HC], and active education-only control.) Participants (n = 360 middle school children and an index family member/guardian) are randomized equally to these three intervention arms. By design, 50% of the participants were randomized in Year 1, and 50% of the sample will be randomized in Year 2 of the trial. In addition, approximately half of the participants are also students enrolled in a local K-8 public or charter school that offers an innovative community-sponsored fitness program, augmented by study-supported navigators. Mediator, moderator, and outcome measures are assessed at baseline and at 12, 24, and 36 months after randomization. The trial at Case Western Reserve University (CWRU) is one of four projects funded under a multi-site NIH-funded collaborative referred to as the Childhood Obesity Prevention and Treatment Research (COPTR) program sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

3.2. Conceptual model

The IMPACT study addresses obesity in urban youth by focusing on two levels of the child's environment: the child–family environment and the school–community environment. The primary goals of both the child–family and the school interventions are to reduce BMI by producing changes in lifestyle (diet, physical activity, sedentary behavior, sleep, and stress management). Fig. 1 illustrates the proposed relationships among the major study variables and their corresponding study aims. Our primary aim is to determine the effect of the two innovative child–family interventions (SystemCHANGE, HealthyCHANGE) compared to a brief education-only approach (control group), on reducing BMI (Path A), as well as assess the moderating impact of an enriched school environment (Path B).

BMI is considered a distal outcome as it depends on changes in other more proximal outcomes – dietary intake, physical activity, sedentary behaviors, and sleep. As part of our secondary aims, we will explore the impact of the child–family interventions and the moderating impact of the enriched school environment on these more proximal outcomes (Paths D and C, respectively), as well as secondary outcomes, including cardiovascular risk factors, body composition, cost and quality of life (also Path A).

Proposed mediators through which the interventions effect changes in both proximal and distal outcomes are: child's self-efficacy, social support, motivation, and family problem-solving, systems thinking, and self-regulation (Paths E and F). The mediators represent the targeted approaches of each intervention (e.g., systems thinking for SystemCHANGE, motivation for HealthyCHANGE). Lastly, we will explore potential