

Culturally-grounded diabetes prevention program for obese Latino youth: Rationale, design, and methods☆



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ARTICLE INFO

Article history:

Received 16 September 2016

Received in revised form 13 January 2017

Accepted 14 January 2017

Available online 16 January 2017

Keywords:

Diabetes prevention

Latino

Health disparities

Health promotion

Obesity

ABSTRACT

Background: Type 2 diabetes (T2D) disproportionately impacts Latino youth yet few diabetes prevention programs address this important source of health disparities.

Objectives: To address this knowledge gap, we describe the rationale, design, and methodology underpinning a culturally-grounded T2D prevention program for obese Latino youth. The study aims to: 1) to test the efficacy of the intervention for reducing T2D risk, 2) explore potential mediators and moderators of changes in health behaviors and health outcomes and, 3) examine the incremental cost-effectiveness for reducing T2D risk. Latino adolescents (N = 160, age 14–16) will be randomized to either a 3-month intensive lifestyle intervention or a control condition. The intervention consists of weekly health education delivered by bilingual/bicultural promotores and 3 moderate-to-vigorous physical activity (PA) sessions/week. Control youth receive health information and results from their laboratory testing. Insulin sensitivity, glucose tolerance, and weight-specific quality of life are assessed at baseline, 3-months, 6-months, and 12-months. We will explore whether enhanced self-efficacy and/or social support mediate improvements in nutrition/PA behaviors and T2D outcomes. We will also explore whether effects are moderated by sex and/or acculturation. Cost-effectiveness from the health system perspective will be estimated by the incremental cost-effectiveness ratio using changes in insulin sensitivity at 12-months.

Conclusions: The results of this study will provide much needed information on how T2D prevention interventions for obese Latino youth are developed, implemented and evaluated. This innovative approach is an essential step in the development of scalable, cost-effective, solution oriented programs to prevent T2D in this and other high-risk populations.

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1. Introduction

Obesity and type 2 diabetes (T2D) represent some of the most significant public health challenges facing our society. Disparities in obesity and T2D emerge early in life and disproportionately impact Latino populations. Latino youth exhibit higher rates of insulin resistance [1] and pre-diabetes [2] than white youth and nearly 30% of obese Latino youth exhibit pre-diabetes [3]. These data support estimates by the

CDC that up to 50% of all Latino youth born in the year 2000 will develop T2D in their lifetime [4]. In addition to adverse physical health, recent data suggest that obese Latino youth are more likely to experience psychosocial consequences including symptoms of depression and anxiety [5] as well as reduced perceived quality of life (QoL). The extent and magnitude of adverse negative health consequences among obese Latino youth set the stage for long-term morbidity and mortality. Therefore, interventions aimed at improving physical and psychosocial health outcomes among Latino youth are urgently needed.

Obesity interventions for youth traditionally target individual level behavior changes including diet and exercise to support weight loss [6]. These general approaches to encourage healthy behaviors among heterogeneous populations (overweight/obese, children/adolescents, and minority/non-minority) often fail to address contextual factors

☆ **Trial Registration:** The study is registered at www.clinicaltrials.gov (NCT01236794).

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that influence health behaviors among population sub-groups. As such, most programs to date have shown limited efficacy for reducing obesity among youth [7]. Interventions that do incorporate a multilevel perspective rarely include health outcomes beyond weight-loss, do not consider sociocultural or developmental perspectives in their designs, and almost never explore the mechanisms through which the intervention is mediated [8]. The complexity of obesity-related health disparities necessitates that evidence-based programs include culturally and biologically homogeneous populations, incorporate robust outcome measures, and test the mechanisms of efficacious outcomes using rigorous randomized controlled designs. Such comprehensive studies will provide the framework for solution-oriented programs and policies that will ultimately close the obesity-related health disparities gap among minority youth.

The Diabetes Prevention Program (DPP) has established that T2D can be prevented or delayed in high-risk adult populations [9]. The original DPP curriculum has been successfully adapted and incorporated into the local community setting with community input into its development, design and implementation [10]. The DPP was not designed nor has it been tested in high-risk youth, a population where academic-community partnerships may be ideal. These types of partnerships represent an opportunity for translating obesity and diabetes research findings into “real-world” settings and have proven successful for preventing obesity in young children [11]. However, to date, the availability of community-based diabetes prevention programs focusing on obese Latino adolescents is extremely limited in the scientific literature [12]. Given that adolescence represents a critical period for the onset of adverse obesity-related conditions [13], intervening during this developmental period is a strategic and indicated opportunity for preventing T2D. In order to extend the field, we have developed a 5-year study to test the short-term and long-term efficacy of Every Little Step Counts (ELSC), a culturally-grounded diabetes prevention intervention for obese Latino adolescents (Specific Aim 1). In addition to testing the efficacy, we will explore potential mediators (Specific Aim 2) and moderators (Specific Aim 3) of health behavior changes and health outcomes (Fig. 1). Lastly, we will estimate the initial cost-effectiveness of the intervention for increasing insulin sensitivity (Specific Aim 4). This paper describes the design, methodology, and rationale for the randomized-controlled study.

2. Methods

2.1. Study design

We propose a randomized controlled trial of 160 obese Latino adolescents aged 14–16 to test the short-term (3-month) and long-term (9-month) efficacy of a culturally-grounded, community-based Every

Little Step Counts (ELSC) lifestyle education intervention to improve insulin sensitivity and weight-specific QoL. Youth will be randomized to either 3-months of intensive ELSC lifestyle intervention consisting of weekly group education sessions (~1 h each) and 3 moderate to vigorous group PA sessions per week (~1 h each) or a control group that will receive health information material and monthly phone calls, emails, or texts throughout the 3-month period. The intervention group will complete three monthly booster sessions following the intensive intervention period. All participants will undergo testing at baseline, 3-months (post-intervention), 6-months (post-booster), and 12-months (9-months post-intervention) and control youth will be offered a modified version of the intervention upon completion. This design (Fig. 2) not only allows us to examine the short and long-term efficacy of the intervention but having multiple points of contact with participants facilitates retention efforts. We will oversample with the conservative assumption that 20% of youth approached will be ineligible or not interested and 20% will be lost to attrition over the course of the study, thus leaving a proposed final sample size of 128 participants for analysis at 12-months. Given the rapid onset of T2D in youth with prediabetes and the ethical implications of randomizing a participant with prediabetes to a control group for a year, any participant who meets the American Diabetes Association criteria of prediabetes at baseline (either a fasting glucose ≥ 100 mg/dl and/or a 2-hour post-challenge glucose ≥ 140 mg/dl) will automatically be assigned to the intervention group.

2.2. Ethics

The study protocol and all study-related documents will be approved and monitored by the Institutional Review Board at Arizona State University. The study is registered at www.clinicaltrials.gov (Clinicaltrials.gov Identifier: NCT01236794). Written parental consent and child assent will be obtained by study staff prior to any data collection procedures.

2.3. Participants

Equal number of males and females will be recruited and must meet specific inclusion and exclusion criteria. Inclusion criteria include: Latino ancestry; self-report age 14–16 at time of enrollment; and obesity defined as BMI percentile ≥ 95 th percentile for age and gender or BMI ≥ 30 kg/m². Youth will be excluded if they are taking medication(s) or diagnosed with a condition that could influence carbohydrate metabolism, physical activity, and/or cognition, have type 2 diabetes as defined by a fasting plasma glucose ≥ 126 mg/dl or 2-hour plasma glucose ≥ 200 mg/dl, have been recently hospitalized (previous 2 months), are currently enrolled in (or within previous 6 months) a formal weight

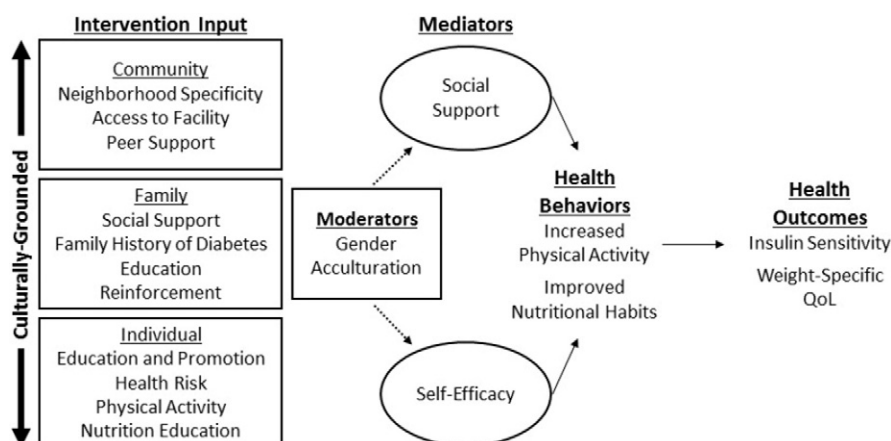


Fig. 1. Theoretical model guiding the study.

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