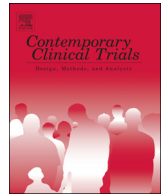




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Protocol for the Imagine HEALTH Study: Guided imagery lifestyle intervention to improve obesity-related behaviors and salivary cortisol patterns in predominantly Latino adolescents

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ABSTRACT

Innovative lifestyle interventions are needed to reduce type 2 diabetes risk in adolescents. This report describes the protocol of the Imagine HEALTH cluster randomized control trial, that tests an intervention based in Self-Determination Theory (SDT) and uses lifestyle education combined with the mind-body, complementary health modality of guided imagery (GI), to address obesity prevention and treatment in predominantly Latino adolescents. The primary aim is to determine the unique effects of each of the three major components of the 12-week lifestyle intervention (lifestyle education, stress reduction guided imagery, and lifestyle behavior guided imagery) compared to control on primary outcomes of physical activity (accelerometry), dietary intake (3-day recall), and stress biomarker levels (salivary cortisol). Secondary aims assess changes compared to controls in psychosocial outcomes (stress, well-being, depression), diabetes-related metabolic outcomes (adiposity, insulin resistance), maintenance of outcome changes for one year post-intervention, and SDT-based mediation of intervention effects. The development and rationale for each of the intervention components, study design, and outcome measurement processes are described. Adolescent participants recruited from four urban schools are cluster randomized by school into one of four arms of the 12-week (3-month) intervention, followed by 6 months of maintenance and 6 months of no contact. Outcome measures are assessed at the end of each period (3-, 9-, and 15-months). Results to date show successful recruitment of 97% of the target study population. Future results will demonstrate the effects of this integrative intervention on primary and secondary outcome measures in adolescents at risk for lifestyle-related metabolic disease.

1. Introduction

The 2013–2014 NHANES estimated that 20.5% of U.S youth, and 22.8% of Hispanic/Latino youth, between 12 and 19 years of age were obese [1]. Among overweight and obese Latino youth, there is a high prevalence (~32%) of pre-diabetes [2–4] and the metabolic syndrome (~30%), both associated with insulin resistance [5]. Furthermore, persistent pre-diabetes and metabolic syndrome are both associated with increasing diabetes risk over time [6, 7]. As in adults, insulin resistance, rather than body fat per se, is the primary patho-physiological factor leading to metabolic disease risk [8, 9]. Therefore, interventions

that target reductions of insulin resistance through lifestyle behavior changes are key in the prevention of type 2 diabetes (T2D) in overweight adolescents.

Previous interventions to prevent and treat childhood obesity have been limited in several areas, including the relative paucity of interventions in minority, high-risk populations [10, 11], lack of interventions that are based in health behavior theory [12], emphasis on cognitive-based interventions that do not take developmental issues adequately into account [13, 14], and failure to address the metabolic outcomes of obesity. While chronic stress has been linked both to the development of obesity, and the development of obesity-related

Abbreviations: T2D, Type 2 diabetes; SDT, Self-Determination Theory; GI, Guided imagery; IGI, Interactive Guided ImagerySM; RCT, Randomized controlled trial

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morbidities, previous intervention strategies have not addressed this issue, nor have they utilized complementary mind-body modalities to reduce chronic stress as part of an integrative approach to obesity prevention and/or treatment.

In response to these considerations, we previously developed and tested the 12-week Imagine HEALTH (Healthy Eating Active Living Total Health) pilot lifestyle intervention for obese Latino adolescents [15]. This multicomponent, integrative intervention had two major components: 1) lifestyle education, and 2) individual Interactive Guided ImagerySM designed to reduce stress and promote healthy lifestyle (physical activity and eating) behaviors. Results demonstrated that compared to controls, IGISM acutely reduced the stress biomarker salivary cortisol across a 45-min span, reduced sedentary behavior, increased moderate physical activity, and marginally decreased caloric intake after the 12-week intervention [15]. These findings led to the randomized controlled trial (RCT) described in this report.

We herein describe the protocol of the Imagine HEALTH cluster randomized control trial that uses lifestyle education combined with the complementary-integrative health modality of guided imagery (GI) to address obesity prevention and treatment in predominantly Latino adolescents. Our primary aim is to determine the unique effects of each of the three major intervention components of a 12-week intervention (lifestyle education, stress reduction guided imagery, and lifestyle behavior guided imagery) on obesity-related lifestyle behavior (physical activity and dietary intake) and stress biomarker (salivary cortisol) outcomes. We hypothesize that at the conclusion of the 12-week intervention, the guided imagery arms of the intervention will show greater improvement in these outcomes than lifestyle education alone. Our secondary aim is to determine if changes in outcomes seen after 12-weeks of intervention will be maintained for an additional 12 months. Additional aims of the study seek to determine intervention effect size estimates for secondary outcomes (insulin resistance, body fat, psychosocial outcomes), and to explore the role of Self-Determination Theory constructs (SDT) in mediating lifestyle behavioral change.

2. Methods

2.1. Theoretical considerations underlying the imagine HEALTH intervention

2.1.1. Theory-based approach

The conceptual model for the intervention is illustrated in Fig. 1. In contrast to most lifestyle interventions in adolescents which do not identify the active theoretical constructs being targeted by the intervention, we utilized SDT [16] as the underlying theoretical basis of the Imagine HEALTH intervention. SDT is a general theory of human motivation addressing both cognitive and affective factors involved in human motivation and highlights the importance of the social context in facilitating or thwarting autonomous human motivation. This approach to human motivation posits three innate human psychological needs that form the basis for optimal self-motivation: *competence, relatedness, and autonomy* [17]. Fulfillment of these three needs is necessary to facilitate psychological growth and integration, as well as for

personal well-being [18–20]. *Autonomous motivation*, performance of behaviors with either intrinsic motivation (i.e. for inherent satisfaction) or with extrinsic motivation with high degrees of internal regulation, has been linked to performance of healthy behaviors [17], weight loss maintenance [21], and increased physical activity in adults [22–26] and adolescents [27–29]. The intervention described in this paper is designed to promote the three major SDT components: relatedness, competence, and autonomy. In so doing, it facilitates a sense of choice, volition, and freedom from excessive external pressure as well as focusing on affective determinants of behavior, thus making it developmentally appropriate for adolescents [30, 31].

2.1.2. Combining obesity prevention and treatment in a single intervention

Typically, interventions to prevent obesity and interventions to treat obesity in children have been considered separately [32, 33]. However, careful consideration of pediatric guidelines shows that many, if not most, treatment modalities are the same or similar for obesity prevention and treatment approaches [34]. Our school-based intervention includes both overweight/obese and normal weight youth, and thus necessarily utilizes elements of both treatment and prevention.

2.1.3. Promoting health and wellness (versus targeting body weight goals)

The Imagine HEALTH intervention approach explicitly targets whole health and well-being. The process (lifestyle behaviors), not the result (weight loss) is emphasized throughout the intervention, and issues relating to insulin resistance and weight loss are viewed in this context. The curriculum intentionally avoids setting program goals based on weight loss, instead focusing on the process of developing healthy lifestyle habits. Weight loss goals would be inappropriate for normal weight participants in the program, and the risks of restrictive eating practices for weight loss in adolescents have been well-documented [35, 36]. The few past interventions sharing this philosophical approach have shown psychological, eating behavior, and body composition benefits [37, 38]. This approach assumes that by improving stress and obesity-related health behaviors (our primary outcomes), improvements in secondary metabolic outcomes (insulin resistance, body fat) will ensue.

2.1.4. Rationale for stress reduction as intervention target: Moving beyond “eat less, exercise more”

Adolescents have experienced an increase in anxiety over the past few decades [39], suggesting that today’s children may be exposed to increased numbers of stressors than in the past. This is supported by data from the recent Stress in America study by the American Psychological Association, which surveyed a nationally representative sample of 1018 youth aged from 13 to 17 years old, and found that at least one third of American youths had felt irritable, nervous, anxious, or overwhelmed due to stress in the past month [40]. Minorities also experience higher levels of stress [41]. Socioeconomic and immigration-related factors can be stress-inducing in Latinos [42], and Latino Los Angeles residents are especially susceptible to these forms of stress, given that Latino individuals are 13 times more likely to live in low-income areas than whites [43]. In addition, the high school years can be

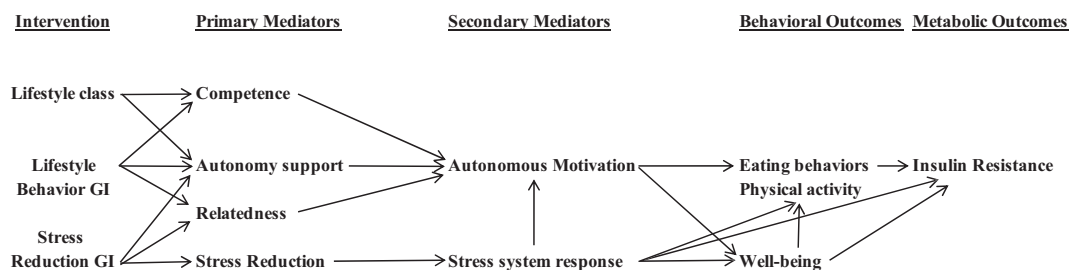


Fig. 1. Conceptual model.

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