Contemporary Clinical Trials 49 (2016) 149–154

Contents lists available at ScienceDirect

Contemporary Clinical Trials

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

Design and rationale of the STRIVE trial to improve cardiometabolic health among children and families

Nicolas M. Oreskovic [a,b,c,*], Richard Fletcher [d], Mona Sharifi [a,c], John D. Knutsen [a,c], Ani Chilingirian [d], Elsie M. Taveras [a,c,e]

[a] Division of General Academic Pediatrics, Department of Pediatrics, MassGeneral Hospital for Children, Boston, MA, USA
[b] Department of Internal Medicine, Massachusetts General Hospital, Boston, MA, USA
[c] Harvard Medical School, Boston, MA, USA
[d] Media Lab, Massachusetts Institute of Technology, Cambridge, MA, USA
[e] Department of Nutrition, Harvard T.H. Chan School of Public Health, Boston, MA, USA

ARTICLE INFO

Article history:
Received 26 April 2016
Received in revised form 5 July 2016
Accepted 10 July 2016
Available online 11 July 2016

Keywords:
mHealth
Health behaviors
Technology
Obesity
Childhood
Cardiometabolic

ABSTRACT

Background: Many of the health behaviors known to contribute to cardiometabolic risk and disease (CMRD), including physical activity, diet, sleep, and screen time, begin during childhood. Given the population-wide burden of CMRD, novel ways of assessing risk and providing feedback to support behavior change are needed.
Purpose: This paper describes the design and rationale for the Study for using Technology to Reach Individual Excellence (STRIVE), a randomized controlled trial testing the use of an integrated, closed-loop feedback system that incorporates longitudinal, patient-generated, mobile health technology (mHealth) data on health behaviors and provides clinical recommendations to help manage CMRD among at-risk families.
Methods: STRIVE is a 6-month trial among 68 children, ages 6–12 year olds with a body mass index ≥ 85th percentile from Massachusetts with at least one parent with CMRD. Data on several health behaviors will be collected daily over 6 months. Children and parents will each wear wristbands that collect objective physical activity, sleep, and screen time data via accelerometry, noise, and infrared detection. Sugar sweetened beverage consumption will be assessed by self-report via a smartphone application. Weight will be collected using a wireless scale. Intervention group parents receive feedback on their child's health behaviors and personalized CMRD counseling via mobile messaging. Control parents receive standard of care recommendations and weekly health behavior reports for self-guided care.
Conclusion: The STRIVE trial will test the use of mHealth and closed-loop feedback systems to improve health behaviors among families at-risk for or with established CMRD.

1. Introduction and background

Cardiometabolic disease, which includes obesity, type II diabetes, coronary artery disease, hypertension, dyslipidemia, and liver enzyme dysregulation, is a significant health problem among the US population [1]. Obesity alone continues to be a serious problem in the United States with nearly one in three children and two in three adults currently overweight or obese [2]. Many of the clinical manifestations of cardiometabolic disease, including obesity, type II diabetes, hyperlipidemia, elevated blood pressure, and liver enzyme abnormalities begin during childhood and track into adulthood [3,4]. Health habits are known to form during childhood and may be harder to change once established during adulthood [5]. Therefore, the prevention of cardiometabolic risk and disease (CMRD) and its associated risk factors should start during childhood [6]. Examining individual-level health behaviors known to be associated with cardiometabolic risk is an important first step to preventing disease. Primary care clinicians have historically assumed this task as part of an effort to prevent and treat disease. Although clinicians can play a valuable role in identifying risk and providing recommendations, multiple factors limit their effectiveness including infrequent and brief visits and dependence on subjective patient-reported information regarding health behaviors [7–9]. Even if health behavior information is collected, clinicians may be uncertain on how to use this information or may lack systems for providing timely feedback to patients [10]. Given the myriad health problems and costs associated with cardiometabolic disease and the obstacles clinicians currently face when counseling patients, novel and effective methods

* Corresponding author at: Division of General Academic Pediatrics, Massachusetts General Hospital, 125 Nashua Street, 8th Floor, Boston, MA 02114, USA.
E-mail addresses: noreskovic@mgh.harvard.edu (N.M. Oreskovic), fletcher@media.mit.edu (R. Fletcher), msharifi@mgh.harvard.edu (M. Sharifi), jknutsen@mgh.harvard.edu (J.D. Knutsen), anic@mit.edu (A. Chilingirian), etaveras@mgh.harvard.edu (E.M. Taveras).

http://dx.doi.org/10.1016/j.cct.2016.07.012
1551-7144/

for collecting objective risk data and providing timely feedback could help mitigate the population-wide burden of CMRD.

Providing timely feedback on health behaviors has recently been shown to have benefits in other chronic lifestyle-mediated conditions, such as the management of tobacco use. In smoking cessation, as with CRMD, automated feedback and support can be linked with clinical recommendations with the goal of modifying health behaviors. Smoking cessation studies have demonstrated the feasibility and efficacy of this approach by employing several techniques which are transferable to CMRD, namely using mobile phone technology to deliver closed-loop feedback in the form of tailored evidence-based clinical messages [11,12]. Closed-loop feedback can be defined as any information transfer that is automated, recipient-directed, and activity-completing. For example, a movie-finding text message program that prompts the end-user to enter their favorite movie category and then automatically texts back all the movies in that category currently playing in cinemas would be an example of closed-loop feedback: the reply is computer generated (automated), provides information directly back to the end-user (recipient-directed), and fully completes the information transfer task that it initiated (activity-completing). Closed-loop feedback systems can be applied to managing CMRD health behaviors and have several related features that are particularly appealing, including the ability to tailor feedback, the ability to provide evidence-based feedback, and the capacity to markedly reduce the feedback cycle time compared to standard medical practice.

The primary aim of STRIVE is to test a Just-In-Time Adaptive Intervention (JITAI) for pediatric CMRD which delivers daily personalized mobile phone-based messages based on four tailoring variables: daily hours of moderate-to-vigorous physical activity, daily hours of sleep, daily consumption of Sugar Sweetened Beverages, and daily number of hours of screen time. This intervention shall be analyzed as a comparative effectiveness study to determine the feasibility and potential benefit of using a mHealth-based closed-loop feedback system that collects longitudinal patient-generated health behavior data and provides evidence-based clinical recommendations compared to a self-guided disease management approach among families with CMRD. We hypothesize that providing rapid, frequent, personalized clinical feedback on health behaviors will improve weight status among at-risk children. The primary outcome is change in child BMI, the most prevalent and earliest manifestation of CMRD in children. The secondary outcomes are change in parent BMI and change in child and parent CMRD-related health behaviors; physical activity, sleep, screen-time, and sugar-sweetened beverage consumption. In this paper, we report the design and rationale for STRIVE.

2. Methods

2.1. Theoretical frameworks

STRIVE is informed by two theoretical frameworks that aim to understand and explain health behaviors and disease self-management: 1) the health belief model; and 2) self-determination theory. The Health Belief Model (HBM) was developed to identify, explain, and predict health behaviors. The model is founded on the basic tenet that patients will take healthful actions if they believe i) negative health consequences can be avoided, and ii) they are capable of taking healthful actions [13,14]. HBM is well-suited for studying cardiometabolic health behaviors and has been widely used to develop messages aimed at promoting healthy habits and decisions, including prior pediatric obesity studies aimed at promoting healthy behaviors [15]. This study will incorporate and test the application multiple HBM concepts including perceived disease severity (define personalized risk based on objective health behavior quantification and feedback), perceived benefits of action (define goals, define health and non-health outcomes), perceived barriers to action (identify health behaviors that are not at goal, educate, motivate), cues to action (provide motivational messages), and self-efficacy (health behavior achievement feedback). Self-determination theory assumes that humans have an inclination towards activity but also a vulnerability to passivity [16], and has been applied in prior research testing obesity-related treatments using mobile technologies [17]. Self-determination theory accounts for the personal motivational factors essential for successfully using patient-driven technology to promote patient engagement in lifestyle modifications.

2.2. Comparative effectiveness research evidence base

Along with having a strong theoretical grounding, STRIVE is also founded on existing comparative effectiveness evidence, and seeks to build new tools that will increase the uptake of proven effective interventions. Prior research among children ages 6–12 years that included computerized decision support has demonstrated that a family-based approach can be beneficial for treating cardiometabolic risk, and that family-based interventions for self-guided behavior change can improve childhood body mass index [18].We designed STRIVE to be a clinical comparative effectiveness study that draws on this evidence to test the benefit of using automated technology to improve the adoption of evidence-based cardiometabolic risk management strategies.

2.3. Patients and recruitment

Patients ages 6–12 years with overweight or obesity (BMI ≥ 85th percentile) followed for obesity care at Massachusetts General Hospital in Boston and who have an adult household family member with one or more elevated cardiometabolic risk (defined as established or elevated risk of overweight, obesity, hypertension, coronary artery disease, diabetes or glucose intolerance, dyslipidemia, non-alcoholic fatty liver disease, cerebrovascular disease) are eligible to participate in this study. Participating parents must also have Wi-Fi Internet at home (required for the bathroom scale), own an Android smartphone, and read English. This study is approved by the Partners HealthCare institutional review board and the protocol is registered on ClinicalTrials.gov (NCT 02659163). Written informed consent is obtained from parents and guardians along with child assent prior to study participation.

2.4. Study design

STRIVE is a prospective randomized controlled trial that will test the feasibility of using mHealth to reduce cardiometabolic risk in children by collecting longitudinal patient-generated health behavior data and providing clinical recommendations in a closed-loop feedback system (Fig. 1). Participants will be randomly assigned in a 1:1 ratio to an intervention or control group based on computer-generated randomization output. Study participants will be blinded to their study assignment, and study team members will be blinded to study group assignment during data analyses. Daily health behavior data will be collected over 6 months, and study outcomes will be measured as the change from baseline to study completion. Participating families will receive $100 ($50 for each child participant and $50 for participating parents) as remuneration after study completion and return of all study equipment.

2.5. Study variables, measures, and data collection

Several types of data sources will be collected from both the child and parent and will be used to compare change over time between the intervention and control groups in body mass index (BMI) and health behaviors. Participants will be informed of all the data sources collected, as well as all the devices and sensors used during the study. The primary outcome is change in BMI. The secondary outcome is change in health behaviors. For the purpose of designing our mHealth intervention, we considered BMI as our primary distal outcome. Individual health behaviors will be used both to determine proximal response as well as the distal outcomes. Proximal response is determined by