Contemporary Clinical Trials Communications 7 (2017) 86–94

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

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

Effect of personal activity trackers on weight loss in families enrolled in a comprehensive behavioral family-lifestyle intervention program in the federally qualified health center setting: A randomized controlled trial

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ARTICLE INFO

Keywords:
Childhood obesity
Fitbit
Physical activity
Activity monitor
Family-based intervention
Wearable devices

ABSTRACT

Background: Childhood obesity continues to be a substantial problem despite major public health efforts, and disproportionately impacts children from low-income families. Digital health tools and consumer technology offer promising opportunities for interventions, but few studies have evaluated how they might be incorporated into existing interventions or used to create new types of interventions. It remains unclear which approaches would be most beneficial for underserved pediatric populations.

Purpose: To describe the design and rationale of a single-center randomized, controlled trial evaluating the effects of personal activity tracker (PAT) use by parents on weight-status improvement in both parents and overweight children enrolled in BodyWorks (BW), a comprehensive behavioral family-lifestyle intervention program (CBFLI), in a primary-care clinic serving a predominantly low-income Latino population.

Methods: This study is being conducted in the AltaMed general pediatrics clinic at Children's Hospital Los Angeles. Eligible participants are families (child and adult caregiver) in which the child is between 7 and 18 years of age, has a BMI ≥85th percentile for age and sex, and has been referred to BW by their AltaMed pediatrician. BW consists of one weekly, two-hour session for 7 weeks. In a given cycle, the program is offered on two separate nights: Monday (Spanish) and Wednesday (English). Families self sort into one of two groups based on language preference. To ensure balanced allocation of language preference groups and prevent in-group cross contamination, block randomization is used to assign whole groups to either the intervention or control arms of the study. The control arm consists of usual care, while the intervention arm adds assigning a Fitbit PAT to the parents and training them in its proper use. Study personnel are blinded to group assignment during the analysis phase. Study outcomes include attendance rate, program completion rate, and changes in weight-status improvement, defined as change in weight and BMI for adults and change in BMI z-score for children. We hypothesize that the intervention arm will have better weight-related outcomes than the control arm. Study completion is anticipated in 2017, after the enrollment of approximately 150 families.

Conclusions: The study aim is to evaluate the effects of PATs on weight-related outcomes in overweight children and parents participating in a CBFLI. The results will be important for determining whether wearable devices are an effective addition to weight loss interventions for overweight and obese children.

1. Introduction

Childhood obesity continues to be a global public concern, with rates of childhood overweight and obesity rapidly rising, and in some cases tripling, in low-, middle-, and high-income countries [1–3]. New evidence suggests that this rise is plateauing in the US, but the problem is still substantial: 16.9% of children ages 2–19 are obese, and 31.8% are overweight or obese, despite major national public health efforts [4–10]. Overweight and obese children are at higher risk of remaining obese throughout their lives, have difficulty losing weight through traditional measures such as dietary change and physical activity, and have lower quality of life in terms of psychological and social health [11–13].

Certain groups of children are at particularly high risk of childhood

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http://dx.doi.org/10.1016/j.conctc.2017.06.004
Received 10 December 2016; Received in revised form 2 June 2017; Accepted 10 June 2017
Available online 15 June 2017

Nomenclature

BW	BodyWorks
CBFLI	Comprehensive Behavioral Family Lifestyle Intervention
PAT	Personal Activity Tracker
PA	physical activity
SRPA	Self Reported Physical Activity
OMPA	Objectively Measured Physical Activity
CSHQ-A	Children's Sleep Habits Questionnaire (Abbreviated)
RAPID	Research in Academic Pediatrics Initiative on Diversity
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
FQHC	Federally Qualified Health Center

obesity. Latino and Black children have a higher risk of obesity and related health problems [5,14]. Children from lower socioeconomic households have a 3.4–4.3 times higher rate of obesity than children from more affluent households [15]. In California, the income disparity in obesity prevalence is twofold in magnitude among children and adolescents, according to The National Health and Nutrition Examination Survey [16].

There is fair to good evidence that medium-to high-intensity comprehensive behavioral family-lifestyle intervention (CBFLI) programs result in the greatest, most sustained weight loss for children [17,18]. CBFLI involves the child and at least one caretaker, and addresses all three major areas of weight-loss interventions: dietary intake, physical activity (PA), and behavioral strategies [19]. Educating and engaging the caretaker enables changes in the home environment, which facilitates child weight-loss or stabilization. Due to their comprehensive nature, CBFLI programs can be expensive to run and difficult to implement in low-resource settings, putting them out of reach of low-income families.

A key component of pediatric weight loss programs in general, and CBFLIs in particular, is parent involvement. Parenting style and practices, family functioning, and family communication have all been linked to pediatric obesity [20–24]. Parents are crucial partners in the treatment of childhood obesity – they are role models, authority figures, providers, and they create the home environment that influences the energy balance and dietary composition of children [25,26]. Parenting interventions in early childhood can decrease the risk of obesity later in life [27–29]. And while parenting-only interventions have in general not been successful as treatment for childhood obesity [30,31], parent-targeted obesity interventions have delivered positive, long-lasting outcomes [25]. Taken together, the literature underscores the primacy of the parent in pediatric weight loss interventions.

Objectively measured physical activity (OMPA) methods, such as accelerometry and doubly labeled water, are more accurate and precise than subjective self–reports [32,33]. The use of accelerometers, or personal activity trackers (PAT), has been validated in adults and children as both feasible and effective in measuring PA [34]. Not enough is known, however, about whether PATs are effective in the management of childhood obesity [35]. In this study, we incorporate OMPA via PAT into BodyWorks (BW), a national CBFLI program at an urban federally qualified health center (FQHC). Uniquely, we provide the PAT intervention to the parents in the family, as well as the child.

This randomized, controlled trial is designed to 1) establish a baseline of enrollment, attendance, completion, and weight outcomes for BW, and 2) evaluate the effects of personal activity trackers on weight-related outcomes in overweight children and their parents. The primary study hypothesis is that children of families utilizing PAT will have improved weight-related outcomes, defined as either a stabilization or decrease of BMI z-scores, over the course of their participation in the BW program. Our secondary hypothesis is that participating parents who use PAT will have better weight-related outcomes at the end of the program. The trial will be open for 24 months. Herein we describe the design, rationale, and challenges related to this study.

2. Materials and methods

This study was funded by a grant from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)-supported Academic Pediatric Association (APA) Research in Academic Pediatrics Initiative on Diversity (RAPID) program (NIH R25DK096944). BW is currently in its third year at our institution. We anticipate enrolling patients for 18–24 months (July 2015–June 2017).

2.1. Conceptual framework

Physical Activity is an important part of both healthy lifestyle and weight loss programs [26]. Self-monitoring is an effective behavior change technique [36,37], and has been demonstrated to increase PA in adults [38,39]. Digital PATs enable self-monitoring of PA while eliminating the burden of manual data entry. Parents enrolled in BW can use PATs to self-monitor PA, which should lead to increases in PA. This increase in parent PA leads to better role modeling for their children and better engagement in the program. These should have an overall impact in the child's PA and engagement. Joint participation and early successes will positively feedback to both parent and child, leading to overall improved weight-related outcomes for both members of the dyad (Fig. 1).

2.2. Human subjects

The Institutional Review Board of Children's Hospital Los Angeles and AltaMed approved this study. Prospective participants were provided a thorough description of the protocol in either English or

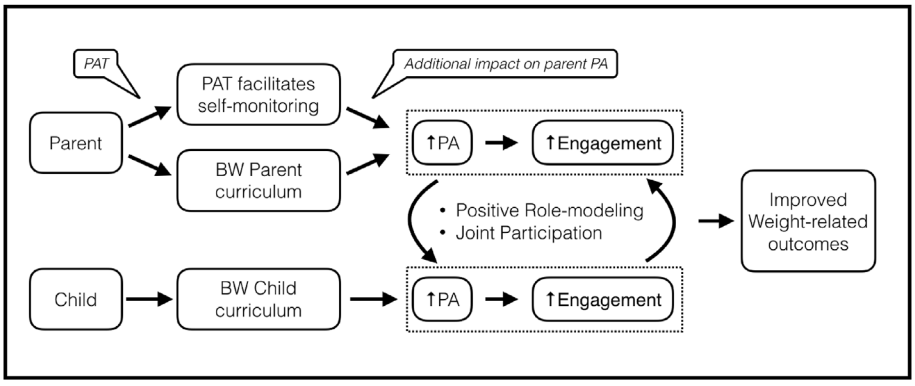

Fig. 1. BW + PAT intervention conceptual framework. PAT = Physical activity monitor, BW = BodyWorks, PA = Physical Activity.