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# Applying Interactive Mobile health to Asthma Care in Teens (AIM2ACT): Development and design of a randomized controlled trial

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ABSTRACT

Early adolescents have difficulties performing asthma self-management behaviors, placing them at-risk for poor asthma control and reduced quality of life. This paper describes the development and plans for testing an interactive mobile health (mHealth) tool for early adolescents, ages 12–15 years, and their caregivers to help improve asthma management. Applying Interactive Mobile health to Asthma Care in Teens (AIM2ACT) is informed by the Pediatric Self-management model, which posits that helpful caregiver support is facilitated by elucidating disease management behaviors and allocating treatment responsibility in the family system, and subsequently engaging in collaborative caregiver-adolescent asthma management. The AIM2ACT intervention was developed through iterative feedback from an advisory board composed of adolescent-caregiver dyads. A pilot randomized controlled trial of AIM2ACT will be conducted with 50 early adolescents with poorly controlled asthma and a caregiver. Adolescent-caregiver dyads will be randomized to receive the AIM2ACT smartphone application (AIM2ACT app) or a self-guided asthma control condition for a 4-month period. Feasibility and acceptability data will be collected throughout the trial. Efficacy outcomes, including family asthma management, lung function, adolescent asthma control, asthma-related quality of life, and self-efficacy for asthma management, will be collected at baseline, post-treatment, and 4-month follow-up. Results from the current study will inform the utility of mHealth to foster the development of asthma self-management skills among early adolescents.

## 1. Introduction

Asthma affects approximately 8.3% of children in the United States and is one of the most common chronic pediatric conditions [1]. Adolescents with persistent asthma experience impaired health and quality of life due to complications that are largely preventable via self-management behaviors [2]. Unfortunately, many adolescents fail to perform the asthma self-management behaviors that help to control asthma symptoms and enhance quality of life [3]. The treatment regimen for persistent asthma is complex, making self-management arduous for adolescents [4]. Exceedingly low adherence to daily preventative medications [5–7], difficulty in monitoring and responding to symptoms, and challenges with trigger avoidance are widespread [8,9].

Responsibilities for managing asthma transition from caregivers to youth during early adolescence [5,10,11]. Caregivers often expect adolescents to assume increased levels of responsibility for their asthma care; however, early adolescents are unlikely to possess the requisite skills needed to manage asthma without caregiver assistance [6]. Discrepancies in the allocation of asthma management responsibilities between parties can also result in a situation where management tasks are poorly executed or left unattended by both the caregiver and adolescent [5,11,12]. Therefore, the presence of helpful caregiver support can determine whether adolescents with asthma are successful in developing and mastering self-management behaviors. Family conflict is related to poor asthma outcomes including poor adherence and frequent emergency department visits [13–15]. Alternatively, helpful caregiver involvement is related to improved asthma control, quality of life, adherence, and lung function [15–16]. The centrality of helpful caregiver support in developing asthma self-management skills [17] is illustrated best in the Pediatric Self-management Model [18]. This model posits that youth self-management behaviors are influenced by the presence of helpful caregiver monitoring and involvement in

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disease management and the relationship quality between the caregiver and adolescent. Based on this model, helpful caregiver support is facilitated by: 1) elucidating disease management behaviors and the allocation of treatment responsibility in the family system and 2) subsequently engaging in collaborative caregiver-adolescent asthma management as early adolescents develop and master self-management behaviors.

Mobile Health (mHealth) technologies can improve disease outcomes [19] and may be an especially powerful tool to deliver effective behavioral health interventions to facilitate helpful family support as early adolescents with asthma develop and master self-management behaviors. Smartphones are owned and habitually carried by approximately 50% of 12–17 year-olds and 75% of adults ages 30–49 [20,21]. mHealth technologies can obtain near real time data that can be used to inform tailored mHealth interventions that are dynamic, user-centric, and continuously adapted [22]. mHealth technology also presents a unique opportunity to provide a safe and structured environment to foster communication between adolescents and caregivers while avoiding emotional escalation and conflict that can occur when dyads try to navigate asthma management on their own.

There is a clear need for a mHealth intervention that targets helpful family support as early adolescents with persistent asthma transition to taking more responsibility for their asthma care. This study aims to develop the AIM2ACT intervention and test the AIM2ACT smartphone application (AIM2ACT app), a novel mHealth tool for youth with poorly controlled asthma and their caregivers. We outline the development of intervention components that will be used in a pilot randomized controlled trial (RCT) that will evaluate feasibility, acceptability, and efficacy of the AIM2ACT intervention.

### 1.1. Design and methods

#### 1.1.1. Objectives

Consistent with Obesity-Related Behavioral Intervention Trials (ORBIT) consortium guidelines [23], the current study includes two phases. Phase I focuses on collaborating with a family advisory board to develop the AIM2ACT intervention, a mHealth tool informed by the Pediatric Self-Management Model [18] designed to increase helpful family support as early adolescents develop and master self-management behaviors. Phase II testing involves conducting a 4-month RCT of AIM2ACT in 50 early adolescents with persistent asthma and their caregivers to evaluate feasibility, acceptability, and efficacy. Families will be randomized to receive the AIM2ACT app or to a self-guided asthma control condition.

### 1.2. AIM2ACT design and development

AIM2ACT intervention materials were developed over a 15-month period. Development was primarily focused on building the AIM2ACT app, which uses existing technology provided by MEI Research through the patented PiLR Health system [24]. PiLR is a cloud-based platform that collects, stores, processes, and reports on objective behavioral data from mobile devices [25]. Additional features were developed for the purpose of this study, including presentation of skills-training videos and interactive behavioral contracting between adolescents and caregivers. The AIM2ACT app was tailored to our targeted population by gathering feedback from advisory board meetings composed of families of youth with persistent asthma.

### 1.3. AIM2ACT advisory board meetings

#### 1.3.1. Methods

Advisory board participants included youth with asthma between the ages of 12–15, and their caregiver. Participants completed a demographic questionnaire and the Asthma Control Test [26] (see Efficacy Outcomes section). Three advisory board meetings were conducted with nine adolescent-caregiver dyads. These meetings were facilitated by the primary investigator, study coordinator, and a graduate student. Advisory board meetings were used to elicit constructive feedback and gauge participant interest, relevance, and potential feasibility and acceptability of the AIM2ACT app (e.g., language used). Specific goals for each advisory board meeting were as follows. The first advisory board meeting focused on introducing the overarching goals of AIM2ACT, presenting wireframes of core AIM2ACT app functionality (e.g., goal setting, behavioral contracting), and presenting initial version of skills-training videos. During the second advisory board, we solicited feedback on surveys embedded within AIM2ACT, using a beta version of the smartphone application, and presented refined versions of skills-training videos. Families completed final beta testing of the AIM2ACT app during the third and final advisory board meeting and were encouraged to think-aloud to provide feedback. Intervention materials for the self-guided asthma control condition were also presented during final advisory board meetings to obtain feedback on language and presentation of materials, and to ensure the control condition accurately mirrored the AIM2ACT app without the mHealth components. Families were compensated for their participation in advisory board meetings.

#### 1.3.2. Results

Nine families participated in the advisory board meetings; six families participated in two or more meetings. Family demographic characteristics are presented in Table 1. During the first advisory board meetings, families perceived the goals of the project as important and felt the framework for using the application was coherent and easy to follow. A number of participants also provided constructive feedback on the initial versions of AIM2ACT skills training videos. Suggestions included using a more engaging multimedia platform for generating videos, replacing text-based information with visual content wherever possible, and reducing the length of the videos to sustain attention. Refined skills-training videos were created, using animated visuals and voiceover, and presented during second advisory board meetings. Families provided feedback on a beta version of the AIM2ACT application during the second advisory board meetings, citing issues with wording and the visuals used in the app. Following final beta testing during the third and final advisory board meetings, families generated additional examples to include in the different components of the behavioral contracts on the AIM2ACT app (e.g., goals and rewards). Families suggested the AIM2ACT app initiate a second assessment of needs, half way through the project period, to show families their overall progress

**Table 1**
Advisory board demographic variables.

| Variables | n (%) or mean ± SD |
|---|---|
| Youth age | 13.33 (1.32) |
| Youth gender | |
| Male | 3 (33.3%) |
| Female | 6 (66.7%) |
| Child race/ethnicity | |
| Caucasian/White | 2(22.2%) |
| African American | 5 (55.6%) |
| Puerto Rican | 1 (11.1%) |
| Other Latino | 1 (11.1%) |
| Parent relationship | |
| Biological mother | 6 (66.7%) |
| Biological father | 1 (11.1%) |
| Step, adoptive, or foster mother | 1 (11.1%) |
| Grandmother | 1 (11.1%) |
| Parent race/ethnicity | |
| Caucasian/White | 2 (22.2%) |
| African American | 4 (44.4%) |
| Other Latino | 1 (11.1%) |
| Mixed or multi-racial | 2 (22.2%) |
| ACT score | 20.44 (2.30) |