



# Effect of a mobile health, sensor-driven asthma management platform on asthma control



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## ABSTRACT

**Background:** Asthma inflicts a significant health and economic burden in the United States. Self-management approaches to monitoring and treatment can be burdensome for patients.

**Objective:** To assess the effect of a digital health management program on asthma outcomes.

**Methods:** Residents of Louisville, Kentucky, with asthma were enrolled in a single-arm pilot study. Participants received electronic inhaler sensors that tracked the time, frequency, and location of short-acting  $\beta$ -agonist (SABA) use. After a 30-day baseline period during which reference medication use was recorded by the sensors, participants received access to a digital health intervention designed to enhance self-management. Changes in outcomes, including mean daily SABA use, symptom-free days, and asthma control status, were compared among the initial 30-day baseline period and all subsequent months of the intervention using mixed-model logistic regressions and  $\chi^2$  tests.

**Results:** The mean number of SABA events per participant per day was 0.44 during the control period and 0.27 after the first month of the intervention, a 39% reduction. The percentage of symptom-free days was 77% during the baseline period and 86% after the first month, a 12% improvement. Improvement was observed throughout the study; each intervention month demonstrated significantly lower SABA use and higher symptom-free days than the baseline month ( $P < .001$ ). Sixty-nine percent had well-controlled asthma during the baseline period, 67% during the first month of the intervention. Each intervention month demonstrated significantly higher percentages than the baseline month ( $P < .001$ ), except for month 1 ( $P = .80$ ).

**Conclusion:** A digital health asthma management intervention demonstrated significant reductions in SABA use, increased number of symptom-free days, and improvements in asthma control.

**Trial Registration:** [ClinicalTrials.gov](https://clinicaltrials.gov) Identifier: NCT02162576.

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## Introduction

Asthma affects 1 in 12 individuals in the United States,<sup>1</sup> disproportionately affecting children, women, African Americans, and those living in poverty.<sup>2</sup> Despite decades of pharmacologic and clinical progress, disease morbidity has not decreased substantially. Each year in the United States, 1.8 million asthma-related emergency department visits and 439,000 asthma hospitalizations occur,<sup>3</sup> with overall costs reaching \$56 billion.<sup>4</sup>

Despite the launch of major strategic initiatives, such as Healthy People 2020 and the National Asthma Education and

Prevention Program (NAEPP),<sup>5</sup> which emphasize appropriate management and control, most individuals with asthma do not have adequate control<sup>6–10</sup> of their symptoms.<sup>11</sup> Improved monitoring, management and control reduce health care use<sup>12</sup>; however, the absence of real-time data collection has hindered the ability to monitor patients and improve treatment, especially self-management. The National Heart, Lung, and Blood Institute's NAEPP, Global Initiative for Asthma, and American Thoracic Society clinical practice guidelines recommend that physicians monitor patients' frequency of short-acting  $\beta$ -agonist (SABA) use as an important indicator of asthma control and impairment.<sup>5,13–15</sup> Most patients and caregivers lack objective ways to assess asthma symptoms and often underestimate their frequency and severity.<sup>14</sup> Survey tools, such as the Asthma Control Test (ACT), can assist in assessing level of control<sup>14</sup> but are limited by infrequent administration and recall bias.

Digital health interventions, such as those leveraging short message service, websites, and sensor technology, are being used increasingly in clinical interventions for asthma. Studies have revealed the effectiveness of digital interventions in improving clinical outcomes, including asthma control and adherence; however, these studies largely occurred within a clinical setting with consistent clinical oversight.<sup>6–10</sup> This pragmatic single-arm pilot study aimed to test whether a digital health intervention could improve specific asthma outcomes in a real-world setting, primarily through participant self-management, without systematic clinical oversight. We hypothesized that a digital health intervention would result in increased frequency of symptom-free days, reduced frequency of SABA use, and improved asthma control.

## Methods

The study was reviewed and approved by the Copernicus Group Independent Review Board. The study received written informed consent from all participants, including written consent from guardians on behalf of minors enrolled in the study.

## The Sensor and Digital Health Intervention

The electronic inhaler sensor used in the study passively and objectively monitors the use of metered dose inhalers, capturing the date and time of use (Fig 1) (Propeller Health, Madison, Wisconsin). The sensor stores up to 3,900 actuations and transmits the information via Bluetooth to a paired smartphone, which determines the geographic location of the use and communicates the information to secure servers. For those participants without a smartphone, a wireless hub was used for data transmission. Either device automatically downloads new actuations from the sensor whenever it is in range (<25 m) and securely uploads this information to encrypted servers. All protected health information associated with the platform is encrypted at rest and in motion in compliance with the Health Insurance Portability and Accountability Act of 1996 privacy laws. The sensor and data transmission processes are fully described elsewhere.<sup>16</sup>

The sensor is a component of a US Food and Drug Administration–cleared digital health platform aimed at promoting self-management and consists of mobile applications, web-based dashboards, and other communication channels, such as short message service and e-mail.<sup>16</sup> Smartphone applications designed for both Android and iOS devices are available in English and Spanish.

These tools aim to promote disease awareness and self-management by enabling the participants to access their own analyzed data, including objective assessments of asthma control, adherence, and potential triggers, and receiving education derived from the national guidelines.<sup>5</sup> In addition, participants were able to authorize their health care practitioners to view their collected data and summary reports through a web interface, which enabled practitioners to integrate timely information about SABA use into their clinical decision making.

## Participant Identification and Enrollment

The pilot study recruited individuals from community asthma activities, clinics, and retail pharmacies. Individuals were eligible if they reported a physician diagnosis of asthma, were 4 years or



**Figure 1.** Electronic sensor attached to a metered-dose inhaler canister, paired with the smartphone and web applications that present visualized data and trends.

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