

group, FEV₁ was significantly higher after the intervention ($P = .04$; Table 1). Between-group analysis did not reveal any significant differences in changes in FEV₁.

In the control group, peak expiratory force (PEF) analysis did not show statistically significant changes between before and after the intervention (Table 1). In the active group, we found a significant improvement in PEF measurements ($P = .02$; Table 1). Between-group analysis revealed no significant differences in changes in PEF.

Changes in FeNO results did not differ before vs after the intervention within groups, nor between groups (Table 1). In active responders, FeNO levels fell significantly after the intervention ($P = .01$).

The ETS exposure scale findings decreased significantly in the control ($P = .02$) and active ($P = .001$) groups; differences between groups were also statistically significant ($P < .001$) (Table 1).

According to our results, the face-to-face intervention among smoking families was effective and led to decreased ETS exposure and lowered cotinine levels in asthmatic children. Children whose parents passed the face-to-face intervention had better lung function and better asthma control than children in the control group. FeNO results did not change after the intervention in either group; however, FeNO levels dropped significantly in active responders. Limitations of our study include its small sample size and relatively short duration.

Several studies have recognized ETS as a risk factor that facilitates the development of asthma in children.^{3–5} The most significant results from our study indicate a change within the intervention group and a between-group difference on the exposure scale. The ETS exposure scale revealed that parents reported changes in smoking habits after both interventions, but the cotinine level fell significantly only in the active group. This result confirms that the effectiveness of any anti-tobacco intervention should

be evaluated with an objective parameter, such as cotinine measurements.

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Learnings from a pragmatic pilot trial of text messaging for high-risk adolescents with asthma



Clinical research with high-risk patient populations is complex because of economic burdens, lack of transportation, and so forth^{1,2}; therefore, conducting pilot studies before entering into a full-scale study is critical. Pilot studies can confirm the design and operational processes for a study³ and increase the likelihood of a successful clinical trial by identifying problems that may occur in the methods.^{4,5} Thus, we conducted a pilot study to identify issues in a research trial with low-income, publically insured, minority adolescents. Our study included multiple technologies that, without proper execution, could reduce the effectiveness of the intervention and the accuracy of the method by which the intervention was measured. Expected and unexpected challenges and the learnings that occurred shed light on issues faced in technology-dependent studies of high-risk adolescents.

We conducted a 5-month longitudinal, randomized text messaging intervention with high-risk adolescents who had long-term poorly controlled asthma. The inhaled corticosteroid (ICS) adherence monitoring and text messaging intervention was technology enabled and previously pilot tested.^{6,7} The intervention was designed to require few resources to enable replication in primary

care. We recruited 31 participants, which was smaller than anticipated because of our stringent criteria for long-term poor control and a change in insurance formularies mid-study, which drastically reduced the number of patients whose formulary ICS was compatible with the adherence monitor. Of the eligible patients approached, only a few declined.

Despite implementing quality control procedures developed by the real-time medication monitoring (RTMM) device company, there were challenges. A software update resulted in the loss of data, there were months in which no actuations were registered for some participants, and the device sleeve, although specific to that ICS, did not always fit the patient's canister. Additionally, when issues did arise, the time difference between our institution and the RTMM device company in Auckland, New Zealand, resulted in delays.

Technological challenges can be particularly problematic when working with a patient population that is known to struggle with having a stable home environment and are prone to losing things.⁸ Even with a working, compatible device, in 3 instances the study participant failed to refill their prescription, resulting in a lapse in medication monitoring. Additionally, if a participant lost an RTMM device (which occurred 4 times), the data could not be recovered. In addition to data loss, the study suffered a \$200 deficit with each device that was not returned. Finally, 5 participants allocated to receive the text messaging intervention struggled to maintain the same, working cell phone (ie, lost cell phone; no cell phone minutes; cell phone change) for the duration of the study, which intermittently prevented them from receiving the text messaging intervention.

Disclosures: Authors have nothing to disclose.

Funding Sources: Research reported in this publication was supported by the National Heart, Lung and Blood Institute of the National Institutes of Health [R21HL119826].

Trial Registration: ClinicalTrials.gov Identifier: NCT02176694.

To preserve the pragmatic nature of the trial, we ordered RTMM devices that were compatible with the medication most prescribed to our eligible population, which was completely dependent on the patient's insurance. Eight months after study activation, our patient population's primary public insurance provider changed their formulary to only cover ICS medication (ie, twisthaler and a canister with a built-in holding chamber), for which no RTMM devices were available. Not only did this significantly reduce our eligible patient population, but the active study participants insured by this company could no longer be monitored.

Many of the potential solutions for the technological challenges faced while piloting this study threatened the pragmatic nature of the trial. For instance, a solution for the change in insurance medication coverage was to provide the medication for the patient while they were in the study. Similarly, providing each participant with a cell phone and cell phone minutes would allow the study staff to make sure that the adolescent had enough cell phone minutes for the intervention portion of the study. Additionally, issues that arose from both the RTMM and the text message intervention could have been curtailed by increasing the frequency of communication with study participants throughout the study, whether through in-person visits or telephone encounters. This would have provided the study staff with more opportunities to inquire about cell phone minutes and medication availability.

The long-term goal for piloting this project with this population was to develop an effective intervention that would be feasible in primary care where personal interventions were not likely to succeed. Unfortunately, we discovered that, to increase the effectiveness of the intervention, we would be compromising feasibility. For example, a typical primary care clinic, especially one caring for a high-needs population, will not have the resources to provide ICS medication and cell phones to all patients who qualify for this type of intervention, proving our intervention unrealistic for this high-risk population. The second major learning is that even though we tested prior iterations of the text messaging intervention and the RTMM before conducting the pilot study, new issues arose when software updates were rolled out. The third major learning is that the company providing the study-related technology components needs to have the manpower to handle technological malfunctions in real time. With each hour that passes, a malfunction could result in loss of data and loss of the intervention.

Although research has shown that pilot studies are beneficial in identifying issues with the conceptualization, methodology, and ex-

ecution of a study,^{3–5} conducting this pilot study created an extra layer of complexity. We learned that reaching a balance between feasibility in a primary care setting and efficacy of the intervention was an issue. By increasing the practicality of the intervention, we reduced our ability to actually study and determine effectiveness. Also, although technology was necessary to make both the medication monitoring and the text messaging intervention possible, the downfall is that it sometimes did not work, and immediate assistance was not always available. This pilot study can provide valuable information to future researchers with similar patient populations, study objectives, and methodologies, especially those researchers that are looking to technology as a means to innovate their research.

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