

A Randomized Trial of User-Controlled Text Messaging to Improve Asthma Outcomes: A Pilot Study

Clinical Pediatrics

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DOI: 10.1177/0009922816684857

journals.sagepub.com/home/cpj



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Abstract

We enrolled 64 patients age 12 to 22 years with a diagnosis of poorly controlled persistent asthma in a 6-month longitudinal crossover study. During the 3 intervention months, participants created personalized text messages to be sent to their phones. Adherence was objectively monitored in 22 of the participants. The adolescent participants gave high ratings on the acceptability of the text messaging system. Asthma control improved from baseline to month 1 regardless of whether teens were in the texting or control group. While participants were in the texting group, their quality of life improved and worry about their asthma decreased. Receiving the text intervention resulted in an increase in adherence of 2.75% each month relative to no intervention, but the improvements were not sustained. There was modest improvement in asthma control and quality of life outcomes, as well as improved adherence during the texting intervention.

Keywords

adolescents, chronic disease, cellular phone, medication adherence, reminders, SmartInhaler

Asthma is the most common chronic condition of childhood¹ resulting in the greatest number of hospitalizations, emergency department visits, and missed school days per year,² exceeding \$3 billion in US health care costs.^{3,4} Adherence to treatment is critical to asthma control and reducing asthma morbidity. However, research has found low adherence rates to inhaled corticosteroids (ICSs) in pediatric patients^{5–8} including economically disadvantaged minority adolescents,^{9–11} which ranged from 31% to 67%. Previous research indicated that mean adherence rates for ICS is typically less than 50%.^{12,13} Although adherence is influenced by a complex set of factors, one reason for these poor adherence rates is that adolescents with asthma typically forget to take their medication.^{14–17}

Researchers have tried novel interventions to promote adherence to asthma medication. Recent pilot studies^{18,19} have shown promising results using multi-component motivational interviewing, problem-solving, and text messaging interventions to improve adherence in low-income, minority adolescents. These interventions, however, may not be feasible in typical primary care settings as they often require substantial involvement of specially trained clinic staff. Neither of these research interventions have been implemented outside a

research setting to date. Recent research investigating adherence promotion interventions delivered in routine clinical care or in addition to routine clinical care has shown promising results with the majority of patients (ie, increasing adherence rates across the duration of the intervention).^{20–23}

Text messages are gaining acceptance in health care both as appointment reminders and direct inquiries, and studies have shown that 34% of individuals wanting reminder calls preferred a text message.²⁴ A recent study found that 87% of adolescents and young adults from a variety of primary care practices had a cell phone and that 85% agreed to provide their number to be contacted for a research study through means of a text message.²⁵

Recent studies have looked at text reminders as a potential intervention in individuals with a chronic

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illness, such as adolescents/young adults with HIV/AIDS,²⁶ young adults with systemic lupus erythematosus,²⁷ patients with schizophrenia,²⁸ and urban African Americans with diabetes.²⁹ Results from these studies have shown that text messaging may be a feasible and useful approach to improve medication adherence.

We previously undertook a small uncontrolled pilot study to determine the feasibility of a developmentally appropriate, adolescent controlled, calendar-to-text system for adolescents with persistent asthma. The adolescents liked the ability to personalize the messages to their preferences, and 81% of the messages sent were scheduled to be delivered at least 5 days per week.³⁰ In this larger pilot study that builds on our prior work, we used a randomized design and, in a subset of participants, trialed the use of an objective adherence monitor. We hypothesized that the text messaging intervention would result in improved adherence to prescribed ICSs. We also hypothesized that this developmentally appropriate intervention would be feasible, well liked, and have a positive effect on asthma control and asthma-related quality of life.

Methods

Study Setting

Cincinnati Children's Hospital Medical Center (CCHMC) is a large academically oriented children's hospital. The Teen Health Center at CCHMC provides primary care to low-income, minority (primarily African American) youths 12 to 22 years of age. There are few non-English-speaking patients in this clinic. Approximately 600 patients seen annually at the Teen Health Center have a diagnosis of asthma.

Study Design

An a priori power analysis revealed that over 200 participants would be required to detect a 20% change in asthma control. Thus, this study was a pilot to determine feasibility and provide preliminary results for a larger, more definitive study.

We conducted a 6-month longitudinal randomized crossover study of a web calendar-to-text system specifically designed by a mobile marketing company (CMSText) for this study. Participants were randomized to either the control arm or the participant arm at the start of enrollment and remained in that arm for 3 months. At the participant's month 3 visit, the participant switched to the other arm for the remaining 3 months of the study. There were no per text costs associated with the web calendar-to-text system beyond the one time development cost.

Study Subjects

Patients were eligible for the study if they were between the ages of 12 and 22 years, had provider-diagnosed persistent asthma, and were prescribed an ICS controller medication. The patient also had to have a cell phone capable of receiving text messages for the duration of the study. Patients could not participate if they had ever received text message adherence reminders as a part of their clinical care or through another research study. Parents or participants over the age of 18 had to be willing to incur any charges related to receiving daily text messages.

This study was approved by the institutional review board at CCHMC. Participants were recruited from the Teen Health Center by a study staff member after initial approach and introduction by the teen's provider. Trained in procedures used in the pilot study, a study staff member approached the teen during their clinic visit and obtained written informed consent from those over 18 years of age or assent and parental consent for those younger than 18 years.

Intervention

At the start of the 3-month intervention arm, a study staff member created a unique account for each teen and showed them how to log-on to their personal calendar system via the Internet and how to schedule text messages to be sent to their phones. Since behavior change research has shown that untailored text messages are less effective in engaging participants,³¹ participants were given the opportunity to personalize their text message reminders. They could schedule non-asthma medication reminders, appointment reminders, or other messages of their choice. The adolescent participants could change, add, or delete the reminders as they wished. Each participant was given a notecard that included the name of the website as well as their personal username and password. Participants were encouraged to contact study staff if they experienced problems with the system. During the 3-month control arm the participants did not have access to the web calendar-to-text system or the text message reminders.

Outcome Measures

The primary outcome measures were asthma symptom control as measured by the Asthma Control Test (ACT)³² and quality of life as measured by the Pediatric Quality of Life Scale (PedsQL) Asthma Module.³³ The ACT measures frequency of day and night symptoms, frequency of fast-acting inhaler use, limitations of activities, and perception of asthma control. The PedsQL Asthma Module

measures how much asthma has been a problem for them in the last month (eg, “It is hard for me to be responsible for my medications,” “I worry about my asthma”). For all participants, the secondary outcome measures were the feasibility, acceptability, and utility of the text messaging system based on quantitative items employing Likert-type scales and qualitative responses captured on a measure used in the previous pilot study.³⁰ This measure assessed how easy the system was to use, whether they liked using it, as well as likes and dislikes.

Adherence to prescribed ICSs was measured for a subsample of the population ($N = 22$). Electronic monitoring was chosen as the primary method to objectively measure adherence to treatment because it has been shown to be feasible and valid in previous research, including pediatric asthma,^{9,20,23,34-36} and provides a continuous record of treatment adherence in real time. Adherence was defined as the number of medication doses taken each day divided by the number of prescribed doses taken each day.

Data Collection

After consent was obtained, the ACT was administered to the adolescent and a text message was sent from the web calendar-to-text system to the adolescent’s mobile phone. The patient was enrolled in the study if their ACT score indicated that their asthma was less than well controlled (ie, ACT <20) and if the text message was successfully delivered to their mobile phone.

Once enrolled, a study staff member obtained demographic information from the participant. The adolescent then completed the PedsQL Asthma Module for baseline values. Using a random number table and sealed assignment envelopes, the participants were randomly assigned to either the participant arm or the comparison arm for a period of 3 months.

The longitudinal study procedures involved 3- and 6-month visits that were conducted in person and follow-up telephone calls at 1, 2, 4, and 5 months. After each completed monthly visit and follow-up telephone call, the adolescent received \$10 for time, travel, and text messaging costs. During each in-person visit the adolescent was asked to complete the PedsQL Asthma Module and the ACT. During telephone calls, the adolescent was asked to complete only the ACT in order to minimize respondent burden. In addition, the adolescents were asked to answer questions related to the usability and acceptability of the system while enrolled in the web calendar-to-text system. A study staff member reviewed the adolescents’ electronic health record monthly to determine if any changes in the ICS medication or dosing instructions had occurred.

For the subsample of patients who participated in the adherence monitoring, adherence to ICS treatment was measured by the SmartInhaler (Nexus 6 Ltd, Auckland, New Zealand). This device contains a microprocessor that records and stores data concerning medication adherence, including a time stamp that records the date and time the device was actuated.^{14,36} Study participants were introduced to the electronic monitoring device at their baseline visit. Introduction procedures included instructions on how to use the SmartInhaler and information on who to call should any issues arise. Participants were asked to have the device attached to their daily ICS medication for the duration of the study. Data were obtained from the SmartInhaler during the participants’ 3- and 6-month visits. Recommended quality control procedures for electronic monitoring were followed.³⁵

To increase retention rates, a study staff member obtained multiple phone numbers and an email address at the participant’s first visit. The participant was also asked for phone numbers of those people who would be able to reach them should their primary phone number/cell phone number be disconnected. Phone attempts were made after school hours, and most communication with participants occurred through a dedicated texting-enabled study cell phone. In addition, social networking (ie, Facebook) was used to increase communication with the adolescents in the study, and study reminder postcards were sent out to those participants who were difficult to reach.

Analysis

Descriptive statistics, including means and standard deviations, for continuous data and frequency distributions for categorical data were generated for demographic characteristics. Fisher’s exact test and *t* test were used to test differences in demographic characteristics of participants in the 2 study arms.

A repeated-measures analysis using SAS PROC MIXED was used to evaluate the impact of texting on asthma control and quality of life measures. For asthma control, the dependent variable was the ACT score at 6 time periods. The independent variables were time (ie, denotes time period), intervention (ie, signifies if adolescent was receiving text messages), sequence (ie, denotes if intervention was received the first or the last 3 months of the study), the interaction of time by intervention, and the interaction of time by intervention sequence. For quality of life, the dependent variable was the subscale scores for the PedsQL asthma module (ie, worry, communication, treatment, symptoms). The independent variables were sequence, intervention, and the interaction of the intervention by sequence.

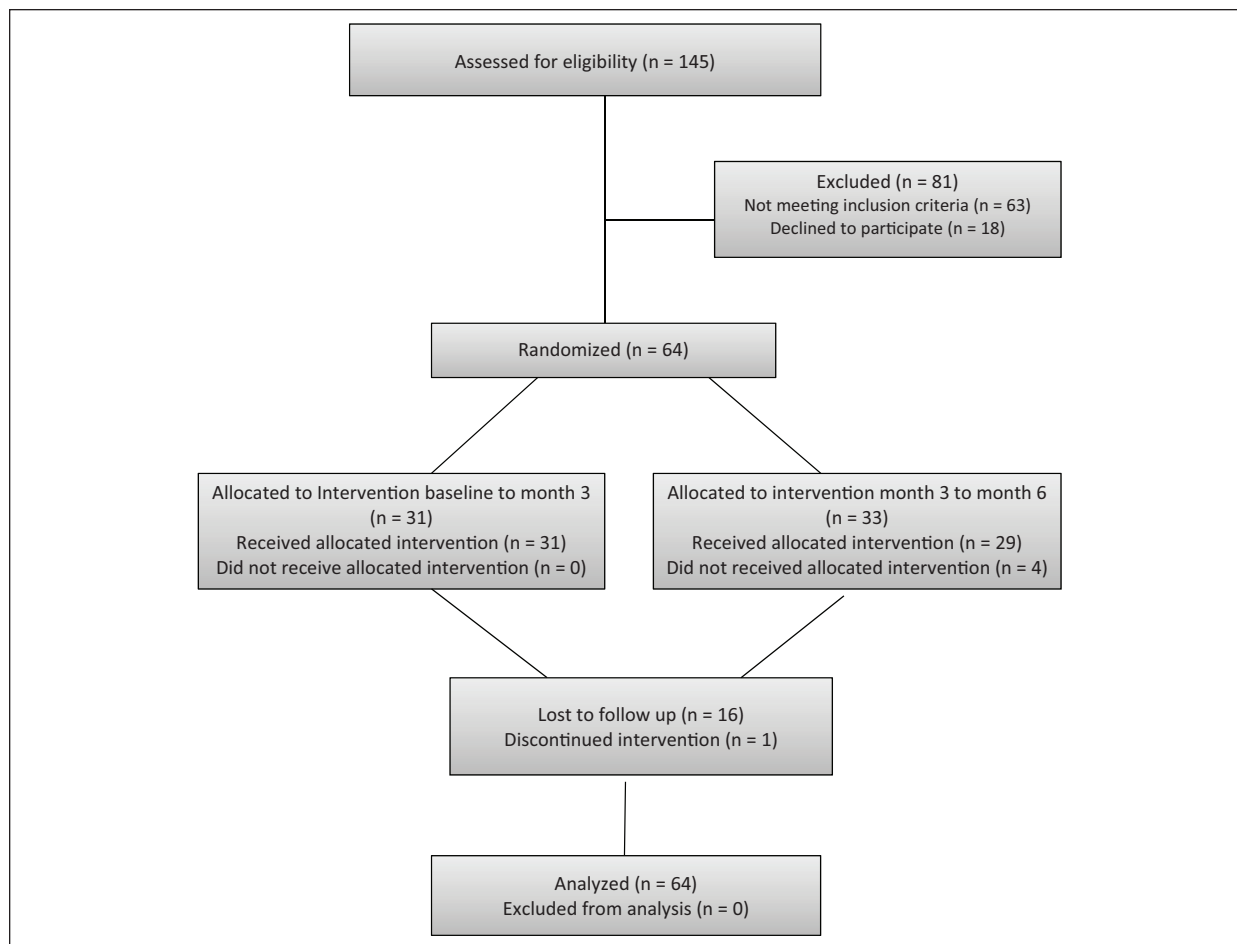


Figure 1. Recruitment Flow Diagram

All outcome measures analyses adjusted for baseline scores, asthma severity, gender, race, age, new (first visit at Teen Health Center ≤ 180 days) established (first visit at the Teen Health Center > 180 days) patient and total number of emergency department and inpatient visits over the study period.

Data from the usability and acceptability of the text messaging system were analyzed by generating means and standard deviations for Likert-type scale responses. Text responses to open-ended questions were summarized and grouped into themes.

We examined whether the adherence promotion intervention (ie, text messaging reminders) improved patient adherence to ICSs relative to periods in which text messaging reminders were not provided from a subset of 22 patients using pooled time series analysis in SAS 9.3.^{37,38} Pooled time series is advantageous for examining intervention effects over time for small sample sizes.^{37,38} Pooled time series models are more robust in comparing group differences for small samples because they allow

all available data points to be modeled over time as opposed to examining a mean score.³⁷⁻³⁹

Results

Study Participants

Sixty-four eligible patients enrolled in the study; 31 started in the intervention group and 33 started in the control group. Six out of the 33 participants that started in the control group were lost to follow-up despite numerous attempts to reestablish contact. Four of the 6 participants that were lost to follow-up never partook in the intervention (text messaging) portion of the study as contact was lost prior to switching to the intervention arm. Eighteen otherwise eligible patients declined to participate in the study because of time constraints, text messaging fees associated with the study, and lack of transportation (see Figure 1). Eighty-six percent of all visits were completed. Demographic and asthma characteristics are shown in Table 1. Emergency department and admissions for

Table 1. Participant Demographic and Asthma Characteristics^a.

	Participant First (N = 31)	Control First (N = 33)
Mean age, years $\pm$ SD	17.2 $\pm$ 1.9	17.4 $\pm$ 2.7
Males, n (%)	6 (19.4%)	5 (15.2%)
Race, n (%)		
Black	27 (87.1%)	26 (78.8%)
White	3 (9.7%)	3 (9.1%)
Other	1 (3.2%)	4 (12.1%)
Insurance, n (%)		
None	1 (3.2%)	3 (9.1%)
Private	5 (16.1%)	2 (6.1%)
Public	25 (80.6%)	28 (84.8%)
Mother's education, n (%)		
No high school or GED	4 (12.9%)	5 (15.2%)
High school or GED	19 (61.3%)	18 (54.5%)
Some college	1 (3.2%)	2 (6.1%)
College degree	3 (9.7%)	6 (18.2%)
Professional training beyond college	2 (6.5%)	1 (3.0%)
Unknown	2 (6.4%)	1 (3.0%)
Asthma severity, n (%)		
Mild persistent	11 (35.5%)	13 (39.4%)
Moderate persistent	18 (58.1%)	16 (48.5%)
Severe persistent	2 (6.4%)	4 (12.1%)
Healthcare utilization (during study period), n (%)		
Emergency department visits	4 (13.0%)	6 (18.2%)
Hospitalizations	1 (3.2%)	3 (9.1%)

^aAll $P > .05$.

asthma were rare. No non-English-speaking patients presented as possible study participants. There were no statistically significant differences between those assigned first to intervention versus control.

Text Messages

As the result of technical errors, 12.5% of participants received at least one text message while in the control arm and 11% did not receive text messages at some point during the intervention arm. Most messages adolescents sent to themselves were ICS reminders, although a few were related to other medications. Examples include "You know what time it is get to the Qvar," "Don't forget to take your Symbicort," "Remember to take your prenatal vitamins," and "Take two puffs of Symbicort take albuterol as needed." Even though adolescents had the opportunity to change, delete, or add reminders outside of the study session, only about 20% of the teens reported that they logged into the system on their own during the text messaging intervention.

Usefulness and Usability

Adolescents reported high acceptability and ease of use for the intervention with mean scores all above 4 on a 5-point scale (see Table 2). At enrollment, adolescents endorsed that the website was user-friendly. Over time, adolescents consistently agreed with statements such as "Text message reminders always help me remember to take my medication," "I always like receiving text reminders," and "I always get my reminders when I should." When asked what they liked best about the website and text message reminders, representative responses included "I can send the messages to my phone and pick what I get to say," "It keeps you updated on your medication," "It tells you what time to take it and basically you've got a schedule," and "It can always remind you whenever you forget." When asked what they liked least about the website and text message reminders, representative responses included "Sometimes, after a while it gets annoying but I have to remember I need extra help to get my medication together," "Sometimes it's difficult to log on [to the website]," and "It stopped working and I forgot to take my medicine."

Effect of Text Messaging Intervention on Asthma Control

There was a significant 3-way interaction among time, sequence (ie, denotes if the adolescent was randomized to the texting arm first or second), and intervention (adjusted $P = .029$). The sequence was marginally significant ($P = .056$). The trajectories of the ACT scores were different depending on whether or not the teen was randomized to the texting arm first or second (see Figure 2). Adolescents who received text messages the first 3 months of the study improved from baseline to month 1 and stayed at an elevated level even when they were without the intervention for the remaining 3 months of the study. Adolescents that began the study in the control group also had improved asthma control scores from baseline to month 1. They maintained this initial improvement in months 2 and 3. Months 4 through 6 (the intervention period) resulted in slightly higher ACT scores for this group.

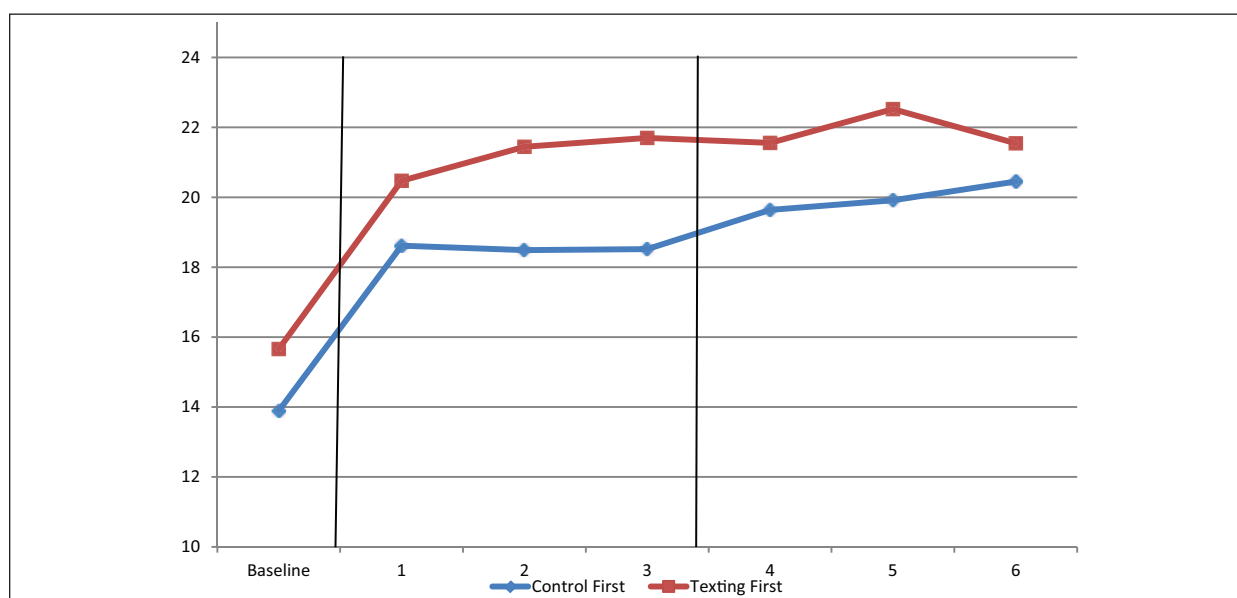
Effect of Text Messaging Intervention on Quality of Life for Pediatric Patients With Asthma

PedsQL, Asthma Symptoms. There was a significant interaction between intervention and sequence (adjusted $P = .038$). The change in scores from baseline was different depending on whether or not the teen was randomized to the texting arm first or second (see Figure 3). Adolescents who received the text messages in the first

Table 2. Perceived Usefulness and Usability of Text Message Reminders^a.

	Enrollment (Baseline), N = 57	1 Month Post Enrollment, N = 50	2 Months Post Enrollment, N = 52	3 Months Post Enrollment, N = 50
Perceived usefulness				
Text message reminders always help me remember to take my medication	NA	4.56 ± 0.54	4.44 ± 0.54	4.68 ± 0.47
Acceptability				
I always like using this system for reminders	NA	4.44 ± 0.61	4.44 ± 0.54	4.64 ± 0.60
I always like receiving text reminders	NA	4.44 ± 0.58	4.37 ± 0.56	4.42 ± 0.73
Satisfaction				
I always get my reminders when I should	NA	4.34 ± 0.94	4.37 ± 0.71	4.32 ± 0.98
I am not worried that someone other than myself or the Teen Health Center staff could see my calendar	NA	4.22 ± 0.82	4.14 ± 0.94	4.44 ± 0.58
Ease of use				
It is always easy to log-in to the system	4.19 ± 0.69	3.81 ± 1.25 (N = 11)	4.36 ± 0.50 (N = 11)	4.27 ± 0.65 (N = 11)
It is easy to learn to use this system	4.25 ± 0.61	3.91 ± 0.83 (N = 11)	4.18 ± 0.60 (N = 11)	4.27 ± 0.90 (N = 11)
I can always easily change the reminders on my calendar	4.37 ± 0.67	4.10 ± 0.70 (N = 11)	4.27 ± 0.47 (N = 11)	4.36 ± 0.67 (N = 11)

^aLikert-type scale ranged from 1 (strongly disagree) to 5 (strongly agree). Results presented are means ± standard deviations.

**Figure 2.** Adjusted ACT score.

3 months of the study reported improved symptoms at 3 months and maintained the improvement at 6 months. Adolescents who received the text messages in the last 3 months of the study also reported improved symptoms at 3 months. They reported additional improvement at month 6 after receiving the intervention.

PedsQL, Asthma Worry. The main effect of the intervention on scores from the worry portion of the PedsQL was significant (adjusted $P = .031$). Figure 3 shows that adolescents worried less about their asthma while receiving text messages.

Adherence Rates Over Time

Adherence rates over time are shown in Figure 4 for the 22 participants who were electronically monitored. At baseline (day 1 of monitoring), the average adherence rate was 12.5%. Pooled time series analysis indicated that receiving the texting intervention improved adherence to ICSs by 2.75% per month ($P < .01$). When text messages were not received, adherence was lower regardless of whether the text messages were received in the first or second 6 months. For the group that received text messages first, intervention effects were not sustained and adherence declined.

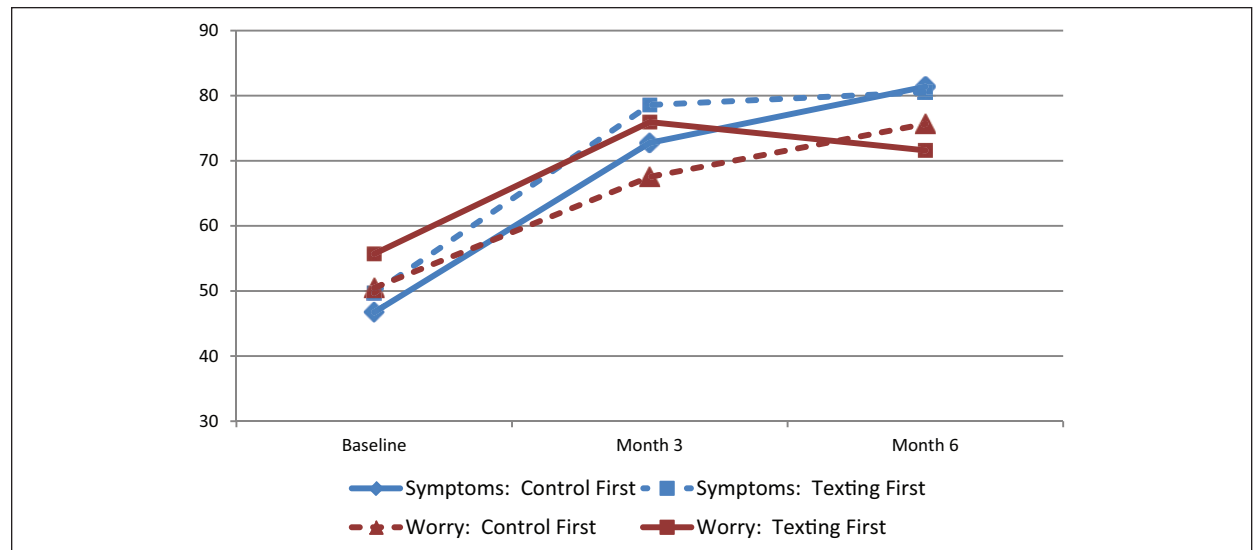


Figure 3. Adjusted PEDSQL score subscale: Worry & Symptoms.

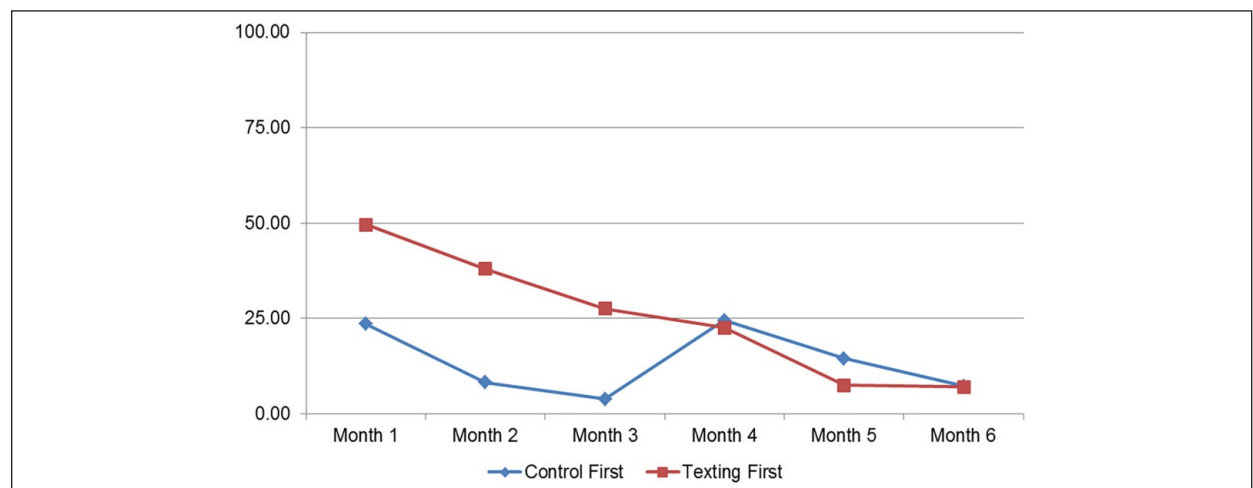


Figure 4. Adherence rates.

Discussion

Our most notable finding was the extremely low rate of adherence to ICS in month 1—only 25%, among those randomized to control first. This is worse than reported in prior, mostly self-report studies of adherence.⁹⁻¹¹ While it was twice as high, 50%, among the texting first group at month 1, it declined in both groups over the intervention and control periods. This suggests that 3 months of messages did not create a long-term habit of ICS use. A recent, large retrospective cohort study of ICS refill dates from a network that included data from 5 major health plans found similarly low levels of adherence in comparison to our study. Among patients of all ages with asthma who were newly prescribed ICS, the

proportion of days calculated to be “covered” based on the date of the first prescription and refill dates ranged from 21% to 25% depending on the ICS prescribed.⁴⁰ Age was not a predictor of adherence in this study. However, African American and Hispanic patients were not as adherent to their ICS medication as Caucasian and Asian patients.

A second notable finding was the improvement in ACT score, our primary outcome measure, from baseline to month 1, whether teens were in the texting or control group. This is likely due to the episodic nature of asthma symptoms and also regression to the mean. Additionally, this initial improvement in ACT score regardless of group allocation could have been a result of the “Hawthorne effect” (ie, participant’s asthma control

improved as a result of study participation).⁴¹ To enroll, patients had to have ACT scores <20. This suggests a run in period may be important to future studies that seek to enroll patients with persistently poor control who are likely to benefit most from adherence interventions.

Given the initial improvement in asthma control in both groups, despite low ICS adherence (at least among the subgroup who had monitors), our findings are somewhat difficult to interpret. There was modest improvement clinically and in quality of life outcomes as well as improved adherence during the texting intervention, but the improvements were not sustained.

There were a number of issues identified in this pilot study that likely affected our results. First, technical problems with the calendar to texting system resulted in 12% to 13% of adolescents missing at least one message while in the texting arm or receiving messages while in the control arm. This likely reduced the measured efficacy of the intervention. Fortunately, the technical difficulties we encountered early in the study were corrected. Second, participants sometimes did not notify us when their phone number changed or their phone was lost. This is a real-world limitation of texting interventions, especially among populations whose phones and phone numbers change frequently. Despite our use of intense, state-of-the-art retention methods, 16% of our patients were lost to follow-up, which reduces our ability to understand the true impact of the intervention. We did not assess pulmonary function as this was a primary care study where pulmonary function data are not usually available to guide therapy. Also, we did not assess recent exacerbations of patients prior to entering the study. However, there were few episodes of care for asthma exacerbations (ie, 4 hospitalizations, 10 emergency department visits) during study participation, precluding any analysis of study's effect on these measures. Given the small sample size for adherence monitoring and only 3 to 7 data points for each subject for clinical and quality of life outcomes, we could not conduct a pooled time series analysis to determine the impact of adherence on clinical and quality of life outcomes.

The intervention itself was well liked and perceived as useful by the participants. No adolescent discontinued the messages during the 3-month intervention period. This contrasts with some prior studies of investigator-initiated text messages, where participants found repeated messages annoying and sometimes discontinued them.⁴²

Overall, this pilot study demonstrated that, among high-risk adolescents with uncontrolled asthma, ICS adherence is abysmally low. Text messages, generated and controlled by the adolescents, are appealing and well-liked by adolescents. The intervention had a transient effect of improving ICS adherence, asthma control, and quality of life. While our results are preliminary, they demonstrate that adolescent control and customization

enhance the acceptability of texting interventions and may prove to be useful in improving adherence.

Authors' Note

CMSText, the funding agency, had no involvement in collection, analysis, or interpretation of the data; writing of the report; or decision to submit this article for publication.

Author Contributions

MTB: Conception, design, drafting of the manuscript, critical revision, statistical expertise, and administrative, technical, and material support;

JMR: Design, acquisition of data, drafting of the manuscript, statistical expertise and critical revision.

CMD: Design, acquisition of data, drafting of the manuscript and critical revision.

TLB: Drafting of the manuscript, critical revision, and statistical expertise.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: CMSText provided technical support for the text messaging program and subject reimbursement.

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