Improving Asthma Outcomes and Self-management Behaviors of Inner-city Children

A Randomized Trial of the Health Buddy Interactive Device and an Asthma Diary

Sylvia Guendelman, PhD; Kelley Meade, MD; Mindy Benson, PNP; Ying Qing Chen, PhD; Steven Samuels, PhD

Background: Asthma is an important cause of morbidity, absence from school, and use of health services among children. Computer-based educational programs can be designed to enhance children's self-management skills and to reduce adverse outcomes.

Objective: To assess the effectiveness of an interactive device programmed for the management of pediatric asthma.

Design: A randomized controlled trial (66 participants were in the intervention group and 68 were in the control group).

Setting: Interventions conducted at home and in an outpatient hospital clinic.

Participants: Inner-city children aged 8 to 16 years diagnosed as having asthma by a physician.

Intervention: An asthma self-management and education program, the Health Buddy, designed to enable children to assess and monitor their asthma symptoms and quality of life and to transmit this information to health care providers (physicians, nurses, or other case managers) through a secure Web site. Control group participants used an asthma diary.

Main Outcome Measures: Any limitation in activity was the primary outcome. Secondary outcomes included perceived asthma symptoms, absence from school, any peak flow reading in the yellow or red zone, and use of health services.

Results: After adjusting for covariates, the odds of having any limitation in activity during the 90-day trial were significantly (P = .03) lower for children randomized to the Health Buddy. The intervention group also was significantly (P = .01) less likely to report peak flow readings in the yellow or red zone or to make urgent calls to the hospital (P = .05). Self-care behaviors, which were important correlates of asthma outcomes, also improved far more for the intervention group.

Conclusion: Compared with the asthma diary, monitoring asthma symptoms and functional status with the Health Buddy increases self-management skills and improves asthma outcomes.

Arch Pediatr Adolesc Med. 2002;156:114-120
PARTICIPANTS AND METHODS

SAMPLE AND STUDY PROTOCOL

A randomized controlled trial of a computerized interactive asthma self-management and education program, the Health Buddy, was conducted in the primary care clinic at Children’s Hospital Oakland, Oakland, Calif. This clinic is a comprehensive pediatric health center and resident teaching facility that serves a predominantly Medicaid-insured population. Children were eligible for inclusion in the study if they were between the ages of 8 and 16 years, had an English-speaking caregiver, had a telephone at home, and were diagnosed as having persistent asthma following NHLBI clinical practice guidelines. Patients with 2 or more emergency department (ED) visits and/or at least 1 inpatient admission during the year before the study were identified for possible recruitment through hospital administrative lists. All other children were recruited at the time of their scheduled clinic appointment for either a health care maintenance or an illness visit, including asthma. Patient lists were reviewed the day before the clinic appointment, and all children with asthma as the reason for the visit were screened for study eligibility. Potential recruits were also referred by the attending physicians at the hospital.

Patients were excluded if they were involved in other asthma or drug efficacy studies, if they were involved in research that required behavior modification, or if they had mental or physical challenges that made it difficult to use the Health Buddy. Children with comorbid conditions that could affect their quality of life were also excluded.

Approximately 500 children aged 8 to 16 years attending the clinic had asthma, not necessarily persistently. A screening tool that included the criteria previously described was used, and 136 children identified as eligible were approached for participation in the study between April 8, 1999, and July 5, 2000. Families were told that the purpose of the study was to find out if keeping track of asthma symptoms at home would help the families and physicians to manage the child’s asthma better and that 2 methods of keeping track were being evaluated. The nurse coordinator (M.B.) obtained informed consent for 134 children and their parents or legal guardians. Two families declined to participate because of time constraints.

After consent was given, the nurse conducted a standardized teaching session in which each participating child was given a peak flow measuring device and instructed on proper technique and how to establish his or her personal best. In addition, this teaching session also covered green-yellow-red zone determination and the appropriate use of medications and of health care services. Subsequently, the nurse coordinator administered the baseline questionnaire to the child and the accompanying family member, and gave each family a $20 incentive for completing the interview. Following the interview, the nurse opened a sealed envelope containing the treatment assignment and children were randomized to either the intervention (n=66) or the control (n=68) group and given instructions on how to use the assigned tracking method to record their peak flow readings and symptoms. (Sample size calculations were based on a comparison of 2 management approaches by Lieu et al., who observed mean numbers of episodes of children’s cough and other asthma symptoms in the previous 2 months of 2.43 for intensively treated children and 3.08 for controls, with a pooled SD of 1.25. To detect a similar difference with 85% power, a 2-sided 2-sample t-test requires 67 subjects per group.)

INTERVENTION

The Health Buddy is a personal and interactive communication device developed by Health Hero Network, Mountain View, Calif. The device is connected to a home telephone and can be programmed to present questions and information on a screen and to record responses. The nurse coordinator sends a set of queries each day using a standard Internet browser. The patient answers the queries, called dialogues, by pressing 1 of 4 buttons. The device automatically telephones a data processing center at night, which processes the responses and publishes them to a secure Web site the next day, from which the nurse coordinator reviews the information. Three of us (S.G., K.M., and M.B.) developed a protocol with a team of software programmers and asthma specialists at Health Hero Network. Following the NHLBI clinical practice guidelines, the protocol consisted of 10 questions about asthma symptoms, peak flow readings, use of medications and of health services, and functional status, such as school attendance and activity limitations. Each answer to a question received immediate feedback from the device: praise for a correct answer or encouragement to try again. In addition to the core immutable questions, asthma facts and trivia questions, which changed daily, were included to peak children’s curiosity and enhance learning. The dialogues were designed for a third-grade reading level. The following excerpt illustrates the dialogue between the child and the Health Buddy:

Hi! Thanks for hanging out with your Health Buddy today. Your questions are now ready for you.

Do you know how much a McDonald’s hamburger cost in 1963? (Trivia)

Have you had any coughing or wheezing in the last day?

If child answers Yes:

This could be a sign that your asthma is acting up. You may need to take your Albuterol as directed by your doctor when you are coughing and wheezing.

If No:

That’s great! You must be taking your preventor [sic] medicine.

Did you miss out on any sports, exercise, or play yesterday because of your asthma?

If child answers Yes:

Sorry to hear you missed out on some fun. If your asthma acts up while doing sports, exercise, or play, please talk to your doctor about this. It is important to know what activities might trigger your asthma.

If No:

That’s fantastic! Sports and exercise are fun and healthy.

Continued on next page

Several self-management programs that seek to enhance the child’s and the family’s efficacy in asthma care have been developed. While education programs delivered to parents and children by health professionals in health care settings can improve asthma management skills, these programs often imply large expenditures of staff time and operational challenges. Furthermore, life strains and health care access barriers refrain many poor
By protocol, children had to access the device once a day, preferably at a regular time. The children were encouraged to access and interact with the Health Buddy on their own. Parents were instructed on its use at the first visit and requested to be available to supervise its use only when the child indicated a need for help. Before implementation, the protocol was piloted among children of comparable age to the study children, but of higher socioeconomic status.

The comparison method for monitoring symptoms was a standard asthma diary. The diary allowed patients to log their symptoms and to monitor peak flow, medication use, and restricted activity.

Families whose children were assigned to the Health Buddy were given a demonstration on how to use the device and explained how to install it at home. The nurse coordinator called those families who—because they had not installed the device properly—were not transmitting information through the Web to review the installation instructions. No further telephone contact was established with the participants other than to schedule follow-up appointments. All children were asked to return for 2 follow-up visits at 6 and 12 weeks. At each follow-up visit, families were interviewed by the nurse coordinator and given a standardized teaching session that reinforced peak flow measurement, compliance with medicines, and tracking of symptoms. Families received a participation incentive, and children were asked to hand in their health diaries. They were also examined by a physician. Medical management remained at the discretion of the physician and followed NHLBI guidelines. Because all participants were diagnosed as having persistent asthma before the study, they were prescribed a daily prevention medication and a quick-relief medication to use as needed, and were requested to measure peak flows. Treatment regimens were kept constant between visits and changed at the follow-up visits only if there was a significant deterioration or improvement in asthma symptoms.

MEASURES

The measures for this study were obtained from the interviews that the nurse coordinator conducted with the child and the primary caregiver at each visit. The questionnaire was designed according to well-validated instruments. The self-reported information at the follow-up visits was validated against the nurse’s knowledge of the patients and assisted by a medical record review at the time of the visit.

The primary outcome measure was limitation in activity, which referred to the occurrence of restricted physical activity, such as exercise or play, due to asthma. This measure has been a valid indicator of functional status in other studies.

Secondary outcome measures consisted of other self-reported perceived asthma symptoms in the 14 days before the interview, any missed school days because of asthma in the 6 weeks before the interview, any peak flow reading in the red or yellow zone in the 14 days before the interview, and use of health services because of asthma in the past 6 weeks. The symptom indicators included the occurrence of chest tightness, coughing, shortness of breath or wheezing, and trouble sleeping at night as a result of coughing or wheezing. Peak flow readings in the yellow or red zone were based on the best of 3 readings obtained by the patient on the peak flow meter, a measure of the maximum flow rate that can be generated during a forced expiratory maneuver. Although peak flow meters are criticized because they tend to measure the amount of obstruction in the larger airways only, and often compliance with its use is low, they provide the only readily available objective means of patient monitoring at home. Peak flow readings in the yellow zone (50%-80% of the personal best) indicated that the child’s asthma was not under sufficient control and required additional medication. Readings in the red zone (<50% of the personal best) signaled a severe asthma exacerbation. Children were instructed to take daily peak flow measurements and to record them in their diary.

Use of health services was measured by the presence of hospital admissions, ER visits, or urgent calls to the hospital.

Self-care behaviors assessed the degree of compliance with prescribed medications and with the use of the Health Buddy or asthma diary, as appraised by the main caregiver. These self-care behaviors, along with the asthma outcomes and demographic characteristics, were assessed through a 30-minute questionnaire consisting predominantly of close-ended questions. The questionnaires were administered at baseline and at the 2 follow-up visits at 6 and 12 weeks. In addition, tracking with the Health Buddy or asthma diary was recorded by each child. At baseline, children were classified according to NHLBI practice guidelines into mild persistent, moderate persistent, or severe persistent asthmatic categories. These levels of asthma severity are based on symptom frequency and severity, exercise tolerance, ER visits, hospitalizations, and current medications.

DATA ANALYSIS

χ² Tests, Fisher exact tests, and 2-sample t tests were used to compare the 2 study groups for demographic characteristics (at baseline), asthma outcomes, and self-care behaviors at baseline and at the 2 follow-up visits. Logistic regression was used to model the main effects of treatment. The results with P<.05 were justified as significant. Because observations at the 2 follow-up visits were not independent, the technique of generalized estimating equations was used to estimate treatment effects. For each outcome, the baseline results, the asthma severity score, and the visit were included as covariates. The effect is presented as the intervention odds ratio, which is the ratio of odds of an outcome in the Health Buddy group to the odds of the same outcome in the asthma diary group, adjusted for visit, baseline responses, and asthma severity. A generalized estimating equation was also used to evaluate the effects of self-care behaviors on selected asthma outcomes, adjusted for visit, other behaviors, and treatment effects. Interaction terms between treatment and time were evaluated for all outcomes. Missing data were handled by assuming missing at random.

©2002 American Medical Association. All rights reserved.

Downloaded From: http://archpedi.jamanetwork.com/pdfaccess.ashx?url=/data/journals/peds/4690/ on 06/16/2017

families from participating in teaching sessions and finding the time and resources required to manage asthma.

More recently, interactive computer-based educational programs, such as Asthma Command and Asthma Control, have appeared. Unlike traditional methods, these programs do not rely on the interaction between the child and a health professional. Randomized trials of these software programs in clinic settings have
demonstrated mixed results in their ability to affect asthma management behaviors.

Another approach, the use of interactive health communication devices, through its information and decision support, has the potential to change behaviors and thereby improve patient quality of life and reduce the burden of illness. These devices work on the premise that the best method of affecting behaviors is to learn specific behaviors in a safe and stimulating environment while trying them out in a real environment.

We evaluated the efficacy of a new interactive device, the Health Buddy, programmed for the care of inner-city children with asthma (children were defined as those aged 8–16 years in this study). This home-based device monitors asthma symptoms, quality of life, and self-care, and sends information through a secured Web site to the health care provider (physicians, nurses, or other case managers). We postulated that by allowing children an opportunity to acquire knowledge about asthma and symptom recognition and receive immediate feedback on their decisions and behaviors, asthma symptoms among Health Buddy users would decrease. The continued use of the Health Buddy would also help to increase self-care behaviors, which in turn would reduce symptoms.

RESULT

The Health Buddy and asthma diary groups had similar demographic characteristics, illness history, home environment, and use of health services at baseline, as expected from the random assignment (Table 1). Follow-up of participants occurred similarly across all 4 seasons in the 2 groups. Ninety-six percent of the participants (63 in the Health Buddy group and 65 in the asthma diary group) returned for the first follow-up visit at 6 weeks and 91% (62 in the Health Buddy group and 60 in the asthma diary group) returned for the follow-up visit at 12 weeks. Reasons for dropping out of the study included moving out of the area (n = 3) or life crises experiences (n = 4). Five families who dropped out were unavailable for contact. Baseline characteristics of children who did and did not complete the trial did not differ.

Children in both arms of the study reported a decrease in asthma symptoms and a decrease in peak flow readings in the yellow or red zone at 6 and 12 weeks compared with baseline (Table 2). Although almost half of the children did not use a peak flow device at baseline, at the 6-week follow-up visit, 85% of the participants reported that they used it. Significantly fewer children randomized to the Health Buddy had peak flow readings in the yellow or red zone during the 14 days before the 6-week follow-up visit compared with children randomized to the asthma diary (P = .02).

After adjusting for time and baseline covariates, children in the Health Buddy group were less likely to report limitation in activities. Furthermore, the odds of having peak flow readings in the yellow or red zone were significantly lower for children randomized to the Health Buddy.

The use of health services did not vary significantly between the 2 groups, except for urgent calls. The odds of an urgent call with the Health Buddy was 0.43 of the odds of an urgent call with the asthma diary, after adjusting for time and baseline covariates (Table 3). No significant interactions between treatment and time were found for any outcome.

For self-care behaviors, at 12 weeks children with the Health Buddy were significantly more likely to take asthma medicines without reminders (P = .04) and to use the Health Buddy with few or no reminders (P = .001) (Table 4). These self-care behaviors were significant correlates of asthma outcomes after adjusting for treatment effects, time, and other self-care behaviors (data not shown). Children who always used the Health Buddy or the asthma diary without a reminder were significantly less likely to report coughing or wheezing (odds ratio, 0.70; 95% confidence interval, 0.50–0.90) and to use an oral corticosteroid (odds ratio, 0.50; 95% confidence interval, 0.30–0.80).

On average, during the 90-day trial period, 77% of the children used their tracking system 3 days a week or more (59 [89%] of the 66 children in the Health Buddy...
group vs 44 [65%] of the 68 children in the asthma diary group; \( P \leq 0.001 \). The daily compliance rates declined as time progressed for both treatment arms, but the decline was faster in the early stages of the intervention for the asthma diary group (\( P = 0.0004 \), data not shown). An analysis of time effects adjusted for treatment assignment (data not shown) indicated that asthma symptoms and use of health services declined markedly from one visit to the next for both groups.

We found no strong indication that the correlation between asthma diary and Health Buddy responses and interview responses differed between the 2 study groups. However, responses across visits seemed to be more stable for the Health Buddy group.

**COMMENT**

This randomized trial conducted in an inner-city ambulatory care clinic assessed the efficacy of the Health Buddy for self-management of persistent asthma in children. We compared the effects of this device, which is a nonintrusive interactive system that linked patients at home to the nurse coordinator, with the effects of the standard asthma diary.

One of the goals of asthma control is to be free of activity limitation. Children randomized to the Health Buddy had 48% lower odds of reporting a limitation in activity after adjusting for baseline response, asthma se-
verity, and time. Children randomized to the Health Buddy also had significantly lower odds of reporting a peak flow reading below 80% of their personal best (red or yellow zone) after adjusting for covariates. Despite missing data for this outcome, especially among children in the asthma diary group, the higher rate of children with peak flow readings remaining in the green zone among Health Buddy users is an indicator of improved control of asthma symptoms and improved response to anti-inflammatory therapy. Spirometry was not available for the study.

The percentage of children randomized to the Health Buddy who used the device was, until near the end of the study, much larger than the percentage of children who kept diaries. This leads to the following question: Was self-monitoring, per se, associated with improved outcomes? The analysis of this question does not benefit from randomization. Children who used the Health Buddy or asthma diaries with few or no reminders were far less likely to report coughing or wheezing and to have a limitation in activities.

Several children reported after the trial that they liked the Health Buddy because it was fun and it reminded them to take their medicines. In contrast, several children who received the asthma diary reported that they either lost it or forgot to log information in it. Many children who kept diaries reported that they had forgotten to take their medicines. These results occurred despite the decline in Health Buddy use and suggest that children with the Health Buddy device learned management skills that helped them to comply with their treatment and medication regimens.

The short duration of the trial and the small sample size did not yield marked group differences in the occurrence of ED visits or hospital admissions. However, after adjusting for time, asthma severity, and urgent calls before the baseline interview, the risk of urgent calls was twice as high for children assigned to the asthma diary group. This finding would suggest a weaker autonomy in the management of asthma for the child and the family assigned to the control arm of the study.

Despite the marked advantages of the Health Buddy monitoring system over the standard asthma diary, use in both groups declined as children approached the end of the trial. These declines probably reflect the anticipated end of the study, the lack of perceived additional benefit of monitoring, and, for Health Buddy users, saturation with the educational messages. This trend would suggest that the benefits of self-monitoring with a device like the Health Buddy might be especially strong at critical care management times (eg, at the start of care for asthma or after an acute asthma exacerbation, an ED visit, a hospitalization, or a step up in severity class).

Although asthma symptoms declined more for the Health Buddy group, symptoms also declined for the asthma diary group. This decline may have partly resulted from the consistent standardized asthma education given to children in both arms of the study and the availability of the nurse coordinator, which was a new intervention to the clinic. Furthermore, because this intervention took place shortly after dissemination of the revised NHLBI asthma guidelines, the findings may reflect enhanced care by the hospital staff resulting from adherence to these guidelines.

The results must be interpreted with caution given the study limitations. Despite the attempts by the nurse coordinator to check the self-reported data at each interview, there may have been some case ascertainment bias. Furthermore, children in the asthma diary group who filled out diaries retrospectively may have overstated compliance. In addition, some of the results were leaning toward significance, suggesting that there might have been a lack of power to detect significant differences because of a small sample size. Further research is needed to assess the effects of this device on the behavior of health care providers. At the time of the study, implementation graphs and other data outputs were not readily or consistently available for providers. The system now has the capacity to summarize longitudinally patient data on symptoms, health behaviors, and knowledge levels. Research is also warranted to evaluate individual differences in self-management skills, outcomes, and saturation points associated with Health Buddy use among minority children. A longer follow-up study could determine whether changes in asthma self-care behaviors and symp-

Table 4. Trial Period Comparisons of Self-management Behaviors*

<table>
<thead>
<tr>
<th>Compliance</th>
<th>Takes asthma medicine without a reminder</th>
<th>Reminded to use the Health Buddy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Health Buddy Group (n = 66)</td>
<td>Asthma Diary Group (n = 68)</td>
</tr>
<tr>
<td>Takes seldom or never</td>
<td>31 (47)</td>
<td>31 (46)</td>
</tr>
<tr>
<td>Takes most of the time</td>
<td>19 (29)</td>
<td>23 (34)</td>
</tr>
<tr>
<td>Takes all of the time</td>
<td>16 (24)</td>
<td>14 (21)</td>
</tr>
<tr>
<td>Missing data</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>All the time</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>Sometimes</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>Seldom</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>Never</td>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

*Data are given as number (percentage) of children (defined as those aged 8-16 years in this study). Percentages are based on totals within each category, and may not total 100 because of rounding. Ellipses indicate data not applicable.
Several programs that seek to enhance efficacy in self-management have been developed in asthma care. Randomized trials of computer-based educational programs conducted in clinic settings have demonstrated mixed results in their ability to affect asthma management behaviors. We evaluated the efficacy of a new home-based interactive health communication device, the Health Buddy, that was designed to enable children to assess and monitor their asthma symptoms and quality of life and to transmit this information to a case manager through a secure Web site. This study presents the results of a randomized, controlled, 90-day clinical trial of inner-city children with persistent asthma. Compared with children assigned to an asthma diary, children randomized to the Health Buddy were more likely to improve self-care behaviors and to reduce asthma symptoms, while making fewer urgent calls to the hospital, after adjusting for other factors. Easy-to-use Web-based devices such as the Health Buddy may be useful tools to empower children to provide their own care while reducing asthma symptoms and health care use in pediatric settings.

Accepted for publication October 18, 2001.

This study was supported in part by an unrestricted educational grant from Health Management Services, Merck & Co, Inc, Whitehouse Station, NJ.

We thank Scott Hambly and Mara Sanderson for their clerical support.

Corresponding author and reprints: Sylvia Guendelman, PhD, Division of Health Policy and Management, University of California, Berkeley, 404 Earl Warren Hall, 7360, Berkeley, CA 94720-7360 (e-mail: sylvig@uclink4.berkeley.edu).