

The talking card: Randomized controlled trial of a novel audio-recording tool for asthma control

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ABSTRACT

Background: Asthma care plans typically include complicated written instructions. Customized, audio-recorded instructions may bridge health literacy gaps and improve treatment plan understanding.

Objective: To measure the effects of a recordable greeting card-style tool (Talking Card) on asthma control and parental care of children with asthma.

Methods: Multisite randomized trial in two primary care clinics, including children 4–11 years old with uncontrolled asthma and their parents. Parent-child dyads were randomized to usual care of asthma or usual care plus the Talking Card. Dyads completed three asthma-focused visits over 3 months. At the visit, card recipients received customized instructions recorded by the pediatrician onto an audio chip in the card. Asthma control was measured by using the Childhood Asthma Control Test. Card use and parental satisfaction were measured by parental survey (card arm only). Outcomes were analyzed by using generalized estimating equations and frequency distributions.

Results: Sixty-four dyads participated and attended 166 clinic visits. Card use was associated with a 1.6-point increase in Childhood Asthma Control Test score ($p = 0.02$) and a clinic visit regardless of card use with a three-point increase ($p < 0.001$). Satisfaction and self-efficacy were high among the card users. The mean satisfaction score was 8.9 of 10, with 96% agreeing or strongly agreeing that the card helped them take better care of asthma.

Conclusions: The Talking Card, a novel audio communication tool, was associated with improved asthma control and deemed highly desirable by parents and children struggling to control asthma. This inexpensive portable tool may be useful in other chronic disorders and in locales with low literacy and poor access to digital technology.

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Health literacy is “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”¹ It includes reading, listening, analytical, and decision-making skills. Although reading skill is just one aspect of literacy, the predominance of written information in the health care system has led researchers to focus on a patient’s or parent’s ability to read information.^{2–4} An emerging alternative to enhancing health communication in-

volves multimedia materials, including text, audio, and visual imagery. These integrated materials take advantage of evidence from cognition and learning science that shows that comprehension, recall, and problem solving can be improved by engaging multiple senses.⁵ The creation of inexpensive, recordable audio cards by greeting card companies has introduced the possibility of providing customized audio information in the provider’s voice on a device that can be replayed without special equipment after a health visit. In addition to an audio chip, such cards include images and text, which allows three modes of communication to reinforce each other.

When treating asthma, providers must convey complicated information in an accurate, understandable way while providing a format that can be easily consulted in the home setting. Currently, the most widely used method involves the written asthma action plan, which organizes treatment instructions according to severity of asthma symptoms. Although the concept of the asthma action plan may be easily grasped, the detailed instructions can be confusing and difficult to remember. Asthma is an appropriate disease in which to study a recordable audio card because it is relatively common, has a standard of care that is widely accepted

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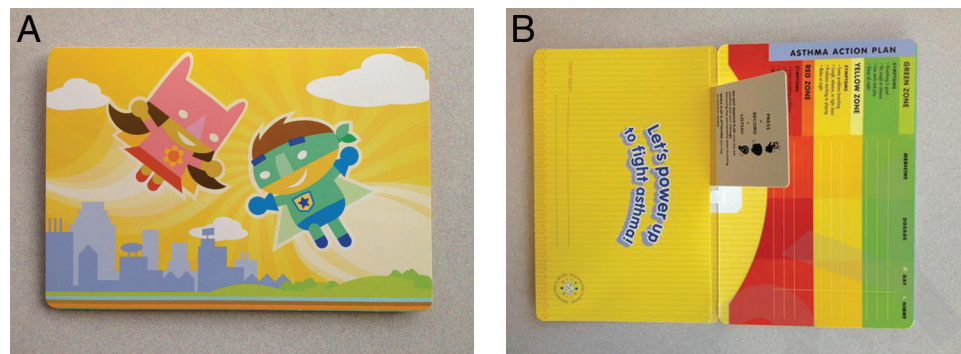


Figure 1. The Talking Card, front cover and inside views.

and applied, and has important measurable outcomes (e.g., asthma control scores, asthma attacks, emergency department use, hospitalization, death). Furthermore, poor asthma outcomes are associated with low socioeconomic status⁶ and low parental health literacy,^{7,8} which makes use of a self-contained, portable audio tool a potentially effective intervention for families with one or both of these characteristics.

The objective of this study was to measure the effects of a recordable greeting card–style asthma instruction tool (the Talking Card) on asthma control and a family's ability to care for children with asthma. We hypothesize that asthma control in children 4–11 years of age with uncontrolled asthma will improve to a greater extent among those receive and use a custom-recordable audio discharge instruction card than among those who receive only usual care.

PATIENTS AND METHODS

Study Design, Setting, and Dates

This randomized controlled study took place between July 2010 and September 2012 in two academic pediatric primary care clinics (Kansas City, MO, and Tampa, FL). Both clinics serve urban safety net populations, with a majority of patients either insured by Medicaid or uninsured (85–90% in Kansas City, 70–80% in Tampa). The protocol was approved by institutional review boards at Children's Mercy Hospital and the University of South Florida.

Participants

Children were recruited from existing study-site clinic populations through telephone calls to known patients with asthma (identified by using existing patient lists) and in-clinic invitation by providers. Inclusion criteria were the following: (1) child's age 4–11 years old, (2) English-speaking primary care giver and child, (3) diagnosis of asthma in the clinic medical record, (4) a visit to the study clinic for asthma within 12 months of study recruitment, and (5) a Childhood Asthma Control Test (cACT) score ≤ 19 (which indicates uncontrolled asthma). Subjects with limited Eng-

lish proficiency were not recruited for this pilot study because the prototype Talking Card is a factory-made product with preprinted and prerecorded audio information in English.

Exclusion criteria were the following: (1) a history of premature birth <33 weeks gestation or requirement of a significant level of respiratory care, including mechanical ventilation as a neonate; (2) any major chronic illness or other conditions that would interfere with participation in the study; (3) a visit to any provider who gave asthma action plan advice during the previous month; and (4) anticipated departure from the study area before the study period ended.

Study Intervention

An audio-recordable greeting-card style asthma instruction tool, called the Talking Card, was designed specifically for this study in partnership with a greeting card company. The cover of the card included a colorful cartoon graphic of two child superheroes flying above a stylized cityscape (Fig. 1). The inside of the front flap showed a colored, simplified asthma action plan template with blank medication lines for the physician to fill in. The inside page included the message, "Let's power up to fight asthma!," a button for playing the audio recording, and an area for writing comments and next appointment information (Fig. 1). The front flap included a pocket for folded documents (e.g., detailed asthma action plan). The audio chip was divided into two parts, one part was a prerecorded message in the voices of the superheroes encouraging the child to "knock out asthma" by remembering to "take your medicine every day, even when you feel great!" This was followed by a customizable recording space of 40 seconds to be used by the physician at the time of the study visits.

Study Procedure

Visit 1 (baseline). On acceptance of the study invitation, parent-child dyads were scheduled for an initial clinic visit, which included preenrollment screening by study coordinators by using the inclusion and exclu-

sion criteria mentioned above. Dyads also completed a baseline cACT. After obtaining signed consent from the caregiver and assent from the child, dyads were randomized into two study arms (usual care and usual care plus the Talking Card). Randomization was done by using sealed envelopes that contained a random sequence of study arm assignments prepared before the study. An envelope was given to the study physician who then completed an asthma-focused visit, including evaluation and treatment planning. The physician opened the envelope at the end of the visit so that the initial evaluation and planning would not be influenced by study arm assignment.

For dyads assigned to usual care, standard discharge instructions were provided, including a printed asthma action plan. For those assigned to the Talking Card arm, the physician recorded a personalized message, including points of emphasis specific to the child, and completed the simplified asthma action plan on the inside of the card. Recordings did not include the entire asthma action plan but were tailored to areas of particular challenge for the child and/or family. A typical recorded message would reinforce specific trigger avoidance and encourage the child to take daily medications in the specific dose and frequency prescribed. Recordings were played back to be sure that the dyad understood the message and how to use the card. Standard discharge instructions, including a detailed asthma action plan, were folded and tucked into the pocket inside the card. Before leaving the clinic, each dyad received a \$20 gift card to a local store and visit 2 was scheduled for 1 month after visit 1.

Visits 2 and 3. Dyads completed the cACT on arrival to visit 2, and those in the Talking Card arm completed a survey on card use and family satisfaction with the card. The study physician completed a second asthma evaluation and treatment planning session. Those in the Talking Card arm exchanged their old card for a new one with updated instructions and customized provider recording. Visit 3 was scheduled for 2 months after visit 2 and was identical to it in procedure. All dyads received a Talking Card at the end of visit 3 (study's end). Dyads stayed with the same physician throughout, and each physician saw patients in both arms.

Measures

Asthma Control. The cACT is a validated questionnaire demonstrated to be helpful in ambulatory assessment and monitoring of asthma control.⁹ It consists of seven self-reported symptom scores, four completed by the child, and three by the parent. The maximum score is 27, and a lack of asthma control is indicated by a score of ≤ 19 .

Card Use and Family Satisfaction. The study team designed a 15-item survey to measure participants' use and impressions of the Talking Card. Four items related to the amount and purpose of card use and whether the family still had the card. Nine items asked about ease of use, attractiveness, elements of the card (audio, images, written material), how the card affected their ability to care for the child's asthma, and whether the family would like to receive similar cards in the future. Two open-ended questions captured comments and suggestions.

Analysis

The relationship of Talking Card receipt to the cACT score across multiple visits was measured by using a generalized estimating equation with robust standard errors (Huber-White sandwich estimator).^{10,11} Variables in the generalized estimating equation included the cACT score (baseline), study arm, and clinic visit number (two to three per child, including a baseline). The subjects with a baseline visit only were not included. Age was not used in the final analysis due to a lack of correlation with the cACT score and a lack of significance in regressions. Stata version 12.1 was used for all statistical analyses (Stata Release 12.0, 2011; StataCorp, College Station, TX). A population-averaged generalized estimating equation was estimated with Stata 12.1 defaults: identity link, family Gaussian, and correlation exchangeable. The statistical routine adjusted for censored data, which allows all subjects with two or three visits to be included. Survey responses were summarized by using descriptive statistics.

The original study design involved subjects in Kansas City only. Power calculations determined the smallest sample size required to demonstrate cACT score changes of 0.50 standard deviations (moderate-to-large effect size).¹¹ By using a power of 0.80, $\alpha = 0.05$ and a 20% assumed loss to follow-up, the analysis indicated that 15 subjects in each study arm and 90 total observations would be adequate. An opportunity arose 2 months into the study to accrue additional subjects in Tampa, FL. Because no statistically significant differences were found between subjects and study groups at the two sites, the analysis that follows includes a combined sample.

RESULTS

Sixty-four child-parent dyads participated; they attended 166 clinic visits (54 completed two visits, 48 completed three visits) (Fig. 2; Table 1).

Asthma Control

Baseline cACT scores did not differ between study sites ($p = 1.00$) or study arms ($p = 0.31$). Talking Card

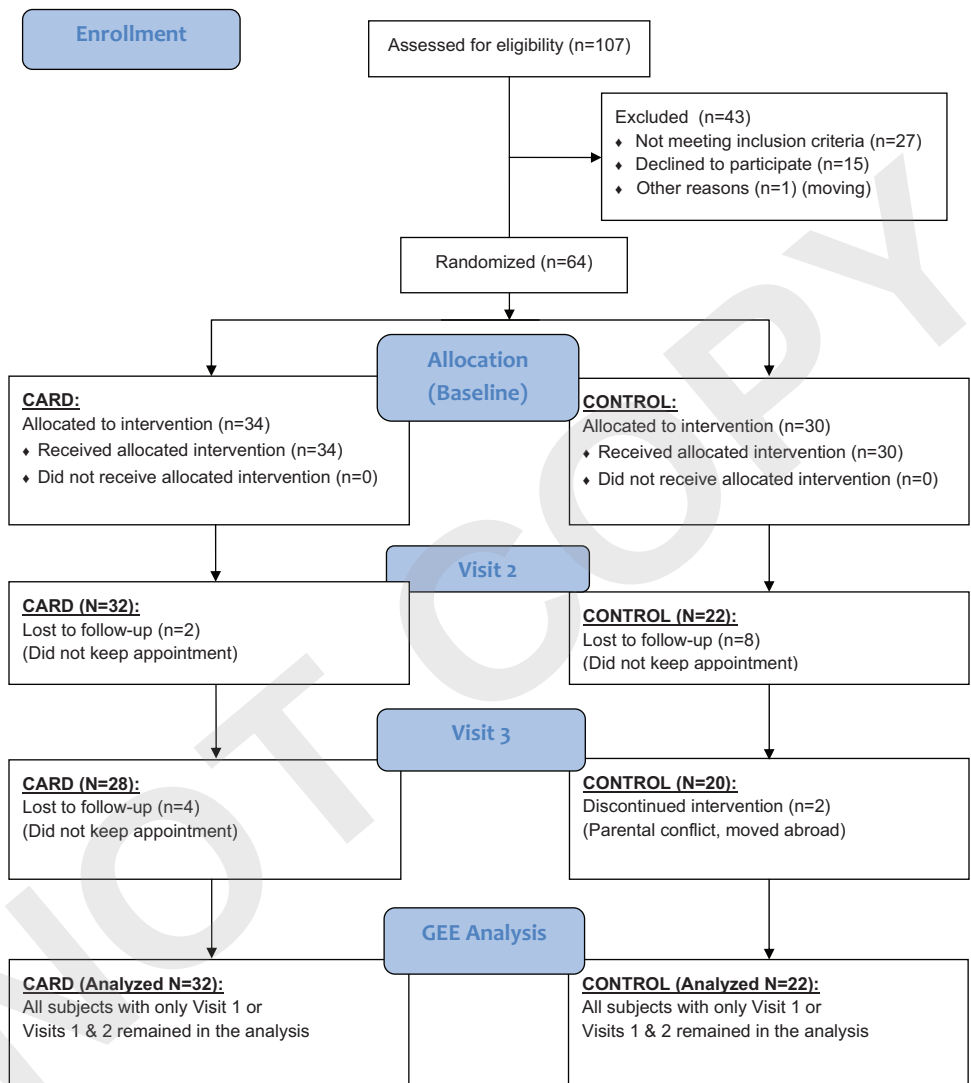


Figure 2. CONSORT (Consolidated Standards Of Reporting Trials) flow diagram.

Table 1 Accrual of subjects into card and no card groups at the two study sites

Visit No.	Kansas City			Tampa			Grand Total
	No Card	Card	Total	No Card	Card	Total	
1	18	16	34	12	18	30	64
2	14	14	28	8	18	26	54
3	13	13	26	7	15	22	48
Total	45	43	88	27	51	78	166

use was associated with a 1.6-point increase in cACT score (95% confidence interval, 0.13–3.06; $p = 0.02$). Having a clinic visit regardless of card use was associated with a cACT increase of 3.0 points (95% confidence interval, 2.28–3.64; $p < 0.0001$). A clinic visit with card use led to an average increase of 4.6 points.

Card Use and Parental Impressions

Responses from the survey of card use and parental impressions are summarized in Table 2. Parents found

the card attractive and reported high satisfaction and self-efficacy related to card use. All the respondents found the card easy to use. The mean overall satisfaction score was 8.9 of 10. Ninety-four percent agreed or strongly agreed that the card helped them take better care of asthma, and 98% would like to continue receiving Talking Cards for asthma and other conditions. Among those who believed that the card helped them take better care of their children's asthma ($N = 49$), all thought that the audio recording helped, either alone

Table 2 Responses to card use and parent impression survey

Question	Visits 2 and 3*
Played the card at home	56/60 (93%)
Times played at home	
1–5	11/56 (20%)
6–10	9/56 (16%)
11–15	7/56 (13%)
16–20	12/56 (21%)
>20	17/56 (30%)
Why was the card played	
For fun or curiosity	8/56 (14%)
For asthma instructions	9/56 (16%)
Both	39/56 (70%)
Easy to use#	56/56 (100%)
Attractive appearance#	50/56 (89%)
Information hard to hear#	16/56 (29%)
Information made sense#	51/51 (100%)
Helped me take better care of asthma#	49/52 (94%)
Written information alone§	0/49 (0%)
Written with recorded information	9/49 (18%)
Pictures alone	0/49 (0%)
Pictures with recorded information	5/49 (10%)
Recorded information alone	26/49 (53%)
All elements of the card	9/49 (18%)
Helped me remember next appointment#	21/52 (40%)
Would like to keep receiving cards for asthma care#	51/52 (98%)
Would like to receive similar cards for other health issues#	51/52 (98%)
Overall satisfaction with card, mean (standard deviation)	8.9 ± 1.8

*Denominator varies because some respondents did not answer all the questions.

#Agreed or strongly agreed.

§For respondents who agreed or strongly agreed that the card helped them take better care of their child's asthma, list of single or combined card elements that helped.

or in combination with written information and pictures. No respondents indicated that only written information or pictures helped.

DISCUSSION

Use of the Talking Card, a novel health communication tool, was associated with an improvement in asthma control and a strongly positive reception by families of children with uncontrolled asthma. The magnitude of asthma improvement (a 1.6 point in-

crease on the cACT) must be judged by whether it represents a minimally important difference (MID). Voorend-van Bergen *et al.*¹² recently calculated an MID for the cACT of 1.6 points, based on an asthma quality-of-life measure, but suggested using an MID of 2.0 points (presumably because the cACT scale consists of whole numbers). The point estimate in this study, then, meets the MID for the cACT, and, when added to the effect of making a clinic visit (4.6 points for a visit with the card), represents a notable increase in control.

At a time when innovation in health communication has focused on the smartphone, texting, and computer-based interventions,^{13–17} there remains a need to innovate in alternative ways for those who lack access to digital technologies or the propensity to use them. The combination of customizable audio instruction and a tangible, attractive greeting card format provides a variation on multimedia communication that is affordable and flexible.

The Talking Card includes a combination of features that differentiate it from both traditional printed instructions and newer digital interventions: (1) replayable with customized audio instructions directed specifically to the patient; (2) attractive, professional greeting card design; and (3) tactile physical format (as opposed to electronic, screen-based format).

Currently, it is common practice for health care providers to send only printed instructions home with families. Having the provider's voice available on an audio chip in a card with specific instructions and encouragement provides support for families struggling to understand complicated text and imagery. Unlike printed materials designed by health care providers and their teams, the Talking Card was designed by greeting card company professionals with decades of experience in connecting through imagery and design. Finally, despite the rush to create electronic-based education materials, results of studies have shown that comprehension and retention from reading electronics-based text may not be as good as with paper-based text.^{18–20}

An advantage of the multimedia format embodied in the Talking Card is the delivery of information in three forms: text, imagery, and sound. Evidence from the education and asthma literature indicates that, instead of focusing on specific learning styles for a given individual (*e.g.*, visual, auditory, kinesthetic), educators should integrate multiple modes of information (audio, video, text, manipulated materials) for all learners.^{5,21,22} The design of the Talking Card uses this approach, with each of three modes reinforcing the others.

The Talking Card may be especially well suited for use when little audio communication infrastructure exists and when there is low literacy. Portability and flexibility, and low relative cost compared with inter-

ventions that rely on Internet systems and smartphone or computer ownership, make the Talking Card a promising option in communities and countries with low health literacy and limited resources.

The strengths of this pilot study include its randomized, partially blinded methodology, use of a validated asthma control outcome measure (cACT), and inclusion of secondary card usability outcomes. The partially blinded methodology is also a limitation because study physicians might unconsciously have changed their education in favor of the treatment arm during visit 2. Other limitations include the small sample size, which prohibited subgroup analysis (*e.g.*, reactions of younger versus older children). This study included children with uncontrolled asthma only and did not survey participants in the usual care group about their opinions of usual discharge instructions. A larger study, including children in and out of asthma control, with a comparison of self-efficacy between caregiver groups (intervention and usual care) would be helpful in further describing the benefits of the Talking Card. A larger, longer-term study also would allow for a variety of important outcomes, such as emergency department use, hospitalization, other measures of asthma control, and health care expenses.

CONCLUSIONS

The Talking Card, a novel audio communication tool, led to improvement in asthma control and was deemed highly desirable by parents and children struggling to control asthma. Although this pilot study was limited in size and length of observation period, the results indicate that this inexpensive, portable tool may be useful for multiple chronic conditions and in areas with low literacy and poor access to technology.

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