

A randomized controlled trial of a mobile application-assisted nurse-led model used to improve treatment outcomes in children with asthma

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Abstract

Aim: To evaluate the effectiveness of a mobile application-assisted nurse-led management model in childhood asthma.

Background: Studies have shown that a nurse-led asthma management model can improve asthma outcomes. However, the role of a mobile application-assisted nurse-led model in paediatric asthma management has not been studied well.

Design: A multi-centre randomized clinical trial.

Methods: The trial was conducted between March 2017–March 2018. A total of 152 children (6 to 11.9 years old) were enrolled, with 77 children in the experimental group and 75 in the control group. All children received nurse-led asthma management and other routine treatment measures, including inhaled corticosteroids. Meanwhile, a mobile application was used to manage asthma only for children in the experimental group. Primary outcome was frequency of asthma exacerbations. All outcomes were evaluated twice a month for 12 months.

Results: Compared with the pre-enrollment period, frequency of asthma exacerbations decreased in the post-enrollment period in the two groups, with a greater decrease in the experimental group. Compared with children in the control group, children in the experimental group had better secondary outcomes, such as improved adherence, higher Childhood Asthma Control Test scores, decreased respiratory tract infections, days of antibiotic use, days of school absence, parental work loss, and medical expenses.

Conclusion: A mobile application-assisted nurse-led management model decreased asthma exacerbations and improved secondary outcomes in children with asthma. Further research is needed to verify its validity in larger population samples.

Impact: Children with asthma benefited from a nurse-led asthma management model when combined with mobile application. This trial suggested that computer

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and Internet technologies should be incorporated into nurse-led asthma strategy in paediatric asthma management.

Trial registration: The current trial was registered online with the Chinese Clinical Trial Registry (registration number: ChiCTR1800016726).

KEYWORDS

adherence, asthma management, childhood, exacerbation, management strategy, mobile phone, model, nurse, self-management, software application

1 | INTRODUCTION

Asthma is one of the most common chronic paediatric respiratory diseases (Global Initiative for Asthma, 2017), with increased prevalence in the past decades (Ding & Small, 2018; Global Initiative for Asthma, 2017; Guo et al., 2018). The main presentations of asthma include recurrent wheezing, cough, shortness of breath, and chest tightness. For children, frequent asthma exacerbations could cause decreased physical activity, missed school days, impaired growth and development, and gradually declining pulmonary function (Global Initiative for Asthma, 2017; McGeachie et al., 2016; Sullivan et al., 2018). Parents of asthmatic children may be affected by more work loss, higher medical expenses, and greater parenting pressures (Sullivan et al., 2017, 2018). Even with more accurate diagnosis and prompt treatments including corticosteroids, asthma exacerbations and its adverse outcomes are still major problems in clinical practice (Ding & Small, 2018; Global Initiative for Asthma, 2017). Given the global asthma burden, efforts to improve asthma outcomes and reduce economic and social consequences are important.

1.1 | Background

Asthma requires long-term monitoring and treatments. Previous studies have demonstrated that the quality of asthma care provided by specially trained asthma nurses (nurse-led asthma care) was equal to that provided by physicians, with an additional advantage of reducing medical expenses (Kamps et al., 2004; Kuethe, Vaessen-Verberne, Elbers, & Van Aalderen, 2013). Studies also showed that appropriate asthma management measures to ensure patient treatment adherence could significantly improve clinical outcomes for children with asthma (Farzandipour, Nabovati, Sharif, Arani, & Anvari, 2017; Global Initiative for Asthma, 2017; Morton et al., 2017). Computer and internet applications are more frequently applied in health care these days and asthma management programs adopting technological interventions to encourage patient engagement could improve asthma management (Arnold, Stingone, & Claudio, 2012; Katwa & Rivera, 2018; Morita et al., 2019; Trivedi, 2015; Voorend-van Bergen et al., 2015). With the popularity of smartphones in recent years, people's interest in whether children with asthma could benefit from a nurse-led asthma management model when combined with a mobile application has increased.

We developed a nurse-led asthma care model similar to those reported before (Xu et al., 2017). Every child would be followed and monitored by a nurse in local hospitals or community healthcare centres for treatment adherence. We also developed a software program that could be used in a mobile smartphone and/or desktop computer to assist with asthma management. Specifically, we focused on the relationship between mobile application usage and a range of disease, life style, and economic outcomes. Here, we report the results of applying this mobile application-assisted nurse-led management model in paediatric asthma management.

2 | THE STUDY

2.1 | Aim

To evaluate the effectiveness of a mobile application-assisted nurse-led management model in children with asthma.

2.2 | Hypothesis

A mobile application-assisted nurse-led management model will improve both asthma management and disease-driven outcomes in children.

2.3 | Study design

We performed a multi-centre randomized clinical trial in two community healthcare centres and two hospitals between March 2017 and March 2018. The CONSORT flow chart is shown in Figure 1.

2.4 | Participants

A total of 152 children with asthma were enrolled in the study, with 77 children in the experimental group and 75 in the control group. Participants were enrolled from four clinical centres in Jinhua City, located in the southeastern part of China, of which two were tertiary hospitals and the others were community healthcare centres. All participants were Han Chinese. Inclusion criteria were: (a) Age between 6 and 12 years old; (b) medical history, symptoms and signs consistent with the diagnosis of asthma (Global Initiative for Asthma, 2017); (c) positive asthma predictive

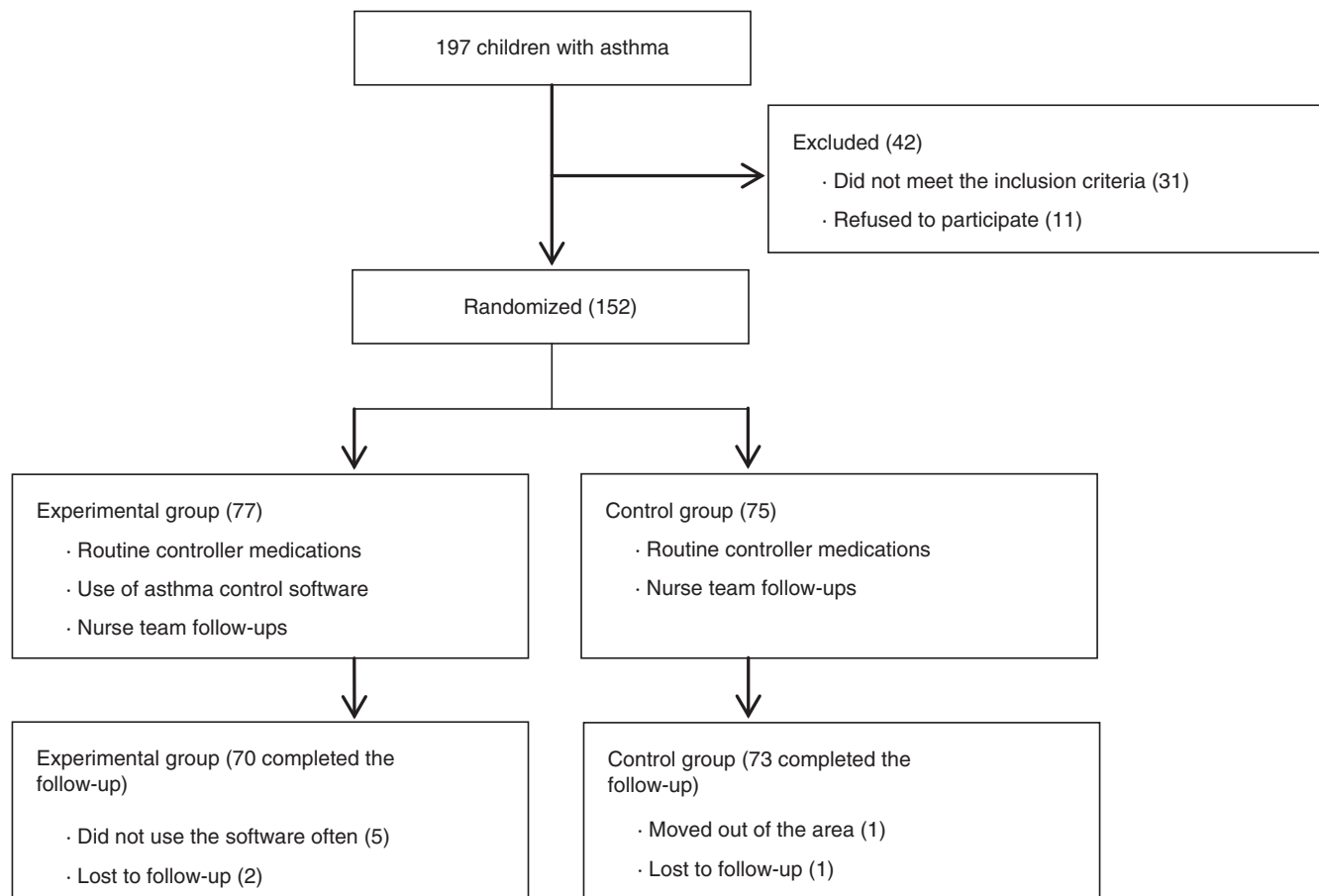


FIGURE 1 CONSORT flow chart

index (API) (Global Initiative for Asthma, 2017); (d) willingness and ability to correctly use an inhaler; (e) possession of a smartphone and ability to use the mobile application; and (f) ability to correctly use the Childhood Asthma Control Test (C-ACT) (Liu et al., 2007). Exclusion criteria were: (a) severe asthma exacerbation at the time of enrollment; (b) currently suffering from concurrent acute or chronic rhinosinusitis, obstructive sleep apnea, or rheumatic diseases; (c) co-morbidities including bronchopulmonary dysplasia, bronchiectasis, tracheal or bronchial malacia, obliterative bronchiolitis, diffuse panbronchiolitis, or tuberculosis; and (d) diagnosed primary immunodeficiency. Patients were deemed ineligible for enrollment if they had a history of those diseases mentioned in the exclusion criteria. Laboratory and other relevant examinations would be implemented if physicians could not exclude the possible diseases through review of the medical history and physical examination.

2.5 | Interventions

After the informed consent process, children were randomized into either the experimental group (mobile application + nurse-led) or the control group (nurse-led). Randomization was performed with a random number table, with odd numbers assigned to the experimental group and even numbers assigned to the control group.

Most of the children in the two groups received the fluticasone propionate inhaled aerosol. For those who required long-term inhaled corticosteroids together with long-acting β_2 -agonist, a salmeterol-fluticasone dry powder inhaler was prescribed. Treatment was stepped down by the participant's physician when asthma symptoms had been well-controlled for three or more months.

We developed computer software for use in desktop computers and on Android smartphones. The software included the following basic modules: medication reminder, adherence management, alert of acute asthma exacerbations, assessment of exacerbation severity, treatment recommendation, keeping a health diary, instant communication with healthcare providers and health education. This software application was installed in the smartphones of children or parents in the experimental group and on desktop computers in the healthcare centres. All the information input into the smartphone software application was transmitted to the desktop computers in the healthcare centres, which could be monitored by designated nurse staff. The electronic application collected demographic data such as name, gender, age, address, phone number, medical history and any text messages sent by the patients via the application.

Children in the two groups visited their paediatricians at four hospitals once a month for a total of 12 months. Asthma assessment, routine examination, adjustment of medications if needed,

and health education were performed at each visit. Two weeks after each visit, the designated nurses would call their parents to review asthma status and obtain health information, which included symptoms, current medications, control of asthma exacerbations, C-ACT scores, treatment adherence, and medical expenses. Additionally, during every phone call, nurses reminded parents in the experimental group to use the mobile application and record their children's health information into the application. In addition to clinic visits and phone call follow-ups, nurses and physicians input the children's medical history into the mobile application, reviewed the information patients recorded every day and answered questions via the software application for parents in the experimental group.

2.6 | Outcome measurements

The primary outcome was the frequency of asthma exacerbations during the study period. Secondary outcomes included treatment adherence, C-ACT scores, number of respiratory infections, days of antibiotic use, requirements for oral steroid intake, days of school absence, days of parental work loss and medical expenses, which were obtained from electronic medical history systems, mobile application we developed and paper forms of outpatient medical records. The medical history before enrollment in this study was obtained retrospectively: disease duration, asthma severity, and number of asthma exacerbations in the past year. Treatment adherence was calculated as (the total number of days taking ICS over a year/365) $\times$ 100. C-ACT was first proposed by Liu et al. and was used to evaluate asthma management in children aged 4–11 years old (Liu et al., 2007). This test method is simple, easy to use and reproducible and has been widely accepted in clinical practice (Arakawa et al., 2017; Global Initiative for Asthma, 2017; Papadopoulos et al., 2012). The amount of medical expenses, calculated according to medical invoices, was the total expenses in one year, which included two parts: the out-of-pocket expenses and the reimbursement. Patients only need to pay the former and the latter will be returned to the hospitals from the medical insurance bureau.

2.7 | Ethical considerations

The current study was approved by the ethics committee in each study centre and was registered online at the Chinese Clinical Trial Registry (registration number ChiCTR1800016726). Informed consent was obtained from the parents or healthcare proxies. For children 10 years of age or younger, their parents were asked to sign an informed consent form. For children older than 10 years of age, both the child and his/her parents were asked to sign an informed consent form. Healthcare providers informed every participant in the experimental group the exact information the application would collect from their mobile phone and precisely how that information would be handled and protected. Voluntary participation with the right to withdraw at any time,

and the confidentiality of data collection, was explained in detail to all children and their parents or healthcare proxies. The cellular phone application was compatible only with Android-type devices, thus disqualifying potential participants who did not have such a device.

2.8 | Validity and reliability

The standardized study protocol was strictly followed during the trial. Children were randomly assigned to either the experimental group or the control group. Before the trial, all the physicians and nurses involved in the study, and the children and their parents in the experimental group, were trained on how to install and use the software. Information technology support was provided by the hospital telehealth departments. In particular, all four clinical centres involved in this study have electronic medical history systems. Physicians and nurses can record medical history for every patient at each visit. We obtained medical histories from those systems and, in certain cases, from the paper outpatient records. Furthermore, prior to enrollment, all children were classified into either a positive API or negative API. The former was defined as frequent wheezing during the first 3 years of life and either one major risk factor (parental history of asthma or eczema) or two of three minor risk factors (eosinophilia, wheezing without colds and allergic rhinitis) (Castro-Rodriguez, Holberg, Wright, & Martinez, 2000). Children with a negative API tend to have lower exacerbations when they are six years of age or older compared with children with positive API. To avoid the confounding of results secondary to differences in API status, only participants with positive API were recruited for the study.

2.9 | Statistical analysis

Sample size was calculated based on the primary outcome, namely the frequency of asthma exacerbations. With an $\alpha = 0.05$ and power of 0.80, each group should have at least 70 children after consideration of dropouts and lost cases during the follow-up period. Power and Sample Size online software, which is available at <http://www.powerandsamplesize.com>, was employed. Specifically, the module "2-Sample, 2-Sided Equality" was used to run the sample size calculation with the primary objective of the study being to test whether the means (frequency of asthma exacerbations) of the two groups were different. According to our preliminary experiment, the following arguments (parameters) were used to calculate sample size: $\alpha = 0.05$, $\beta = 0.2$, mean in group A (μ_A) = 3.3, mean in group B (μ_B) = 4.1 and Standard Deviation (σ) = 1.44. The calculation result was 51. Thus, we assigned a cohort size of 70 participants per group after considering dropouts and lost cases during the follow-up period. Continuous data were presented as the mean (standard deviation) and were tested by the Student's *t* test, or the median with interquartile ranges and were tested by Mann–Whitney U test, as appropriate. Categorical data were presented as percentages and were tested by Chi square analysis or Fisher's exact test. All

tests were two-sided tests. A $p < 0.05$ was considered statistically significant. All statistical analyses were performed with SPSS (version 21.0, IBM, USA).

3 | RESULTS

A total of 152 children with asthma were enrolled in the study, with 77 children in the experimental group and 75 in the control group. Seven children in the experimental group and two children in the control group were lost to follow-up (Figure 1), which was similar in both groups ($\chi^2 = 1.780$, $p = 0.167$). There were no statistically significant differences in baseline characteristics between two groups (Table 1).

3.1 | Primary outcome—asthma exacerbations

Compared with the pre-enrollment period, the frequency of asthma exacerbations significantly decreased in the post-enrollment period in the two groups (experimental group pre- versus post-treatment 9 (7–10) versus 3 (2–4), $Z = 10.361$, $p < 0.001$; control group pre- versus

post-treatment 9 (7–11) versus 4 (3–5), $Z = 9.808$, $p < 0.001$), with a more significant decrease observed in the experimental group (Figure 2).

3.2 | Secondary outcomes—adherence, C-ACT, respiratory infections, antibiotic and oral steroid use, school and work attendance, and medical expenses

Children in the experimental group had a statistically significant higher treatment adherence and C-ACT scores than those in the control group. The former also had fewer numbers of diagnosed respiratory tract infections and days of antibiotic use than the latter, which was statistically significant (Figure 3). During the follow-up period, C-ACT scores started to show significant differences between the experimental and control groups one month after enrollment. This difference gradually got larger and stabilized at approximately three months after enrollment (Figure 4). When reviewing the C-ACT scores throughout the study period, decreased values were observed during the winter and spring seasons (Figure 4). There was no statistically significant difference in the number of children who required

TABLE 1 Baseline characteristics and asthma status before enrolment

Characteristics	Experimental group (N = 77)	Control group (N = 75)	Statistic	p
Age, year, M (SD)	7.8 (1.4)	8.1 (1.4)	$F = 1.754$	0.187
Gender, N (%)			$\chi^2 = 0.000$	0.991
Male	41 (53.2%)	35 (46.7%)		
Disease duration, months, median (IQR)	36.0 (17.5–48.0)	36.0 (24.0–48.0)	$Z = 0.298$	0.766
Asthma severity, N (%)			$\chi^2 = 0.756$	0.384
Mild	71 (92.2%)	66 (88.0%)		
Moderate	6 (8.8%)	9 (12.0%)		
Number of asthma exacerbations in the past one year before study enrollment, median (IQR)	9 (7–10)	9 (7–11)	$Z = 0.973$	0.331
Serum allergen test, N (%)			$\chi^2 = 0.400$	0.940
Positive dust mites	54 (70.1%)	56 (74.7%)		
Others or unknown	23 (29.9%)	19 (25.3%)		
Controller medications used prior to study, N (%)			$\chi^2 = 0.851$	0.654
pMDI	11 (14.3%)	9 (12.0%)		
Intermittent use of high dose ICS	60 (77.9%)	57 (76.0%)		
ICS/LABA	6 (7.8%)	9 (12.0%)		
Influenza vaccination, N (%)	34 (44.2%)	29 (38.7%)	$\chi^2 = 0.472$	0.492
Education of healthcare guardian, N (%)			$\chi^2 = 1.829$	0.609
College or above	26 (33.8%)	25 (33.3%)		
Associate degree	25 (32.5%)	21 (28.0%)		
Senior high school	14 (18.2%)	20 (26.7%)		
Junior high school or below	12 (15.6%)	9 (12.0%)		
Geography, N (%)			$\chi^2 = 1.343$	0.247
Urban	52 (67.5%)	57 (76.0%)		
Rural	25 (32.5%)	18 (24.0%)		

Abbreviations: ICS, inhaled corticosteroid; IQR, interquartile range; LABA, long-acting β_2 -agonist; M (SD), mean (standard deviation); pMDI, pressurized metered dose inhaler.

oral steroid treatment between the two groups (five children in the experimental group and nine children in the control group, $p = 0.241$). In children with moderate asthma, five of six in the experimental group and seven of nine in the control group, stepped down in treatment (Fisher's exact test, $p = 1.000$). No patient in either group required treatment step-ups during the study period.

During the follow-up period, median days of school absence and parental work loss in the experimental group were lower than those in the control group. Medical expenses decreased significantly in the experimental group compared with those in the control group (Figure 5).

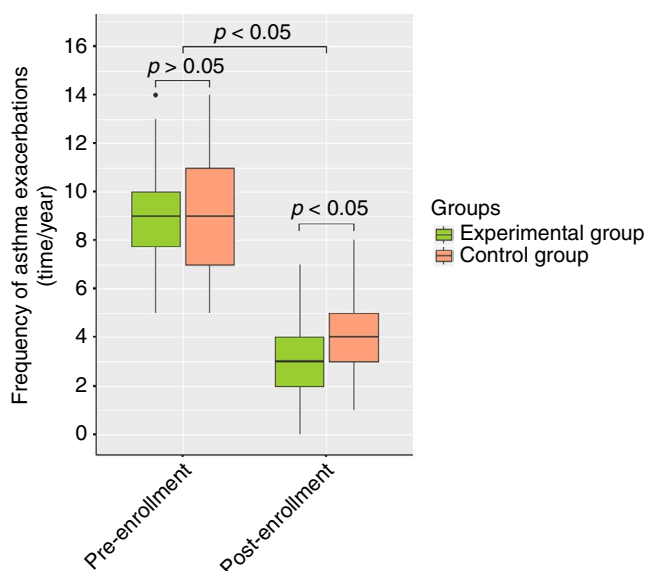


FIGURE 2 Frequency of asthma exacerbations during pre-enrollment and post-enrollment periods in the study and control groups. The lower and upper hinges correspond to the first and third quartiles (the 25th and 75th percentiles). The upper and lower whiskers extending from the hinges include value of $1.5 \times$ IQR (interquartile range) [Colour figure can be viewed at [wileyonlinelibrary.com](#)]

4 | DISCUSSION

Asthma is a chronic respiratory condition. Asthma management mainly relies on close clinical symptom monitoring and medication adherence, which could be affected by many factors. This supports the concept that the successful control of asthma exacerbations requires a comprehensive approach that integrates patient self-monitoring and close clinical follow-ups. Previous studies have shown that a nurse-led model could improve asthma management (Kamps et al., 2004; Kuethe et al., 2013; Trivedi et al., 2017). In the current study, we have demonstrated that a mobile application could further increase treatment adherence and reduce the frequency of asthma exacerbations, with additional benefits of decreasing the chances of child school absences and parental work loss, and reduced medical expenses. Together these findings support the idea of incorporating mobile technology into nurse-led care for childhood asthma. In regard to the primary outcome of asthma exacerbations, others have shown that primary care interventions can impact this positively (Kennedy et al., 2017). However, the role of mobile and cellular applications in this process is minimally interrogated. This also applies to the role of mobile applications in the several secondary outcomes that we tracked.

Poor medication adherence is one of the main reasons for inadequate asthma control (Blake, 2017). In the present study, the eHealth solution was managed by a team of physicians and nurses. However, the physicians and nurses each had different duties. For example, the follow-ups were completed by the nurses. Children in the experimental group had better medication adherence than those in the control group. Since these two groups had similar nurse-led asthma management (with the only difference being the computer software application), this suggested that the use of this asthma management software could improve patient compliance and prevent or reduce asthma exacerbations. The following functions of the application improved adherence. First, the function of a medication reminder could remind patients to use asthma medications in time. Second,

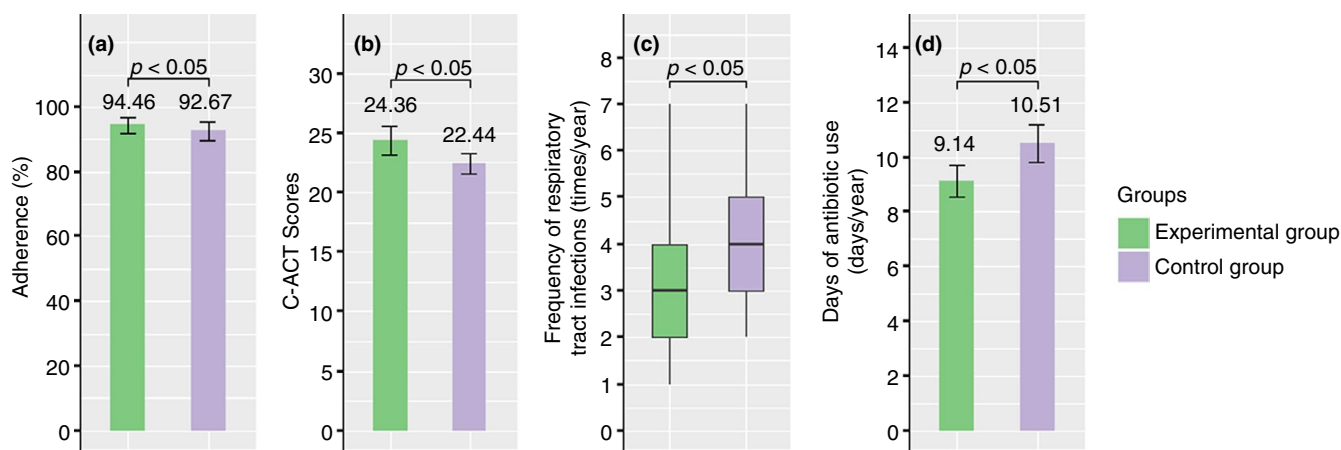


FIGURE 3 Children in the experimental group had higher treatment adherence (a) and C-ACT scores (b), but lower frequency of respiratory tract infection (c) and days on antibiotics (d) compared to children in the control group. The error bars represent the 95% confidence intervals, with mean values above the bars [Colour figure can be viewed at [wileyonlinelibrary.com](#)]

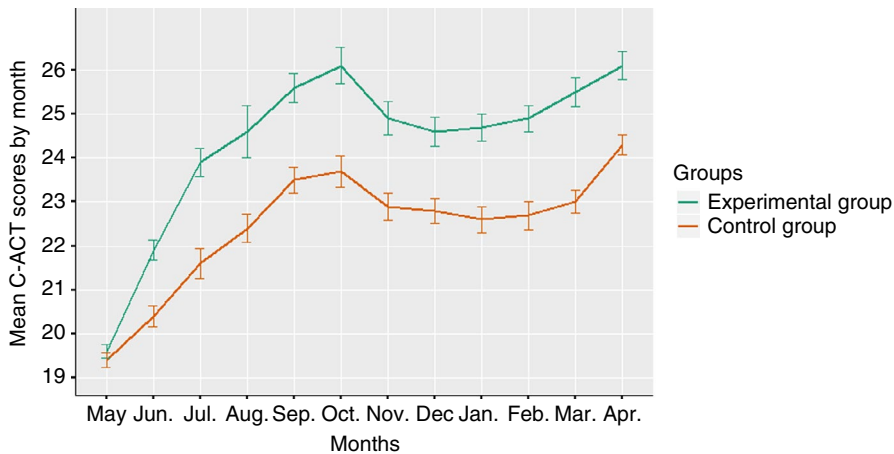


FIGURE 4 C-ACT scores in children during the study period. The error bars represent 95% confidence intervals [Colour figure can be viewed at wileyonlinelibrary.com]

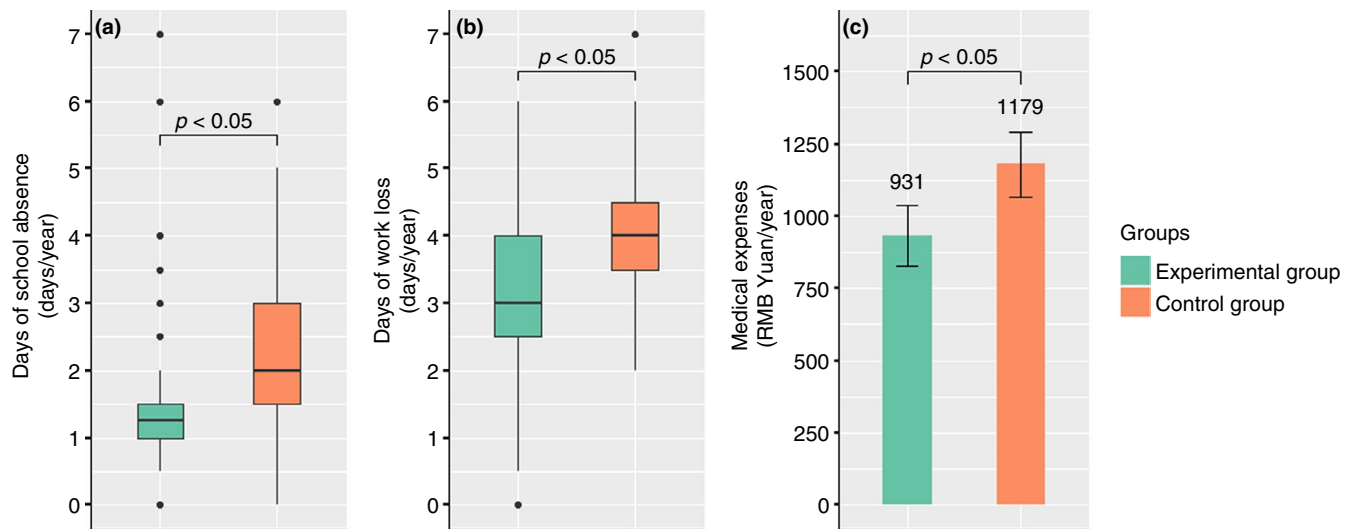


FIGURE 5 Comparisons of school absence for children (a), days of work loss for parents (b), and medical expenses (c) for the two groups. The error bars represent the 95% confidence intervals, with mean values above the bars [Colour figure can be viewed at wileyonlinelibrary.com]

the function of adherence management could analyse whether a patient used medications regularly and remind nurses to take appropriate measures. Lastly, the application provided a real-time connection between children (parents) and the nurses. Children and parents could ask questions and receive immediate answers from the nurses.

C-ACT changed sequentially during the study period. At the beginning stage of the current study, C-ACT gave similar results between children in the two groups. Two months after enrollment, C-ACT revealed better results for the experimental group than for the control group and this difference in status stabilized three months after enrollment. The delayed benefits from integrating the mobile application into asthma care might be due to the time required for children and their parents to become familiar with the software application. The fact that C-ACT scores showed low scores from November to March was likely due to increased respiratory tract infections and asthma exacerbations that occur during the winter and spring seasons.

Viral respiratory infections are key triggers of asthma exacerbations (Global Initiative for Asthma, 2017; Jaratti & Gern, 2017). Interestingly, in the current study, we found that children in the

experimental group had fewer diagnosed respiratory infections compared with those in the control group. This suggested that the obverse may be true: that adequate control of asthma exacerbations could reduce the incidence of diagnosis of respiratory tract infections, as was reported in a previous study (Pelaia et al., 2006). The underlying mechanism might be due to un-disrupted interferon production in children with adequate asthma control compared with decreased interferon production in those with poor asthma control (Edwards et al., 2017; Sykes et al., 2014). Interferon is a major cytokine that regulates lung inflammation and protects lungs from infections. Previous studies have focused on the mechanism of asthma exacerbations induced by respiratory tract infections (Jaratti & Gern, 2017; Liao et al., 2016). Further research might also consider studies of the concomitant changes in asthma exacerbations and respiratory tract infections.

Risk factors such as environmental exposure to pollution, allergens, and tobacco smoke may also trigger asthma exacerbations. The mobile application contained a module named "health education", which included videos and articles describing methods to reduce risk factors of asthma exacerbations. The following measures reduced, at

least in part, the risk factors. First, environmental triggers and other risk factors were assessed at each visit. Second, designated nurses called participant parents to review asthma status and potential risk factors. Lastly, Children only in the experimental group accessed the education information and they received education messages from healthcare providers via the mobile application.

With the decreases in asthma exacerbations and respiratory tract infections, days of antibiotic use in the experimental group decreased significantly. The decreases in days of school absence, parental work loss and medical expenses in the experimental group also benefited from the above factors. However, no difference was observed regarding oral steroid treatment between the two groups, which may be attributed to the low incidence of severe exacerbations because of improved asthma management in both groups. A few children whose guardians did not have smartphones or were not able to use the mobile application correctly were excluded from the study, which may lead to exclusion bias and limit the model availability in some patients, especially in poor and aged individuals.

Still, it is arguable that the improved outcomes in both groups benefited from the continuity in healthcare visits and the enhanced attention given by family and medical providers. The nature of the study does not allow for separation of this from any primary mobile application-driven benefits. However, the experimental group fared better in the outcomes compared with the control group, which supports the hypothesis that the mobile application itself accounted for these findings.

5 | LIMITATIONS

There were several limitations to our study. First, the frequency of asthma exacerbations during the pre-enrollment period was obtained retrospectively, which could cause recall bias. Second, children and parents who did not have a smartphone or did not know how to use the software application were excluded from the study, which may have limited the generalizability of our study results. Third, the application was only compatible with Android software so that the participant who had smartphone with other operation systems were excluded, which may lead to selection bias. Lastly, study results on asthma exacerbations and treatment adherence were partly obtained from the software application, which was recorded into their smartphone by the children and parents. This could have caused information bias if they did not follow the instructions carefully. Future studies with a large sample size and longer follow-up time should be performed to confirm our results.

6 | CONCLUSION

In summary, our asthma management model of mobile application-assisted nurse-led asthma care successfully decreased the frequency of asthma exacerbations, improved treatment adherence, increased

C-ACT scores, decreased the incidence of respiratory tract infection diagnoses and reduced days of antibiotic use. Use of this model could also reduce days of child school absence and parental work loss, and decrease medical expenses. Mobile application-assisted nurse-led care was better than the nurse-led care alone and should be studied further to promote active nurse involvement in the health care of children with asthma. The results of the present study were based on the use of advanced technology and devices. This raises broader issues, namely equitable access to technology and, beyond this, equitable access to modern health care in all its forms. Nurses, as advocates for the well-being of all people, are well-positioned to be leaders in the discussions of these important issues.

CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

AUTHOR CONTRIBUTIONS

SL, XY, XC, XQ made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; SL, XY, XQ involved in drafting the manuscript or revising it critically for important intellectual content; SL, XY, ZW, WW, YQ, YC, XC, XQ given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; SL, XY, XC, XQ agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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