



A pilot randomized controlled trial on the impact of text messaging check-ins and a web-based asthma action plan versus a written action plan on asthma exacerbations

Iraj Poureslami, Jessica Shum, Richard T. Lester, Hamid Tavakoli, Delbert R. Dorscheid & J. Mark FitzGerald

To cite this article: Iraj Poureslami, Jessica Shum, Richard T. Lester, Hamid Tavakoli, Delbert R. Dorscheid & J. Mark FitzGerald (2018): A pilot randomized controlled trial on the impact of text messaging check-ins and a web-based asthma action plan versus a written action plan on asthma exacerbations, Journal of Asthma, DOI: [10.1080/02770903.2018.1500583](https://doi.org/10.1080/02770903.2018.1500583)

To link to this article: <https://doi.org/10.1080/02770903.2018.1500583>



Accepted author version posted online: 13 Jul 2018.



Submit your article to this journal [↗](#)



Article views: 21



View Crossmark data [↗](#)

TITLE PAGE

A pilot randomized controlled trial on the impact of text messaging check-ins and a web-based asthma action plan versus a written action plan on asthma exacerbations

Iraj Poureslami^{1,2}, Jessica Shum^{1,2}, Richard T. Lester³, Hamid Tavakoli⁴, Delbert R. Dorscheid⁵, J. Mark FitzGerald^{1,2*}

1. Division of Respiratory Medicine, Department of Medicine, Institute for Heart and Lung Health, The University of British Columbia, Vancouver, Canada
2. Centre for Clinical Epidemiology and Evaluation, Vancouver Coastal Health Research Institute, The University of British Columbia, Vancouver, Canada
3. Division of Infectious Diseases, Department of Medicine, The University of British Columbia, Vancouver, Canada
4. Collaboration for Outcomes Research and Evaluation, Faculty of Pharmaceutical Sciences, The University of British Columbia, Vancouver Canada
5. Centre for Heart Lung Innovation, St. Paul's Hospital, The University of British Columbia, Vancouver, Canada

*Corresponding author: J. Mark FitzGerald
The Lung Centre, 7th floor
Gordon and Leslie Diamond Health Care Centre
2775 Laurel Street, Vancouver BC Canada, V5Z 1M9
Telephone: +1 604.875.4122
mark.fitzgerald@vch.ca

Keywords: asthma, Telehealth, short messaging service (SMS), action plan, exacerbation, asthma control, quality of life, randomized controlled trial

ABSTRACT

Objective: We compared electronic asthma action plans (eAAP) supported by automated text messaging service (SMS) with written asthma action plans (AAP) on assessing acceptability and asthma control improvement. We hypothesized that the patients in eAAP group would have more improvements in their quality of life, asthma control, and decreased asthma exacerbations.

Methods: Patients with physician-diagnosed asthma having at least one asthma exacerbation in the previous 12 months were recruited. Participants received individualized action plans and were randomly assigned into either the intervention (eAAP) or control (AAP) group. Intervention participants received weekly SMS, triggering assessment of asthma control and viewing their eAAP. We assessed applicability of Telehealth platform on asthma exacerbations, asthma control, and quality of life over a 12-month period.

Results: 106 patients were enrolled (eAAP=52, AAP=54). The cumulative response rate to all weekly SMS check-ins was 68.4%. Overall, 28% of patients checked into their eAAP during the intervention period. There were fewer exacerbations in the eAAP group (18%) compared to the AAP group (RR=0.82 [95%CI 0.49, 1.36]), (P=0.44). The mean scores for asthma control and quality of life were higher in the eAAP group compared to the AAP group by 4% (RR=1.04 [95%CI 0.83, 1.30]), (P=0.73) and 5.5% (RR=1.06 [95%CI 0.87, 1.28]), (P=0.59), respectively, but were not statistically significant.

Conclusions: We demonstrated that the eAAP presented improved asthma control outcomes, but as expected the sample size was inadequate to show a significant difference but based on this pilot study we plan a larger appropriately powered RCT.

INTRODUCTION

Asthma is a chronic respiratory disease and a growing global health problem [1-3]. It is characterized by variable symptoms including cough, wheeze, and shortness of breath [2,3]. In addition to these symptoms, patients are prone to exacerbations defined as, an acute or sub-acute episode of progressive worsening of symptoms [4,5], which increases the burden of asthma to the individual patient in terms of high morbidity as well as being costly to the healthcare system [6-9]. Although asthma outcomes can be improved with structured care, less than half of the people with asthma achieve good control [10,11]. Lack of asthma control is multi-factorial with a major factor being poor adherence in the use of controller medications, resulting in worse outcomes such as a greater risk of asthma exacerbations [10, 12,13]. Numerous studies have shown that when patients properly understand and apply asthma action plans (AAP) in self-management practices, less episodes of exacerbations and higher quality of life and asthma control can be observed [ref]. An AAP is usually provided in a written format and is best developed by a respiratory educator with appropriate prescribing by a physician or nurse practitioner [14-16] and has been associated with reduced asthma-related symptoms and morbidity [17]. Such an action plan provides a framework for an asthma patient to manage a worsening of their symptoms, with the primary goal of preventing progression to an exacerbation, if used and followed accurately [15,16]. However, there are many barriers to the widespread use of AAP, which have recently been documented [17,18]. For instance, patients only followed the instructions on their AAP around 50% of the time [17], mainly due to the lack of education, which can be complemented with physicians' and allied clinical staffs' limited time to adequately educate their patients about the use of AAP, especially between clinical visits [14,15]. Other reasons for not using the AAP could be a lack of timely access to the action plan when needed, as well as difficulty understanding the information in the action plan by the patient [16,19,20]. This pattern of response suggests non-adherence or difficulty in following self-

management for most patients [21,22], leads to poor control which is disruptive to patients and costly to the health care system [7,8,10,23].

Telehealth, also known as eHealth and mHealth (when using mobile devices), is a general term referring to the delivery of health care services, health information, and health care education through telecommunication technologies [24-26]. Telehealth technology has been widely used in health care systems for various medical interventions in both chronic and communicable diseases [27-30]. Although researchers have recognized that lighter touch, community-based Telehealth (e/mHealth) may be helpful for asthma research [31-33], the application of mobile technology and SMS approach in asthma has resulted in mixed findings. Researchers have reported improvements in asthma symptoms and self-efficacy among participants using a SMS approach [32], while other researchers have reported no improvement in clinical outcomes, including exacerbations, medication adherence, and quality of life [34-35]. We have discussed the conflicting results across the different studies in a critical review that we conducted on 13 systematic reviews summarizing 438 articles assessing the effect of Telehealth on asthma and COPD outcomes [31]. Our review identified that there was a consistent efficacy signal but that there was a need to conduct an intervention trial to assess the link between Telehealth and asthma clinical outcomes, in particular on the reduction of exacerbations and hospitalizations. Our review also concluded that the SMS approach offered a convenient, reliable, affordable and secure means of Telehealth, and demonstrated strong potential as a tool for health care improvement: it is available on almost every model of mobile phone [34], the cost is relatively low [35], its use is widespread [32], it does not require great technological expertise and it is widely applicable to a variety of health behaviors and conditions [36]. SMS might be suitable for reminding patients to engage in their healthcare [36,37]. Recent studies have also shown SMS is best used as a two-way communication that allows patients to better engage in their care in an interactive way with their

providers or self-management practices [38,39] that can be also considered as a complementary disease management intervention; because it allows for “in-the-moment”, personally tailored health communication and reinforcement. Considering the features and applicability of a SMS approach in promoting self-management practices, the purpose of this study was to evaluate whether an electronic digitalized asthma action plan (eAAP), supported by weekly SMS can improve asthma outcomes among adult patients. Due to the uncertainty in the literature, we thought it would be important to complete a feasibility study first. In this paper, we report the findings, from such a study.

METHODS

Outcomes of interest: In this study, we divided the clinical outcomes into primary outcome (reduction in exacerbations) and secondary outcomes (improved quality of life and asthma control). Our hypothesis was that a Telehealth self-management intervention (the eAAP) would show improvement in clinical outcomes compared to the current usual care (e.g., a static/written AAP) with a reduction in exacerbations as well as an effect on secondary outcomes.

Needs assessment stage: Based on our previous experience [40,41], we actively engaged patients and health professionals in the design and implementation of our trial. Initially, patients’ views and values were sought during 4 focus groups (N=31) where participants shared their perspectives about their research priorities, better ways to manage asthma, and how we could improve our proposed Telehealth study. Next, we reviewed our findings from the patient group sessions with clinicians and IT technologists to design the SMS layout, study procedures, and development of the training materials and process that would be most relevant and appealing to our study participants. The training sessions were enriched by incorporating key-stakeholders’ suggestions; which included reviewing all steps of the trial, as well as exclusive training for the eAAP group in terms of website connection, online

checking of the action plan, responding to the SMS for online access, ID/password set up, and intervention procedures.

Inclusion criteria and recruitment strategy: Adult asthma patients (19 years of age or older) with a history of an asthma exacerbation (defined as the need for a course of oral corticosteroids (OCS) for at least three days, a visit to the emergency department (ED) or admission to the hospital for asthma) in the previous 12 months, currently prescribed asthma medications including inhaled corticosteroids alone or in a combination inhaler on a regular basis [42] were recruited and enrolled from two specialty asthma clinics in the Greater Vancouver Area between 2014 and 2016. The verification of exacerbations 12 months prior to the baseline assessment (as a primary criteria to being eligible for this study) was confirmed by the respiratory educators at each site using the medical records of patients before referring the patient to the study.

The inclusion of patients with an exacerbation in the previous 12 months was based on the knowledge that these patients were more likely to have recurrent exacerbations [12]. Participants had to be able to understand and communicate in English and own a mobile phone with the ability to receive and send SMS and have access to the internet either via a mobile phone or computer. Patients with a greater than ten pack year smoking history (to exclude possible COPD patients), a history of significant comorbid disease judged by the investigator, as well as plans for relocation or extended vacation in the coming year were excluded. The recruitment process included identification of potential patients by study team respirologists who referred them to certified respiratory educators (CREs) and provided them with a recruitment flyer to be contacted. Participants were recruited in two healthcare settings that routinely provides standard AAPs to asthma patients. Eligible patients were contacted by the study staff via phone or e-mail to enroll in the study and participate in the baseline assessment after signing the informed consent form.

Study procedures: After confirmation of eligibility, each patient had a baseline assessment conducted by a research assistant and responded to questions on asthma status, duration of asthma, current medications, current digital communication approaches, satisfaction with care provider, and prior health care utilization using a general questionnaire developed by our team. Frequency of exacerbations, hospitalizations, ED visits, and use of OCS in the previous 12 months were also assessed. Asthma control was assessed using the Asthma Control Test (ACT) [43] and quality of life was assessed using the Mini Asthma Quality of Life Questionnaire (MiniAQLQ) [44]. Spirometry was also measured according to the American Thoracic Society (ATS) guidelines [45]. At the end of each in-person assessment, participants were given \$25 as an honorarium to cover parking and transportation costs.

Participants were then seen by a respiratory educator who provided them with an individualized asthma action plan (AAP), based on an incremental increase in controller medication as outlined in the GINA asthma management strategy [46], and were instructed on how to apply the AAP, and reinforcement on the importance of increasing anti-inflammatory medications in the face of a loss of asthma control (Figures 1 & 2). All participants were advised to increase their reliever therapy use and were provided with a prescription for a five-day course of OCS if the initial adjustment was ineffective or if there was an initial sign of an exacerbation. This was defined as being present in the “orange zone” according to their AAP. In more detail, the treatment and steps each patient in the study (both group) needs to take following their action plan irrespective of which group they were assigned to, were included:

1. Patients on maintenance inhaled corticosteroids less than 500 micrograms of fluticasone will be provided with an action plan which will trigger the quadrupling of the maintenance dose of ICS.

2. Patients using a salmeterol containing regimen will have an additional 500 micrograms of ICS added to their maintenance treatment based on a worsening of their asthma.
3. Patients using a budesonide and formoterol combination inhaler will be instructed to follow the SMART strategy for 48 hours and if there is no improvement will be recommended to add a course of daily oral corticosteroid (OCS) requirements.
- 4 Subjects taking a mometasone fumarate and formoterol combination inhaler will be instructed in the first instance to double the dose of their maintenance therapy and if there is no improvement after 48 hours to start a course of OCS

Figure 3 depicts an illustration of a sample asthma action plan developed in this study.

After meeting with the respiratory educator, a coloured copy of the action plan was given to each participant to keep at home, and a copy was also kept in the participant's folder in the study's locked cabinet. A copy of the action plan along with study information was sent to each patient's family doctor, to inform them about their patient's participation in the trial. Once an action plan was developed, participants were allocated at random using a computer-generated randomization method into one of the two study groups based on their assigned ID number and not considering patients' gender, age, or other characteristics. Therefore, we observed some imbalance in terms of patient characteristics allocated to either of the two groups; for instance, we observed more female participants in the eAAP versus the AAP group. The contact information of the respiratory educator and research staff was provided to all study participants in case they had study- or asthma-related questions.

Intervention: The digitalized asthma action plan (eAAP) was integrated into the WelTel mHealth platform (www.weltel.org) which has been used previously for the ambulatory care of patients with HIV, TB, and for maternal and child health [47,48]. The WelTel service consists of a secure server based platform hosted at UBC that has a web-application front-end whereby clinicians and research

staff can sign into the system using a unique password to register patients via their phone numbers and follow them via mobile phone communications. Custom text messages, generated by the implementing team, are thereafter sent automatically via a cellular gateway to patients via SMS each week. No personal health information was sent out to patients' phones automatically other than the check-in question. For this project, the messages were designed to trigger the participant to assess their asthma control each week, and if they experienced a worsening of asthma symptoms, be linked to an electronic version of their individual AAP. To access their eAAP, patients needed to use a password-protected link which was sent to them via text and could be opened directly on a smartphone with an internet connection or be copied into any web-enabled computer. The eAAP, as with the standard AAP, provided guidance to recommend adjusting their asthma therapy or further action by self-management or seeking help. In this case, the patient could click on the colour coded zone they were in which then presented self-management instructions or if they should seek medical attention.

Specifically, enrolled patients in the eAAP group received the automated weekly text message to their phones on each Monday for 52 weeks that read 'Have your symptoms worsened?' If no response was received by Wednesday, a reminder text was sent. If they replied "yes", at any time, they were texted a link to their individualized eAAP for reference and self- management instructions. Once they had accessed their action plan, participants were required to indicate which zone they were in by clicking on the corresponding coloured zones. If participants responded 'no' to the weekly text, they were sent a message: "Thanks! Talk to you next week!" (Figures 2 & 3). An in-person training session, for use of the Telehealth intervention, was conducted by the research assistant and all participants were asked if they had any difficulty to access and use their action plan at each in-person and telephone follow-up assessment and appropriate steps were taken to resolve these issues. In addition, the CREs informed the research staff and participants when there was a need to modify the action plans, which were updated

online as well. Patient FEV1 was measured at each in-person assessment (baseline, 6-month, and 12-month assessment), using a portable Spirometry device.

Follow up assessments: Using the same measurement tools and spirometry as at the baseline assessment, participants in both study groups were seen at 6 and 12 months post baseline visit. At these follow-up assessments, all participants were also asked to provide their feedback about the study process, any communication barriers with their care provider, further education/information they need about their action plan, and any comments and suggestions they may have to improve the study and intervention procedures. In addition, we conducted two telephone follow-up calls at 3 and 9 months post baseline to check participants' health status and primarily track health care utilization and recent exacerbations as defined in the protocol (Figure 4). All participants were asked to proactively contact the study RAs or CREs in the event of an asthma exacerbation. No verification or references to medical records were made to compare participants' self-reported hospitalization and exacerbations for the telephone follow-ups. Each patient's baseline and follow up data were entered, into a password protected, online database at UBC (OpenClinica) [49].

Statistical analysis: This pilot study was designed to include approximately 100 patients. As it was a feasibility study, no formal sample size estimate was completed. SAS Enterprise Guide (Version 6.1, Cary, NC, USA) [50] was used to analyze the data for the assessment of the clinical outcomes between the intervention and control groups. Depending on the nature of the dependent variable, different regression models were used. 1. Number of exacerbations (primary outcome): The count of exacerbations was modeled using a Poisson regression model (a Generalized Linear Model (GLM) [51] with logarithmic link and Poisson distributing). Exacerbations were verified by either or all three indicators; whether used OCS, whether admitted to hospital due to asthma, or whether visited the ED

due to asthma in the past 12 months. 2. Asthma control test score (secondary outcome): Asthma control was treated as a Poisson variable. The mean score of GLM Poisson regression model was fitted for modeling all measured ACTs during the 12-month follow-up. 3. Asthma quality of life (secondary outcome): Asthma quality of life was assessed using the MiniAQLQ scale with 16 items. The mean score using the GLM model was applied on self-reported items during the 12-month follow-up. In all models, the main independent variable was the intervention group. Participants' age and gender were considered as confounders. We applied multilevel modelling to control for the baseline score of the respective outcome measures, key covariates, and intraclass correlation. Job status, education level, and disease severity (as identified by FEV1) were removed from the regression model. The reason for removing the FEV1 from the regression model was because we did not observe any significant changes for this variable from the initial visit to the 12 months follow-up in either of the study groups.

Therefore, FEV1 was only reported as a characteristic in the manuscript (Table 1) and not as a clinical outcome. We also applied the concepts of Intention to Treat (ITT) analysis [52] to detect improvements in health outcomes. In doing so, all patients who were enrolled and randomly allocated to the study groups were included in the analysis and were analysed in the group to which they were randomized.

Ethics approval: The study was approved by the UBC Clinical Research Ethics Framework. Ethics approval was also obtained at each participating medical site (Vancouver General Hospital and St. Paul's Hospital). The trial was registered at Clinicaltrials.gov (registration number: NCT02017795 – Updated May 25, 2017). All subjects gave written medical consent prior to enrollment in the study.

RESULTS

Participant characteristics: A total of 151 potential patients were screened and 115 (76%) patients were recruited into the study. Of those enrolled, 4 patients engaged in the development of the study framework and participated in the study implementation, 5 patients participated in an initial pilot

testing. Therefore, 106 participated in the randomized trial [52 in the eAAP group and 54 in the AAP group]. Age and gender were used as the confounders in the regression model. There were no significant differences between the control and intervention groups in terms of age and duration of asthma. Participant characteristics and distribution of age, gender, duration of asthma, daytime and nighttime symptoms and the use of rescue inhaler within the past 2 weeks separated by each study group, as well as the use of medications in the total sample are shown in Table 1. As shown in Table 1, more females were enrolled in the eAAP group versus AAP group as we applied randomization based on entry to the study and did not stratified based on gender or age or other participant characteristics to allocate the participants into the two study groups; therefore, the observed distributions of the participants in each study group was by random and not intentional.

Clinical outcomes: Parameter estimates for the primary and secondary outcomes, analogous to regression coefficients and significance level of patients who completed the study in the eAAP and AAP groups are shown in Table 2-1 (showing the within group changes from baseline to 12 months assessment) and 3-2 (showing the changes between the 2 groups at the 12 months assessment).

Overall, the likelihood of exacerbations was reduced in both study arms as shown in Table 2-1. Comparing the eAAP treatment arm with the AAP control arm, there were fewer exacerbations in the eAAP group (18%) compared to the AAP group (RR=0.82 [95%CI 0.49, 1.36]), (P=0.44) (Table 2-2). In addition, the likelihood of using OCS was reduced by 32.7% more in eAAP group compared to AAP (RR=0.67 [95%CI 0.34, 1.33]), (P=0.25) (Table 2-2). In terms of hospitalizations due to asthma, the risk of hospitalizations was 53.4% less in the eAAP group compared to the AAP group (RR=0.47 [95%CI 0.12, 1.84]), (P=0.28) (Table 2-2). Furthermore, the risk of visiting the ED due to asthma was reduced significantly in both study groups (Table 2-1). However, upon completion of the intervention,

the risk of ED visits was 13% less among eAAP patients compared to AAP patients (RR=1.13 [95%CI 0.31, 4.13]), (P=0.85) (Table 2-2). The number of these events was overall small. The mean scores for ACT and asthma QOL were higher in the eAAP group compared to the AAP group by 4% (RR=1.04 [95%CI 0.83, 1.30]), (P=0.73) and 5.5% (RR=1.06 [95%CI 0.87, 1.28]), (P=0.59), respectively, but these differences were not statistically significant (Table 2-2). Medication adherence data were collected in this study; however, the results are not shown here because the data was collected by a PhD student as part of an ongoing project on adherence in a number of studies and will be reported separately in his doctoral dissertation.

Patient satisfaction and adherence to action plan: A total of 48 participants in the eAAP group (92.3%) completed the study compared to 47 participants in the AAP group (90.4%). All patients except one in the eAAP group responded to their SMS at least once. The overall cumulative response rate to the weekly possible check-ins on their asthma status by SMS was 68.4%. Also, in total, 28% of patients checked-in to their online eAAP at least once during the intervention period. The patients in the eAAP group provided comments on what they liked and did not like about the Telehealth intervention. For instance, patients emphasized they preferred to receive the weekly text message as a reminder to control their asthma and suggested that the text messages also could include additional educational information such as lifestyle information (e.g., diet and routine exercise) on a regular basis. In addition, a few participants complained about receiving similar messages for the 52-week study. Some additional recommendations included: (1) adding an interactive system where the patient can ask their questions via text and have someone (e.g., a healthcare provider) responding their queries; (2) developing a variety of text messages and sending at random while keeping similar content; and (3) providing easy and fast access to the AAP using an ‘app’ on the phone rather than sending a website

link that requires data usage. However, many of the participants were content with the Telehealth self-management intervention and did not believe that any modifications were needed.

DISCUSSION

Telehealth interventions to improve outpatient asthma management have yielded mixed results [31,35]. Therefore, we designed a feasibility study for a novel digital intervention to improve asthma self-management using a web-based telecommunication platform linked with direct communication with patients in the community. In our intervention, we integrated weekly SMS check-ins to asthma patients linked with online access to an eAAP in order to investigate the practicability of a Telehealth intervention for improving asthma outcomes, specifically a reduction in asthma exacerbations.

The results of our feasibility study demonstrated that improvements were shown in both groups, as may be expected by enhanced standard of care by participating in a clinical trial and expressed usage of educators and action plans. Moreover, our Telehealth approach showed promise against the current standard of care, due to more timely access to the AAP by the patients through sending the reminder SMS to monitor asthma control. By combining low-touch communication via SMS with online resources when needed, participants in the eAAP group were engaged to proactively assess their asthma symptoms by checking their AAP online and take the necessary action to act on steps to improve their condition/prevent further worsening. This was supported by observed trends toward lower exacerbation rates in the eAAP group which was also accompanied by trends in the reduction in the number of courses of OCS used, ED visits and hospitalizations. Furthermore, the comparison between the eAAP and standard AAP groups indicated small differences in terms of asthma control and quality of life. None of these comparisons were statistically significant. Inconclusive results have also

been previously reported re the effect of Telehealth on health related QOL [53,54]. These trends, while promising, support the need for a larger clinical trial to see if in such a more appropriately powered study the trends seen in this study can be shown to be statistically and clinically significant. Although our results showed a moderate level of regular engagement with our Telehealth intervention by the participants with only 28% of patients checked-in to their online eAAP during the intervention period, these results could also reflect the proportion of patients whose asthma was controlled and did not need to access the action plan. Future evaluations will include relative assessments of their interaction with their action plans and other resources. In this study, participants' age and gender were considered as confounders in the analysis. Age and duration of asthma did not show any impact on the obtained results. In other words, there were no significant differences between the control and intervention groups in terms of age and duration of asthma. We observed more females enrolled in the eAAP group versus AAP group that was occurred by random and not by intention as we applied the randomization through entry into the study and not based on patients' characteristics.

Despite the encouraging results of this pilot study, we are considering inclusion of additional features to the intervention based on feedback. These include opportunities for patients to communicate directly with healthcare staff, access to additional educational and lifestyle information, and ability to access their action plans offline, such as with a smartphone App. Each of these features, however, increases the complexity of the intervention and has other considerations such as levels of accessibility, privacy and cost. Apps, for example, store information on participants' phones and need a higher degree of technical support and updates than web-based access. Many studies have shown smartphone applications to be a feasible tool for the monitoring and the management of asthma [55,56]. Other studies among patients with lung cancer, COPD and asthma reported the participants receiving an interactive SMS and monitoring system had improvement in their QOL, reported fewer ED visits and

hospitalizations, and lower risk of exacerbations [57,58]. It would be interesting to determine whether there was an effect on our clinical outcomes if the intervention was modified to include an interactive feature for patients to communicate with health care providers as well as providing additional education information such as lifestyle changes via SMS.

Limitations: As it was not a formal validation study, it is limited in providing any true estimate of effectiveness and requires further study. Although feasibility was determined as a pilot, the study was also unable to determine technical factors and costs that would be associated with rolling out a similar program at scale and in different settings. In addition, for practical reasons, we were unable to enroll all patients who could be eligible but were excluded from the study due to language issues, disease severity, improper daily use of prescribed medication, and lack of ownership of a mobile phone, which may have minimized the generalizability of our findings. Potential threats to external validity from selection bias need to be taken care of in a larger RCT aiming to generalize the findings beyond the context of the trial. However, the relatively high level of active participation and the heterogeneous group of participants supports our affirmation that any effect on the external validity of the trial is likely to be minor if a larger sample size is studied. Finally, the use of a self-reported primary outcome measure ie asthma exacerbations is a potential limitation [59,60].

CONCLUSIONS/KEY FINDINGS

Our Telehealth intervention delivered a tailored care service that was acceptable to our patients. This pilot study demonstrated that a novel Telehealth platform in the form of an electronic digitalized AAP with SMS reminders was feasible to support self-management practices for adult patients with asthma. Improvements were noticed among the eAAP group when the Telehealth approach was added to the current standard of care. In our study, fewer exacerbations were reported in the eAAP group and mean

scores of Asthma control and Quality of life improved in this group, however as anticipated in a pilot study, these did not reach statistical significance. The results of our study support the utility of undergoing a larger RCT powered to potentially show a clinically significant effect.

Accepted Manuscript

References

1. Balter M, Ernest P, Watson W, et al., Asthma worsenings: approaches to prevention and management from the Asthma Worsenings Working Group. *Can Respir J*. 2008; 15 Suppl B:1B-19B.
2. Myers TR. Guidelines for Asthma Management: A Review and Comparison of 5 Current Guidelines. *Respiratory Care*. 2008; 53(6): 751-769
3. Public Health Agency of Canada. The Prevention and Management of Asthma in Canada. Available at: <http://www.phac-aspc.gc.ca/publicat/pma-pca00/>
4. Denlinger LC, Phillips BR, Ramratnam S, et al. Inflammatory and Comorbid Features of Patients with Severe Asthma and Frequent Exacerbations. *American Journal of Respiratory and Critical Care Medicine*, 2017; 195(3)
5. Jackson DJ, Sykes A, Mallia P, Johnston SL. Asthma exacerbations: Origin, effect, and prevention. *J Allergy Clin Immunol*. 2011;128:1165-74
6. Sadatsafavi M; Rousseau R, Chen W, et al. The Preventable Burden of Productivity Loss Due to Suboptimal Asthma Control: A Population-Based Study. *Chest*, 2014; 145(4): 787-793.
7. Sadatsafavi M, Lynd L, Marra C, et al. Direct health care costs associated with asthma in British Columbia. *Can Respir J*. 2010;17: 74-80.
8. Bahadori K, Quon BS, Doyle-Waters MM, et al., A systematic review of economic evaluations of therapy in asthma. *J Asthma Allergy*, 2010; 3: 33-42.
9. Sadatsafavi M, Chen W, Tavakoli H, et al. Saving in medical costs by achieving and maintaining guideline-based asthma symptom control: a longitudinal study. *Allergy*, 2015; 3. doi: 10.1111/all.12803.
10. Wilson SR, Strub P, Buist AS, et al., Shared treatment decision making improves adherence and outcomes in poorly controlled asthma. *Am J Respir Crit Care Med*, 2010. 181(6): 566-77.
11. Peters SP, Ferguson G, Deniz Y, Reisner C. Uncontrolled asthma: A review of the prevalence, disease burden and options for treatment. *Respiratory Medicine* 2006; 100: 1139-1151.
12. Griswold SK, Nordstrom CR, Clark S, et al. Asthma exacerbations in North American adults: who are the “frequent fliers” in the emergency department? *Chest*. 2005; 127: 1579–86.
13. Bateman ED, Reddel HK, Eriksson G, et al. Overall asthma control: the relationship between current control and future risk. *J Allergy Clin Immunol*. 2010 Mar; 125(3): 600-6008, 608.e1-608.e6. doi: 10.1016/j.jaci.2009.11.033. Epub 2010 Feb 11.
14. Roberts NJ, Evans G, Blenkhorn P, Partridge MR. The development and comprehensibility of a pictorial asthma action plan. *Patient Education and Counseling*, 2010; 80: 141–146.
15. Joyce E. Kaferle, MD, Leslie A. A Team-Based Approach to Providing Asthma Action Plans. *J Am Board Fam Med* March, 2012; 25 (2): 247-249

16. Ruchi SY, Gupta S, Tomopoulos S, et al. A Low-Literacy Asthma Action Plan to Improve Provider Asthma Counseling: A Randomized Study. *Pediatrics* 2016; 137(1): e20150468.
17. Ring N, Booth H, Wilson C, et al. The 'vicious cycle' of personalised asthma action plan implementation in primary care: a qualitative study of patients and health professionals' views. *BMC Family Practice* 2015; 16: 145.
18. Djandji F, Lamontagne AJ, Blais L, et al. Enablers and determinants of the provision of written action plans to patients with asthma: a stratified survey of Canadian physicians. *npj Primary Care Respiratory Medicine* 2017; 27: 1-7
19. Afshar S, FitzGerald JM. Asthma patient education, the overlooked aspect of disease management. *Canadian Journal of Respiratory, Critical Care and Sleep Medicine. Canadian Journal of Respiratory, Critical Care, and Sleep Medicine.* 2017; 1(1): 43–45
20. Bailey SC, Oramasionwu CU, Wolf MS. Rethinking Adherence: A Health Literacy-Informed Model of Medication Self-Management. *Journal of Health Communication*, 2013; 18:20–30.
21. Eakin MN, Rand CS. Improving Patient Adherence with Asthma Self-Management Practices: What Works? *Annals of allergy, asthma & immunology* 2012; 109(2): 90-92
22. Lindsay JT, Heaney LG. Nonadherence in difficult asthma – facts, myths, and a time to act. *Patient Prefer Adherence* 2013; 7: 329-336.
23. Haughney J, Price D, Kaplan A, et al. Achieving asthma control in practice: Understanding the reasons for poor control *Respiratory Medicine* 2008; 102: 1681-1693
24. Barello S, Triberti S, Graffigna G, et al. eHealth for Patient Engagement: A Systematic Review. *Front Psychol.* 2016; 8: 6-13.
25. Whitehead L, Seaton P. The Effectiveness of Self-Management Mobile Phone and Tablet Apps in Long-term Condition Management: A Systematic Review. *J Med Internet Res.* 2016; 18(5): e97-e105.
26. Medical technology of Australia. A telehealth strategy for Australia: supporting patients in the community May 2012. Available at: <https://www.mtaa.org.au/sites/default/files/uploaded-content/website-content/supporting-a-telehealth-strategy-for-australia-release-version-may-2012.pdf>
27. Chi NC, Demiris G. A systematic review of telehealth tools and interventions to support family caregivers. *Journal of Telemedicine and Telecare.* 2015; 21(1): 37–44
28. Lunny C, Taylor D, Memetovic J, et al. Short message service (SMS) interventions for the prevention and treatment of sexually transmitted infections: a systematic review. *Systematic Reviews.* 2014; 3(7): 1-8.
29. Jones KR, Lekhak N, Kaewluang N. Using Mobile Phones and Short Message Service to Deliver Self-Management Interventions for Chronic Conditions: A Meta-Review. *Worldviews on Evidence-Based Nursing*, 2014; 11:2, 81–88.

30. Lester RT. Ask, Don't Tell — Mobile Phones to Improve HIV Care. *N Engl J Med*. 2013; 369(19): 1867-1868.
31. Nimmon L, Poureslami I, FitzGerald JM. Telehealth Interventions for Management of Chronic Obstructive Lung Disease (COPD) and Asthma: A Critical Review. *J Telemed Telecare*. 2012; 18: 425-42648.
32. Hui CY, Walton R, McKinsty B, et al. The use of mobile applications to support self-management for people with asthma: a systematic review of controlled studies to identify features associated with clinical effectiveness and adherence. *J Am Med Inform Assoc*, 2016. pii: ocw143. doi: 10.1093/jamia/ocw143.
33. Licskai CJ, Sands TW, Ferrone M. Development and pilot testing of a mobile health solution for asthma self-management: Asthma action plan smartphone application pilot study. *Can Respir J*, 2013; 20(4): 301-306.
34. Strandbygaard U, Thomsen SF, Backer V. A daily SMS reminder increases adherence to asthma treatment: a three-month follow-up study. *Respir Med*, 2010. 104(2): 166-71.
35. Ryan D, Price D, Musgrave SD, et al. Clinical and cost effectiveness of mobile phone supported self-monitoring of asthma: multicentre randomised controlled trial. *BMJ*. 2012; 344: e1756-e1771
36. Hall AK, Cole-Lewis H, Bernhardt JM. Mobile Text Messaging for Health: A Systematic Review of Reviews. *Annual review of public health* 2015; 36: 393-415.
37. Sarabi RE, Sadoughi F, Bahaadinbeigy K. The Effectiveness of Mobile Phone Text Messaging in Improving Medication Adherence for Patients with Chronic Diseases: A Systematic Review. *Iranian Red Crescent Medical Journal* 2016; 18 (5): e183-e185
38. Wald DS, Butt S, Bestwick JP. One-way versus two-way text messaging on improving medication adherence: meta-analysis of randomized trials. *Am J Med*. 2015;128(10):1139.e1-5. doi: 10.1016/j.amjmed.2015.05.035.
39. Lauffenburger JC, Choudhry NK. Text Messaging and Patient Engagement in an Increasingly Mobile World. *Circulation* 2016;133: 555-556.
40. Poureslami I, Rootman I, Nimmon L, FitzGerald J. Health Literacy, Language, and Ethnicity-Related Factors in Newcomer Asthma Patients to Canada: A Qualitative Study. *Journal of Immigrant and Minority Health*, 2011; 13(2): 315-322
41. Poureslami I, Nimmon L, Doyle-Waters M, et al. Effectiveness of Educational Interventions on Asthma Self-Management in Punjabi and Chinese Asthma Patients: A Randomized Controlled Trial. *J asthma*, 2012; 49(5): 542-551.
42. Loughheed MD, Lemiere C, Dell S, et al., Canadian Thoracic Society Asthma (CTS) Committee commentary on long-acting beta-2 agonist use for asthma in Canada. *Can Respir J*, 2010. 17(2): 57-60.

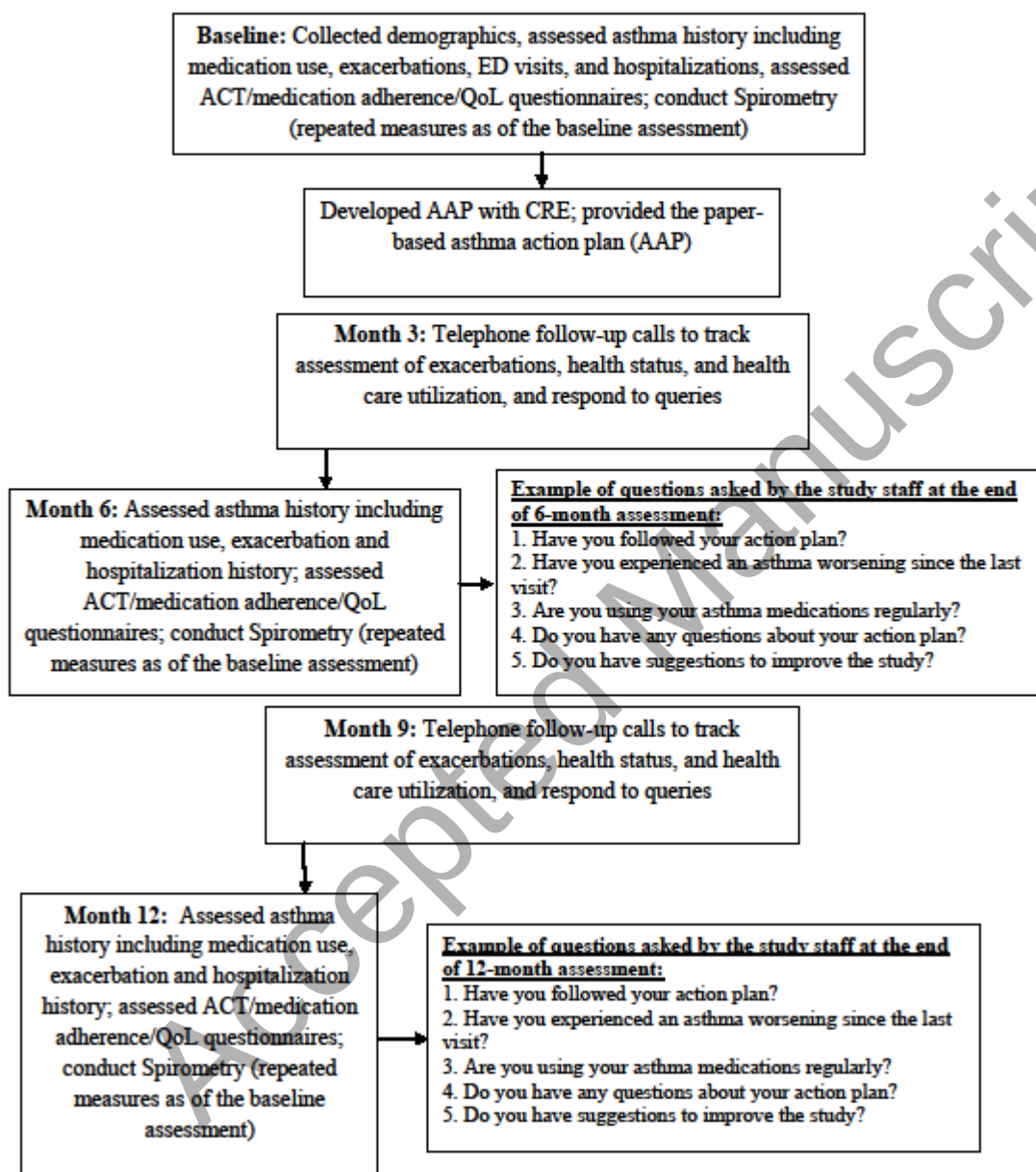
43. Juniper EF, O'byrne PM, Ferrie PJ, et al. Measuring Asthma Control: Clinic Questionnaire or Daily Diary? *Am J Respir Crit Care Med*, 2000; 162(4): 1330-1334
44. Juniper EF, Buist S, Cox FM, et al. Validation of a Standardized Version of the Asthma Quality of Life Questionnaire. *CHEST*, 1999; 115(5):1265-1270.
45. Miller MR, Hankinson J, Brusasco V, et al. Standardisation of Spirometry- Lung Function Testing. ATS/ERS Task Force. *Eur Respir J* 2005; 26: 319–338.
46. Bateman ED, Hurd SS, Barnes PJ, et al. Global strategy for asthma management and prevention: GINA executive summary. *Eur Respir J* 2008. 31(1): 143-78.
47. Lester R, Ritvo P, Mills EJ, et al. Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WelTel Kenya1): a randomised trial. *The Lancet*. 2010 DOI:10.1016/S0140- 6736(10): 61997-61998.
48. Van der Kop ML, Memetovic J, Smillie K, et al. Use of the WelTel mobile health intervention at a tuberculosis clinic in British Columbia: a pilot study. *JMTM* 2013; 2(3): 7-14.
49. OpenClinica- Structured project database®: Medical Free/Libre and Open Source Software. Available at: <https://www.medfloss.org/node/46>
50. SAS® Enterprise Guide® Available at: <https://support.sas.com/documentation/onlinedoc/guide/>
51. McCullagh P. Generalized linear models (GLM). *European Journal of Operational Research*. 1984; 16 (3): 285-292
52. Gupta SK. Intention-to-treat concept: A review. *Perspectives in Clinical Research* 2011; 2(3): 109-112.
53. McLean S, Chandler D, Nurmatov U, et al. Telehealthcare for asthma. *CMAJ*, 2011; 183: E733–E742.
54. Marcano Belisario JS, Huckvale K, Greenfield G, et al. Smartphone and tablet self-management apps for asthma. *Cochrane Database of Systematic Reviews* 2013; 11. Art. No.: CD010013.
55. Finkelstein J, O'Connor G, Friedmann RH. Development and Implementation of the Home Asthma Telemonitoring (HAT) System to Facilitate Asthma Self-Care. *Studies in Health Technology and Informatics* 2001; 84(1):810-814.
56. Mi-Yeong Kim, Suh-Young Lee, Yoon-Seok Chang. Feasibility of a smartphone application based action plan and monitoring in asthma. *Asia Pac Allergy*. 2016; 6(3): 174-180.
57. Koff PB, Jones RH, Cashman JM, Voelkel NF, Vandivier RW. Proactive integrated care improves quality of life in patients with COPD. *European Respiratory Journal*. 2009; 33(5): 1031-8.
58. Halpin DM, Laing-Morton T, Spedding S, et al. A randomised controlled trial of the effect of automated interactive calling combined with a health risk forecast on frequency and severity of exacerbations of COPD assessed clinically and using EXACT PRO. *Primary Care Respiratory Journal*. 2011; 20(3): 324-31.

59. Petite TM, Narsavage GL, Chen Y-J, et al. Feasibility study: home telemonitoring for patients with lung cancer in a mountainous rural area. *Oncol Nurs Forum*, 2014; 41: 153-161.
60. Short ME, Goetzel RZ, Pei X, et al. How Accurate are Self-Reports? An Analysis of Self-Reported Healthcare Utilization and Absence When Compared to Administrative Data. *J Occup Environ Med*. 2009; 51(7): 786-796.

Accepted Manuscript

**A pilot randomized controlled trial on the impact of text messaging check-ins and a web-based
asthma action plan versus a written action plan on asthma exacerbations**

Figure 1. Group 1 - Regular-care control group (AAP) flowchart



A pilot randomized controlled trial on the impact of text messaging check-ins and a web-based asthma action plan versus a written action plan on asthma exacerbations

Table 1. Details of the patients studied. The values shown are the number and percentage (%)

	AAP Group	eAAP Group		
<i>Total number of individuals</i>	54	52		
<i>Female gender (%)</i>	24 (44.4%)	36 (69.2%)		
<i>Age (SD)</i>	52.8 (±15)	50.6 (±15.3)		
<i>FEV1</i>				
<i>Baseline (SD)</i>	2.29±0.93	2.29±0.71		
<i>12-month (SD)</i>	2.42±1.02	2.40±0.66		
<i>Duration of asthma (SD)</i>	17.44 (±15.57)	24.83 (±16.33)		
<i>Daytime symptoms- yes (%)</i>	57.41%	65.38%		
<i>Nighttime symptoms- yes (%)</i>	55.56%	46.15%		
<i>Use of rescue inhaler- yes (%)</i>	44.44%	57.69%		
<i>Medication use- all patients</i>				
<i>Inhaled Corticosteroids (ICS)</i>	<i>Short acting Beta2-Agonists</i>	<i>Combination of ICS and LABA</i>	<i>Long acting anticholinergics</i>	<i>Short Acting anticholinergic</i>
33 (31.15%)	82 (77.4%)	90 (84.91%)	14 (13.21%)	6 (5.66%)

Table 2-1. Primary & Secondary objectives - Comparison within the AAP group and eAAP group after 12 months of study:

Outcomes	Group	Relative Risk (95% CI Lower-Upper)	Change	LCI	UCI	P value
Exacerbation	Within AAP	0.56 (0.43, 0.73)	-44%	-57%	27%	0.0001
	Within eAAP	0.43 (0.31, 0.59)	-57%	-69%	41%	0.0001
OCS use	Within AAP	0.96 (0.72, 1.28)	-4%	-28%	28%	0.76
	Within eAAP	0.60 (0.39, 0.92)	-40%	-61%	8%	0.02
Hospitalization	Within AAP	1.60 (0.71, 3.63)	60%	-29%	263%	0.26
	Within eAAP	1.00 (0.20, 4.95)	0%	-80%	395%	0.10
ED visit	Within AAP	0.36 (0.18, 0.72)	-64%	-82%	28%	0.004
	Within eAAP	0.31 (0.13, 0.77)	-69%	-87%	23%	0.01
Quality of Life	Within AAP	1.04 (0.96, 1.13)	4%	-4%	13%	0.38
	Within eAAP	1.09 (1.02, 1.16)	9%	2%	16%	0.01
Asthma Control	Within AAP	1.02 (0.94, 1.12)	2%	-6%	12%	0.59
	Within eAAP	1.05 (0.97, 1.14)	5%	-3%	14%	0.25

Table 2-2. Primary & Secondary objectives - Comparison between eAAP group and AAP group after 12 months of study:

Outcome	Outcomes	Relative Risk (95% CI Lower-Upper)	Change	LCI	UCI	P value
Primary	Exacerbation	0.82 (0.49, 1.36)	-18%	-51%	36%	0.44
	OCS use	0.67 (0.34, 1.32)	-33%	-66%	32%	0.25
	Hospitalization	0.47 (0.12, 1.84)	-53%	-88%	84%	0.27
	ED visit	1.13 (0.31, 4.13)	13%	-69%	313%	0.85
Secondary	Quality of Life	1.05 (0.39, 1.28)	5%	-13%	28%	0.59
	Asthma Control	1.04 (0.83, 1.29)	4%	-17%	29%	0.72