A pilot study of a mobile-phone-based home monitoring system to assist in remote interventions in cases of acute exacerbation of COPD

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Summary
We conducted a six-month feasibility study of a mobile-phone-based home monitoring system, called M-COPD. Patients with a history of moderate Acute Exacerbation of COPD (AECOPD) were given a mobile phone to record major symptoms (dyspnoea, sputum colour and volume), minor symptoms (cough and wheezing) and vital signs. A care team remotely monitored the recorded data and provided clinical interventions. Eight patients (mean age 65 years) completed the trial. Ten acute exacerbations occurred during the trial and were successfully treated at home. Prior to the AECOPD episode, the combined score of the major symptoms increased significantly ($P < 0.05$). Following the intervention, it decreased significantly ($P < 0.05$) within two weeks and returned to the baseline. The score of the minor symptoms also increased significantly ($P < 0.05$), but the decrease following the intervention was not significant. There were significantly fewer hospital admissions during the trial, fewer ED presentations and fewer GP visits than in a six-month matched period in the preceding year. The results demonstrate the potential of home monitoring for analysing respiratory symptoms for early intervention of AECOPD.

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Introduction
Chronic Obstructive Pulmonary Disease (COPD), a progressive life-threatening lung disease, is amongst the top five causes of global morbidity and mortality,¹ and is a major chronic disease in Australia. There are about 65 million people living with COPD in the world, and about 3 million people die of COPD each year, corresponding to 5% of all deaths globally. In Australia, COPD is a major cause of hospital admissions, with an average length of stay of 7.5 days.² The direct health expenditure on COPD is over half a billion dollars per year in Australia.

Patients with COPD often suffer from Acute Exacerbations (AECOPD), a sudden worsening of respiratory symptoms such as dyspnoea and sputum, triggered by infections from bacteria, viruses or environmental pollutants. In the management of patients with COPD, timely intervention of AECOPD is important because exacerbations are responsible for gradual but irreversible progression of the disease and often require emergency department (ED) treatment. However, in practice patients with AECOPD often take the “wait and see” approach,³ and some of them fail to receive treatment, probably due to the unmet needs for health care.⁴ The delayed or failed treatments often result in severe exacerbations requiring hospital admission. Therefore, a major step in improving COPD care is to diagnose and treat AECOPD at an early stage.

Telemedicine has been explored in remote monitoring and managing of COPD patients.⁵ Several studies have shown beneficial outcomes in terms of improved COPD care and reduced hospital admissions.⁶,⁷ More recently, mobile health (i.e. telemedicine via a mobile device) has been trialled. Some pilot studies have demonstrated a high level of satisfaction with mobile health,⁸ high compliance with self monitoring of pulmonary function and significantly reduced hospitalizations.⁹ However, the literature on mobile health applications is limited by small clinical trials of differing study design. This poses a difficulty in drawing conclusions about the use of mobile health systems in the management of AECOPD.

In current clinical practice, the core information needed to diagnose AECOPD is based on the worsening of baseline COPD symptoms, such as dyspnoea and sputum

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volume. Although physiological data such as blood oxygen level and lung function have also been used for early diagnosis of AECOPD, the effectiveness of such analysis is inconclusive. Clinical diagnosis of AECOPD still relies on traditional symptom assessments. Thus knowledge about the symptom variation caused by AECOPD is important in telemedicine-based clinical applications. However, such knowledge remains limited. In addition, analysis of the symptom response following telemedicine-induced intervention is important, but few studies have analysed the response through a telemedicine setup. We have examined these two aspects of mobile health for the management of AECOPD.

We have developed a simple smart-phone health diary application for home use, called M-COPD, to determine early AECOPD. The objective of the study was to evaluate the feasibility of the M-COPD application.

Methods

Patients used mobile phones to record observed COPD symptoms and vital signs, such as shortness of breath, cough, heart rate, SpO2 and body temperature. Two interfaces which allowed users to update the symptoms and vital signs are shown in Figure 1. The data were stored in a remote server and provided to clinicians via a web portal, see Figure 2. The portal provided graphs allowing clinicians to visualise the variation of symptoms over time. Clinicians reviewed the monitored data daily and followed up patients with telephone calls. Patients with identified AECOPD were monitored and treated at home.

Figure 1. Screenshots from the user interface of the mobile web application. (a) questionnaire to record cough symptoms. (b) dialogue to enter vital sign measurements.

Pilot trial

A pilot trial was conducted to evaluate the feasibility of the M-COPD program. The study was approved by an appropriate ethics committee. Ten patients were recruited from the Royal Perth Hospital. The inclusion criteria were: (1) patients comfortable to use mobile phones and take part in a home teleconsultation, and (2) patients with at least two admissions for AECOPD in the previous year. Exclusion criteria were severe end-organ failure (including respiratory, cardiac, liver and renal failure), previous stroke, major neurological disorder or psychiatric disorder. Following consent, nurses from the COPD clinic provided each patient with a mobile phone (iPhone 4, Apple Inc, Cupertino, CA, USA) pre-loaded with the M-COPD application. Through the application, patients recorded a self-assessment of their COPD symptoms and measured vital signs. The major symptoms (sputum colour, shortness of breath and sputum volume) and minor symptoms (wheeze and cough) were selected for the analysis, in agreement with the studies in this field. Based on questionnaires such as the dyspnoea scale, EXACT and SGRQ, we developed a short questionnaire suitable for daily monitoring of the symptoms on mobile phones. In the questionnaire, each symptom was given a score, see Table 1. The vital signs of body temperature, heart rate and oxygen saturation of blood (SpO2) were also monitored to ensure the safety and effectiveness of treatment. A normal thermometer and a pulse oximeter were provided for patients to measure their vital signs.

AECOPD was diagnosed by respiratory physicians at the Royal Perth Hospital through the web portal.
diagnosed with moderate AECOPD were monitored and treated at home. Moderate AECOPD was defined as an exacerbation which could be treated safely with oral corticosteroids and antibiotics and did not require hospital admission.17 Physicians reviewed the patients' data daily in collaboration with community nurses, and provided consultations and interventions through telephone calls. Records of hospitalizations, GP visits and ED presentations, during the trial and in the 6-months prior to the trial were collected for comparison.

**Statistical analysis**

The symptom scores and vital signs in a ten-week period (5-weeks before the diagnosed AECOPDs and 5-weeks afterwards) were extracted for analysis. The averaged values in the fifth week prior to the AECOPD onset were used as the baseline. Regression analysis was used to estimate the relationship between the symptoms and the time in the two separate periods, the five-week period prior to the diagnosed AECOPD events and three-week period after the diagnosis respectively, using the model:

\[ y = A \cdot \exp(B \cdot x) + C \]

where \( y \) is the symptom score, \( x \) is the time (day), and \( A, B \) and \( C \) are the model parameters.18

The null hypothesis was that the relationship, in the equation above, was not significant.

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**Figure 2.** Screenshot from the user interface of the web portal showing the vital signs and symptom scores.
The hospitalizations, GP visits and ED presentations during the trial (August–January) were compared with those from the same 6-month period as in the previous year using paired t-tests. Patients’ usage of the system was defined as the percentage of the number of days with data entries during the trial.

**Results**

Ten patients agreed to participate in the trial. The baseline characteristics of the patients are summarised in Table 2. Of the ten patients, two had severe COPD exacerbations that were unlikely to be controlled with medications at home, and were directed for treatment at hospital. These two patients were unable to continue using the daily diary and withdrew from the trial. The remaining eight patients were managed at home through the use of M-COPD. Each of the patients suffered at least one COPD exacerbation during the study. A total of 10 exacerbations was treated with steroids, bronchodilators or antibiotics at home. The average mobile data entry rate was 3.5 entries per week (SD 1.4) for each score or measure.

The development of COPD exacerbation and intervention effects were observed by the change of the symptoms. Compared with the baseline, the scores of the symptoms generally increased (or symptoms worsened) in the week prior to the exacerbation, see Figure 3. Clinical interventions following AECOPD led to a decrease in the scores in the first week following the onset, except sputum volume. The regression analysis demonstrated a significant increase in the combined score for the major symptoms ($P < 0.05$) prior to the onset, Figure 4. After the intervention, the major symptoms decreased significantly ($P < 0.05$) down to a score of 1.2, which was below the baseline. In the fifth week the major symptoms returned to baseline. A significant increase was also found in the combined score for the minor symptoms ($P < 0.05$), Figure 5. This score also showed a decrease to the baseline (approximately 1.86) in the first week after the intervention. However, the decrease was not significant ($P > 0.05$).

There were significantly lower hospital admissions with M-COPD, ED presentations and GP visits than in the matched period (Table 3).

**Discussion**

In the present study the scores of the minor and major symptoms were significantly increased ($P < 0.05$) prior to AECOPD, reflecting the deterioration of the symptoms due to AECOPD. A study by Seemungal et al. also demonstrated that deterioration of certain symptoms was associated with AECOPD, including dyspnoea (associated with 64% of exacerbations), sputum volume (26%), sputum purulence (42%) and wheeze (35%), although the design of their study differed from ours. Our study combined the symptom scores together. This enabled clinicians to easily compare the treatment effects with the baseline.

A longitudinal analysis of the baseline scores would help understand the long-term progression of COPD. However, the causes and responses of AECOPD often vary greatly. Therefore, further studies through larger trials are required.

The regression analysis demonstrated an increase in both major and minor symptoms across all patients. The increase was mild at the beginning, but gradually escalated while approaching the onset of AECOPD. A recent study by Aaron et al. also found that some exacerbations (44%) were characterized by a gradual onset of COPD symptoms (median of 4 days from symptom onset to exacerbation), and those exacerbations were of low severity. This finding is consistent with the gradual escalation in the patients with moderate AECOPD in our study. These results suggest that some exacerbations – probably

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**Table 1.** Scores of major and minor COPD symptoms assessed by patients through self-observation.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Major symptoms</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sputum colour</td>
<td>0</td>
<td>No sputum</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Clear</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>White</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Discoloured</td>
</tr>
<tr>
<td>Sputum volume</td>
<td>0</td>
<td>Never</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Tablespoon</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Half a cup</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>A cup or more</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>0</td>
<td>Exercise</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Daily activities</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Limited to sitting</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Bed-bound</td>
</tr>
<tr>
<td><strong>Minor symptoms</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wheeze</td>
<td>0</td>
<td>Never</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>1–5 times per week</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Daily</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Continuously</td>
</tr>
<tr>
<td>Cough</td>
<td>0</td>
<td>Never</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Less than daily, but weekly</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Daily</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Daily and nocturnally</td>
</tr>
</tbody>
</table>

**Table 2.** Baseline characteristics of the patients ($n = 10$).

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>65</td>
<td>9</td>
</tr>
<tr>
<td>Males, %</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Six-minute walk, m</td>
<td>320</td>
<td>80</td>
</tr>
<tr>
<td>FEV1 (predicted), L</td>
<td>51</td>
<td>15</td>
</tr>
<tr>
<td>FEV1/FVC, %</td>
<td>48</td>
<td>10</td>
</tr>
<tr>
<td>Current active smokers, %</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Pack years of smoking, pack-y</td>
<td>32</td>
<td>8</td>
</tr>
</tbody>
</table>
determined by level of severity – might potentially be diagnosed earlier through a consolidated score of major and minor symptoms.

We observed that hospital admissions, ED presentations and GP visits in the trial were significantly lower ($P < 0.05$) than those in the same 6-month period in the previous year. This is consistent with other telemonitoring studies. However, contradictory outcomes have also been reported. For example, a review by Wong et al. showed improvement of quality of care, but little benefit in terms of reduced hospitalization. The studies reviewed by Wong et al. were mainly focused on providing self-management of COPD with limited clinical support from community nurses. Recent studies have found that,

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**Figure 3.** Average score for major and minor symptoms before and after the onset of ten AECOPD events. Day 0 represents the onset of the event, which is also the first day when the intervention was provided.

**Figure 4.** Average combined score of major symptoms prior to and after the onset of the ten AECOPD events diagnosed in the trial. The broken line is the regression Prior to exacerbation: $y = 0.25 \exp(0.10 x) + 1.26$. Following exacerbation: $y = 0.29 \exp(-0.32 x) + 1.20$.

**Figure 5.** Average combined score of minor symptoms prior to and after the onset of the ten AECOPD events diagnosed in the trial. The broken line is the regression Prior to exacerbation: $y = 0.43 \exp(0.08 x) + 1.83$. Following exacerbation: $y = 0.29 \exp(-1.15 x) + 1.87$. 
in the management of chronic disease, multidisciplinary teams are required to improve the effectiveness and quality of care.\textsuperscript{23,26} Accordingly, the M-COPD enhanced care service was delivered by a collaborative team with respiratory physicians and community nurses, which had the ability to provide clinical diagnoses and timely interventions. The return of the symptoms to the baseline demonstrated that the patients were effectively treated at home.

Mortality is another key outcome. A review study found three randomized controlled trials which demonstrated a higher mortality rate among COPD patients with telehealth support compared with usual care.\textsuperscript{27} In view of these contradictory outcomes, future studies should also examine different intervention strategies, clinical protocols, components and tools to help understand how and why an intervention works.

Although the regression analysis demonstrated that the symptom scores were significantly associated with the time course of AECOPD, the results cannot be applied to the general population because of the small sample size of the pilot study. Similarly, the data on the reduction of hospital readmissions, ED presentations and GP visits may not be representative of the clinical outcomes of general health services. In addition, the M-COPD application is a prototype and needs to be improved in future research. For example, the questionnaire developed for the mobile application was not validated. Another potential problem with the M-COPD system is that the data entry rate was low (3.5 entries per week or 50\%). This low rate may cause delays in detecting rapid symptom changes. Despite our efforts to simplify the questionnaire and data collection through the mobile application, entering data on a daily basis may have posed an extra burden for patients and hence, caused adherence difficulties. Therefore, to improve the data collection, future studies should also investigate reducing the number of symptoms to be monitored and/or the use of wireless sensors to measure the symptoms automatically.

In conclusion, we have evaluated a mobile health home monitoring system in a pilot trial. The results demonstrate the potential to analyse respiratory symptoms for early intervention of AECOPD.

**References**


16. Barr JT, Schumacher GE, Freeman S, LeMoine M, Bakst AW, Jones PW. American translation, modification, and
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