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An expert-supported monitoring system for patients with chronic obstructive pulmonary disease in general practice: results of a cluster randomised controlled trial


Recent changes in general practice have increased possibilities to diagnose and manage chronic diseases such as chronic obstructive pulmonary disease (COPD). Several national and international guidelines for COPD are available1-4 to help general practitioners with this.

“Monitoring”, or regular surveillance of patients’ health status, is a cornerstone of COPD management.5 Input of specialist knowledge into monitoring enables comparison of the process and outcome of care with evidence-based guidelines. It can also alert GPs to areas in which individual patient care falls short, and introduce explicit recommendations for management. Our group has demonstrated the effectiveness of expert-supported monitoring on the outcome of diabetes care in general practice.6 COPD management places a substantial demand on medical resources,7,8 and patient adherence is important to the success of treatment.9 Any expert-supported respiratory monitoring system depends on the cooperation of various groups (ie, GPs, specialists and patients), contains interacting components, and is, therefore, a complex intervention.10

We aimed to investigate the long-term effectiveness of a primary care monitoring system with respiratory expert recommendations for general practitioners’ management of patients with chronic obstructive pulmonary disease (COPD), compared with usual care.

**Objective:** To investigate the long-term effectiveness of a general practice monitoring system with respiratory expert recommendations for general practitioners’ management of patients with chronic obstructive pulmonary disease (COPD), compared with usual care.

**Design, settings and participants:** A multicentre randomised controlled trial of patients with COPD, clustered by general practices; 200 participants were recruited to maintain at least 75 participants per group for analysis. The trial took place from July 2005 to February 2008 in the south-western region of the Netherlands.

**Intervention:** Ongoing half-yearly monitoring of COPD patients with respiratory expert recommendations for the GP was compared with usual care.

**Main outcome measures:** Primary outcome — Chronic Respiratory Questionnaire (CRQ) score; secondary outcomes — CRQ domain scores, generic health-related quality of life (Short-Form 12 and EuroQol-5D), breathlessness (Modified Medical Research Council score), exacerbations, and decline in forced expiratory volume in 1 second. A detailed process evaluation was performed along with the trial.

**Results:** Data from 170 participants were analysed. Based on repeated measurement analyses, the additional gain in CRQ score during follow-up was 0.004 points for monitoring compared with usual care (95% CI, -0.172 to 0.180). Also, no important differences between monitoring and the usual care group were found for secondary outcomes. Half the monitoring visits resulted in disease management recommendations by a respiratory expert, and 46% of these recommendations were implemented by the GPs. Patient adherence to lifestyle recommendations was low.

**Conclusion:** An expert-supported monitoring system for patients with COPD was not clinically effective. As patients had a pre-existing entry in the monitoring system, the population may be well regulated, with reduced room for improvement.

**Trial registration:** www.clinicaltrials.gov NCT00542061.
GPs at practices who had referred more than six patients to the RDC were contacted and asked to participate. We used computerised minimisation to allocate practices to the monitoring and usual care groups\textsuperscript{13,14} while stratifying for:

- group versus solo practice;
- practice nurse employed versus no practice nurse employed; and
- ≤10 versus >10 patients fulfilling the study inclusion criteria.

A multilevel power calculation (ie, correction for clustering of subjects within general practices) was based on the mean difference in change in Chronic Respiratory Questionnaire (CRQ) score between monitoring and usual care. A difference of 0.5 points is generally accepted as a minimum important clinical difference for the CRQ score.\textsuperscript{15} We initially aimed to recruit 100 participants per group based on the following assumptions: an intracluster correlation coefficient of 0.04, α = 0.05, 1 - β = 0.80, and a drop-out rate of 25%.

**Blinding**

In their study information letters, GPs and patients were informed that patients were invited for an unspecified number of visits to the RDC. GPs were informed that participation could imply that the outcome of their patients’ visits would not be forwarded to them during the study as it had been previously. After minimisation, GPs received specific research information for their practice. The respiratory experts involved and the lung function technicians who performed the spirometric tests and collected medical information were not aware of patients’ participation and allocation.

**Intervention**

The expert-supported COPD monitoring system had been in use in the RDC since 1995, and comprised several steps.

**Step A.** Patients with COPD were invited to the RDC for monitoring visits every 6 months. Pre- and post- (after inhaling 400 μg salbutamol) bronchodilator FEV\textsubscript{1} and FVC were measured at each visit with a SpiroPerfect spirometer (WelchAllyn, Delft, The Netherlands) by certified lung function technicians. Body mass index was assessed, and information on respiratory symptoms, exacerbations, smoking and medication use in the previous 6 months was collected in a standardised way.

**Step B.** Information from the monitoring visit and previous visits was sent to a respiratory expert (chest physician or GP with special respiratory interest). The respiratory experts gave recommendations regarding treatment, additional diagnostic tests and referrals to other disciplines, based on national clinical practice guidelines for COPD and asthma.\textsuperscript{11,12} Experts’ interpretation based on spirometry results and written information has been shown to be valid.\textsuperscript{16}

**Step C.** Written feedback was sent to the patient’s GP. The patient was instructed to visit the GP 2 weeks after the monitoring visit to discuss the outcome. During these visits, the expert recommendations could be implemented by the GP (eg, checking inhalation technique) or recommended to the patient. Half-yearly visits from a nurse consultant to the practice to support GPs in implementing the recommendations were an integral part of the expert-supported monitoring system.

**Step D.** Ultimately, the patient should implement the recommendations made (eg, quit smoking, increase exercise).

**Usual care**

We invited participants from the usual care group for spirometry at the beginning and at the end of the study period. No recommendations or feedback were given, and no nurse consultant practice visits were scheduled during the study period.

**Outcomes and process evaluation**

Participants completed questionnaires at baseline, at 1 year, and at the end of the trial.
study. The primary study outcome was the CRQ score.17 Secondary outcomes were: CRQ domain scores; generic health-related quality of life (physical and mental domains of the Short-Form 12 [SF-12] and the EuroQol-5D)18-20 breathlessness according to level of exertion (Modified Medical Research Council [MMRC] score,2 dichotomised as 0–1 and 2–4); occurrence rate of self-reported exacerbations; and annual FEV1 decline.

For the process evaluation, the respiratory experts’ database was examined to collect data on their recommendations. The nurse consultant collected data on GPs’ implementation of recommendations. Patient questionnaires comprised questions about disease management. At the end of the study, the nurse consultant collected information on disease management from GPs in the usual care group.

Statistical analysis
Baseline characteristics for the participants in each group were compared using unpaired $t$ tests, $\chi^2$ tests, and Mann–Whitney $U$ tests, depending on the type of variable and normality of distribution.

Multilevel repeated measurement regression analysis was used to model the effect of monitoring on CRQ overall score, CRQ domain scores, SF-12 scores, EuroQol-5D scores, FEV1 decline, and dichotomised MMRC scores. We used a PROC MIXED procedure in SAS statistical software (SAS Institute, Cary, NC, USA), with general practice as the random coefficient and compound symmetry correlation structure. Multilevel logistic regression analysis was used to analyse effects on exacerbations. All models were corrected for sex, age, socioeconomic status, baseline cigarette smoking status, reversibility, exacerbations at baseline, use of inhaled corticosteroids, use of long-acting bronchodilators, and post-bronchodilator FEV1 % of the predicted value. Participants were included in the analysis if they participated in the study (intention-to-treat analysis).

RESULTS
Study population
Box 1 shows the process of practice and patient recruitment and follow-up. Thirty-four general practices participated. From these, 261 of 286 eligible patients (91%) responded to the invitation, and 213 (74%) were willing to participate. No significant differences between participants and non-participants with regard to sociodemographic characteristics, medication use, and spirometric indices were found. Twenty-four patients did not enter the study, and 19 patients were excluded from analyses. Data from 170 participants were used for the analyses. Box 2 shows the baseline characteristics of both groups.

The study was originally designed to evaluate monitoring of patients with COPD and asthma with a chronic airflow obstruction. However, after the recruitment phase we found that almost all of the patients fulfilled the criteria for COPD (ie, FEV1/FVC < 70% postbronchodilator); therefore, we decided to focus on COPD.

Clinical effectiveness of the expert-supported monitoring system
Box 3 shows the mean overall CRQ scores in the monitoring and usual care groups. Based on repeated measurement analyses, the additional gain in CRQ score during follow-up was 0.004 points for monitoring compared with usual care (95% CI, 0.172 to 0.180). Box 4 summarises the results for the secondary outcomes. No significant differences between the monitoring and usual care groups were observed other than CRQ domain mastery.

Process evaluation
A total of 292 visits took place among the monitoring group participants. Fifty-eight participants attended all four planned monitoring visits at the RDC (71%). Fifteen patients (18%) attended three, six patients attended two, and three patients attended one planned visit.

In total, respiratory experts gave 290 recommendations (Box 5). Smoking cessation was the most frequent recommendation (28% of all recommendations), and inhaler technique training and assessment of compliance with medical treatment were also recommended regularly. In 146 monitoring visits (50%), the respiratory experts did not consider any modification in disease management necessary. For 73 patients (89%), the GPs received at least one recommendation to change disease management.

Information about 274 of the 290 recommendations could be collected (Box 5). According to GPs, they attempted to implement 125 (46%) of the 274 recommenda-
A. Mean (95% CI) at baseline, change (95% CI) at follow-up, and difference between groups (95% CI) for continuous variables

<table>
<thead>
<tr>
<th>Monitoring group</th>
<th>Usual care group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong> (n = 82)</td>
<td><strong>Change at 2-year follow-up</strong> (n = 76)</td>
</tr>
<tr>
<td><strong>Overall CRQ score</strong></td>
<td>5.1 (4.9 to 5.3)</td>
</tr>
<tr>
<td><strong>CRQ domain dyspnoea</strong></td>
<td>4.9 (4.6 to 5.3)</td>
</tr>
<tr>
<td><strong>CRQ domain fatigue</strong></td>
<td>4.9 (4.7 to 5.2)</td>
</tr>
<tr>
<td><strong>CRQ domain emotions</strong></td>
<td>5.4 (5.2 to 5.6)</td>
</tr>
<tr>
<td><strong>CRQ domain mastery</strong></td>
<td>4.8 (4.7 to 5.0)</td>
</tr>
<tr>
<td><strong>SF-12 physical scale</strong></td>
<td>44.5 (43.0 to 46.1)</td>
</tr>
<tr>
<td><strong>SF-12 mental scale</strong></td>
<td>52.2 (50.2 to 54.1)</td>
</tr>
<tr>
<td><strong>EuroQol-5D score</strong></td>
<td>0.89 (0.86 to 0.92)</td>
</tr>
</tbody>
</table>

**B. Frequency (no. [%]) of categorical variables at baseline and follow-up, and odds ratios**

<table>
<thead>
<tr>
<th>Monitoring group</th>
<th>Usual care group</th>
<th>Odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MMRC score</strong></td>
<td><strong>Baseline</strong> (n = 82)</td>
<td><strong>Change at 2-year follow-up</strong> (n = 76)</td>
</tr>
<tr>
<td><strong>= 2</strong></td>
<td>8 (9.9%)</td>
<td>12 (15.8%)</td>
</tr>
<tr>
<td>≥ 1 exacerbations in previous year</td>
<td>16 (20.0%)</td>
<td>12 (15.8%)</td>
</tr>
</tbody>
</table>

**DISCUSSION**

We did not find a clinical benefit for patients who received ongoing care according to a well structured respiratory expert-supported COPD monitoring system compared with usual care by GPs. The adherence of patients to the monitoring visits was good. In half the cases, the respiratory experts felt that disease management could be improved, and almost half the recommenda-
tions by respiratory experts were implemented by GPs. Non-adherence of patients to visiting the GPs and making lifestyle changes, and the low adherence of GPs to some recommendations (eg, referral to chest physician, chest x-ray) were the main barriers to the implementation of the expert recommendations.

All patients who were invited had previously visited the diagnostic centre for at least one lung function assessment. It may be argued that we did not find effects in the study because we studied the effect of monitoring on a population with pre-existing entry into the monitoring system, rather than the effect of monitoring on a newly diagnosed population. Essentially, we compared health effects in a control group that had continued and asthma-related quality of life scores compared with usual care group participants.

As far as we are aware, this is the first time the effectiveness of a COPD expert-supported monitoring system has been evaluated. However, other programs that focus on monitoring, like an integrated COPD and/or asthma management care model, a GP feedback system, and monitoring of health-related quality of life of patients with asthma and COPD, also did not result in clinical benefits, although some improvements in patient satisfaction and process outcomes were found.

Other monitoring systems, such as monitoring of COPD by respiratory nurses in a general practice or a "patient-tailored" monitoring system, should be explored. Moreover, more information on the initial effect of the expert-supported monitoring system in newly diagnosed patients is needed (ie, including patients who were not already known to the RDC). It may be that the support system is able to put COPD management on track, and that after this initial support, GPs are sufficiently equipped to manage the patients.

The question remains whether the lack of effect was due to implementation failure — and therefore the system has the potential to be effective if implementation could be improved — or was a result of an ineffective intervention. 10 Many participants failed to visit the GP, although the adherence rate to GP visits was significantly higher in general practices that invited patients for regular visits. Moreover, the presence of a practice nurse resulted in higher implementation levels. Therefore, implementation can be improved, but it is not possible to fully prevent dilution of effects in the process of monitoring and feedback. Options to reduce disease progression are limited in COPD. 25,26 Moreover, little evidence exists that chronic disease management in primary care patients with COPD is effective. 27 Potential effects are further diminished by the low adherence of the participants to health behaviour recommendations, which is in concordance with other studies. 25,28

In conclusion, an ongoing respiratory expert-supported monitoring system for patients with COPD was not effective in terms of clinical outcomes. The lack of effectiveness may have been the result of a combination of limited options to intervene, the diluting effect on the intervention caused by the many steps in this complex process, and the low adherence of patients to crucial recommendations such as smoking cessation.

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COMPETING INTERESTS
None identified.
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