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# The effects of additional care by a pulmonary nurse for asthma and COPD patients at a respiratory outpatient clinic: Results from a double blind, randomized clinical trial

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**Abstract**

*Objective:* To assess the effects of additional information based nursing care program in the treatment of asthma and COPD patients at a pulmonary outpatient clinic.

*Methods:* In a double blind, randomized clinical trial, 191 patients were allocated to an additional care group or control group. Patients in the intervention group received a protocol-based education program on individual basis by a pulmonary nurse on individual basis (average duration 60 min per patient). All patients were masked for the trial objectives. Effectiveness was expressed in terms of knowledge, inhalation technique, self-management, exacerbation rate (primary outcomes), and health-related quality of life and satisfaction with care received (secondary outcomes). The time interval between the initial and final assessments was 6 months.

*Results:* Ninety-seven patients were randomized into the additional care group and 94 into the control group, of which 157 had a complete dataset. (Un)adjusted analyses did not show differences between treatment groups in terms of knowledge, inhalation technique, self-management, health-related quality of life, and satisfaction with care. Multivariate logistic regression adjusting for baseline covariates showed a significant treatment effect with regard to exacerbation rate (odds ratio = 0.35; 95% confidence limits: 0.13/0.94, $p = 0.04$).

*Conclusion:* With the exception of exacerbation rate, we could not demonstrate efficacy of additional nursing care in a broad range of outcome parameters.

*Practice implications:* At present we do not recommend to implement our patient-tailored education program in daily practice.


*Keywords:* Patient education; Nursing care; COPD; Asthma; Outpatient clinic

## 1. Introduction

An important component in the international treatment guidelines for asthma and COPD is the recommendation for patient education and regular medical review [1–3]. Patient education has been defined as a planned learning experience using a combination of methods such as teaching, counselling and behaviour modification techniques which influence patients' knowledge and behaviour and involves an interactive process which assists patients to participate actively in their health care. Education is considered to be necessary to help patients gain the motivation, skills and confidence to control their asthma or COPD. Systematic reviews showed that education in asthma self-management did improve health outcomes for adults with asthma [4,5]. In COPD this is less clear [6–8].

In order to implement these recommendations, we involved a pulmonary nurse in the treatment of asthma and COPD patients at our pulmonary outpatient clinic. Nursing care provided brief education that individually focused on disease-specific knowl-

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edge, pathophysiological mechanisms, action of medication, self-management skills, and the prevention of exacerbations. Inhalation technique was checked and corrected when needed. We assessed the effectiveness of this additional nursing care intervention in a double blind, randomized clinical trial.

Comparison between clinical trials is difficult since education programs, patients, and outcomes show major variations. A methodological concern is that in all previous trials on educational interventions, patients or observers knew that an extra service was assessed for effectiveness. The knowledge that other patients had received extra care may bias the results to a less favourable outcome in controls. Conversely, in patients who had received additional care this knowledge may introduce a more favourable assessment because of loyalty to the staff applying the program. To avoid the above-mentioned bias, patients were masked for the trial objective.

## 2. Patients and methods

### 2.1. Setting and patients

Patients were recruited from the pulmonary outpatient clinic at the Academic Medical Centre in Amsterdam, the Netherlands. Patients were eligible if they met the following criteria: (1) diagnosed having asthma or COPD by a pulmonary physician, (2) age over 18 years, (3) understood Dutch sufficiently to answer the questionnaires, and (4) never had consulted a pulmonary nurse.

### 2.2. Recruitment and randomization

Outpatient record files were screened for eligibility. Before their visit to the pulmonary physician, patients were randomized in advance into either the control group (pulmonary physician care) or the additional care group (pulmonary physician with additional educational care from a pulmonary nurse). So, the randomization was performed before informed consent was obtained. We chose for this approach to maintain a double-blind design. Randomization results were reported to the pulmonary physician just before the patient's visit. During the consultation the physician asked the patient to participate into the study and could in this way refer the patients assigned to the additional care group to the pulmonary nurse in a natural way. If patients declined to participate, randomization results were ignored and these patients were still excluded. After the consultation and initial consent, a trial investigator provided extra information about the trial, obtained formal verbal and written 'informed consent' (see next paragraph) and registered the following baseline characteristics: age, sex, educational level, smoking behaviour, treatment history, diagnosis, the use of oral corticosteroids in the previous 6 months, co-morbidity, and pulmonary function. Since communication between the physician and nurse were part of our care model, the physician could not be blinded. Hence, this could introduce bias. Therefore, patients were asked directly after their doctors' visit about the length of it, in order to detect a potential difference in attention between the groups.

Our computerized randomization procedure was based on a minimization procedure. This approach focuses on minimizing imbalance in the distribution numbers within the various levels of each individual possible prognostic factor [9]. The minimization factors were diagnosis (asthma or COPD) and treatment history (treated or not by a pulmonary physician previous 2 years).

### 2.3. Informed consent to postponed information

We informed all patients that, besides the description of care given and outcome assessment after 6 months, the study had another purpose. Patients were told that they would be informed about this additional research question only after follow-up because informing during recruitment would affect the results. This informed consent procedure to postpone information, which enables a double-blind design, has also been performed and evaluated by Boter et al. and did not show major objections [10,11]. The study was approved by the Medical Ethics Committee of our hospital. A letter with the postponed information about the additional research question, the randomization, and the reasons for not informing the patients during recruitment was sent after the collection of all outcome data.

### 2.4. Additional nursing care

Patients in the additional care group received a protocol-based education program on individual basis given by an experienced pulmonary nurse. During a 45-min individual session patients received information about their disease, the underlying pathophysiological mechanisms, action and proper use of their medications and oxygen, avoidance of allergic and non-specific triggers, influenza vaccination, self-monitoring, instructions about smoking cessation, and individual instructions for self-management and what to do in case of exacerbations. In addition, inhalation technique was checked and corrected when needed. Patients were instructed how to prevent and act in case of an exacerbation. Depending on the patient characteristics, they were instructed to increase their medication. Emergency supplies of oral steroids or antibiotics were providing to some, others were advised to contact the pulmonary nurse or their physician in case of progressive respiratory complaints. Follow-up consultations were scheduled only when the pulmonary nurse considered this necessary. All interventions were guided by a checklist and recorded in a special nursing dossier.

### 2.5. Outcome assessments

After informed consent was obtained two assessment sessions (initial and final) were scheduled with a 6-month interval. Primary outcomes included: (1) knowledge, (2) inhalation technique, (3) self-management, and (4) exacerbation incidence. Secondary outcomes were (5) general- and disease-specific health-related quality of life (HRQoL) and (6) satisfaction with care received.