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# Effect of a pharmacist intervention on asthma control. A cluster randomised trial

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Received 22 January 2013; accepted 24 May 2013

## KEYWORDS

Asthma;  
Asthma control;  
Inhaler technique;  
Medication  
adherence;  
Patient education;  
Community pharmacy

## Summary

**Introduction:** Achievement and maintenance of good asthma control is a major objective in asthma management. However, asthma control in many patients is suboptimal, due to improper use of asthma medications and non-adherence. The aim of this study was to evaluate the effect of a pharmacist intervention on asthma control in adult patients.

**Methods:** A 6-month cluster randomized controlled trial was undertaken with allocation of community pharmacies to intervention or control group. Adult asthma patients in the intervention group received a protocol-based intervention addressing individual needs related to asthma control, inhaler technique and medication adherence. Patients in the control group received usual care. Main variables were measured at baseline, 3 and 6 months.

**Results:** 336 patients completed the study, 150 in the control group and 186 in the intervention group. The intervention resulted in enhanced asthma control: Patients receiving the intervention had an Odds ratio of 3.06 (95% CI:1.63–5.73;  $p < 0.001$ ) of having controlled asthma six months later. In the intervention group mean ACQ scores significantly improved [0.66 points (SD: 0.78);  $p < 0.001$ ] and the number of controlled asthma patients increased by 30.1% ( $p < 0.001$ ) after 6 months. The intervention also resulted in improved medication adherence (by 40.3%,  $p < 0.001$ ) and inhaler technique (by 56.2%,  $p < 0.001$ ). No significant changes for any of these variables were observed in the control group.

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**Conclusion:** The AFasma study focused on the important outcomes of asthma management, and showed that through the designed intervention, community pharmacists can increase controlled asthma patients compared to usual care. Trial registration NCT01085474.

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## Introduction

In 2006 a new asthma management approach was adopted by the Global Initiative for Asthma (GINA) signalling an important change of philosophy based on asthma control rather than asthma severity or symptoms [1]. Since then, good asthma control has become a primary objective in the management of asthma patients [2], that is an absence of daily symptoms and exacerbations, minimisation of lung function variability or no impairment of quality of life. However, asthma control in many patients is sub-optimal [3,4], with negative implications for the patient's health, quality of life and/or health care costs. Reasons for this poor asthma control are complex including clinical and behavioral issues, such as co-morbidity, ineffective delivery of treatment, low adherence and/or ongoing exposure to triggers [5] among others.

Adherence to preventer medications represents a major challenge [6] since non-adherence to inhaled therapy is common among asthma patients due to intentional or unintentional causes [7]. Despite correct inhaler technique being essential for effective drug delivery, a literature review found that misuse of inhaler devices is frequent in practice [8] contributing to poor asthma control [9–12]. Hence updated asthma guidelines [2,13] highlight the importance of implementing strategies aimed at improving patients' knowledge, skills and aptitudes to self-manage their asthma.

A literature review [14] revealed an increase of pharmacists' participation in outcome-based asthma management programs, with positive impact in symptoms [15–21], pulmonary function [16–23] or severity [16,22–24]. At the time this study was undertaken only one other intervention study [25] in a community pharmacy setting had applied the new asthma management "control" approach. Results showed a positive impact on asthma control only in a subgroup of uncontrolled patients at baseline, suggesting that the impact of a community pharmacist's intervention on asthma control had yet to be established. An additional recently published study in 2012 has found significant improvements in asthma control for patients receiving a pharmacy asthma service during 6 months of follow-up [26].

The objective of the present trial (AFasma study) was to evaluate whether a pharmacist intervention focused on asthma control, medication adherence and inhaler technique would result in an improved asthma control in adult asthma patients.

## Methods

### Study design

This study was a 6-month cluster randomized controlled trial undertaken between November 2010 and June 2011 in Spain.

## Patients

Patients were recruited consecutively in the participant pharmacies (recruitment period: November–December 2010). To be eligible, patients were required to have been prescribed Symbicort (Budesonide/Formeterol, AstraZeneca) for their own use. Inclusion criteria were: aged 18 years or older and have a physician's diagnosis of asthma. Exclusion criteria included: participation in another asthma education program, pregnancy, presence of communication difficulties, suffering from seasonal asthma (asthma symptoms that only occurred in a seasonal pattern) or other pathologies such as Chronic Obstructive Pulmonary Disease, emphysema, lung cancer, respiratory infection and terminal illness (considered as any disease that was reasonably expected to result in the death of the patient).

Sample size was calculated to detect a difference in asthma control of greater than or equal to 20% between study groups. We applied a two-tailed test for comparing two binominal proportions, considering a type II error of 20% ( $\beta = 0.80$ ) and 95% significance ( $p = 0.05$ ). Sample size was adjusted according to standard criteria for cluster randomized trials, using a design effect (DE) of 1.45. The DE was calculated as follows:  $DE = 1 + (n_c - 1) * ICC$  (Where  $n_c$  is the mean number of individuals in the cluster and ICC the intra-cluster correlation coefficient). The ICC in the present work was considered to be 0.05, and the mean cluster size was assumed to be 10 patients [27]. A potential loss of 20% was estimated. Therefore, a minimum of 342 patients and 35 pharmacies were required.

All community pharmacies in the province of Malaga and all members of the Spanish Society of Community Pharmacy in the province of Madrid were invited by letter, with all responders enrolled.

Pharmacies were the unit of randomization and were assigned by an independent researcher after they agreed to participate in the study to either intervention (IG) or control group (CG) using a computer-generated list of random numbers with ratio 1:1. Cluster-randomization was used to minimize cross-contamination. Given the nature of the intervention pharmacists or patients could not be blinded.

## Outcome measures

Asthma control was the primary outcome and was assessed using the Asthma Control Questionnaire (ACQ; 5 item version, Spanish) [28,29]. ACQ was self-completed by the patient and the pharmacist calculated the mean of 5 items scored on a 7-point interval scale. For statistical purposes this variable was dichotomized into well-controlled (ACQ score  $\leq 0.75$ ) and uncontrolled/partly controlled (ACQ score  $> 0.75$ ) [30]. A decrease of 0.5 points on the patient's ACQ punctuation was considered clinically relevant [29].

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