# Asthma self-management model: randomized controlled trial

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### Abstract

Information for patients provided by the pharmacist is reflected in adhesion to treatment, clinical results and patient quality of life. The objective of this study was to assess an asthma self-management model for rational medicine use. This was a randomized controlled trial with 60 asthmatic patients assigned to attend five modules presented by a pharmacist (intervention group) and 59 patients in the control group. Data collection was performed before and after this 4-month intervention and included an evaluation of asthma knowledge, lifestyle, inhaler techniques, adhesion to treatment, pulmonary function and quality of life. An economic viability analysis was also performed. The intervention group obtained an increase in asthma knowledge scores of 58.3-79.5% (P < 0.001). In this group, there was also an increase in the number of individuals who practiced physical exercise (36-43%), in the number of correct replies regarding the use of inhalers, in the percentage of adherent patients, and in quality of life scores for all domains. We concluded that this asthma selfmanagement model was effective in improving the quality of life of asthma patients.

## Introduction

The treatment of asthma is aimed at controlling symptoms, preventing exacerbations, and improving pulmonary function. An early introduction of pharmacological treatment with anti-inflammatory agents such as inhaled corticosteroids results in better symptom control, possibly preserving pulmonary function on a long-term basis [1].

Self-management programmes can reduce asthma morbidity, such as hospitalizations; emergency room visits or unscheduled visits to the doctor; and days off work or school; and can improve quality of life. Furthermore, these programmes improve asthma knowledge and the appropriate use of medication [2–4]. Additionally, whether as single or mixed modes, these programmes reduce the overall cost of asthma [5, 6].

However, there is scarce information about public projects for the rational use of medicine. In addition, it was not possible to determine the cost–benefit relationship among the various approaches. Thus, a vicious cycle is formed, with projects often poorly planned, weakly implemented and assessed without the rigor necessary to satisfy future financers. The lack of formal evaluation of cost data means that the cost/benefit analysis of different approaches needs more studies [1, 7-11].

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The objective of this study was to test an original self-management model directed at the asthmatic population. The model was assessed according to the following parameters: asthma knowledge, mastery of inhaler techniques, adhesion to medicinal treatment, pulmonary function, quality of life, economic viability and user satisfaction.

## Methods

This was a controlled, randomized, longitudinal, prospective study conducted among 119 individuals (60 assigned to the control group and 59 to the intervention group) from March 2011 to October 2012 at the Asthma Outpatient Clinic of the University Hospital, Medical School of Ribeirão Preto, University of São Paulo.

This study included asthmatic patients with different degrees of disease severity diagnosed according to the criteria of the Global Strategy for Asthma Management and Prevention [1]. The patients were of both sexes, aged 18-73 years; with access to medicines provided by the public health system; and without cognitive diseases or dysfunctions that would impair their understanding of guidelines or limit the possibility of their participation in the study. These individuals were able to attend monthly meetings, to give written informed consent and to attend the first visit for evaluation. The exclusion criteria were the occurrence of serious adverse events, the inability to execute the procedures of the clinical protocol, having conditions that might affect the results of the study, such as pregnancy, and non-adhesion to the clinical protocol.

The participants randomized to the control group were evaluated at the beginning and at the end of the study, and for ethical reasons, they were oriented about the correct use of their inhalers after the first evaluation. They received monthly telephone calls for data collection without transmitting information and differed from the intervention group only because they did not participate in the intervention meetings.

Considering the proportions of participants (in the control and intervention groups) who answered the

questionnaire about their knowledge of asthma at two time points, a level of significance of 5% and a test power of 80%, the sample size required to detect a difference between proportions is 46 individuals per group [12]. Taking into account possible loss to follow-up during the study, the sample size was increased by 18%, for a total of ~ 60 individuals per group, assigned to the two groups with the use of a random number generator.

The present project ( $n^{\circ}$  13526/2010) was approved by the Research Ethics Committee of the University Hospital, Medical School of Ribeirão Preto, University of São Paulo, on 21/01/2011, and authorization for the use of images was granted. All subjects gave written informed consent to participate in the study.

This study was duly registered under  $n^{\circ}$  NCT01281215 in the protocol registration system at www.clinicaltrials.gov.

### Asthma self-management model

The asthma self-management meetings for the intervention group were led by pharmacists on a monthly basis for 4 months, involved a maximum of 10 participants, and each meeting lasted 60 min.

The programme content of the model was organized in the following order of five modules: asthma; adherence to medicinal treatment; medicines used for the treatment of asthma; inhaled medicine techniques; and care with medicines. The following material was also elaborated on and included in the programme: photos (inhaler use); leaflets (environmental control); folders (asthma with a summary of the modules); folders about inhaler techniques; metred-dose, Pulvinal and Aerolizer inhalers; banners (illustrating the modules); and PowerPoint tutorials (module summary). The learning methodology chosen for the present model was that recommended by Dr Bruce Wilkinson [13].

# Sociodemographic data, clinical data and life style habits

Data were collected based on the self-report of the volunteers and were complemented with

information obtained from their medical records using instruments based on sociodemographic data (gender, age and race), clinical data (comorbidities and adverse reactions to the medicines used), anthropometric data (weight, height and body mass index) and life habits (the practice of physical activity, smoking and alcoholism).

### Knowledge about asthma

A questionnaire developed and validated in Portuguese was used to determine the individual's asthma knowledge before and after the intervention. This instrument contains 34 questions related to the care of asthma, and the contents of the teaching programme include the aetiology and physiopathology, symptoms, treatment (environmental and drug control), prevention and action plans for the treatment of asthma [14]. The knowledge score was calculated using the following formula: (number of correct answers/total number of questions answered)  $\times$  100.

### Inhaler handling

The correct use of inhalers was evaluated in a practical manner using a validated instrument [15]. The score of the technical domain of the use of inhalers as a percentage was calculated using the following formula: (number of correct steps/total number of steps)  $\times$  100.

### **Evaluating medication adhesion**

Medication adhesion was assessed using two indirect methods: the Morisky-Green test (with subjects being defined as 'more adherent' when they scored 3 or 4 points) and renewal of the prescription by consultation of the pharmacy's informatized systems. The mean percent of drug dispensing was calculated by the following formula: number of months of dispensing/total number of months  $\times$  100.

### **Pulmonary function**

The spirometry exam was performed with the Koko spirometer and its programme (PDS Instrumentation, Inc., Louisville, CO, USA). The instrument was calibrated daily after the insertion of environmental condition data such as temperature (°C), barometric pressure (mmHg) and air relative humidity (%). To avoid contamination, a disposable mouthpiece with a filter was used for each individual. The spirometric parameters were calculated using the equations of Crapo *et al.* (1982) [16].

### Assessment of quality of life

In this study, we used the Outcomes Studies 36-item short form survey (MOS SF-36v2) obtained from the original authors with permission and with a certified translation from English to Portuguese. The results were scored according to the pre-established norms of the manual and by means of the programme of the health assessment lab, Medical Outcomes Trust and Quality Metric, Incorporated.

The SF-36 consists of 36 items divided into two components: the physical component (physical function or functional capacity, physical role limitations aspects, bodily pain and general health) and the mental component (social aspects, vitality, mental health and emotional aspects). The physical capacity refers to the levels and types of constraints between the extremes of the exercise. Low scores indicate limitations in performing physical activities. The physical aspects are related to problems with work or other activities due to physical problems. High scores indicate little or no problem in this regard.

### Criteria used to assess economic viability

The analysis of the economic viability considered the value of the investment for the implementation of the proposed model by outputs and cash inflows. The cash outflow refers to the cost of direct labour (investment), such as hiring a pharmacist to provide the service. The entries refer to reductions of variables corresponding to the reduction in the number of emergency room visits due to asthma exacerbation; reducing the number of hospital admissions for reasons related to asthma and the number of medicines used.

The cost related to the visits was determined by comparing two periods: a retrospective 1-year period (pre-intervention) and a prospective 1-year period (starting from the intervention). Analysis of this parameter permitted us to determine whether the implementation of the model achieved a reduction of costs and, thus, to identify the marginal economic effect of the intervention.

The methodology for the economic evaluation compared the direct costs of patients undergoing self-management intervention with patients in the control group. Economic viability was analysed using the net present value method as an economic indicator. The net present value is one of the major financial concepts and all financial decisions aim to produce its highest value. This value is obtained as the difference between the present value of the net cash benefits (cash inputs) predicted for each period of the duration horizon of the project and the present investment value (cash output). This method requires a previous definition of the discount rate to be used in the various cash flows. Thus, when the net present value is > \$0, the project adds economic value [17].

The net present value was calculated using the discount rate (k) provided by the government, known as the Selic rate, of 7.89% per year [18], referring to the funding cost of the public sector at the federal level. The effect time of the interventions was determined by the mean life expectancy for the study population, which was calculated by subtracting from the mean life expectancy of 75.5 years for the Brazilian population [19] 0.45% of the value of the years for males and the 0.46% of the value for females, corresponding to the negative impact of the disease on life expectancy [20]. Thus, life expectancy adjusted for the disease for males was 73.17 years and for females was 73.16 years. These values were subtracted from the ages of the enrolled males and females, respectively, and the average of the adjusted age  $(52.00 \pm 10.21 \text{ years})$  was calculated, resulting in the average additional life expectancy of the study population of 21 years.

The entries relate to cost reductions related to the measured variables corresponding to the number of cuts: the amount of medicines used, emergency department visits due to asthma exacerbations and hospital admissions related to asthma.

Initially, we calculated the increase or decrease in prescriptions for asthma medications. Both values

were multiplied by the cost of the medicine. Then, the amount of the increase (economic loss) of all medications for the value of the cost reduction was subtracted from the value obtained reduction (economic gain). The cost of medicines prescribed to asthma patients was calculated using the price table employed for the acquisition of medicines by users at the beginning and at the end of therapeutic follow-up, with the determination of whether a reduction in total cost had occurred for the municipality.

Emergency visits and hospital admissions were obtained from medical records and were quantified from an economic viewpoint by consulting the description of the prices of the procedures in the table of the Hospital and Ambulatory System of the Unified Health System [21].

### User satisfaction

The comments of the participants of both groups were recorded at the end of the activities. Thus, the use of questionnaires was not necessary to assess patient satisfaction and would have been inappropriate due the additional time needed for evaluation.

### Data analysis and interpretation

The data were statistically analysed to compare the groups before and after the interventions. Exploratory data analysis was first performed to summarize a series of values of the same nature and, thus, to obtain a global view of their variation. The data were organized and described in two ways: by means of tables with descriptive measures and graphs. Mixed-effects (random and fixed effects) linear regression models were used for analysis. These models are used to analyse data in which the responses are grouped (repeated measures for the same individual) and the assumption of independence between observations in the same group is not adequate [22, 23]. The model presupposes that the residues obtained by the difference between the values predicted by the model and the observed values have a normal distribution, with a mean of 0 and constant variance. The model was adjusted

	Intervention group	Control group	Total	P values baseline	
Age	$52.00 \pm 10.05$	$53.00 \pm 10.45$	$52.00 \pm 10.21$		
Sex	37 ♀ 15 ♂	39 ♀ 14 ♂	76 ♀ 29 ♂	$0.82^{**}$	
Asthma severity Patient nu	mber				
Intermittent	0	0	0	0.94**	
Mild	3 (5.77%)	4 (7.55%)	7 (6.67)		
Moderate	4 (7.69%)	8 (15.09%)	12 (11.43)		
Severe	45 (86.54%)	41 (77.36%)	86 (81.90)		
Rhinitis	24 (46.15%)	27 (46.15%)	51 (48.57%)	0.98*	

Table I.	Clinical	and	demographic	characteristics	of	the	participants
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\*\* *P* values obtained by Fisher's exact test; *P* values obtained by Student's *t* test.

using the SAS version 9.0 software. Fisher's exact test was used to determine the association between adhesion measured by the Morisky-Green test and the groups, also using the SAS 9.0 software. We used SAS 9.0 software (SAS Institute Inc., Cary, NC, USA) and a significance level of 5% in all statistical analyses. For graph construction, we used the R programme [24].

### Results

A total of 119 subjects were randomized; 14 withdrew and 105 completed the study protocol. Demands of work and distance were the most commonly cited reasons for non-adherence to the clinical protocol.

# Sociodemographic data, clinical data and lifestyle habits

Most participants were white women with incomplete elementary education, active workers, married, and had an average age of 52.00 (SD = 10.21 years)(Table I). Most volunteers had severe asthma and had received three to five diagnoses, including asthma. Allergic rhinitis was the most frequent diagnosis besides asthma.

There was an increase in the number of individuals who practiced physical exercise (43% versus 36%) after the asthma self-management interventions. In contrast, in the control group, there was a reduction in physical activity between the initial and final evaluations. On the second evaluation, there was a reduction in the number of individuals consuming alcohol and smoking.

### Asthma knowledge

The mean (SD) percentage of correct replies to the instrument used to determine asthma knowledge was 61.85% (13.52%) at the first evaluation and 65.47% (12.93%) at the second evaluation for the control group, confirming the results of a previous study that reported a baseline value of 63% [14]. The intervention group obtained a 21% increase in knowledge at the second evaluation compared with the first, 79.46% (14.83%) and 58.33% (15.67%), respectively, reaching the goal of a 20% increase in information initially proposed by the team. The intragroup (intervention) and intergroup (control and intervention) differences in the results were statistically significant (P < 0.0001) (Fig. 1).

### Inhaler techniques evaluation

A comparison of the initial and final evaluations revealed a significant intra- and intergroup increase (P < 0.0001) in the number of correct replies regarding the use of a metred-dose aerosol inhaler (Fig. 2), Pulvinal inhaler (Fig. 3) and Aerolizer inhaler (Fig. 4).

### **Evaluating medication adherence**

Most control volunteers were classified as adhering less to treatment at the first evaluation and having improved adherence at the second evaluation

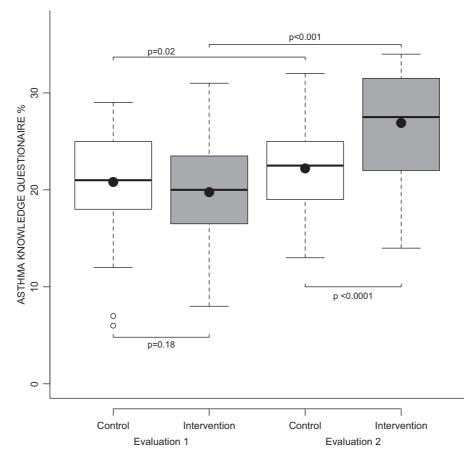


Fig. 1. Boxplot of the number of correct answers to the questionnaire about knowledge of asthma for the control and intervention groups at the initial and final evaluations (*P*-values indicated).

according to the Morisky-Green test. In contrast, most individuals in the intervention group were classified as having better adherence at both evaluations, with an approximate 5% increase in the number of more adherent participants at the second evaluation. The difference between the first and second evaluations was statistically significant (P = 0.0244).

The user's data from the hospital pharmacy were collected with the Medex computerized system. The results showed increased dispensation of medicines for the intervention group throughout the programme, indicating better adherence to medicinal treatment, with statistical intragroup significance (P = 0.0113).

### **Pulmonary function evaluation**

The pulmonary function test revealed that the control group obtained a similar forced expiratory volume at the first and second evaluations [mean (SD)]: 67.98% (19.08%) and 67.38% (20.78%), respectively. The intervention group values were 74.56% (17.24%) and 72.5% (19.35%) at the first and second evaluations, respectively.

The control group had reduced forced vital capacity (FVC) from the first to the second evaluation: 84.34% (18.04%) and 81.85% (18.94%), respectively. For the intervention group, the mean FVC was higher at the second evaluation compared with the first: 89.44% (15.44%) and 88.54%

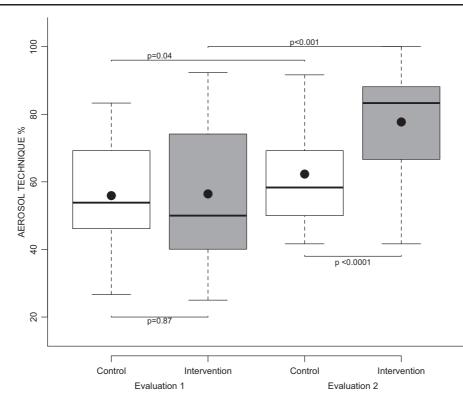


Fig. 2. Boxplot of the number of correct uses of the technique of the metred-dose inhaler for the control and intervention groups at the initial and final evaluations (n = 105) (P-values indicated).

(17.29%), respectively, with a significant difference between groups (P = 0.0287).

# Quality of life evaluation

The intervention group had increased quality of life, with increased intragroup scores for all domains, which was not observed in the control group (Figs. 5 and 6).

The quality of life evaluation considering the main confounding variables (age, sex, number of comorbidities, asthma severity, educational level, alcoholism and smoking) showed that sex, the number of comorbidities, alcoholism and smoking were confounding factors, although they didn't change the general results of the analysis.

# **Economic analysis**

The cash outflow refers to the direct labour cost of manpower (investment), i.e. hiring a pharmacist to provide the service. The labour cost was calculated based on the salary of the professional, and their benefits and charges. The calculated cost was \$973.7/month and \$8.11/h. The 20 5-h interventions required a total number of 105 implementation hours. The cost/hour value multiplied by the total number of 105 h was \$851.98.

The reduction of medicine expenses provided by the public health network to the participants in the intervention group was estimated at \$1128.24. Thus, the reduction of costs related to the number of emergency visits and hospital admissions was \$511.54 (\$9.89/individual) and \$2696.17 (\$157/individual), respectively.

The net present value was \$4033.44 for 1 year. The value for 21 years, presuming that the reduction would persist through the individual life expectancy, would be \$44 300.40 according to the values of current money. Because the net present value was positive, the investment in the inclusion of the

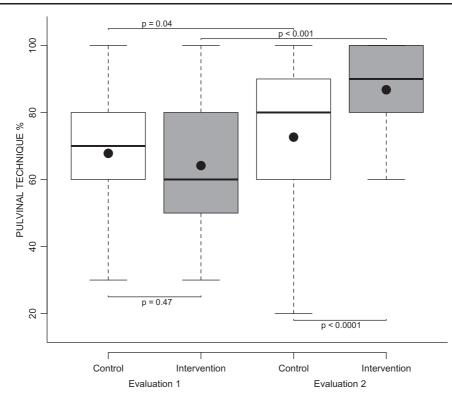


Fig. 3. Boxplot of the number of correct uses of the Pulvinal inhaler technique for the control and intervention groups at the initial and final evaluations (n = 105) (*P*-values indicated).

proposed asthma self-management model was acceptable and increased the economic value for society.

### **Users satisfaction**

The positive comments of the volunteers confirmed their satisfaction with the current proposed model, as some cited below:

'I liked it a lot; I learned the proper use of medicine. Before the programme, I received the medicines and I didnt even know how to use them.'

'It helped me a lot, not only in relation to asthma medicines, but others as well. Through the meeting about the medicines, I realized I was using a lot of calming medicines and getting addicted. I decided to solve the cause of my family problems and I'm feeling better now.'

'I liked it a lot; there should always be programmes like this at the hospital.'

'Now I use the knowledge I received during the course to help my mother use the medicine properly.'

'I was afraid that asthma medicines could harm my heart, but through what you taught us, I realized I could use them without fear.' 'Before the self-management programme,

I didn't use the medicines for fear of side effects.' 'Yes, it was worth it because before it I didn't know anything; knowledge was in the air. I made many friends, and most importantly, I improved my health.'

'For me it was worth participating in the programme; I learned things that I didít

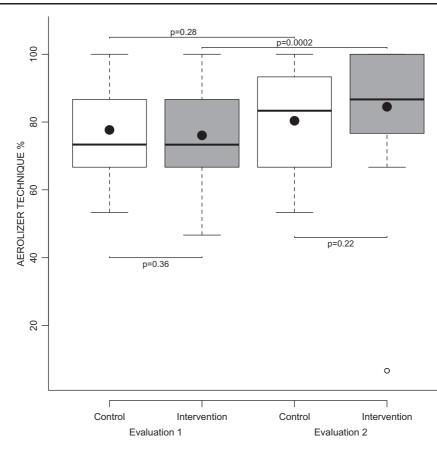


Fig. 4. Boxplot of the number of correct uses of the Aerolizer technique for the control and intervention groups at the initial and final evaluations (n = 105) (P-values indicated).

know. Through what I learned here, I could make changes at home; we removed the curtains and carpets, left the house airy to prevent mould, and put pillows and mattresses under the sun. After that I started to feel better.'

'When we started the course I still had seizures, but after I started the programme my health improved and now asthma attacks are rare. The group helped me a lot.'

'Now my asthma is under control, but not my other diseases; I have diabetes and uncontrolled high blood pressure. Do you know if there is a programme like this for diabetes? When you start one, let me know.'

## Discussion

Based on the observation of the individuals, professionals and their relationship, it is possible to determine the existing pharmacotherapeutic necessities and to elaborate strategies to satisfy them through interventions. According to self-management programmes involving individual-centred care by a multiprofessional team are more effective than programmes independently offered by basic care professionals [25, 26].

Multi-professional team work has increasingly become an important feature of the organization of work in all sectors. When decisions and actions

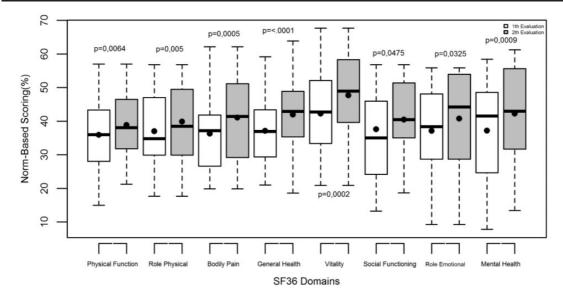


Fig. 5. Boxplot of the values of the normatized scores for the eight domains of the SF-36v2 questionnaire for the control group at the initial and final evaluations.

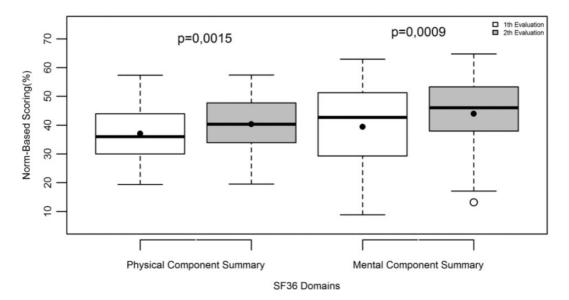


Fig. 6. Boxplot of the values of the normatized scores for the physical and mental components of the SF-36v2 questionnaire for the control group at the initial and final evaluations.

made by multi-professional teams are based on the perspectives of all members they are generally of higher quality than those made by single discipline teams and individuals acting alone [27]. With a diverse group of healthcare professionals, such as physicians, nurses, pharmacists, physiotherapists and health educators, with the patient at the centre of the team, the team can ensure treatment goals are maintained for chronic diseases. The team healthcare approach implements patient satisfaction and self-management, the development of a community support network, team coordination and communication, patient follow-up, the use of protocols and other tools, the use of computerized information systems, and outcome evaluations. As patient conditions changes over time, the composition of the team may change to reflect the changing clinical and psychosocial needs of the patient [28, 29].

According to Gibson *et al.* (2003) [2], an asthma self-management programme based only on providing information (videos, pamphlets or guidelines) has been recognized as ineffective for decades. The approaches should be systematic and centred on the individual. For this reason, the priority of the present model was to hold collective sessions to permit the expression of doubts on the part of the participants and to provide necessary information.

The main objectives of the information provided during the meetings in this model were a change of paradigm, a change in the way of thinking, balancing extreme behaviours such as abusive medicine use without medical guidance and the mistrust of medical science, as well as to provide information about the appropriate use of inhalers, the adoption of measures of environmental control, and the ability to differentiate between relief and preventive medicines.

The intervention group obtained a 21% increase in knowledge about the disease at the second evaluation, reaching the goal initially proposed by the multi-professional team. Because some participants responded correctly to 100% of the questions about asthma knowledge, we may state that the teachinglearning method employed in the present model was effective. After the interventions, there was an increase in the number of volunteers who practiced physical exercise and who reduced their consumption of alcoholic drinks and tobacco.

The results showed a significantly increased number of correct answers about the use of inhalers (metered-dose aerosol, Aerolizer and Pulvinal) both intra- and inter-group in a comparison of the final and initial evaluation. The largest number of errors occurred in the use of the aerosol technique, probably owing to the larger number of steps to be followed. In addition, the smallest number of errors occurred in the Aerolizer technique, a fact that can be attributed to the lower complexity of the technique.

This study demonstrated the importance of selfmanagement programmes asthma because the intervention group, resulted in greater knowledge about the disease and thus can prevent future exacerbations by previously ignored triggers, or poor adherence to treatment. In addition, with disease control, there is a significant savings with expenses resulting from emergency care or hospitalization.

The improved medication treatment adherence among the patients in the intervention group was confirmed by the statistically significant results obtained with three methods of evaluation and may have been the result of learning the correct inhaler techniques. The main possible reasons for better adherence to the treatment of asthma are knowledge on the part of the patient about the disease, about the proper use of medications and their effects, and the use of inhalers.

The effect of the self-management interventions on the pulmonary function of the intervention group compared with the controls can be explained by increased adherence to treatment regarding both environmental controls and the use of prescribed medicines. In addition, the increase in FVC may indicate a better ability to perform spirometry.

The improved quality of life among the participants in the intervention group in all domains of the SF-36 may reflect better adherence to treatment from both pharmacological and environmental control perspectives, resulting in better disease control and fewer physical, emotional and social restrictions. Bettencourt *et al.* (2002) [30] observed a significant increase in quality of life among individuals participating in a self-management program, especially in the areas of physical limitations and the frequency of symptoms, predicted to be a result of disease control. However, in contrast to the present study, the authors did not observe a difference in psychosocial scores. Evaluations of quality of life considering the main confounding variables revealed that sex, the number of comorbidities, alcoholism and smoking were confounding factors, although they didn't alter the general results in the current analysis.

Self-management interventions resulted in the reduction of costs regarding the quantity of medicines used, the number of emergency visits due to asthma crises and hospitalizations for asthma-related reasons. The values attributed to the number of emergency visits were underestimated because we did not compute expenses related to intravenous medication, the use of equipment and the exams performed. Indirect costs such as the loss of a job, work and school absenteeism were also not computed, a fact that would increase the cost-benefit relationship of the programme.

The qualifications of the professionals participating in the model proposed here include permanent training of health professionals, curricular reforms for undergraduate courses and encouragement of the professionals to participate in multiprofessional residency.

The qualification of the professionals required to work with the model is an important factor for the efficacy of the model. We propose continued health professional training, including activities such as contacting patients and interactions with multiprofessional teams. In a study investigating the knowledge of the principles and implementation of selfcare for the treatment of asthma, Steurer-stey et al. (2006) [31] showed that only 60% of the doctors participating in the investigation checked the inhaling techniques of asthmatic patients and 66% expressed the desire to receive more training about effective patient orientation. Only 32% preferred to orientate patients personally, while two-thirds stated that they preferred to identify a specialized centre for the self-management service. Moreover, interprofessional team-based care has been shown to improve asthma control and quality of life and reduce costs [32]. Gums et al. [33] showed that a physician-pharmacist collaborative model in primary care reduced emergency department visits, hospitalizations and improved asthma control and quality of life, mainly during the intervention.

The inclusion of disciplines such as psychology, ethics and clinical pharmacology with notions about clinical guidelines for the treatment of the main chronic conditions in the curriculum of undergraduate courses in the health area, as well as internships in health units and hospitals, contribute to the qualification of the professionals working public selfmanagement programmes. In addition, multiprofessional residency permits multiprofessional interaction and proper qualification for the provision of integral care at the three levels of health care, with the advantage that the practical workload would be superior to the theoretical workload.

This study had limited human and financial resources, which didnt allow for a single-blind study design to avoid possible investigator bias in its interpretation during the evaluation phases. Despite this limitation, this study guaranteed uniformity in the criteria for the initial and final evaluations by using a single investigator. Most instruments were self-administered and managed in the same way by subjects. Some information was collected with computerized systems. When possible, the data were confirmed by hospital records. The participation of the pharmacists in both the implementation and in the evaluation was favourable because it made it possible to meet the individual volunteers' needs and thus devise strategies for the development and implementation of this self-management intervention.

Reducing the cost associated with the use of medicines used to calculate the net present value has the limitations of time point collection, one at the beginning and one at the end of the study, and this value was multiplied to 12 months, assuming no change in the prescription during the period of 1 year; however, doctor appointments occurred every 6 months.

Moreover, the cost related to the reduction of the dose was not analysed because the collection of the second evaluation data were performed after (up to 3 months) the end of assistance and medication doses are usually reduced after 4 months of stable clinical conditions. Thus, it is estimated that dose reduction has an economic benefit in the long run. Information concerning the changing the therapeutic regimen

were collected, but it was not used for economic analysis.

The values assigned to the number of emergency consultations are underestimated because it does not compute the costs of intravenous medication, the use of equipment and tests performed. Indirect costs, such as job loss, absenteeism from work and school, mortality and waiting time for the service were not counted, which would increase the costeffectiveness of the programme.

We may conclude that this asthma self-management model for rational medicine use is effective in improving parameters that may have indirect effects on asthma morbidity and in improving quality of life and economic viability. Thus, this model could be an example for the implementation of asthma care programmes, and after the appropriate adaptations, it could be used for other chronic conditions.

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### **Conflict of interest statement**

None declared.

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