

Effectiveness of an asthma integrated care program on asthma control and adherence to inhaled corticosteroids.

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Abstract

Objective: To measure the effectiveness of an integrated care program for individuals with asthma aged 12 to 45 years, on asthma control and adherence to inhaled corticosteroids (ICS).

Methods: Researchers used a theoretical model to develop the program and assessed effectiveness at 12 months, using a pragmatic controlled clinical trial design. Forty-two community pharmacists in Quebec, Canada recruited participants with either uncontrolled or mild-to-severe asthma. One group was exposed to the program; another received usual care. Asthma control was measured with the Asthma Control Questionnaire; ICS adherence was assessed with the Morisky medication adherence scale and the medication possession ratio. Program effectiveness was assessed

with an intention-to-treat approach using multivariate generalized estimating equation models.

Results: Among 108 exposed and 241 non-exposed, 52.2% had controlled asthma at baseline. At 12-months, asthma control had improved in both groups but the interaction between study groups and time was not significant ($p=0.09$). The proportion of participants with good ICS adherence was low at baseline. Exposed participants showed improvement in adherence and the interaction between study groups and time was significant ($p=0.02$).

Conclusion: An integrated intervention, with healthcare professionals collaborating to amend asthma control, can improve ICS adherence.



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ABSTRACT

Objective: To measure the effectiveness of an integrated care program for individuals with asthma aged 12 to 45 years, on asthma control and adherence to inhaled corticosteroids (ICS).

Methods: Researchers used a theoretical model to develop the program and assessed effectiveness at 12 months, using a pragmatic controlled clinical trial design. Forty-two community pharmacists in Quebec, Canada recruited participants with either uncontrolled or mild-to-severe asthma. One group was exposed to the program; another received usual care. Asthma control was measured with the Asthma Control Questionnaire; ICS adherence was assessed with the Morisky medication adherence scale and the medication possession ratio. Program effectiveness was assessed with an intention-to-treat approach using multivariate generalized estimating equation models.

Results: Among 108 exposed and 241 non-exposed, 52.2% had controlled asthma at baseline. At 12-months, asthma control had improved in both groups but the interaction between study groups and time was not significant ($p=0.09$). The proportion of participants with good ICS adherence was low at baseline. Exposed participants showed improvement in adherence and the interaction between study groups and time was significant ($p=0.02$).

Conclusion: An integrated intervention, with healthcare professionals collaborating to amend asthma control, can improve ICS adherence.

1. INTRODUCTION

Asthma is a chronic respiratory illness affecting around 235 million people worldwide [1]. In 2010, asthma prevalence in Canada was 8.5% among the population aged 12 and over [2]. Despite availability of effective medications and the distribution of treatment guidelines, asthma control is not adequate for

some 53% of Canadians with asthma [3]. Sub-optimal asthma control affects patients' quality of life [4] and has important economic consequences, arising from the associated use of emergency health services and loss of productivity [5].

To improve this burden, the Quebec provincial government in Canada implemented interventions such as publishing short versions of Canadian treatment guidelines and action plan pamphlets and setting up Asthma Education Centers (AEC). However, publishing guidelines does not change practice appreciably [6, 7], while patient education alone does not improve self-management or health outcomes[8, 9]. According to a Cochrane systematic review, improving patient knowledge alone does not reduce hospitalisations, doctor visits or medication use for asthma[8].

To achieve a continuous improvement of asthma management by caregivers and patients, a publicly founded 4-phase disease management program (Towards Excellence in Asthma Management – TEAM) was carried-out in the province. Asthma education programs based on self-management plans, continuity of care, and integration of care have been identified as potential solutions to close therapeutic gaps in asthma treatment described in the first phases [10]. Integrated care is a process to ensure that services provided by health professionals from different organizations are mapped and linked to the particular needs of each individual [11]. In the fourth phase, interventions for physicians, other healthcare professionals and patients were defined, applied and evaluated. This study assesses one of those interventions. It describes the effectiveness of an integrated asthma care program offered to individuals with asthma aged 12 to 45 years, on asthma control. Implementation, effectiveness on adherence to inhaled corticosteroids (ICS), and factors involved in effectiveness are also described.

2. METHODS

2.1 Study population and recruitment

Forty-two community pharmacists recruited participants with uncontrolled or mild-to-severe asthma from across Quebec province. Individuals aged 12 to 45 years, for whom the pharmacists had dispensed at least one anti-asthma drug in the previous six months were screened and randomly contacted by phone. Based on the Canadian asthma guidelines then in force [12], researchers retained those who reported an asthma diagnosis and who were using a short-acting beta-2-agonist (SABA) >3 times a week (except before exercise) or a corticosteroid (inhaled or oral), irrespective of frequency. According to the guidelines we used, more than 3 doses of SABA per week is a sign of uncontrolled asthma while use of an ICS indicates at least controlled mild asthma. Exclusion criteria were pregnancy, no prior asthma diagnosis, participation in an ongoing respiratory study, or another respiratory illness. Eligible individuals interested in taking part in the study were asked to read, sign and return their consent form to the study centre. Recruitment began on May 2004 and the last participant was recruited in June 2005.

2.2 Design and setting

We used a controlled pragmatic clinical trial design. It is one of the most appropriate designs for studying the effectiveness of a multifaceted clinical intervention, since it lessens the risk of the intervention contaminating the control group [13]. The establishment of a family medicine group (FMG) in the Saguenay-Lac-St-Jean region of Quebec province facilitated the introduction of an integrated care program, since FMG doctors work closely with nurses and other healthcare professionals in the public health and social services network. Moreover, this region had the province's highest rate of emergency department (ED) visits for asthma [14]. The exposed group comprised all participants under the care of this FMG and was recruited by 11 participating local pharmacists. These participants were assigned to the program for 12 months. Individuals in the control group were recruited by 31 pharmacists from other regions of Quebec province. They were not exposed to the integrated care program and received usual care. The Ethics in Research Committee of the *Centre hospitalier affilié universitaire de Québec* approved this study.

2.3 Data collection and variables

Trained, blinded research assistants collected baseline data using a structured pre-tested computer-assisted phone questionnaire based on the study's conceptual framework [15]. The baseline questionnaire included validated questionnaires [16, 17] plus questions designed specifically for this study (see Supplemental Table 1). All participants who completed the baseline questionnaire were included in the study. As a reward, they were mailed a peak flow meter with instructions, plus an uncompleted sample asthma action plan.

2.3.1 The integrated care program

We used the PRECEDE-PROCEED approach [15] which provides a comprehensive method for assessing health needs, and for designing, implementing and evaluating health programs. To develop a model specific to asthma we began with a thorough literature review. The PRECEDE phase defined program targets and intermediate factors to be evaluated. We identified 19 predisposing factors, 23 enabling factors, 4 reinforcing factors, 1 lifestyle factor and 7 environmental factors (see supplemental online table). The PROCEED phase consisted of implementing the program and evaluating its implementation and effectiveness.

Three principles form the basis of integrated care and guided the program. They are information sharing between healthcare professionals, knowledge improvement, and coherent interventions [11]. Integration entailed setting up a multidisciplinary team of professionals: the physicians and nurses from the participating FMG, all pharmacists practicing in the region, a lung specialist and a certified asthma educator nurse from the local AEC.

Integrated care meant in effect, calling on the FMG nurses to evaluate and support patients with asthma. The FMG and AEC nurses received special training and followed a protocol based on the PRECEDE-PROCEED model developed and the Canadian asthma management recommendations then in force [12].

The protocol had five main aspects: 1) asthma assessment, 2) self-management, 3) environment and lifestyle, 4) collaborative care plan, and 5) information sharing and follow-up.

More specifically, here are the interventions that were included in the protocol. The FMG nurses contacted each exposed participant to schedule an initial asthma assessment and perform spirometry to confirm the asthma diagnosis. If diagnosis could not be confirmed, the individuals were referred to the lung specialist for a methacholine provocation test. If the methacholine test was negative, the person was referred to his/her treating physician with a summary of observations. Once this first evaluation was completed, the participant together with a summary of their disease, met with the AEC nurse, who performed a computer-assisted evaluation of the participant's management behaviors and needs. Software especially developed for the study facilitated the customization, standardization and description of the interventions. The AEC nurse used this software to assess each participant's asthma control (with a modified version of the 30 Second Asthma Test [18]), asthma severity (for participants with controlled asthma), medication, peak flow, and valved holding chamber use. Potential contributory factors of suboptimal asthma control or factors hindering efficient asthma management were also assessed during this first visit. These included medication adherence (underuse or overuse) and related barriers, inhaler technique, self-management capabilities, environmental triggers and allergies, knowledge and beliefs about, and attitudes toward asthma and asthma treatment. The software suggested actions in accordance with the results obtained; e.g. if inhalation technique was inappropriate, it prompted the nurse to reinforce the positive and correct any inappropriate elements; if the person was still misusing the inhaler after education, a suggestion was made to the treating physician to consider treatment options (e.g. changing the device or prescribing a spacer). If there were behavioral issues, the nurse would identify the elements suspected of being an obstacle to behavior modification and carry out a tailored intervention, taking the psychosocial factors into consideration.

According to the situation and complexity of the problem, interventions consisted of properly educating the patient, supplying educational material, encouraging behavior modifications and, if needed, a referral

to the general practitioner, lung specialist or pharmacist, together with a summary of observations and actions to be taken. For example, if non-adherence to therapy was detected, barriers to adherence (complexity of treatment, costs, forgetfulness, fear of adverse effects, inappropriate asthma knowledge) were assessed and appropriate interventions were suggested (e.g. referral to physician for treatment simplification or with a suggestion for a less expensive treatment). The software generated pre-filled follow-up and referral forms to summarize observations and actions to be taken, and to facilitate the communication and the sharing of clinical information between the professionals. Subsequent visits were scheduled according to each situation.

Next, the FMG and AEC nurses would discuss each participant's situation thoroughly and if need be, request additional information from the treating physician. The nurses then developed an individualized self-management action plan for asthma exacerbation, which the physician verified and endorsed before it was given to the participant. Finally, a copy was forwarded to the participant's pharmacist. In this way, all healthcare professionals were kept informed and responsible for patient follow-up and reinforcement. Participants that were exposed to all 5 aspects of the protocol were deemed to have received the full integrated care program.

2.3.2 Outcomes

One year after inclusion in the study (from June 2005 to July 2006), we collected follow-up data using the same procedures as for baseline data. Recruiting pharmacists also provided all participants' pharmacy records for the year before and after their inclusion in the study. To ensure completeness of data, we also contacted other pharmacists to obtain the pharmacy records of those participants who mentioned they had visited more than one pharmacy during this period.

Asthma control

The primary outcome was asthma control, measured with a shortened version (5 items: symptoms alone) of the validated Asthma Control Questionnaire (ACQ) [16, 19, 20]. A score below 1.5 (0=totally controlled, 6=poorly controlled) indicates adequately controlled asthma [21].

Adherence to ICS

Adherence to medication for each participant reporting an ICS prescription (n=319), was assessed using two measures; the validated Morisky medication adherence scale (MMAS-4) [17, 22] composed of 4 questions (yes/no) about past medication use patterns, and the medication possession ratio (MPR), a validated objective measure based on pharmacy records [23]. Using more than one measure provides a more effective estimate of adherence [24, 25] and informs different concepts [26]. Self-reported adherence measures seek problems with medication taking [17] while pharmacy-based adherence measures assess medication availability [27]. Participants who answered “no” to all 4 questions (score=0) were deemed to have good adherence. We calculated the MPR by summing all ICS days-of-supply during the year preceding and following the interview, divided by 365 days, multiplied by 100. We calculated the days-of-supply for each participant by dividing the number of doses filled by the dosing frequency prescribed. Participants with a MPR $\geq 75\%$ were deemed adherent, since this threshold is associated with a significant reduction in exacerbations [28].

Intermediate factors

All 54 factors targeted by the program were also assessed (Supplemental online table 1).

2.4 Statistical analysis

Study target sample size was 77 participants per group to provide 80% power to detect a clinically significant difference of 0.5 in ACQ score [20], with a level of significance of 0.05 using a two-sided *t* test.

Using independent sample *t* tests and chi-square tests we compared participant characteristics between groups at baseline. We conducted our main analyses with an intention-to-treat approach, using baseline data carried forward for participants lost to follow-up.

To assess intervention effectiveness on our main outcomes, we used generalized estimating equation (GEE) models. This regression model takes into account the correlation between repeated measures over time by robust estimation of the variances of the regression coefficients. Each GEE model included the examined time variable (baseline vs. 12-month follow-up), the treatment group and an interaction term between time and treatment group. We calculated adjusted mean change in asthma control score between participants in the exposed and those in the control group with 95% confidence intervals (95% CIs). To account for the fact that allocation was not randomized we adjusted all analyses for baseline imbalance between exposed and control group (i.e. those with a p -value ≤ 0.2). We pursued a similar analysis strategy for evaluating mean change in adherence scores. For our main outcomes we used multilevel regression to assess intraclass correlation coefficients (ICC) per recruitment site.

To identify the mediators of program effect, we first estimated the effectiveness of the program on the intermediate factors that were potentially involved, by computing unadjusted and adjusted prevalence ratios (PRs) and their 95% CIs, using a GEE model with a log link and a Poisson working model. Bootstrapping procedures were used to determine the significance (95 % bias-corrected CIs) of the mediation effects. We considered factors statistically significantly associated with a program effect in the GEE models (log link/Poisson working model) ($p \leq 0.05$) as potential mediators of program effectiveness. Random sampling with replacement generated a total of 1,000 bootstrap samples from the original dataset ($N=349$).

All analyses were performed using SAS version 9.2 (SAS Institute Inc., Cary, North Carolina).

3. RESULTS

3.1 Participants and implementation of the program

Of 1,036 patients screened, 476 satisfied enrolment criteria, 371 were willing to participate (Figure 1) and 349 (73.3%) actually participated. Only 19 (5.4%) participants were lost to follow-up at 12-months: 8/108 (7.4%) in the exposed group and 11/241 (4.6%) in the control group. Table 1 displays patient characteristics at baseline for both groups.

One year after recruitment of the last participant, 75/108 (69.4%) participants assigned to the exposed group met the FMG nurse for a spirometry test. The AEC nurse had seen 58 (77.3%) of them at least once and 26 had received more than one intervention; a total of 95 encounters (range 1-4). In 65 of these visits inhaler technique was assessed and in 51 (78.5%) poor technique was detected. During these visits, 39 (67.2%) and 36 (62.1%) participants were found to have asthma control issues and adherence issues, respectively. Frequently identified barriers to adherence concerned adverse effects or fear of same (30.6%), forgetfulness (19.4%), lack of knowledge (13.9%) and cost issues (11.1%). The meeting with the AEC nurse resulted in further interventions: referrals to another healthcare professional (70.5%); education (90.5%); material provided or suggested (26.3%); referrals to another resource (14.7%). Moreover, 53 (91.4%) of these participants received a personalized action plan in case of exacerbations, during an in-person visit or by mail. These participants were deemed to have received the full integrated care program.

3.2 Effectiveness of the program on asthma control and adherence to ICS

Of the 349 participants, 52.2% had well-controlled asthma at baseline: 50/108 (46.3%) in the exposed group and 132/241 (54.8%) in the control group, with mean ACQ scores of 1.59 and 1.63, respectively. At 12-month follow-up, asthma control had improved significantly in both groups ($p < 0.001$), with ACQ scores of 1.09 (38.9% had a clinically meaningful change of 0.5

points) and 1.37 (33.2% improved clinically) for the exposed and control groups respectively. However, interaction between study groups and time was not significant, meaning the effectiveness of the integrated care program on asthma control was not statistically significant ($p=0.0889$) (Table 2).

The proportion of participants with good ICS adherence was low in both groups at baseline: 15.8% and 9.1% with the MMAS-4 and MPR, respectively. Only exposed group participants showed a statistically significant improvement in ICS adherence (MMAS-4 at baseline/12-month follow-up=1.98/1.70, $p=0.0151$). Moreover, there was a significant interaction between study groups and time, meaning the program had statistically significant effectiveness on ICS adherence ($p=0.0197$) (Table 2). We observed similar results with the MPR (Table 2).

Given that we observed program effectiveness on ICS adherence and that the intervention was multifaceted, we performed analyses to assess which intermediate factors were involved. Of the 54 factors targeted by the program, we observed that the program had a significant impact on 11 of them ($p\leq 0.05$). Compared to the control group, participants in the intervention group were more likely: to obtain information on asthma and appointment with healthcare professionals, to be tested for allergies, to have asthma ever tested with a spirometry, to have obtained written information on asthma from healthcare professionals, to have received education about asthma and asthma triggers, to have had their inhaler technique verified by a healthcare professional, and to be satisfied with information provided and with attention given by healthcare professionals. Two of these factors mediated the program effectiveness on ICS adherence: a change in the provision of written information on asthma (MMAS-4) and in the provision of asthma education (MMAS-4 and MPR). Results are presented in Table 3.

4. DISCUSSION AND CONCLUSION

4.1 Discussion

To our knowledge, this is the first study designed to measure the effectiveness of an integrated care program on asthma control and ICS adherence. Other quality improvement strategies such as self-management, patient education and organizational change interventions have been studied but very few were based on the three principles of integrated care [29]. Integrated care is of importance in this chronic disease considering the complexity of asthma management and the frequent involvement of several primary care providers and specialists who may not be communicating effectively with each other.

We found no between-group difference in asthma control at 12-months. In fact, both groups improved significantly. Improvement in the control group may have been due to the Hawthorne effect, i.e. a response to the fact that participants know they are being studied [30]. Improvement may also have been because control group participants received a peak flow meter and an asthma action plan upon inclusion in the study. This incentive could be considered an intervention that potentially increased these participants' self-management and consequently, their asthma control.

Conversely, we observed that the program had a statistically significant effect on ICS adherence when measured with the self-reported MMAS-4 and also with the more objective MPR, which we calculated using pharmacy record data. Although statistically significant, actual improvement for the patients was modest. Thus, the improved adherence seen among the exposed group did not translate to better asthma control.

The proportion of asthmatic participants with well-controlled asthma at baseline was average (52.2%) and similar to what is reported in the literature [31-33]. The proportion of those with good adherence to ICS ($MPR \geq 75\%$: 9.1% and $MMAS-4 = 0$: 15.8%) was however among the lowest in the literature [34]. This could be explained by the fact that we enrolled people using a SABA more than three times a week, indicating, by itself, poor asthma control. The prevalence of non-adherence to ICS has been reported to be higher among poorly controlled asthmatics [35].

Of the 54 factors targeted by the program, only 11 were significantly impacted by interventions and two mediated the effect on ICS adherence. They were provision of written information on asthma (MMAS-4) and asthma education (MMAS-4 and MPR). These results are consistent with previous intervention studies, in which written information and asthma education improved ICS adherence [36-38].

Implementation of our program was not altogether successful; not as we first feared, because of low participation by professionals, but rather because of low patient participation. Of the 108 participants assigned to the integrated care program, only 53 (49.1%) were exposed to the full program despite several attempts by the nurses to reach and engage them all. This underexposure might explain the modest effectiveness observed. Intervention intensity (duration, type of contact and frequency) is also crucial to observing effectiveness [39]. In this study, the AEC nurse saw only 26 participants (24.1%) more than once. Since all interventions were not gathered, these participants may have received interventions from the other professionals in the integrated care program. Because intensity was tailored to patients' needs, it could indicate that only a few patients needed an intensive program.

We carefully planned this integrated care program in collaboration with all the professionals who were to perform the interventions. Throughout the course of the study we held several review meetings, which proved very useful for program implementation by the professionals and led to several adaptations to the initial program. For instance, some of the tasks that were first devoted to the FMG nurses were transferred to the AEC nurse to ease implementation. However, no patients were involved in these meetings and we received little feedback from them. To ensure that what is planned is suited to both patients and healthcare professionals, we recommend including at least one potential participant in the preparatory meetings of any future intervention to improve implementation and engagement on their part.

Our study has several strengths. The planning, implementation and evaluation of the integrated care program made use of a conceptual framework [15]. This facilitated a comprehensive evidence-based assessment of asthma management in Quebec province and led to the development of a tailored

intervention and a sound evaluation approach. We used validated instruments to measure asthma control [16, 19] and ICS adherence [17, 22, 23]. As suggested in the literature, we used two different measures of adherence [24, 25] to produce valid and reliable results. Since the integrated care program was multifaceted, we also performed analyses to highlight components involved in improving ICS adherence. Finally, we carried out a proper intention-to-treat analysis to account for missing data on the small proportion of patients lost to follow-up in both groups.

This study also has certain limitations. Because we did not randomize individuals or groups to the program, the groups were imbalanced at baseline. However, we adjusted for this by entering patient characteristics with a significant difference in the multivariate GEE model. In addition, our results may be difficult to generalize to other populations, different settings and other time periods. We offered the integrated care program to a specific population with the highest rate of ED visits for asthma at that time [14] and the program took place in one particular FMG. Nevertheless, inclusion criteria were broad and recruitment was at the community level. Transfer of successful elements of the integrated care program to another population or setting would necessitate further research. Moreover, since we based this intervention upon the Canadian asthma management recommendations accessible at the time, it would require updating with available new clinical guidelines. Although exposure to this integrated care program improved ICS adherence over a 12-month period, the program needs long-term evaluation and an assessment of its economic impact.

4.2 Conclusion

Integrated care is a way to increase collaboration between healthcare professionals and to optimize asthma care. Despite the low patient participation, the program improved several intermediate factors important for asthma control. Written instructions and asthma education were especially important to the

effectiveness of this program. However, improved ICS adherence did not translate into a statistically significant increase in asthma control among participants exposed to the program over a 12-month period. Nevertheless both groups showed some improvement and had a mean score of adequately controlled asthma at program end.

4.3 Practice Implications

The results of this study suggest that an integrated intervention, involving FMG nurses, a certified asthma educator, pharmacists, physicians and a lung specialist, working together to improve asthma control and sharing clinical information with the aid of pre-filled follow-up and referral forms, can improve ICS adherence. However, engaging patients in such intervention can be very difficult and needs to be addressed by healthcare professionals. Even though the program improved 11 intermediate factors important for asthma control, several factors remained unchanged. There is thus a potential for greater improvement in the quality of care. Written instructions and asthma education were important to the effectiveness of this program with potential implications for asthma care.

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DISCLOSURE

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

JUST ACCEPTED

Table 1. Participant characteristics by group at baseline (N=349)

Participant characteristics	Intervention group		Control group		P value ^a
	N=108	%	N=241	%	
Age (years), mean (±SD)	28.44 (±11.06)		31.62 (±10.17)		0.0091
Age (years)					
12-17	25	23.2	36	14.9	0.1747
18-39	56	51.8	137	56.9	
40-45	27	25.0	68	28.2	
Sex					
Male	51	47.2	90	37.3	0.0821
Female	57	52.8	151	62.7	
Level of education					
Elementary or high school not completed	60	55.6	107	44.4	0.0308
High school or college completed	35	32.4	77	31.9	
University completed	13	12.0	57	23.7	
Main occupation					
Worker/student	96	88.9	201	83.4	0.1833
Others	12	11.2	40	16.6	

	Intervention group		Control group		
	N=108	%	N=241	%	P value ^a
Participant characteristics					
Socio-economic status					
Very poor, poor	14	13.0	31	12.9	0.0308
Average	62	57.4	141	58.5	
Superior	27	25.0	52	21.6	
Missing	5	4.6	17	7.2	
Number of years with asthma treatment since asthma diagnosis, mean (±SD)					
	12.75 (±7.54)		15.44 (±10.05)		0.0060
Number of asthma medications used, mean (±SD) ^b					
	1.89 (±0.60)		3.00 (±0.62)		0.0032
Number of asthma medications used ^b					
1	22	20.4	25	10.4	0.0037
2	79	73.1	176	73.0	
≥3	7	6.5	40	16.6	

SD: standard deviation

^aParticipant characteristics variables at baseline were compared between groups using independent sample *t* tests and chi-square tests

^bNumber of asthma medications used was assessed at the interview

Table 2. Mean (SD) scores for asthma control and ICS adherence at baseline and at 12-month follow-up, plus adjusted effectiveness of the intervention within and between groups

	Baseline N=349	12-month follow-up N=330	Adjusted mean difference within group ^a (12-month follow-up - baseline) N=349			Adjusted mean difference between group ^a (12-month follow-up - baseline) (Interaction term) N=349		
	Mean score ± SD	Mean score ± SD	Mean score ± SD	95 % CI	P Value	Mean score ± SD	95 % CI	P Value
Asthma control								
ACQ score (range 0-6): lower score=better asthma control						-0.19±0.11 ^b	-0.40 to 0.03	0.0889
Intervention group	1.59±1.05	1.09±1.07	-0.43±0.09	-0.61 to -0.24	<0.001			
Control group	1.63±1.15	1.37±1.13	-0.24±0.06	-0.35 to -0.13	<0.001			
Intraclass correlation coefficient	0.0981							
ICS adherence^d								
MMAS-4 (range 0-4): lower						-0.29± 0.13 ^c	-0.54 to -0.05	0.0197

score=better adherence

Intervention group	1.98±1.09	1.70±1.02	-0.26±0.11	-0.46 to -0.05	0.0151
Control group	1.65±1.19	1.67±1.14	-0.04±0.07	-0.10 to 0.17	0.5768
Intraclass correlation coefficient	N/A				

ICS adherence

Pharmacy records MPR (range 1-100) higher score=better adherence

5.28±2.66^c 0.07 to 10.49 0.0471

Intervention group	19.41±19.17	22.86±25.16	4.02±2.16	0.22 to 8.26	0.0629
Control group	31.85±29.08	30.10±32.90	-1.26±1.56	-4.32 to 1.80	0.4209
Intraclass correlation coefficient	0.0494				

SD: standard deviation

^aAnalyses conducted with an intention-to-treat approach

^bAdjusted for baseline differences in age, sex, education level, main occupation, number of years with asthma treatment, number of asthma medications used, allergen immunotherapy, body mass index

^cAdjusted for baseline differences (p≤0.20) in age, sex, education level, main occupation, number of years with asthma treatment and number of asthma medications used

^dICS adherence: baseline: n=319; 12-month follow-up: n=292; adjusted mean difference within group: n=319; adjusted mean difference between groups: n=319

N/A: The SAS procedure to estimate the intraclass correlation coefficient was not feasible for this outcome because the inter-recruitment site variance estimate was equal to zero.

JUST ACCEPTED

Table 3. Mediators of the intervention effectiveness on ICS adherence (n=349)

Mediators	Adjusted PR ^a	95% CI	P-value	MMAS-4 Adjusted β	P-value	MPR Adjusted β	P- value
Ease in obtaining information on asthma and appointment with healthcare professionals	1.25	1.00-1.55	0.0491	0.01	0.5710	-0.00	0.9875
Ever tested for allergies	2.24	1.32-3.81	0.0030	-0.01	0.7841	0.66	0.2165
Asthma ever assessed with a spirometry	4.44	2.90-6.78	<0.0001	0.04	0.2290	-0.42	0.6379
Written information on asthma obtained from healthcare professionals	4.70	2.80-7.88	<0.0001	-0.08	0.0546	0.19	0.8250
Education about asthma received	18.56	4.04-85.27	0.0002	-0.17	0.0027	2.65	0.0535
Education about asthma triggers received	3.16	2.16-4.63	<0.0001	-0.03	0.2851	-0.68	0.2116

Verification of inhaler technique by healthcare professionals	3.31	2.28-4.81	<0.0001	-0.02	0.5700	-0.36	0.6144
Possession of a written action plan	2.34	1.34-4.09	0.0028	-0.03	0.2638	0.97	0.1135
Verification of asthma triggers by healthcare professionals	1.81	1.16-2.80	0.0082	-0.01	0.7265	-0.01	0.9778
Satisfaction with information provided by healthcare professionals	1.26	1.05-1.51	0.0135	-0.00	0.9151	-0.05	0.8239
Satisfaction with attention given by healthcare professionals	1.21	1.00-1.46	0.0491	0.00	0.8823	0.00	0.9942

^aPrevalence ratios (PR) are adjusted for baseline differences ($p \leq 0.20$) in age, sex, education level, main occupation, number of years with asthma treatment and number of asthma medications use.

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DISCLOSURE

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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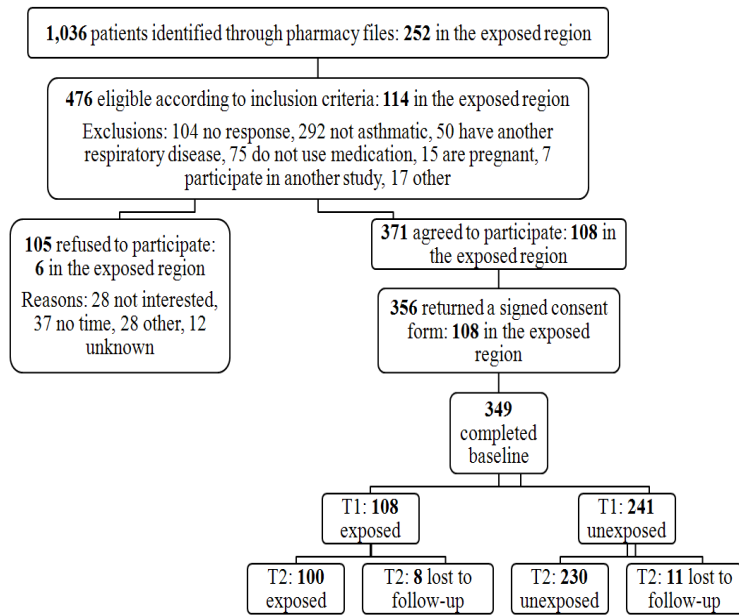


Figure 1. Flow of participants through the study.

Supplemental table 1. Factors potentially associated with asthma control and adherence to ICS

Factors	Brief description	Type of variable
Predisposing factors		
Age	(Interview date – Birth date reported by participants)/365	Continuous Categorical (12-17; 18-39; ≥40)
Sex	Confirmed during the interview	Dichotomous (male/female)
Level of education	Highest level completed	Categorical (none/elementary; high school or college; university)
Socio-economic status	Based on reported income and household*	Categorical (very poor/poor; average; superior)
Main occupation	Main occupation at interview date	Categorical (worker/student; other)
Body mass index (BMI)	Height and weight reported. BMI (kg/m ²)	Categorical (<25; 25-29; ≥30)
Number of years with asthma treatment since asthma diagnosis	Age at interview – age (years) at asthma diagnosis	Continuous
Perceived health status	Measured by a 5-point scale question ranging from poor to excellent and then dichotomized	Dichotomous (excellent/very good/good; average/bad)

Factors	Brief description	Type of variable
Perceived asthma severity	Measured by a 5-point scale question ranging from very mild to very severe and then dichotomized	Dichotomous (very mild/mild; moderate/severe/very severe)
Beliefs about asthma	Measured by six yes/no questions referring to positive and negative beliefs about asthma dichotomized by grouping individuals having five responses corresponding to positive beliefs	Dichotomous (good; average/bad)
Beliefs about asthma medication usefulness	Measured by a 4-point scale question ranging from useless to very useful and then dichotomized	Dichotomous (useless, low or moderately useful/very useful)
Attitudes toward asthma	Measured by eight yes/no questions referring to positive and negative attitudes toward asthma dichotomized by grouping individuals having seven responses corresponding to positive attitudes	Dichotomous (good; average/bad)
Self-confidence	Measured by two yes/no questions referring to confidence in personal ability to contribute to the management of asthma dichotomized by grouping individuals who answered “yes” to two questions	Dichotomous (high; moderate/poor)
Knowledge of asthma physiopathology	Measured by three true/false questions dichotomized by grouping individuals having three good responses	Dichotomous (good; moderate/bad)
Knowledge of asthma triggers	Measured by two true/false questions dichotomized by grouping individuals having two good responses	Dichotomous (good; moderate/bad)

Factors	Brief description	Type of variable
Knowledge of asthma management	Measured by six true/false questions dichotomized by grouping individuals having five good responses	Dichotomous (good; moderate/bad)
Knowledge of ICS	Measured by four true/false questions dichotomized by grouping individuals having four good responses	Dichotomous (good; moderate/bad)
Knowledge of LABA	Measured by two true/false questions dichotomized by grouping individuals having two good responses	Dichotomous (good; moderate/bad)
Knowledge of SABA	Measured by two true/false questions dichotomized by grouping individuals having two good responses	Dichotomous (good; moderate/bad)
Enabling factors		
Possession of an asthma spacer	Measured by one yes/no question	Dichotomous (yes; no)
Possession of a peak flow meter	Measured by one yes/no question	Dichotomous (yes; no)
Ease to follow asthma prescriptions for the next 12 months	Measured by a 4-point scale question, for each asthma drug reported by participant, ranging from very easy to very difficult and then dichotomized by grouping individuals who answered “difficult” or “very difficult” for at least one of their drugs	Dichotomous (very easy/easy; difficult/very difficult)
Number of asthma medications used	Number of asthma medications reported being used	Dichotomous (1 to 2/ ≥ 3)

Factors	Brief description	Type of variable
Perceived effects of asthma treatment	Measured by a 4-point scale question, for each asthma drug reported by participant, ranging from no effect to high effect and then dichotomized by grouping individuals who answered “moderate effect” or “high effect” for at least one of their drugs	Dichotomous (no effect/low effect; moderate effect/high effect)
Perceived risk of dying due to asthma if drug is taken as prescribed	Measured by a 4-point scale question, for each asthma drug reported by participant, ranging from no risk to very high risk and then dichotomized by grouping individuals who answered “high risk” or “very high risk” for at least one of their drugs	Dichotomous (no risk/moderate risk; high/very high risk)
Perceived risk of dying due to asthma if drug is not taken as prescribed	Measured by a 4-point scale question, for each asthma drug reported by participant, ranging from no risk to very high risk and then dichotomized by grouping individuals who answered “high risk” or “very high risk” for at least one of their drugs	Dichotomous (no risk/moderate risk; high/very high risk)
Self-reported side effects due to asthma medication	Measured by one yes/no question for each asthma drug reported by participant then dichotomized by grouping individuals who answered “yes” for at least one of their drugs	Dichotomous (yes; no)
Distance between the physician's office and the patient's home	Distance (in km) reported by participant between the physician's office and the patient's home	Dichotomous (0 to 15 km; >15 km)
Ease in obtaining information on asthma and appointment with healthcare professionals	Measured by a 5-point scale question, ranging from very easy to very difficult and then dichotomized by grouping individuals having at least one response corresponding to very easy or easy	Dichotomous (very easy/easy; moderate/difficult/very difficult)

Factors	Brief description	Type of variable
	in obtaining information on asthma and making appointment	
Economic accessibility to asthma medications	Measured by one yes/no question for each asthma drug mentioned by participant and then dichotomized by grouping individuals who answered “difficult” for at least one of their drugs	Dichotomous (easy; difficult)
Vaccination against influenza[†]	Measured by one yes/no question	Dichotomous (yes; no)
Vaccination against pneumonia[‡]	Measured by one yes/no question	Dichotomous (yes; no)
Ever tested for allergies[‡]	Measured by one yes/no question	Dichotomous (yes; no)
Allergies shots received[‡]	Measured by a 3-point scale question (yes, no or no allergies) dichotomized by grouping individuals who answered “yes” and “no allergies”	Dichotomous (yes; no)
Asthma ever assessed with a spirometry[†]	Measured by one yes/no question	Dichotomous (yes; no)
Written information on asthma obtained from healthcare professionals[†]	Measured by five yes/no questions and then dichotomized by grouping individuals responding “yes” to any question	Dichotomous (yes; no)
Discussion with the physician about goals to reach[†]	Measured by a 4-point scale question ranging from never to often dichotomized by grouping individuals who answered	Dichotomous (never/rarely; sometime/often)

Factors	Brief description	Type of variable
	“never” or “rarely”	
Education about asthma received or suggested[†]	Measured by one yes/no question	Dichotomous (yes; no)
Education about asthma triggers received[†]	Measured by one yes/no question	Dichotomous (yes; no)
Verification of inhaler technique by healthcare professionals[†]	Measured by five yes/no questions and then dichotomized by grouping individuals responding yes to any question	Dichotomous (yes; no)
Verification of asthma triggers by healthcare professionals[†]	Measured by one yes/no question	Dichotomous (yes; no)
Possession of a written action plan[†]	Measured by one yes/no question	Dichotomous (yes; no)
Reinforcing factors		
Coherence of information	Measured by two yes/no questions dichotomized by grouping individuals responding yes to any question	Dichotomous (yes; no)
Satisfaction with information provided by healthcare professionals[†]	Measured by five 5-point scale questions, ranging from very satisfied to very unsatisfied, dichotomized by grouping individuals responding very satisfied or satisfied to at least one	Dichotomous (satisfied; not satisfied)

Factors	Brief description	Type of variable
	question	
Satisfaction with attention given by healthcare professionals[†]	Measured by five 5-point scale questions, ranging from very satisfied to very unsatisfied, dichotomized by grouping individuals responding very satisfied or satisfied to at least one question	Dichotomous (satisfied; not satisfied)
Social support level[‡]	Measured by five 3-point scale questions, ranging from good to bad, dichotomized by grouping individual having four responses corresponding to good social support	Dichotomous (good; average to bad)
Satisfaction with social support received	Measured by a 4-point scale question, ranging from very unsatisfied to very satisfied, dichotomized by grouping individuals who answered “satisfied” or “very satisfied”	Dichotomous (very unsatisfied/unsatisfied; satisfied/very satisfied)
Lifestyle factors		
Smoking	Measured by one yes/no question	Dichotomous (yes; no)
Environmental factors		
Exposition to cigarette smoke at home	Measured by one yes/no question	Dichotomous (yes; no)
Presence of indoor mold at home	Measured by one yes/no question	Dichotomous (yes; no)

Factors	Brief description	Type of variable
Presence of carpet at home	Measured by one yes/no question	Dichotomous (yes; no)
Presence of humidifier at home	Measured by one yes/no question	Dichotomous (yes; no)
Wood heating at home	Measured by one yes/no question	Dichotomous (yes; no)
Oil or kerosene heating at home	Measured by one yes/no question	Dichotomous (yes; no)
Presence of animal with hair or feather at home	Measured by one yes/no question	Dichotomous (yes; no)

ICS: inhaled corticosteroids; LABA: long-acting beta-2 agonist; SABA: short-acting beta-2 agonist

* Institut de la statistique du Québec, enquête sociale et de santé 1998, table C22

† Self-management, ease in obtaining information on asthma and appointment with healthcare professionals, vaccination against influenza, vaccination against pneumonia, asthma ever assessed with a spirometry, written information on asthma from health professionals, education about asthma, education about asthma triggers, verification of asthma triggers, possession of a written action plan, satisfaction with information provided by health professionals and satisfaction with attention given by health professionals were assessed in the 12-month period prior to the interview

‡ Allergies tests and allergies shots were assessed during lifetime

¥ Social support was assessed since asthma diagnosis