Feasibility and effectiveness of an evidence-based asthma service in Australian community pharmacies: a pragmatic cluster randomised trial

Running head: Effectiveness of a pharmacy asthma service

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Key words: asthma, pharmacy services, disease management, primary care, asthma control.

Abstract

Objective: To test the feasibility, effectiveness and sustainability of a pharmacy asthma service in primary care.

Methods: A pragmatic cluster randomised trial in community pharmacies in four Australian states/territories in 2009. Specially trained pharmacists were randomised to deliver an asthma service in two groups, providing 3 or 4 consultations over 6 months. People with poorly-controlled asthma or no recent asthma review were included. Follow-up for 12 months after service completion occurred in 30% of randomly-selected completing patients. Outcomes included change in asthma control (poor, fair/good) and Asthma Control Questionnaire (ACQ) score, inhaler technique, quality of life, perceived control, adherence, asthma knowledge and asthma action plan ownership.

Results: Ninety-six pharmacists enrolled 570 patients, with 398 (70%) completing. Asthma control significantly improved with both the 3 and 4 visit service, with no significant difference between groups (good/fair control 29% and 21% at baseline, 61% and 59% at end, p=0.791). Significant improvements were also evident in the ACQ (mean change 0.56), inhaler technique (17-33% correct baseline, 57-72% end), asthma action plan ownership (19% baseline, 56% end), quality of life, adherence, perceived control and asthma knowledge, with no significant difference between groups for any variable. Outcomes were sustained at 12 months post-service.

Conclusions: The pharmacy asthma service delivered clinically important improvements in both a 3-visit and 4-visit service. Pharmacists were able to

recruit and deliver the service with minimal intervention suggesting it is practical to implement in practice. The 3-visit service would be feasible and effective to implement, with a review at 12 months.

Introduction

Asthma is a disease with a high global prevalence, including in Australia[1]. The high burden of asthma places an additional burden on primary care clinicians who are also managing increased caseloads relating to other chronic diseases. Research evidence suggests that despite improvements in mortality, asthma control generally remains inadequate[2, 3], care may not be in line with guidelines[4] and ownership of written asthma action plans is suboptimal, with only approximately 20% of patients having an action plan[1].

Thus, some innovation in primary care is needed to manage asthma, and there is increasing interest in the role of other health care professionals such as community pharmacists. With over 5000 community pharmacies nationwide, extending to rural and remote areas, community pharmacy represents an established and visible network of easily accessible health professionals. Models of asthma care delivered from community pharmacy have been developed; in randomised controlled trials (RCTs) they have been shown to be cost-effective and to lead to significant improvement in health outcomes[5, 6]. The success of asthma care models delivered from community pharmacy has been established [5, 7 -12].

RCTs recruit practitioners and patients in an ideal environment for hypothesis testing. In the real world, however, ideal conditions do not exist, and this has led to the emergence of pragmatic controlled trials to evaluate interventions in 'normal practice'[13]. In addition if a service is to be implemented in practice we

need to minimise the use of health resources while maintaining good outcomes. It is also important to know how often an asthma review should be repeated to maintain good outcomes.

The aims of this study were to:

I. Investigate the feasibility and effectiveness of a specialist management service in community pharmacy for patients identified as at risk of adverse outcomes.
II. Assess whether similar clinical and humanistic outcomes could be achieved by 3 versus 4 consultations over 6 months.
III. Assess the sustainability of outcomes after 12 months.

Methods

The study protocol was approved by the Human Research Ethics Committees of The University of Sydney, Charles Sturt University, The University of Queensland and Monash University. All pharmacists and patients provided written informed consent. Pharmacists were reimbursed for their time. A cluster randomised design was used, with pharmacists the unit of cluster. The primary outcome measure was asthma control; to detect an improvement of 1 point in the Asthma Control Questionnaire (ACQ) score with a power of 90% at a 5% significance level, allowing for a 20% drop out rate, 120 patients per group were required.

Pharmacist Recruitment

Pharmacists from regional and metropolitan areas in New South Wales, Australian Capital Territory, Queensland and Victoria were invited to participate in the asthma service. Pharmacists were included if they agreed to attend training in recruitment and asthma management, and had the organisational capacity and facilities to perform asthma patient assessments[2]. Pharmacists registered for the trial online. Once the registration period closed, pharmacists from regional and remote areas were proportionally sampled to be representative of the national distribution of pharmacies.

Pharmacist Training

Pharmacists were issued with a manual of peer-reviewed resources for pre-reading, and received face-to-face training on risk assessment, pathophysiology of asthma, asthma medications, asthma guidelines[14], adherence assessment, patient education, goal setting, spirometry and the service protocol during a two-day workshop. At the end of the training, pharmacists completed an accreditation assessment administered by an external body (Australian Association of Consultant Pharmacy).

Randomisation

Before training, pharmacists were randomly assigned to deliver the service at either 3 or 4 visits over 6 months (Figure 1). Randomisation was carried out using a pre-printed number list, conducted by two researchers. Neither pharmacists nor patients were blinded to their randomisation group.

Insert Figure 1

Patient Inclusion Criteria

Pharmacists were asked to recruit up to 10 patients between February and May 2009. Patients were eligible to participate if they were aged ≥18 years, were considered to be at risk of poor asthma outcomes as previously described[2, 5] and were regular clients.

Patient Exclusion Criteria

Patients were excluded if they had a terminal illness, if they did not speak English well enough to communicate with the pharmacist and complete the study questionnaires independently, were enrolled in another study, or if they did not self-administer their medicines/inhalers.

Processes

All patient data were recorded in a patient file. The patient file contained checklists to document assessments and record pharmacists' interventions, as well as a referral letter template for the patient's general practitioner (GP). For any referral, one copy was kept in the file and the other given to the patient to take to his/her GP. Records were audited during the study to document adherence with the study protocol.

Demographic data and asthma history, smoking status, current medications and ownership of a written action plan were recorded. Validated questionnaires – the *Impact of Asthma on Quality of Life Questionnaire*[15] (IAQLQ), *Perceived Control of Asthma Questionnaire*[16] (PCAQ), *Consumer Asthma Knowledge Questionnaire*[17] (CQ), and the *Brief Medication Questionnaire*[18] (BMQ) – were administered at the start and end of the service.

Asthma control was assessed at every visit using a symptom and activity tool, and classified as 'good', 'fair' or 'poor'[2]. Asthma control was also measured using the ACQ[19].

Spirometry was performed at every visit in accordance with current guidelines[20] using EasyOne^{TM} spirometers. Only sessions of quality A, B or C were used for analysis: two acceptable tests and between-test reproducibility for Forced Expiratory Volume in one second (FEV_1) and Forced Vital Capacity (FVC) of ≤200mL[20].

Patient technique for all inhaled medications was assessed at every visit using previously published device-specific checklists[2]. The proportion of patients with correct inhaler technique (all checklist steps performed correctly) was recorded.

Asthma medication profiles were generated at the start and end of the service from a combination of the dispensed medication history for the previous six months (as well as during the 6 month intervention) and medication use reported by the patient using the BMQ[18].

The Asthma Service Protocol

The asthma service protocol included interventions and counselling which focused on medication use and adherence, knowledge of disease and health beliefs, triggers for asthma and use of an asthma action plan. The protocol included written referral to a primary care physician if patients did not have a written asthma action plan, had sub-optimal spirometry (below 80% predicted), required review of medications, and/or they had not had their asthma reviewed in the previous six months. Pharmacists recorded their interventions in the patient file and then assisted patients to set goals and strategies[21]

The asthma assessment was repeated, interventions delivered as appropriate, and goals and strategies reviewed, at one month, and, in the group randomised to 4 visits, also at three months. At the final visit (6 months), the assessments/questionnaires used at the start of the service were repeated and any outstanding issues were addressed.

Evaluation of Sustainability

A randomly-selected subset of patients, 31% (n=125) of those who completed the service, were followed up for 12 months. Pharmacists and patients were re-randomised (at the pharmacy level) for follow up with or without an extra visit. Seventy-four patients received an extra consultation with the pharmacist at 6 months after service completion, whereas the remainder (n=51) had no other intervention and data for both groups were collected 12 months after the main service had been completed.

Data Analyses

Data were analysed using SPSS^{TM} version 17. Analysis was by intention to treat i.e. by original 3- or 4-visit allocation. To test for changes in continuous variables over time, within each group, either paired Student's t tests or Wilcoxon signed ranks test were used. For categorical variables McNemar's test or the marginal homogeneity test were used. To assess between group comparisons for continuous variables over time, the general linear model repeated measures multivariate analysis of variance (MANOVA) was used. The Pearson's Chi squared test was used to check for differences in categorical variables at the final visit. A significance level of 0.05 was used in all analyses.

A *post hoc* analysis was also performed for the primary outcome measure (asthma control category) on those patients who failed to complete the study. In this case their baseline level of control was carried forward.

Results

Process

Of the 106 pharmacists trained, 96 recruited patients. In total, 570 patients, 77% of whom had poor asthma control, were recruited and 398 (70%) completed all visits, 74% in the 3-visit group and 65% in the 4-visit group (Figure 1). There were no clinically important differences between randomisation groups at baseline (Table 1). Audit of the pharmacy and patient records indicated that all pharmacists satisfactorily followed the service protocol. In terms of spirometry, 81% of sessions were of A, B or C quality.

Insert Table 1

During the service, patients set 1,800 goals, and approximately 22,900 interventions were delivered. Of these, 443 interventions were referral letters sent to physicians, for one or more of the following reasons: no asthma review in the previous six months (n=141), no written asthma action plan (n=318), exercise-induced symptoms (n=94), poor asthma control (n=186), spirometry below 80% predicted (n=178), patient may qualify for the physician managed, Asthma Cycle of Care (a government-funded program for quality asthma care) (n=77).

For the 3-visit service, the median duration of consultations were 75 minutes for visit 1, 30 minutes for visit 2, and 50 minutes for the final visit; overall, approximately 40% of this time was for research documentation.

Outcomes

Asthma control significantly improved in both the 3- and 4-visit service, with no significant difference between the two groups; in the 3-visit group, the proportion with good/fair control increased from 29% to 61%, and for the 4-visit group, from 21% to 59% (chi-squared p=0.791) (Figure 2). Using the baseline-observation-carried-forward method, there was again no significant difference between randomisation groups. Likewise, there was no significant difference between groups in change in ACQ score (mean = 0.57 for the 3-visit group, 0.56 for the 4-visit group); overall, 48% patients demonstrated a clinically important reduction of ≥ 0.5 in their ACQ score.

Insert Figure 2

Overall, the proportion of patients with ‘correct’ inhaler technique increased significantly from 17-33% correct at baseline (depending on the device) to 57-72%, and asthma action plan ownership increased significantly from 19% to 56% (Figure 2), with no significant difference between groups. Between the baseline and final visits, there was an increase in the proportion of patients prescribed combination therapy (long acting beta agonist and corticosteroid)

and a decrease in those receiving a reliever (short acting beta-agonist) only (Table 2).

Insert Table 2

Similar significant outcomes were achieved for quality of life, perceived control, adherence and asthma knowledge (Table 3), with no significant differences between groups.

Insert Table 3

Sustainability

There was no significant decrease in asthma control (Figure 3), quality of life or knowledge in patients followed up for 12 months. The group who had an extra visit at the pharmacy, also had inhaler technique reassessed (at 6 months), and no significant decrease ($p>0.05$) was evident.

Insert Figure 3

Discussion

Innovative strategies in primary care can assist asthma management. An evidence-based program implemented by community pharmacists can

positively influence asthma outcomes for patients, with similar benefits achieved with either 3 or 4 structured consultations over 6 months. These benefits were seen in asthma control, inhaler technique, action plan ownership, asthma-related quality of life, perceived control of asthma, medication adherence and asthma knowledge. Follow-up data from a subset of patients suggests that the benefit can be sustained for at least 12 months. These results were achieved with the minimum of support and were observed across rural, small urban and large regional locations, suggesting that the program is generalisable in primary care. The outcomes are similar to those seen in our original randomised controlled trial[5] and those conducted by other groups[7–9, 22], but for the first time, the potential for successful implementation and sustainability has been tested in a pragmatic trial.

Poorly controlled asthma not only indicates an increased burden of symptoms for patients but is also associated with increased risk of exacerbations[23]. The majority of the patients recruited by pharmacists were classified as having poor asthma control (77%). The improvement in asthma control achieved was confirmed by a mean decrease of 0.56 in the ACQ score, above the minimal important difference of 0.5[24].

Referral to a physician was an important component of the service. This resulted in a significant increase in action plan ownership from 19% at baseline to 56% by the end of the service. Asthma action plans provide patients with a framework to recognise and respond to worsening asthma,

and, when combined with self-management education and regular review, have been shown to lead to substantial improvement in asthma outcomes[25].

Although the service paperwork included suggestions for potential interventions, the pharmacist and patient decided which received attention at each visit. Thus, pharmacists were tailoring the service to the individual patient's needs. In response, inhaler technique improved suggesting that patients were achieving more benefits from their prescribed medications. In addition perceived control of asthma improved, suggesting that patients considered that they had greater self-efficacy and greater perceived benefit from their medications.

On the background of our previous randomised controlled trial which demonstrated the clinical effectiveness and cost-effectiveness of a 4-visit pharmacy asthma service[5], the present study demonstrated the feasibility of a more efficient model, with 3 visits over 6 months. The research documentation required for this comparison was time-consuming, however we estimate that the time required for a routine service would be less than approximately 80-90 mins over 6 months. Pharmacists were reimbursed for their time; appropriate reimbursement should be considered if the pharmacy service model were to be implemented in the community.

This is the first study to investigate the sustainability of asthma services offered by pharmacists in primary care. Whilst other studies have

demonstrated positive outcomes in RCT format[9-12], and others have used a longer intervention program[8, 22], sustainability of improvements have not been investigated[7]. Our study showed that improvements in asthma control, knowledge, and quality of life were sustained 12 months after the service.

Limitations

In order to participate in this study, pharmacists were required to have access to a private area for consultations; this is available in 90% of Australian pharmacies. Asthma control was based on patient self-report; this is the case for most validated asthma control instruments. Finally, there was no 'usual care' group, as the effectiveness of the 4-visit service had already been established in a randomised controlled trial[5].

Conclusion/key findings

We have shown that a pharmacy asthma service offered in community practice is feasible and effective, targeting patients identified at risk. With 3 consultations over 6 months, the service delivered statistically significant and clinically important improvements in asthma control and action plan ownership, and the improvement was sustained over a further 12 months.

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Declaration of interest

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Table 1: Patient characteristics at recruitment for patients who completed the service

		3-visit group n=216		4-visit group n=182		All (n=398)	
		n	***%***	**n**	*%*	**n**	*%*
Age of onset of asthma	<2 years	28	*13.0*	21	*11.5*	49	*12.3*
	2-12 years	66	*30.6*	52	*28.6*	118	*29.6*
	>12 years	121	*56.0*	109	*59.9*	230	*57.8*
Hospital admission or visit to emergency in the past year		39	*18.1*	45	*24.7*	84	*21.1*
Life threatening attack in the past 5 years		24	*11.1*	31	*17.0*	55	*13.8*
Last time asthma was reviewed	<6 months	85	*39.3*	93	*51.1*	178	*44.7*
	6-12 months	28	*13.0*	26	*14.3*	54	*13.6*
	1-2 years	35	*16.2*	17	*9.3*	52	*13.1*
	2-5 years	27	*12.5*	19	*10.4*	46	*11.5*
	>5 years	16	*7.4*	9	*5.0*	25	*6.3*
	Cannot remember	25	*11.6*	18	*9.9*	43	*10.8*

Asthma control [2]	Good	10	*4.6*	4	*2.2*	14	*3.5*
	Fair	52	*24.1*	34	*18.7*	86	*21.6*
	Poor	154	*71.3*	144	*79.1*	298	*74.9*
Smoking status	Current smoker	31	*14.4*	32	*17.6*	63	*15.8*
		Mean	***±S.D.***	**Mean**	***±S.D.***	**Mean**	***±S.D.***
Spirometry	FVC % predicted	81.8	*17.2*	80.7	*16.6*	81.3	*16.9*
	FEV_1 % predicted	75.3	*21.7*	74.4	*22.3*	74.9	*22.0*
	FEV_1/FVC % predicted	90.8	*13.3*	90.3	*15.5*	90.5	*14.4*
ACQ-6 score		1.45	*1.02*	1.60	*1.09*	1.52	*1.06*

Table 2: Medication profiles

	Group	Baseline n (%)	End of service n (%)
Any controller medication (ICS with or without LABA, or LTRA)	3 visit	181 (84)	196 (91)
	4 visit	150 (82)	159 (87)
Combined ICS/LABA + reliever	3 visit	146 (68)	158 (73)
	4 visit	119 (66)	124 (68)
ICS or other anti-inflammatory + reliever	3 visit	20 (9)	18 (9)
	4 visit	19 (10)	17 (9)
Combined ICS/LABA only	3 visit	10 (5)	13 (6)
	4 visit	8 (4)	16 (9)
ICS + LABA + reliever	3 visit	5 (2)	7 (3)
	4 visit	4 (2)	2 (1)
Reliever only	3 visit	35 (16)	20 (9)
	4 visit	32 (18)	23 (13)

Data obtained from dispensed medication history for the previous six months, and medication use reported by the patient using the *Brief Medication Questionnaire* (BMQ). LABA = long-acting beta$_2$-agonist, ICS = inhaled corticosteroid, LTRA = leukotriene receptor antagonist, reliever = short-acting beta$_2$-agonist

Total n=398 (3-visit n=216. 4-visit n=182)

Table 3: Patient-centred outcomes

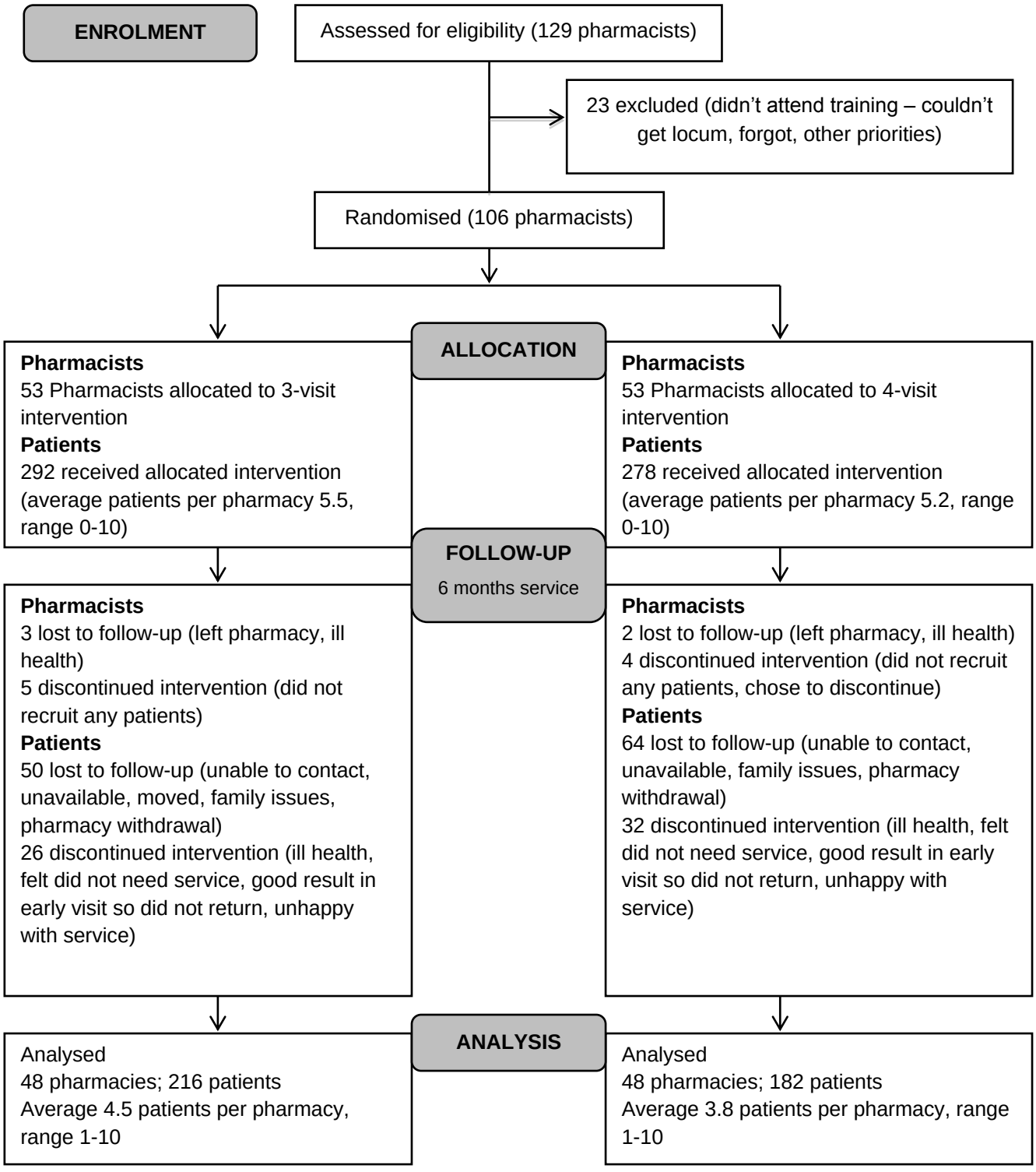
	Group	**n**	**Baseline Mean ± SD**	**End of service Mean ± SD**	**Baseline vs. end of service p value**
Quality of Life Total score (range 2-10) *Lower score is better*	3-visit	203	4.13±1.41	3.39±1.19	<0.001*
	4-visit	163	4.45±1.49	3.57±1.48	<0.001*
Perceived Control of Asthma (range 11-55) *Lower score is better*	3-visit	200	24.38±5.27	21.83±5.17	<0.001†
	4-visit	174	26.01±5.51	22.45±6.19	<0.001†
Consumer Asthma Knowledge (range 0-12) *Higher score is better*	3-visit	186	7.51±2.39	8.76±2.19	<0.001†
	4-visit	179	7.80±2.33	8.98±1.99	<0.001†

Risk of non-adherence (Brief Medication Questionnaire - BMQ) (range 0-12) *Lower score is better*	3-visit	193	2.71±1.90	2.21±1.80	<0.01*
	4-visit	161	2.81±1.90	2.25±1.86	<0.01*

*paired t-test; †Wilcoxon signed ranks test

Repeated measures multivariate ANOVA showed no significant difference between the groups in any measure at any time point.

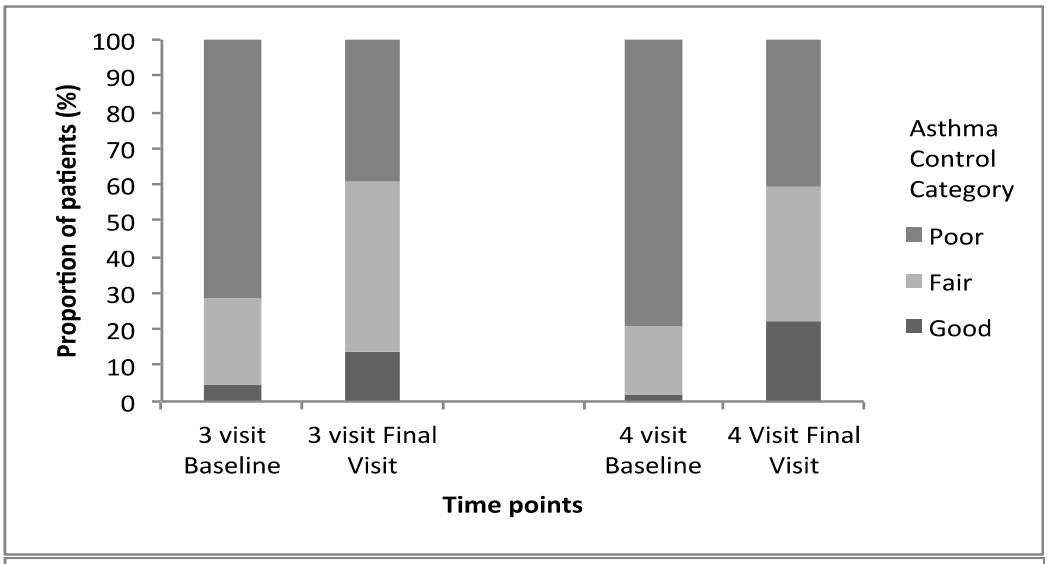
Figure 1: Consort and Timeline Diagram

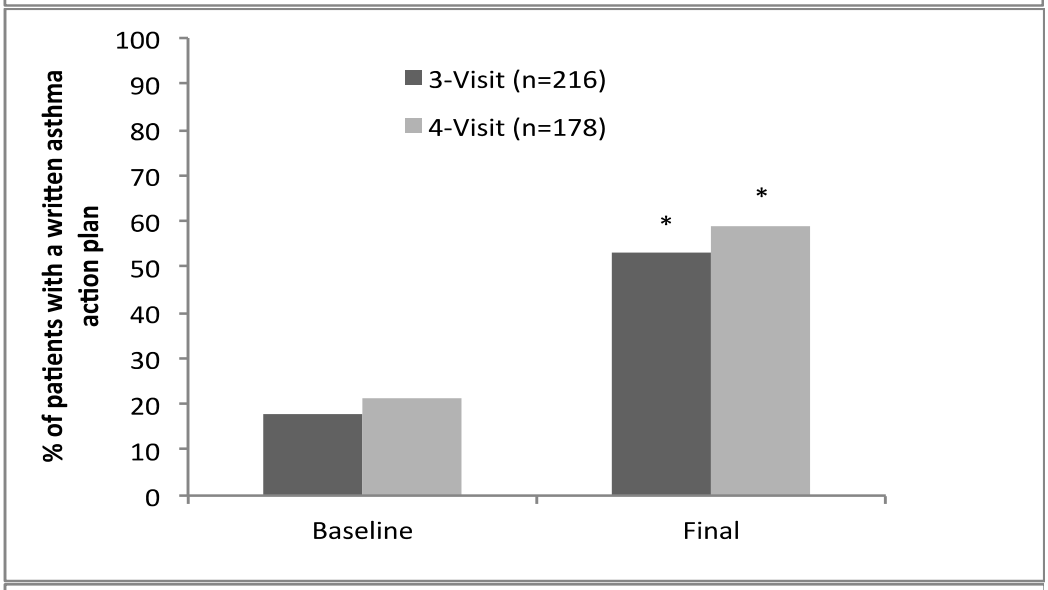


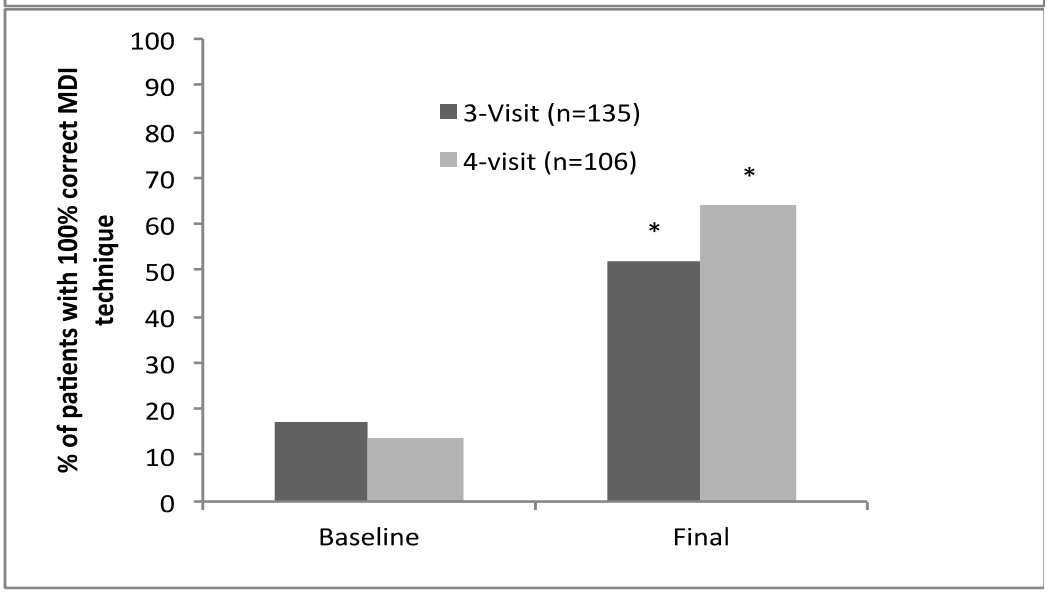
Pharmacists were randomly allocated to either the 3- or 4-visit service group.

Initially 570 patients were recruited by the 96 pharmacists. A total of 398 (70%) completed the service.

Figure 2: Outcomes of the Service



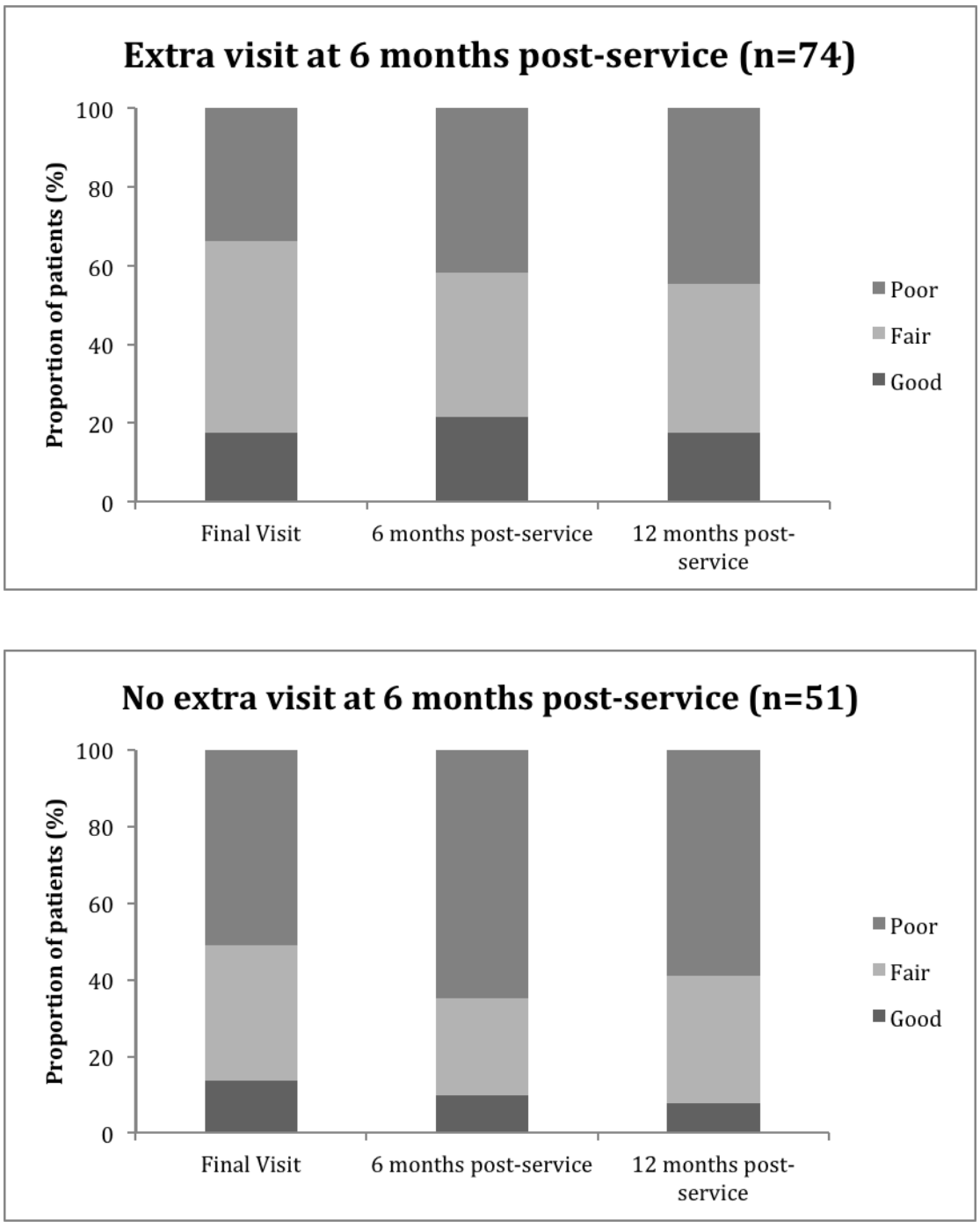




Asthma Control, written asthma action plan ownership, and correct MDI (metered dose inhaler) technique before and after the service for patients completing the 3- and 4-visit service (n=216, 3 visit, n=182, 4 visit).

*significant difference from baseline ($p<0.001$ for both groups, Marginal Homogeneity test); Action plan ($p<0.001$ for both groups) and MDI Technique ($p<0.001$ for both groups) (McNemar's test)

Figure 3: Sustainability of Improvements in Asthma Control.



Patients were followed up 12 months after the service. One group of these patients (n=74) were allocated randomly to an extra pharmacy visit at 6 months with data collection and the other group (n=51) no extra visit. Data for

the group of patients who had no extra visit was collected by the research team from the patients. All patients had data collected by the research team at 12 months. There is no significant change in asthma control over the follow-up period after the initial 6-month service (final visit).