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Pharmaceutical care for adult asthma patients: A controlled intervention one-year follow-up study

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Abstract

Asthma is a clinical problem with social, psychological and economic burdens. To improve patient disease management, different education programmes have been developed. Challenges in asthma management may be partially attributed to non-adherence or improper use of inhalers. This study aimed to implement and assess hospital-based pharmaceutical care services for asthmatic patients. A 12-month, single-centre, randomized, controlled study was initiated in asthmatic adult patients who had been divided into either a control or intervention group. Patients in the control group received the usual care, and patients in the intervention group received patient counselling per study protocol that covered asthma knowledge, control, adherence to treatment and inhalation techniques. The main variables compared measurements at baseline with those at 6 and 12 months. A total of 192 patients completed the study protocol: 90 in the control group and 102 in the intervention group. The control group included 90 patients, and the intervention group included 102 patients. Over the course of the 12-month follow-up period, a significant difference was observed between intervention and control groups with respect to asthma control (38.2% vs 10.0%; $P < .001$), mean correct inhalation technique (confidence interval [CI]: 8.1, 7.8-8.5 vs CI: 6.1; 5.6-6.6; $P = .01$) and good medication adherence (60.7% vs 50.0%, $P = .02$). There were 34% and 25% decreases in emergency room visits and hospital admissions, respectively, in the intervention group compared to the control group. This study emphasizes the importance of patient counselling in asthma management and the significant contribution that the pharmacist's intervention can have on asthma control.

KEYWORDS

adherence, asthma control, inhaler technique, palestine, pharmaceutical care

1 | INTRODUCTION

The Global Initiative for Asthma (GINA, 2018) has defined asthma as a chronic respiratory and inflammatory disease with episodes of chest tightness, shortness of breath, wheezing and coughing.[1] The fact that there are estimates of 300 million asthma patients globally, which may increase to 400 million by 2025, demonstrates high disease prevalence.[2-5] The most recent study (2018) in the Middle East showed some variability in disease prevalence (1%-18%) among countries and within different regions in the same country. This variability may be attributed to differences in environmental conditions, ethnic backgrounds,

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race, sex, socio-economic factors and lifestyles.[6,7] The two most often reported risk factors for asthma are cigarette smoking and genetic predisposition.[8,9]

In spite of the many options available for the treatment of asthma patients and deployment of evidence-based guidelines in recent years, asthma control is still less than optimal as indicated by the fact that there have been no changes in disease-related morbidity and mortality. Asthma is and will continue to be a major health problem worldwide.[10,11]

Many patients have suboptimal asthma control,[12] and this suboptimal control can have implications on their health, healthcare costs and/or quality of life. Factors contributing to poor asthma control include behavioural and clinical factors. Such factors may include continuous exposure to asthma triggers, poor treatment adherence and ineffective treatment delivery[13] among others. Treatment adherence is a critical factor in chronic asthma disease control and prognosis.[14] Improving patient adherence continues to be challenging, and well-designed approaches are needed to improve patient outcome.[15]

Asthma treatment is highly dependent on inhalers. Proper inhalation and device use were very crucial for effective for drug deposit to the lung. Several studies indicate that improper use of inhaler devices is common in clinical practice.[8] Improper technique can contribute to poor asthma control.[16] Most recent asthma guidelines[1] emphasize the need for strategies that can improve patient skills and knowledge for managing their disease.[17]

One notable method for improving adherence, knowledge and inhaler technique leading to improved asthma control is to integrate pharmacists into the healthcare system.

A previous review[18] showed that pharmaceutical care services that utilize pharmacist-based interventions had a positive on primary and secondary outcome, asthma control, adherence to medications, inhalation techniques, pulmonary function[16] and severity.[18] The change in pharmacists' practice should be emphasized in the hospital settings to be a more patient-centred approach, through the provision of professional pharmacy services, supports and focuses on optimizing the use of medicines and improving health outcome.

To the best of our knowledge, this is the first pharmaceutical care service asthma-based study in the West Bank. The main aim of this study was the implementation and assessment of a hospital-based pharmaceutical care service for asthmatic patients.

In this study, we evaluated the possible benefits of pharmaceutical care services on asthma control, medication adherence and inhalation technique in asthmatic adults.

2 | MATERIALS AND METHODS

2.1 | Ethics approval

The Al-Makassed Research Ethics Committee (reference PT-15/June/2015) in addition to research and developmental approvals was obtained.

2.2 | Demography of the study area

The Al-Makassed Charitable Society was officially established in 1964 on the Mount of Olives in Jerusalem. It is a Palestinian non-profit, non-governmental organization that provides diversified humanitarian services in East Jerusalem. Al-Makassed hospital is currently the leading medical centre in Jerusalem, providing secondary and tertiary health services for all citizens of Palestine. The Al-Makassed hospital is a 250-bed hospital and is staffed by 750 employees.

2.3 | Study design

This study was a prospective, 12-month, randomized, controlled trial that was conducted in the outpatient clinic at Al-Makassed. Ethics approval was obtained from Al-Makassed ethics committee, and patients gave written informed consent. The study lasted from September 2015 to September 2016, and the patients were randomized using computer software.

We targeted patients who were ≥18 years with persistent asthma, followed by their consultant, and undergoing inhaled corticosteroid treatment (alone or combined with a long-acting bronchodilator) as maintenance treatment for asthma control. Patients provided informed consent for study participation.

2.4 | Sample size and randomization

Minimum sample sizes were calculated according to previously described methods.[19] Sample sizes were calculated in order to detect ≥20% differences in asthma control between study groups. Based on the previous studies and the literature, the minimum sample size was estimated to be 90 patients in each group with 95% confident level and 0.05 error level. In order to accommodate potential drop-outs, 10% oversampling was done to yield 99 patients in each group. The participants in the study were randomly approached at the respiratory outpatient clinic, while they were waiting for their consultant. Patients were randomly allocated to intervention or control (standard-of-care) groups using Minim software.[20] Two hundred seventeen patients were recruited in this study. Figure 1 shows the study flow chart and the number of patients in each group at baseline and 6 months in addition to the 12-month sample of 102 intervention group and 98 control group patients.

2.5 | Data collection and assessment

During clinic visits, data were collected by a well-trained clinical pharmacist via structured, face-to-face interviews of the patients. Other relevant data were collected after patients underwent clinical examinations, which were performed by

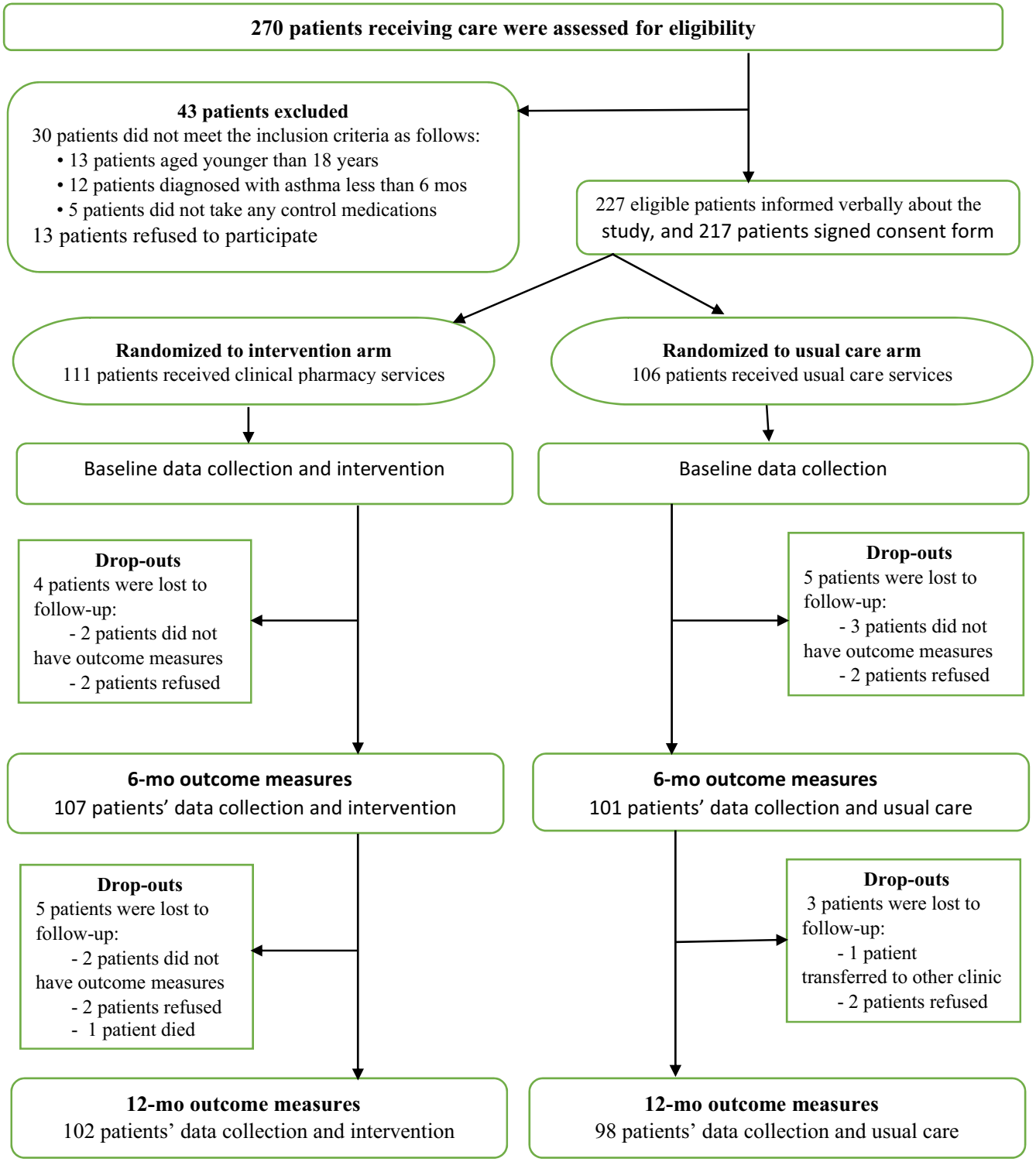

FIGURE 1 Study design flow chart

attending physicians. A standard form was developed for data collection used for both groups.

Consultants evaluated their patients based on several parameters: (a) predicted forced expiratory volume in 1 seconds (FEV_1), (b) symptoms, (c) clinical data and (d) disease characteristics. In addition to clinical variables, other collected information included duration of asthma, a history of smoking, general practitioner (GP) and emergency department (ED) visits, and the number of asthma-related admissions during the last year. Patients were asked questions pertaining to anti-asthma medications that they had received in the last 12 months prior to inclusion in the study. In order to evaluate patient inhaler techniques, pharmacists used specific checklists specific for each study inhaler device type[21] both before and after providing training in correct inhaler use.

2.6 | Measurements

2.6.1 | Asthma control test (ACT)

The asthma control test (ACT) is a five-item self-administered questionnaire developed for asthma control level assessments.[22] It evaluates the most recent 4-week time period. Each item receives a score between 1 and 5 with total scores ranging 5-25 (higher is better). Levels of 20-25 mean well-controlled symptoms, 16-19 not well-controlled, and 5-15 indicate very poorly controlled level (GINA 2018 classifications). An Arabic version of asthma control test in both Lebanon and Saudi Arabia has been translated and validated.[23,24]

Ten patients from Al-Makassed hospital participated in a pilot study. The Cronbach's alpha was 0.81, showing good internal consistency, reliability and suitability for use in our setting.

2.6.2 | Medication adherence test

The Morisky Green Levine Medication Adherence Scale is commonly used to assess patient adherence to a drug regimen. It is a self-administered questionnaire and comprised of four yes or no questions about medication taking history.[25] The Arabic version of the Morisky Green Levine tool is a 4-item questionnaire with four yes/no questions, which is used to explore the type of non-adherence behaviour like: (a) forgetting, (b) carelessness, (c) stopping medications when feeling better and (d) stopping medications when feeling worse. According to the scoring system of the Morisky Green Levine adherence tool, scores can range from 0 to 4, with scores consisting of 0, 1-2, and 3-4 that reflect high, medium and low adherence levels, respectively.[26] Cronbach's alpha was 0.79 for the instrument used in our study, indicating good internal consistency and reliability.

2.6.3 | Inhaler technique

A patient's inhaler technique was assessed by a very well-trained clinical pharmacist using placebo inhalers and standardized inhaler technique checklists that had been translated into Arabic by Basheti et al[27] (see Appendix S1). Based on a literature review, nine steps for each type of device were developed (potential score ranged from 0 to 9). Of the total nine steps, four steps in turbuhaler device (TH) were considered essential steps and and three steps in pressurized metre dose inhaler (pMDI) and Accuhaler [Diskus] were considered essential steps.[28]

2.6.4 | Intervention patient group

During the 12-month follow-up period, participants were approached three times during their consultation visits to the outpatient clinic. The clinical pharmacist ensured that patients received proper asthma management. Intervention patients were educated on an individual basis with respect to their asthma by the clinical pharmacist, therapy management, adherence to ICS, proper device and inhalation technique(s), and asthma symptom management. The clinical pharmacist also educated the participants about side effects, and when to use the rescue and maintenance medication(s).

The pharmacist taught and demonstrated inhaler techniques. Patients were then asked to demonstrate the techniques in order to ensure that they fully comprehended the proper technique for performing each technique. Moreover, follow-up telephone calls were made by the clinical pharmacist to reinforce patient education and motivation in order to achieve their goals (between outpatient clinic appointments). At each visit, all intervention patients were provided with written action plans, written medication lists and their uses, and an asthma manual booklet.

2.6.5 | Control patient group

Control group participants received the usual care at the outpatient clinic arranged by the hospital without any structured interventions by the clinical pharmacist.

During clinical visits, the participants completed the required forms that included demographic and clinical characteristics, perceived asthma control and an asthma knowledge questionnaire, adherence and healthcare utilization at baseline, 6- and 12-month follow-up periods.

2.6.6 | Data analysis

Data collected at baseline, 6- and 12-month assessments were analysed using SPSS computer software version 22. Student's independent *t* test was used to investigate continuous parameter comparability between groups (for variables with normal distribution). Mann-Whitney *U* test was used for non-normally distributed variables. Pearson's χ^2 was used to examine categorical variables between study groups. The significance level was set at $P \leq .05$.

This study was conducted in accordance with the Basic & Clinical Pharmacology & Toxicology policy for experimental and clinical studies [29]

3 | RESULTS

Two hundred seventeen patients (106 control and 111 intervention patients) attending an outpatient asthma clinic at Al-Makassed hospital were recruited. In total 17 participants, nine and eight patients from the intervention and standard-of-care groups, respectively, did not complete the study (Figure 1).

TABLE 1 Baseline characteristics of the population sample

Demographics	Intervention group (n = 111)	Control group (n = 106)
Age (y)[a]		
18-40	45 (40.5%)	41 (38.7%)
41-60	38 (34.3%)	42 (39.6%)
>60	28 (25.2%)	23 (21.6%)
Sex[b]		
Male	48 (43.2%)	41 (38.6%)
Female	63 (56.8%)	65 (61.3%)
Education status[b]		
Primary	21 (18.9%)	18 (17.0%)
Secondary	38 (34.3%)	40 (37.7%)
College/University	52 (46.8%)	48 (45.3%)
Smoking status[b]		
Smoker	28 (25.2%)	31 (29.2%)
Non-smoker	44 (39.6%)	50 (47.1%)
Ex-smoker	39 (35.1%)	25 (23.6%)
Duration of Asthma (Y, SD)[c]	9.4 (± 4.4)	8.6 (± 4.1)
FEV_1%[c]	72.4 (15.2)	69.2 (14.4)
Controller medication %		
ICS	17 (15.3%)	22 (20.7%)
ICS + LABA combination	83 (74.7%)	75 (70.8%)
Theophylline	11 (9.9%)	12 (11.3%)
Leukotriene receptor antagonists	3 (2.7%)	5 (4.7%)
LABA	2 (1.8%)	2 (1.9%)

Abbreviation: FEV_1%, Forced expiratory volume (per cent of predicted values post-bronchodilator).
[a]Mann-Whitney *U* test.
[b]Pearson's $\chi 2$ test.
[c]Student's *t* test.

Therefore, a total of 200 patients (102 intervention and 98 control) completed the 12-month study period (Figure 1).

Baseline characteristics of the patients are reported in Table 1. Baseline characteristics were similar across socio-demographic, clinical and functional variables, including age, sex, education status, smoking status, duration of asthma, asthma severity and pulmonary function. No clinically significant, important differences were found in demographic or baseline characteristics between intervention and control groups.

3.1 | Asthma control test (primary outcome)

The mean asthma control test score was 12.2 ± 4.8 with the majority of patients in both groups (129, 59.3%) having very poorly controlled asthma (ie score 5-15), 75 (34.6%), and some had moderate asthma control (ie score 16-19), and only 13 (6.0%) of participants had well-controlled asthma (ie scores 20-25; Table 2). At baseline, very poorly controlled asthma scores indicated no significant differences between intervention and control groups (60.3% vs 58.4%; $P = .66$). The percentage of patients with well-controlled asthma showed a significant increase in the intervention group at six months (43.0% vs 11.9%; $P = .002$) and at the 12-month assessment points (38.2% vs 10.2%; $P = .001$).

3.2 | Adherence to controlled medications (primary outcome)

Evaluation of maintenance asthma medications at baseline indicates that patients in the intervention group have the same pattern of adherence as the control group (Table 2) with no significant differences ($P = .712$). On the other hand, at the 6- and 12-month follow-up visits, a higher percentage of patients in the intervention group exhibited significantly better adherence to medication relative to control group patients (62.6% vs 50.0%; $P < .001$) and (62.7% vs 49.0%; $P < .001$), respectively.

3.3 | Inhaler technique

The mean scores of inhaler technique performance at baseline were similar in the intervention and control groups (5.8 vs 5.5; $P = .66$). In the intervention group, inhaler technique significantly improved compared to the control group at the 6- (7.9 vs 5.7, $P = .01$) and 12-month assessment points (8.1 vs 6.1; $P = .01$).

3.4 | FEV_1

Forced expiratory volume (per cent of predicted values post-bronchodilator) predicted values were reported at baseline, 6- and 12-month measurement points for both participant groups. No statistical differences in FEV_1 mean values between the two groups at baseline, 6- and 12-month measurement points (Table 2) were seen.

3.5 | Health resources use

At the 1-year measurements, participants allocated in the intervention group compared with control group had a significant reduction in both emergency department visits (29 vs 58; $P = .01$) and hospital admissions (15 vs 36; $P = .03$). For the GP visits (scheduled and unscheduled), no significant differences were observed (249 vs 221; $P = .11$) between the two groups (Table 3). This finding represents a 34% and 25% reduction in both emergency department and hospital admissions, respectively.

TABLE 2 Clinical and humanistic outcomes during baseline, 6- and 12-month follow-up

Variables	Intervention			Control			*P*-value
	Baseline (n = 111)	6 mo (n = 107)	12 mo (n = 102)	Baseline (n = 106)	6 mo (n = 101)	12 mo (n = 98)	
% change FEV_1 (95% CI)	NA	10.9 (1.7-18.8)	8.8 (2.1-16.4)	NA	6.8 (0.9-12.1)	6.6 (1.1-11.4)	t_1 .46[a] t_2 .55
Inhalation technique (range 1-9)	5.1 (4.6-6.1)	7.6 (7.0-8.2)	7.1 (6.8-8.5)	5.5 (5.1-5.9)	5.7 (5.1-6.0)	6.1 (5.6-6.6)	t_0 .66[b] t_1 .01 t_2 .01
Correct inhaler technique[†]	22 (19.8%)	87 (81.3%)	80 (78.4%)	24 (22.6%)	32 (31.7%)	29 (29.6%)	t_0 .51[c] t_1 .01 t_2 .01
Correct essential technique[††]	36 (32.4%)	94 (87.8%)	87 (85.3%)	39 (36.8%)	44 (43.6%)	39 (39.7%)	t_0 .66[c] t_1 .01 t_2 .01
Asthma Control							
Well-controlled(20-25)	6 (5.4%)	46 (43.0%)	39 (38.2%)	7 (6.6%)	12 (11.9%)	10 (10.2%)	t_0 .662[c]
Not well-controlled (16-19)	38 (34.2%)	31 (29.0%)	33 (32.4%)	37 (34.9%)	30 (29.7%)	37 (37.7%)	t_1 .001
Very poor-controlled (5-15)	67 (60.3%)	30 (28.0%)	30 (29.4%)	62 (58.4%)	59 (58.4%)	51 (51.1%)	t_2 .001
Adherence							
High adherence (0)	4 (3.6%)	20 (18.7%)	16 (15.7%)	6 (5.6%)	4 (3.9%)	5 (5.1%)	t_0 .712[c]
Moderate adherence (1-2)	57 (51.4%)	67 (62.6%)	64 (62.7%)	53 (50.0%)	51 (50.4%)	48 (49.0%)	t_1 .001
Non-adherence (3-4)	50 (45.0%)	20 (18.7%)	22 (21.6%)	47 (44.3%)	46 (45.5%)	45 (45.9%)	t_2 .021

Abbreviations: FEV_1%, forced expiratory volume in 1 s; NA, not applicable; t_0 t_1, t_2, intervention vs control at baseline and at 6 and 12 mo, respectively.
[a]Mann-Whitney *U* test.
[b]Student's *t* test.
[c]Pearson's $\chi 2$ test.
[†]Perform all nine steps correctly.
[††]Essential step: if not performed correctly, little/no medication will reach the lung.

4 | DISCUSSION

The addition of pharmaceutical care in asthma management is a relatively new approach that integrates disease management, adherence assessment and education of patients, inhaler technique training, drug pharmacotherapy management and patient education. These skills need to be introduced in a systemic manner in everyday pharmacy practice for asthma and all other chronic diseases.

The results show that the asthma control at the 6- and 12-month assessment points significantly improved in patients who had been allocated to the educational intervention group as compared to those in the standard-of-care group.

The study findings agree with findings from other published reports.[30] A study by Armour et al[31] assessed asthma control using the ACT for patients receiving several (3-4) asthma services during pharmacy visits. Results show a 32% and 38% increase in patients with good asthma control for the 3- and 4-visit groups, respectively; in addition, decreases

TABLE 3 Hospital admission, emergency department (ED) visits and general practitioner (GP) visits during the 12-month follow-up period

Variable	Control (n = 98)	Intervention (n = 102)	*P*-Value
Gp Visit	221	249	.11[†]
ED Visit	58	29	.01[†]
Hospital admission	36	15	.03[†]
Hospital Days	124	49	.001[*]

Abbreviation: ED, Emergency department.
[†]Pearson's χ^2 test.
*Mann-Whitney test.

in the mean ACT scores of 0.57 and 0.56, respectively, were observed.

In the present study, there was a high proportion of patients with very poorly controlled asthma and smoking status; similarly, Gracia et al[32] found in their study that 21% of the participants were current smokers. Mehuys et al[33] measured the effects of education intervention on asthma control using ACT and found that patients benefiting the most from intervention were the ones with insufficient baseline asthma control. On the other hand, the present study shows positive impacts of intervention over a wider range of patients at both 6- and 12-month assessment points. A pharmacist-provided pharmaceutical care service led to significant improvement in self-management by providing an asthma action plan, and other self-care activities such as such as avoiding exposure to triggers and smoke.

As previously suggested, the fact that the education-based intervention may have a more significant impact on patients with poor asthma control suggests that identifying these patients would allow for better asthma management and probably lower costs over time.[34]

According to GINA recommendations, interventions delivered to patients need to be tailored to a patient's current asthma control. For example, in the current study, adherence education was individualized, taking into account an assessment of concerns and beliefs about asthma treatment. Patient counselling had a significant effect on adherence behaviours at all assessment points. In an earlier study by Gallefoss and Bakke[35] that included asthmatic and COPD patients, the pharmacist counselling included two-hour educational sessions and tailored session for needed individuals. The study found that patients who received the educational intervention presented higher adherence (>75% adherence) than those who did not.

Inhaler training included physical demonstrations in addition to written and verbal counselling that were shown to be effective in other studies.[16,36] The intervention group had more patients who were using correct inhaler techniques throughout the study period.

Proper inhalation technique and medication compliance are essential factors and indicators for successful asthma treatment, and the fact that both parameters improved in the intervention group most likely contributed to enhanced asthma control. Unfortunately, in many clinical settings, neither training nor assessment of inhaler technique is performed, thus increasing the risk of inhaler device misuse.[37]

Hospital and ED admissions are the main drivers of cost in chronic disease management. An important finding in this study was the 36% and 25% reductions in ED visits and hospital admissions, respectively, in the intervention group at the 12-month measurement point. An important finding that a higher proportion of moderate and severe participants were presented to the ED and admitted to the hospital indicates that tailored interventions should be targeted those moderate-to-severe cases. It is worth to note that asthma ED visits and hospital admission impose a significant economic cost and expenditure to the health system.

Three other studies[37-39] reported a significant decrease in ED visit and hospital admissions when patients undertook self-management and educational interventions. In a systematic review of twelve studies (involving 1954 adults), Tapp et al reported that education significantly reduced subsequent ED visits with relative risk reduction by 0.5. Boyd et al reported that educational intervention in asthmatic patients significantly reduced the risk of subsequent hospital admissions and ED visits with relative risk by 0.79 and visits to emergency department with relative risk by 0.73 compared to controls. Paptist et al evaluated a self-management programme for adult asthmatic patients for 6 and 12 months and found a significant reduction in healthcare utilization in the self-management group.

4.1 | Study limitations

The study presented some limitations. Firstly, the study used self-report questionnaires to assess control and compliance to medications; this method has the disadvantages of recall bias. Secondly, the study covered only one hospital in East Jerusalem, which may have to some extent limited the overall generalizability of the findings. Further research is needed with more hospitals and medical centres in order to evaluate long-term clinical, humanistic and economic impacts of pharmaceutical care services.

5 | CONCLUSION

Our study confirms other results described in the literature indicating that a trained pharmacist who provides pharmaceutical care can assume a positive role in facilitating effective treatment and increase controlled asthma patients compared to the standard-of-care. A well-structured pharmaceutical care delivery system in the hospital facilitates improvements in patient knowledge, medication adherence, inhaler techniques and asthma control. As such, hospital pharmacists need to be properly trained to assess asthma patients and provide the education needed to address the individual challenges of the condition and its management.

CONFLICT OF INTEREST

None.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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