



# Investigating the value of medication management review for asthma patients: A randomized controlled study

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## ABSTRACT

**Background:** Asthma remains a major worldwide challenge, which threatens health and economies. The vast majority of asthmatics continue to experience uncontrolled asthma; thus, the need for enhancing patients' awareness, targeting the behavior of both physicians and patients to reach optimal medications' use is arising. Medication management review (MMR) service can be delivered by pharmacists to help resolve this dilemma.

**Aims:** To assess the clinical and humanistic outcomes of MMR service for asthmatic patients in Jordan. Via this service, the pharmacist identifies treatment related problems (TRPs) and resolves them either directly or by sending the physician a letter with recommendations.

**Methods:** A prospective randomized single blinded intervention-control study was conducted over 15 months, in outpatient clinics of public hospitals in Jordan. Asthmatics were recruited and randomized into intervention and control groups. MMR service was delivered for all patients by the researcher to identify patients' TRPs based on updated guidelines. Recommendations were sent to intervention patients' physician for resolution. Pharmacist level recommendations were resolved by pharmacist for the intervention patients. All patients were reassessed at three months.

**Results:** Patients with asthma (n=152) were recruited, and 959 TRPs were identified at baseline with no significant differences between both groups. A significant decrease in TRPs was noticed for the intervention group at follow-up, going down from 6.540±1.685 at baseline to 2.800±0.924 TRP per patient at follow-up (p< 0.001). Regarding TRPs at three-month follow-up, a significant difference (intervention group: 2.800±0.924, control group: 5.920±1.679 control, p< 0.001).

**Conclusions:** MMR service, which was delivered to asthma patients for the first time in Jordan proved successful in identifying and resolving TRPs for asthma patients. Such outcomes are beneficial in improving asthma control for asthma patients in Jordan.

**Keywords:** Jordan, medication management review, asthma control, treatment related problems, pharmacist's educational intervention, inhaler technique

## INTRODUCTION

Asthma is a chronic disease that causes noteworthy morbidity and mortality rates in both adults and children, affecting 1.0%-18.0% of population of different countries[1]. Asthma remains a major global problem, which creates a significant burden on primary care, general practice, outpatient clinics and hospitals. A new approach for managing asthma was adopted by the global initiative for asthma [1], which is asthma control in preference to asthma severity or asthma symptoms. Therefore, the primary goal in asthma management is achieving well-control asthma.

Unfortunately, asthma control is sub-optimal in many asthmatic cases, which may be due to clinical and behavioral concerns, morbid diseases, and persistent exposure to triggering factors [2, 3].

Previous studies have shed light on the progressive multifactorial problems, that were facing the vast majority of asthma patients around the world, several studies that were carried out to address asthma therapy related problems, such as controllers under prescribing, quick-reliever overusing, poor inhaling technique and medication non-compliance, furthermore, patients' poor perception of their disease [4, 5].

Thus, various approaches to asthmatic care are essential. The need for enhancing patients' awareness towards their disease, targeting the behavior of both patients' physicians and patients to reach more proper medications' use is arising [6]. Identifying treatment related problems (TRPs), medication errors such as prescribing, dispensing, and administering errors, in addition to the alarming adverse drug reactions or patient's response to a drug that may be deadly and unintended needs to be detected[7].

In addition, it is important to assess the contributing factors for asthma and avoid the modifiable ones in order to control asthma symptoms such as smoking, NSAIDs use, pollen allergy, stress, allergic rhinitis and many other factors that trigger asthma.

Prevalence of asthma among Jordanians is very high, alarming the need for early interventions. Since the critical point of asthma management is proper medication use, education of pharmacists and their experience in medication use plays a critical role in reaching optimal asthma treatment outcomes. Moreover, it is well known that all over the world, asthmatic patients are undermanaged. The need for follow-up, monitoring and education may be achieved by the well-known medication management review (MMR) service; this service was proven advantageous in many aspects. MMR is a patient-directed, designed, and collaborative medical care service, which is provided to improve medications' use [8, 9], boost patients' awareness and reduce the risk of medicines' adverse effects[10]. It involves the patient, their physician, a qualified pharmacist, and the patient's regular pharmacy [11].

Numerous studies have been conducted to assess the impact of MMR service on patients' health outcomes. Results support the pharmacist's role in applying medication review services such as the home subset of MMR service (HMR) and the residential subset of the service (RMMR), the impact of these services has been demonstrated to have a positive effect through assessing a variety of validated clinical and humanistic measures [12, 13].

The benefits gained by patients were reported to include an enhancement of identification and resolution of TRPS, in addition to the opportunity to receive education regarding patients' diseases and improving their disease states [14]. Optimal clinical outcomes were achieved by applying MMR service, which included a decrease of the adverse drug events, illness severity, costs of the healthcare service, and emergency room entries [15]. Moreover, by enhancing patient contribution in decision-making process, encouraging discussions regarding their health, and their preferences, priorities, goals and doubts will enhance concordance, which leads to better clinical outcomes [16].

Long term medication management services, which are provided to asthmatic patients have achieved and maintained significant improvements and significant decrease in the overall asthma-related costs, although medications' high costs, this is due to increased adherence and use [4, 5]. Medication Adherence is a critical base for a successful management of chronic diseases such as asthma, since non-adherence to self-management medication is very common among asthmatics, in an effort to progress asthma management and achieve optimistic health outcomes, Lung Association of Saskatchewan has employed an intervention plan to provide an effective and enhanced quality asthma education for asthmatics patients and the health care providers, along with encouraging access to spirometer instruments [6]. Because of this effort, the overall asthma medication utilization has increased, and healthcare expenses have decreased by providing better disease management.

The aim of this study is to explore the effect of MMR service for asthma patients is living in Jordan on minimizing the total number of TRPs identified, enhancing patients' self-reported adherence and health care measures including exercise and smoking cessation.

## METHODS

### Study Design & Clinical Setting

The study was conducted over 15 months, from 1 February 2018 to 1 May 2019, in Al Basheer Hospital and various health centers in Amman, Jordan, involving asthma patients. Ethics approval was obtained from the Jordanian Ministry of Health before the start of clinical work described in this research. Asthmatic patients were asked to participate in the study after an explanation of study procedure and requirements was given to them. Patients who accepted, signed a patient informed consent form. Only patients who had met the inclusion criteria were recruited into the study.

The inclusion criteria were patients  $\geq 18$  years old, with physician-diagnosed asthma, currently using inhaled corticosteroids with or without long acting B2 agonists via turbuhaler (TH), accuhaler (ACC), or metered dose inhaler (MDI) and have been on the same asthma medication and dose for a minimum of one month prior to study enrolment.

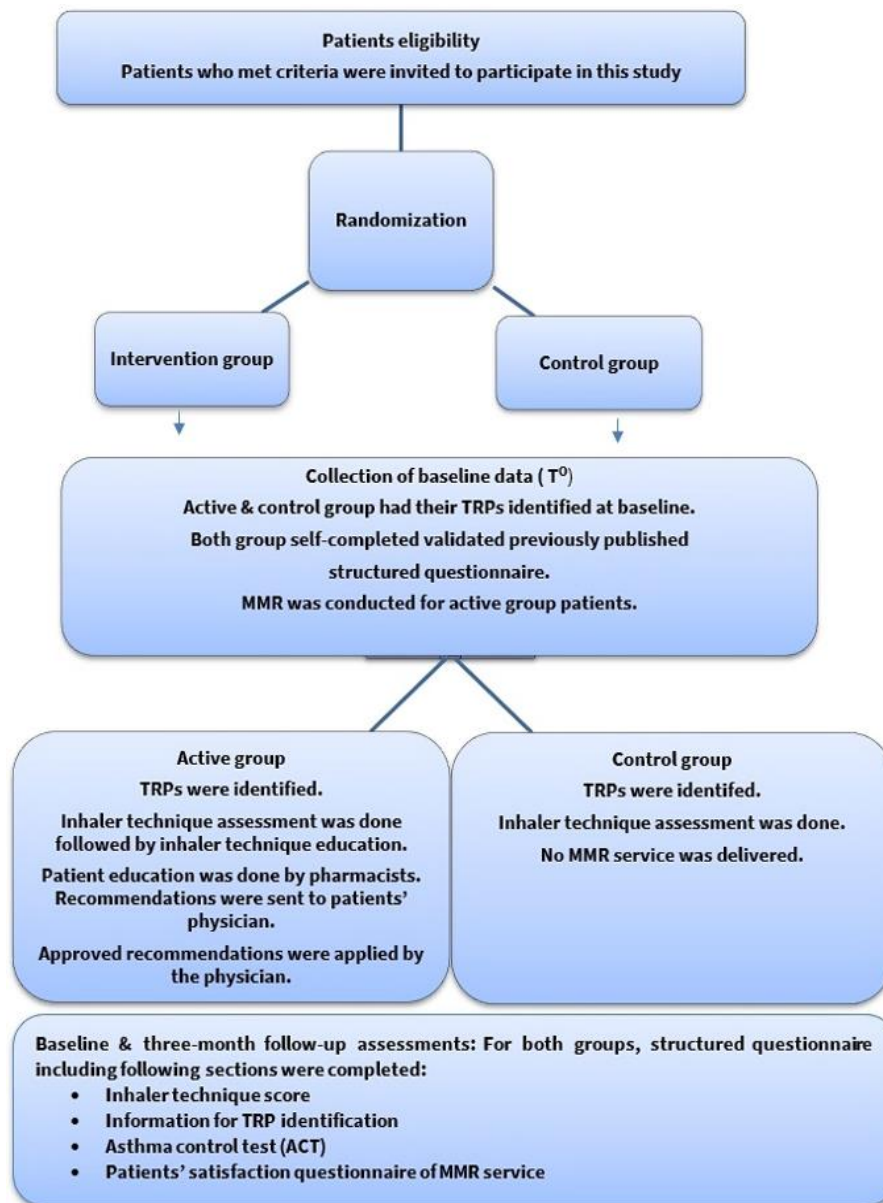
In this prospective randomized single blinded intervention-control study only the physicians and pharmacists were informed of the group assignment of the participants. Eligible patients with asthma were recruited randomly and randomized into two groups, intervention and control. Predetermined randomization number list was designed using a computer-generated randomization program [17].

Upon signing the informed consent and recruiting the participants, the structured questionnaires were completed for all patients, which involved data correlated to the patient demographic, personal and clinical status characteristics in addition to patient's inhaler use technique, which was evaluated and filled by the researcher. TRPs classification system table published previously [18-20] was used to identify the different TRP types and frequency of each for each patient. The table classified TRPs into seven types including unnecessary drug therapy, untreated condition, efficacy, safety, inappropriate knowledge, inappropriate adherence, and miscellaneous [20].

### Baseline Assessment

At baseline, intervention group participants underwent pharmacist- conducted interview for about one-hour at the outpatient clinic, they received educational interventions concerning their disease and their medications. Moreover, inhaler technique of patients was assessed and then patients were educated on correct inhaler technique using the 'show and tell' educational method, improving patients' inhaler technique skills by verbal information plus physical demonstration. The show and tell intervention was repeated until the patient was able to demonstrate correct technique all 9 steps in the inhaler technique checklist were demonstrated correctly, or up to a maximum of three repeats [21].

Control group patients were only assessed on their inhaler technique and other data were collected from them as was the case with intervention group patients, however no education or information provision was provided at this stage of the study. Only control group patients with life threatening TRPs were informed of the case and were excluded from the study and their physician was informed in order to overcome these life threatening TRPs.



**Figure 1.** Study protocol showing study stages, randomization of active & control groups, & data collected (Source: Authors' own elaboration)

TRP types were divided into detailed sections to provide accurate information while identifying and comparing patients' current therapy issues with the most updated clinical practice evidence-based guideline recommendations [1].

Such rich data input led to accurate identification of TRPs. Assessments were addressed, recommendations were sent to patients' physicians, as soon as TRPs were identified, intervention group patients, pharmacist- patients level intervention were delivered to this group patients. In contrast, recommendations for the control group patients were identified but were not revealed to the patients until the follow-up (except if serious TRPs existed, exclusion of patients took place and physicians were informed).

#### Follow-Up Assessment

Both groups were re-interviewed at three-four months after baseline and were reassessed on all outcomes assessed at baseline. Patients in both groups were asked about their satisfaction regarding MMR service that they have received and

pharmacist's cooperation, furthermore patients were asked if they would approve paid MMR service and by whom. **Figure 1** shows study protocol showing study stages, randomization of active and control groups, and data collected.

#### Data Collection Tools

In order to collect and evaluate data, the following questionnaires were used in this study.

#### Treatment related problems

TRPs classification system table published previously [19, 20] was used to identify the different TRP types and frequency of each for each patient. The table classifies TRPs into seven types including unnecessary drug therapy, untreated condition, efficacy, safety, inappropriate knowledge, inappropriate adherence, and miscellaneous [20].

Asthma control test (ACT) is a patient self-reported tool, employed in the identification of uncontrolled asthma. It consists of five questions related to asthma symptoms and

daily functioning, with four-week recall. It can evaluate how frequent the shortness of breath and asthma symptom episodes are, the use of reliever medications, the impact of asthma on daily functioning, and overall self-assessing of asthma control. The score range is five to 25, with well-controlled asthma being defined as a score above 20 [21].

### Baseline & after training inhaler technique assessment

The researcher filled this part in order to assess the patient's ability in using the inhaler device in a correct technique. Standardized inhaler technique checklists, which were translated into Arabic [22, 23] were used. Each checklist included nine steps (score zero-nine). A score of nine/nine was considered as correct technique for the TH, while four out of the nine steps were classified as 'essential' (without which little or no medication would reach the airway). While for ACC and MDI, three steps out of the nine were classified as essential [24].

Patients' satisfaction questionnaire of MMR service, at follow-up patients were asked about their satisfaction regarding MMR service that they have received and pharmacist's cooperation. Finally, the involved patients were asked if they would approve paid MMR service and by whom.

### Sample Size

For this parallel pre-post interventional study, the sample size was based on a distribution-based difference in ACT score of 2.21 points, SD 4.42. For 80.0% power and a two-sided significance level of  $p < 0.050$ , 63 patients per group were needed, giving a total of 126 patients; with an expected drop-out rate of 20.0%, a total sample size of 152 patients were recruited

### Data Analysis

Statistical package for the social science (SPSS) software version 24.0 was used to analyze the study data (IBM Corp, 2016). The level of significance was set at 0.05, consistent with educational intervention literature. Descriptive statistical analysis, including means and standard deviation was used to describe sample characteristics and TRPs. Outliers, skewness and missing data were checked and handled before analyzing the study data. All assumptions for each proposed statistical

test were tested before preceding the implementation of the assigned statistical tests

An independent sample t-test was utilized in order to evaluate differences between groups for continuous variables and normally distributed data, while Mann-Whitney U tests was used if the data was not normally distributed.

Paired t-test was used to evaluate changes within each group, baseline vs. follow-up if the data was not normally distributed, Wilcoxon signed rank test was used instead. Chi-square test was used for categorical variables.

## RESULTS

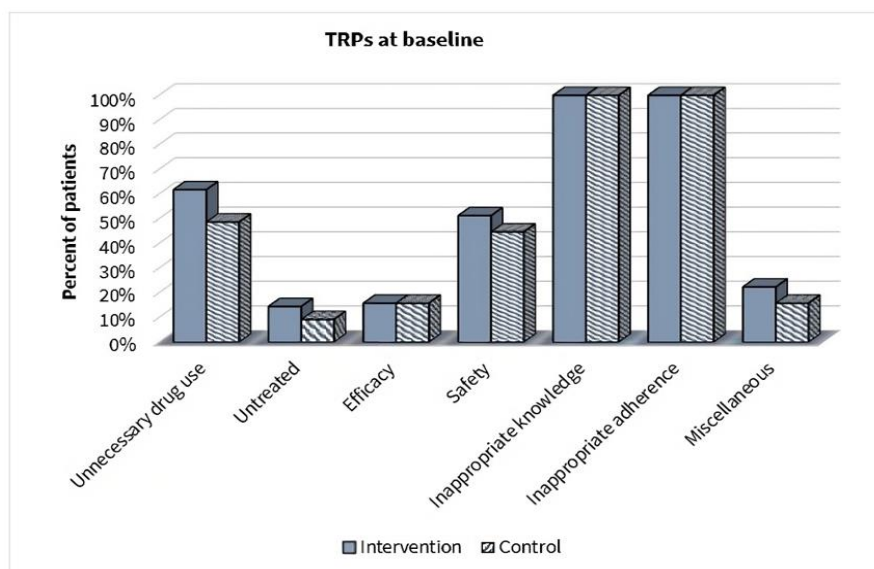
Following the initial evaluation, 152 asthmatic patients were found eligible for study entry. Asthmatic patients who agreed to be enrolled in the study signed a consent form, and their participation was voluntary. The privacy of patients was protected by giving a number for each patient during data collection and analysis, upon signing the consent form by all patients, they were randomized into intervention ( $n=76$ ) and control ( $n=76$ ) groups. Pharmacist-patient face-to-face interviews were done in order to collect data.

### Treatment Related Problems at Baseline

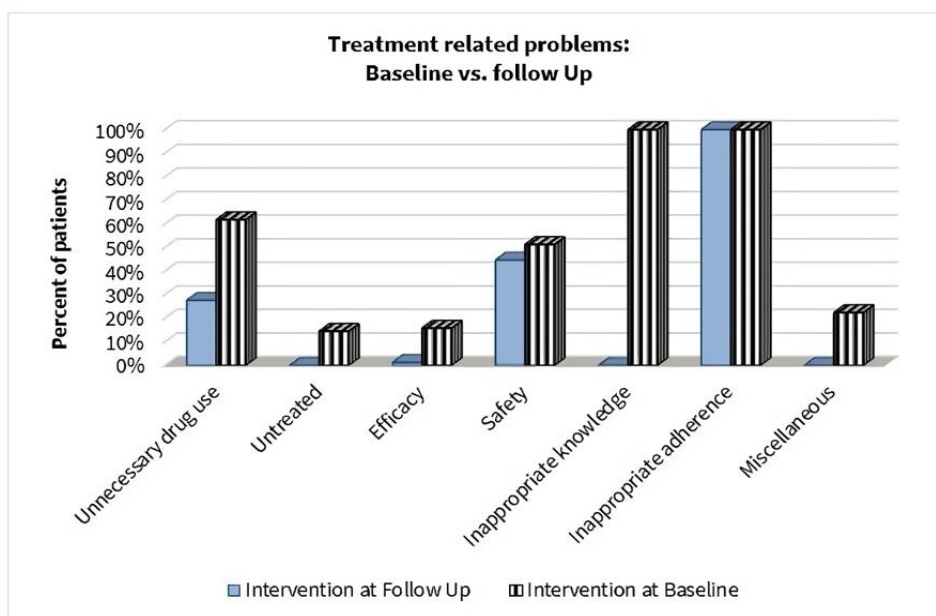
The identified TRPs were divided in seven categories: unnecessary drug therapy, untreated conditions, efficacy, safety, inappropriate knowledge, adherence and miscellaneous. Most of these TRP categories have sub-category divisions in order to enable accurate TRP classification. The majority of patients were facing problems linked to medication adherence, lack of pharmacological and non-pharmacological knowledge. A total number of 959 TRPs were identified.  $6.300 \pm 1.757$  problem per patient.

Comparisons between intervention and control group concerning TRPs identified at baseline is shown in **Figure 2**.

**Figure 3** shows comparison between baseline ( $n=76$ ) and follow-up ( $n=76$ ) data concerning changes in TRPs for intervention group.



**Figure 2.** Comparison between intervention ( $n=76$ ) & control group ( $n=76$ ) concerning TRPs identified at baseline (Source: Authors' own elaboration)



**Figure 3.** Comparison between baseline (n=76) & follow-up (n=76) data concerning changes in TRPs for intervention group (Source: Authors' own elaboration)

### Treatment Related Problems at Follow-Up

Comparing between the intervention and control groups at follow-up revealed significant differences concerning TRPs

frequency. Inappropriate knowledge TRP category was resolved by 100% for the intervention group, 'unnecessary drug therapy' TRP category was reduced by 60.0% and the 'untreated condition' category was 100% resolved (**Table 1**).

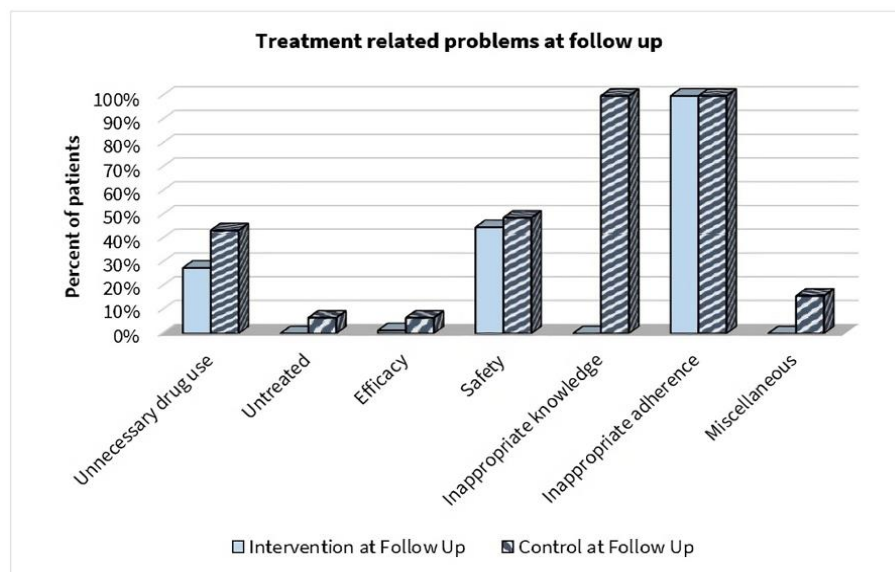
**Table 1.** Comparison of treatment related problems between intervention (n=76) & control (n= 76) groups: baseline vs. follow-up

	Treatment related problems at baseline comparing intervention & control group				Treatment related problems at follow-up comparing intervention & control n group			
	Intervention (n=76)	Control (n=76)	Total (n=152)	P	Intervention (n=76)	Control (n=76)	Total (n=152)	P
Unnecessary drug use.	47 (61.8)	37 (48.7)	84 (55.3)	0.103*	21 (27.6)	33 (43.4)	54 (35.5)	0.042*
Drug use without an indication.	36 (47.4)	29 (38.2)	65 (42.8)	0.251*	1 (1.3)	24 (31.6)	25 (16.4)	<0.001*
Drug use without an indication (according to guidelines).	22 (28.2)	19 (25.0)	41 (27.0)	0.584*	22 (28.9)	19 (25.0)	41 (27.0)	0.584*
Addiction or recreational drug use.	0 (0.0)	0 (0.0)	0 (0.0)	NA	0 (0.0)	0 (0.0)	0 (0.0)	NA
Patient treatment should be stepped down.	0 (0.0)	0 (0.0)	0 (0.0)	NA	0 (0.0)	1 (1.3)	1 (0.7)	0.316*
Duplication.	1 (1.3)	2 (2.6)	3 (2.0)	0.560*	1 (1.3)	2 (2.6)	3 (2.0)	0.560*
Treating avoidable adverse reaction.	0 (0.0)	0 (0.0)	0 (0.0)	NA	0 (0.0)	0 (0.0)	0 (0.0)	NA
Untreated.	11 (14.5)	7 (9.2)	18 (11.8)	0.315*	0 (0.0)	5 (6.6)	5 (3.3)	0.023*
Efficacy.	12 (15.8)	12 (15.8)	24 (15.8)	1.00*	1 (1.3)	5 (6.6)	6 (3.9)	0.096*
More effective drug is available/recommended.	5 (6.6)	2 (2.6)	7 (4.6)	0.246*	0 (0.0)	4 (5.3)	4 (2.6)	0.043*
Patient requires additional/combo therapy.	8 (10.5)	11 (14.5)	19 (12.5)	0.462*	1 (1.3)	3 (3.9)	4 (2.6)	0.311*
Efficacy dosage regimen issue.	0 (0.0)	0 (0.0)	0 (0.0)	NA	0 (0.0)	0 (0.0)	0 (0.0)	NA
Efficacy interaction issue.	0 (0.0)	0 (0.0)	0 (0.0)	NA	0 (0.0)	0 (0.0)	0 (0.0)	NA
Safety.	39 (51.3)	34 (44.7)	73 (48.0)	0.417*	34 (44.7)	37 (48.7)	71 (46.7)	0.626*
A current drug is contraindicated/unsafe/should be monitored or replaced (asthma medication).	24 (3.6)	18 (23.7)	42 (27.6)	0.276*	4 (5.3)	14 (18.4)	18 (1.8)	0.012*
A current drug is contraindicated/unsafe/should be monitored or replaced (other medication).	11 (14.5)	10 (13.2)	21 (13.8)	0.814*	7 (9.2)	9 (11.8)	16 (10.5)	0.597*
Safer drug is recommended.	8 (10.5)	8 (10.5)	16 (10.5)	1.000	3 (3.9)	9 (11.8)	12 (7.9)	0.071*
High risk for ADR.	25 (32.9)	17 (22.4)	42 (27.6)	0.147*	11 (14.5)	13 (17.1)	24 (15.8)	0.656*
Allergic reaction or undesirable effect.	2 (2.6)	3 (3.9)	5 (3.3)	0.649*	6 (7.9)	9 (11.8)	15 (9.9)	0.415*
Safety dosage regimen issue.	17 (22.4)	15 (19.7)	32 (21.1)	0.691*	5 (6.6)	20 (26.3)	25 (16.4)	<0.001*
Safety interaction issue.	0 (0.0)	0 (0.0)	0 (0.0)	NA	0 (0.0)	0 (0.0)	0 (0.0)	NA
Inappropriate knowledge.	76 (100)	76 (100)	152 (100)	NA	0 (0.0)	76 (100)	76 (50.0)	<0.001*
Patient is not instructed or does not understand important information regarding his medication.	76 (100)	76 (100)	152 (100)	NA	0 (0.0)	76 (100)	76 (50.0)	<0.001*
Patient is not instructed or does not understand important information regarding non-pharmacological therapy.	76 (100)	76 (100)	152 (100)	NA	0 (0.0)	76 (100)	76 (50.0)	<0.001*
Inappropriate adherence.	76 (100)	76 (100)	152 (100)	NA	76 (100)	76 (100)	152 (100)	NA

**Table 1 (Continued).** Comparison of treatment related problems between intervention (n=76) & control (n= 76) groups: baseline vs. follow-up

	Treatment related problems at baseline comparing intervention & control group				Treatment related problems at follow-up comparing intervention & control group			
	Intervention (n=76)	Control (n=76)	Total (n=152)	P	Intervention (n=76)	Control (n=76)	Total (n=152)	P
Problem in adherence to pharmacological therapy.	76 (100)	76 (100)	152 (100)	NA	76 (100)	76 (100)	152 (100)	NA
Drug is not available.	0 (0.0)	0 (0.0)	0 (0.0)	NA	76 (100)	76 (100)	152 (100)	NA
Problem in adherence to self-care activities or nonpharmacological therapy.	76 (100)	76 (100)	152 (100)	NA	0 (0.0)	0 (0.0)	0 (0.0)	NA
Miscellaneous.	17 (22.4)	12 (15.8)	29 (19.1)	0.302*	76 (100)	76 (100)	152 (100)	NA
A need for additional or more frequent monitoring.	10 (13.2)	7 (9.2)	17 (11.2)	0.440*	0 (0.0)	12 (15.8)	12 (7.9)	<0.001*
A need for additional diagnostic test.	15 (19.7)	8 (10.5)	23 (15.1)	0.113*	0 (0.0)	7 (9.2)	7 (4.6)	0.007*
A need for consultation.	0 (0.0)	0 (0.0)	0 (0.0)	NA	0 (0.0)	8 (10.5)	8 (5.3)	0.004*
The chosen drug is not cost effective.	0 (0.0)	0 (0.0)	0 (0.0)	NA	0 (0.0)	0 (0.0)	0 (0.0)	NA
Other dosage regimen issues.	0 (0.0)	0 (0.0)	0 (0.0)	NA	0(0.0)	0(0.0)	0 (0.0)	NA
Other interaction issue.	0 (0.0)	0 (0.0)	0 (0.0)	NA	0 (0.0)	0 (0.0)	0 (0.0)	NA
Administering errors.	0 (0.0)	0 (0.0)	0 (0.0)	NA	0 (0.0)	0 (0.0)	0 (0.0)	NA
Dispensing errors.	0 (0.0)	0 (0.0)	0 (0.0)	NA	0 (0.0)	0 (0.0)	0 (0.0)	NA
Mean±SD	6.540±1.6850	6.070±1.806	6.300±1.757	0.046***	0 (0.0)	0 (0.0)	0 (0.0)	NA

Note. \*Chi-square test; \*\*\*Mann-Whitney test; & SD: Standard deviation

**Figure 4.** Comparison between intervention (n=76) & control group (n=76) concerning changes in TRPs at follow-up (Source: Authors' own elaboration)**Table 2.** Changes in mean TRPs scores between baseline & follow-up for both intervention (n=76) & control (n=76) groups

Group	Baseline TRPs score: Mean±SD	Follow up TRPs score: Mean±SD	p-value within same group
Intervention (76)	6.540±1.685	2.800±0.924	<0.001*
Control (76)	6.070±1.806	5.920±1.679	0.214*

Note. \*Wilcoxon test & SD: Standard deviation

Noticeable decrease in the number of intervention group's TRPs per patient was found, 6.540±1.685 at baseline vs. 2.800±0.924 at follow-up, p-value<0.001.

Comparison between baseline and follow-up data concerning changes in TRPs for intervention group is shown in **Figure 4**.

On the other hand, control group results showed no significant differences between baseline and follow-up TRPs (6.000±1.806 at baseline vs. 5.920±1.679 at follow-up, p-value=0.214; **Table 2**).

#### Asthma Control Test at Baseline

The baseline results of ACT are shown in **Table 3**. Baseline scores mean was 13.80±4.954 for the total participants. Intervention and control group scores mean was 13.880±4.954 and 14.630±5.153, respectively, with no significant difference at baseline between the groups (p=0.062). **Table 3** shows that 127 (83.6%) of total population were categorized as under controlled asthmatics, with no significant difference between intervention and control group identified at this stage of the study. Baseline asthma control test levels (under controlled and controlled asthma) were 67 (88.2%) and 9 (11.8%),

**Table 3.** Asthma control test scores for intervention & control groups at baseline, showing responses for each of items in questionnaire

Questions	Intervention (n=76)	Control (n=76)	Total (n=152)	p
1. In <u>past four weeks</u> , how much of time did your asthma keep you from getting as much done at work, school or home?				
a. All of the time	7 (9.2)	8 (10.5)	15 (9.9)	0.284*
b. Most of the time	28 (36.8)	28 (36.8)	56 (36.8)	
c. Some of the time	17 (22.4)	8 (10.5)	25 (16.4)	
1. In <u>past four weeks</u> , how much of time did your asthma keep you from getting as much done at work, school or home?				
d. A little of the time	13 (17.1)	14 (18.4)	27 (17.8)	
e. None of the time	11 (14.5)	18 (23.7)	29 (19.1)	
During <u>past four weeks</u> , how often have you had shortness of breath?				
a. More than once a day	36 (47.4)	23 (30.3)	59 (38.8)	0.098*
b. Once a day	10 (13.2)	13 (17.1)	23 (15.1)	
c. Three to six times a week	6 (7.9)	8 (10.5)	14 (9.2)	
d. Once or twice a week	17 (22.4)	15 (19.7)	32 (21.1)	
e. Not at all	7 (9.2)	17 (22.4)	24 (15.8)	
During <u>past four weeks</u> , how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness, or pain) wake you up at night or earlier than usual in mornings?				
a. Four or more nights a week	49 (64.5)	36 (47.4)	85 (55.9)	0.045*
b. Two to three nights a week	11 (14.5)	17 (22.4)	28 (18.4)	
c. Once a week	4 (5.3)	1 (1.3)	5 (3.3)	
d. Once or twice a month	1 (1.3)	0 (0.0)	1 (0.7)	
e. Not at all	11 (14.5)	22 (28.9)	33 (21.7)	
During <u>past four weeks</u> , how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?				
a. Three or more times per day	6 (7.9)	5 (6.6)	11 (7.2)	0.266*
b. One or two times per day	25 (32.9)	21 (27.6)	46 (30.3)	
c. Two or three times per weeks	19 (25.0)	27 (35.5)	46 (30.3)	
d. Once a week or less	12 (15.8)	5 (6.6)	17 (11.2)	
e. Not at all	14 (18.4)	18 (23.7)	32 (21.1)	
How would you rate your asthma control during <u>past four weeks</u> ?				
a. Not controlled at all	6 (7.9)	4 (5.3)	10 (6.6)	0.089*
b. Poorly controlled	24 (31.6)	16 (21.1)	40 (26.3)	
c. Somewhat controlled	11 (14.5)	24 (31.6)	35 (23.0)	
d. Well controlled	35 (46.1)	31 (40.8)	66 (43.4)	
e. Completely controlled	0 (0.0)	1 (1.3)	1 (0.7)	

Note. \*Chi-square test

respectively for intervention while 60 (78.9%) and 16 (21.1%), respectively for control groups, p-value=0.126.

#### Asthma Control Test at Follow-Up

**Table 4** shows ACT test data that was collected at follow-up, significant differences in ACT score's mean that was found

between the groups (p=0.022, mean out of 25, 16.370±3.702 and 14.840±5.060 intervention and control groups, respectively). Furthermore, an improvement in asthma control for the intervention group was noticed, by comparing baseline with follow-up data within the same group; higher ACT score at follow-up with significant difference was found (p<0.001). No

**Table 4.** Asthma control test scores for intervention & control groups at baseline, showing responses for each of items in questionnaire showing significant differences between groups

Questions	Intervention (n=76)	Control (n=76)	Total (n=152)	p
1. In <u>past four weeks</u> , how much of time did your asthma keep you from getting as much done at work, school or home?				
a. All of the time	6 (7.9)	5 (6.6)	11 (7.2)	0.100*
b. Most of the time	23 (30.3)	31 (40.8)	54 (35.5)	
c. Some of the time	19 (25.0)	8 (10.5)	27 (17.8)	
d. A little of the time	17 (22.4)	14 (18.4)	31 (20.4)	
e. None of the time	11 (14.5)	18 (23.7)	29 (19.1)	
During <u>past four weeks</u> , how often have you had shortness of breath?				
a. More than once a day	3 (3.9)	18 (23.7)	21 (13.8)	<0.001
b. Once a day	10 (13.2)	11 (14.5)	21 (13.8)	
c. Three to six times a week	15 (19.7)	12 (15.8)	27 (17.8)	
d. Once or twice a week	41 (53.9)	18 (23.7)	59 (38.8)	
e. Not at all	7 (9.2)	17 (22.4)	24 (15.8)	
During <u>past four weeks</u> , how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness, or pain) wake you up at night or earlier than usual in mornings?				
a. Four or more nights a week	1 (1.3)	23 (30.3)	24 (15.8)	<0.001*
b. Two to three nights a week	30 (39.5)	28 (36.8)	58 (38.2)	
c. Once a week	31 (40.8)	3 (3.9)	34 (22.4)	
d. Once or twice a month	3 (3.9)	0 (0.0)	3 (2.0)	
e. Not at all	11 (14.5)	22 (28.9)	33 (21.7)	

**Table 4 (Continued).** Asthma control test scores for intervention & control groups at baseline, showing responses for each of items in questionnaire showing significant differences between groups

Questions	Intervention (n=76)	Control (n=76)	Total (n=152)	p
During past four weeks, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?				
a. Three or more times per day	4 (5.3)	11 (14.5)	15 (9.9)	0.172*
b. One or two times per day	14 (18.4)	20 (26.3)	34 (22.4)	
c. Two or three times per weeks	24 (31.6)	21 (27.6)	45 (29.6)	
d. Once a week or less	10 (13.2)	6 (7.9)	16 (10.5)	
e. Not at all	24 (31.6)	18 (23.7)	42 (27.6)	
How would you rate your asthma control during past four weeks?				
a. Not controlled at all	0 (0.0)	3 (3.9)	3 (2.0)	0.010*
b. Poorly controlled	6 (7.9)	19 (25.0)	25 (16.4)	
c. Somewhat controlled	32 (42.1)	23 (30.3)	55 (36.2)	
d. Well controlled	83 (50.0)	30 (39.5)	68 (44.7)	
e. Completely controlled	0 (0.0)	1 (1.3)	1 (0.7)	

Note. Comparison between baseline & follow-up ACT test mean scores for intervention group: baseline ACT score mean±SD=13.880±4.954; follow-up ACT score mean±SD=16.370±3.702; p-value within same group<0.001‡; ‡Wilcoxon test; \*Chi-square test

**Table 5.** Comparison between control & intervention groups for their skills in using MDI baseline and after three-month follow-up

Steps	Baseline correct steps: n (%)		p	Follow-up correct steps: n (%)		p
	Intervention group (n=38)	Control group (n=47)		Intervention group (n=38)	Control group (n=47)	
MDI						
1. Remove mouthpiece cover & shake	33 (86.8)	43 (91.5)	0.489*	38 (100)	44 (93.6)	0.113*
2. Hold inhaler upright	34 (89.5)	35 (74.5)	0.078*	38 (100)	40 (86.1)	0.013*
3. Exhale to residual volume	20 (52.6)	17 (36.2)	0.128*	36 (94.7)	19 (40.4)	<0.001*
4. Keep head upright or slightly tilted	19 (50.0)	26 (55.3)	0.625*	36 (94.7)	26 (55.3)	<0.001*
5. Mouthpiece between teeth & lips	37 (97.4)	45 (95.7)	0.687*	38 (100)	45 (95.7)	0.198*
6. Inhaler slowly & press canister	13 (34.2)	29 (61.7)	0.012*	26 (68.4)	22 (46.8)	0.046*
7. Continue slow & deep inhalation	11 (28.9)	28 (59.6)	0.005*	20 (52.6)	18 (38.3)	0.186*
8. Hold breath for five seconds	24 (63.2)	29 (61.7)	0.890*	33 (86.8)	31 (66.0)	0.026*
9. Close inhaler	37 (97.4)	45 (95.7)	0.687*	38 (100)	45 (95.7)	0.198*
Score (mean±SD)	6.000±2.230	5.960±2.284	0.807***	7.970±1.219	6.150±2.157	<0.001***
MDI correct technique: n (%)	11/38 (14.5)	12/47 (25.5)	0.725*	19/38 (50.0)	12/47 (25.5)	0.020*

Note. \*Chi-square test; \*\*\* Mann-Whitney U test; SD: Standard deviation

**Table 6.** Comparison between control & intervention groups for their skills in using TH baseline & after three-month follow-up

Steps	Baseline correct steps: n (%)		p	Follow-up correct steps: n (%)		p
	Intervention group (n=36)	Control group (n=41)		Intervention group (n=36)	Control group (n=41)	
MDI						
1. Remove cap from inhaler	36 (100.0)	40 (97.6)	0.346*	36 (100.0)	40 (97.6)	0.346*
2. Keep inhaler upright during loading	19 (25.8)	20 (48.8)	0.726*	35 (97.2)	30 (73.2)	0.004*
3. Rotate grip anti-clockwise then back until a click is heard	34 (94.4)	40 (97.6)	0.481*	36 (100.0)	40 (97.6)	0.259*
4. Exhale to residual volume	20 (55.6)	10 (24.4)	0.005*	35 (97.2)	11 (26.8)	<0.001*
5. Exhale away from mouthpiece	21 (58.3)	12 (29.3)	0.010*	35 (97.2)	13 (31.7)	<0.001*
6. Place mouthpiece between teeth & lips	34 (94.4)	38 (92.7)	0.754*	36 (100.0)	38 (92.7)	0.098*
7. Inhale forcefully and deeply	20 (55.6)	32 (78.0)	0.035*	30 (83.3)	32 (78.0)	0.559*
8. Hold breath for five seconds	20 (55.6)	28 (68.3)	0.250*	33 (91.7)	28 (68.3)	0.012*
9. Exhale away from mouthpiece	22 (61.1)	8 (19.5)	0.000*	35 (97.2)	9 (22.0)	<0.001*
10. Close inhaler	34 (94.4)	38 (92.7)	0.754*	36 (100.0)	40 (97.6)	0.346*
Score (mean±SD)	6.28±2.845	5.54±1.976	0.442***	8.64±0.961	5.88±2.002	<0.001***
TH correct technique: n(%)	16/36 (44.4)	7/41 (17.1)	0.009*	29 (80.6)	8 (19.5)	<0.001*

Note. \*Chi-square test; \*\*\* Mann-Whitney U test; SD: Standard deviation

significant difference in control group baseline vs. follow-up data. Patient's inhaler use technique was evaluated by researcher at follow-up, comparison between control and intervention groups and comparison within each group was done to investigate the value of pharmacist interventions.

#### Baseline Inhaler Technique Assessment

Comparison between intervention and control groups with regards to their skills in using MDI shown in **Table 5**, the baseline score for patients' skills in using MDI, mean out of nine for intervention and control groups was 6.000±2.230 and

5.960±2.284, respectively, with no significant difference between the two groups (p-value=0.807).

TH technique score out of 9 for intervention and control group was 6.280±2.845 and 5.540±1.976, respectively, no significant difference between the two groups at the baseline p-value=0.442 shown in **Table 6**.

The mean of ACC technique scores out of nine was 7.380±1.850 intervention and 6.860±1.754 control, no significant difference, p-value=0.533 (**Table 7**).

Comparison between intervention and control groups with regards to percent of correct MDI use technique (**Table 5**)



**Table 7.** Comparison between control & intervention groups for their skills in using ACC baseline & after three-month follow-up

Steps	Baseline correct steps: n (%)		p	Follow-up correct steps: n (%)		p
	Intervention group (n=38)	Control group (n=47)		Intervention group (n=38)	Control group (n=47)	
MDI						
1. Open inhaler	13 (100)	22 (100)		13 (100)	22 (100)	
2. Push lever back completely	13 (100)	19 (86.4)	0.164	13 (100)	19 (86.4)	0.164*
3. Exhale to residual volume	8 (61.5)	13 (59.1)	0.238	13 (100)	9 (40.9)	<0.001*
4. Exhale away from mouthpiece	8 (100)	10 (45.5)	0.358	13 (100)	10 (45.5)	<0.001*
5. Mouthpiece between teeth & lips	12 (92.3)	22 (100.0)	0.187	13 (100)	22 (100)	NA
6. Inhale forcefully and deeply	10 (76.9)	21 (95.5)	0.096	13 (100)	21 (95.5)	0.435*
7. Hold breath for five seconds	9 (69.2)	20 (90.9)	0.100	13 (100)	20 (90.9)	0.263*
8. Exhale away from mouthpiece	10 (6.9)	9 (40.9)	0.039	13 (100)	9 (40.9)	<0.001*
9. Close the inhaler	13 (100)	20 (90.9)	0.263	13 (100)	20 (90.9)	NA
Score (mean±SD)	7.380±1.850	6.860±1.754	0.533***	9.000±0.000	6.860±1.754	<0.001***
ACC correct technique: n(%)	7/13 (53.8)	7/22 (31.8)	0.199*	13 (100)	7 (31.8)	<0.001*

Note. \*Chi-square test; \*\*\* Mann-Whitney U test; SD: Standard deviation

revealed 14.5% and 25.5% for intervention and control group, respectively, no significant difference p-value=0.725, while comparing percent of correct TH use technique between both groups revealed 44.4% intervention and 17.1% control (Table 6), percent of correct ACC use technique was 53.8% for intervention and 31.8% with no significant differences p-value=0.199 (Table 7).

### Follow-Up Inhaler Technique Assessment

Upon comparing between intervention and control groups concerning their skills in using MDI, data shown in Table 5, the follow-up score for patients' skills in using MDI, mean out of nine for intervention and control groups was 7.970±1.219 and 6.150±2.157, respectively, p-value<0.0016 significant difference between the two groups.

TH technique score out of nine for intervention and control group was 8.640±0.961 and 5.880±2.002, respectively with significant difference between the two groups, p-value<0.001 (Table 6). The mean of the ACC technique score out of nine was nine for intervention and 6.86±1.754 for control, with significant difference, p-value<0.001 (Table 7).

Comparison between intervention and control groups with regards to percent of correct MDI use technique (Table 5) revealed and 50.0% for intervention and 25.0% control group, respectively, with significant difference p-value=0.02, while comparing percent of correct TH use technique between both groups revealed 80.6% intervention and 19.5% control with significant difference p-value<0.001 (Table 6), percent of correct ACC use technique was 100% for intervention and 31.8% for control with significant differences p-value<0.001 (Table 7).

### Patients' Satisfaction

High patients' satisfaction rate was detected through this study, which was documented in Table 8. With regards to intervention group 96.1% patients were very satisfied with MMR service delivered to them, 55.3% were very satisfied with the length of the pharmacist's interview through MMR service.

## DISCUSSION

MMR service is emerging as an extending role of pharmacists in countries such as Australia, Canada, the United States of America and number of European countries [25]. Unfortunately, in Jordan, such program has not been launched

**Table 8.** Intervention group patients' satisfaction (n=76)

Questions	n (%)
How would you rate your satisfaction regarding MMR service you received?	
0. Very dissatisfied	0 (0.0)
1. Dissatisfied	0 (0.0)
2. Neutral	0 (0.0)
3. Satisfied	3 (3.9)
4. Very satisfied	73 (96.1)
How satisfied are you with treatment & style of pharmacist through MMR service?	
0. Very dissatisfied	0 (0.0)
1. Dissatisfied	0 (0.0)
2. Neutral	0 (0.0)
3. Satisfied	3 (3.9)
4. Very satisfied	73 (96.1)
How satisfied are you with clarity of information you received through MMR service?	
0. Very dissatisfied	0 (0.0)
1. Dissatisfied	0 (0.0)
2. Neutral	0 (0.0)
3. Satisfied	3 (3.9)
4. Very satisfied	73 (96.1)
How satisfied are you with level & quality of information provided by pharmacist through MMR service?	
0. Very dissatisfied	0 (0.0)
1. Dissatisfied	0 (0.0)
2. Neutral	0 (0.0)
3. Satisfied	3 (3.9)
4. Very satisfied	73 (96.1)
How satisfied are you with length of pharmacist's interview through MMR service?	
0. Very dissatisfied	0 (0.0)
1. Dissatisfied	0 (0.0)
2. Neutral	0 (0.0)
3. Satisfied	3 (3.9)
4. Very satisfied	73 (96.1)
Mean±standard deviation	19.170±1.220

as yet. This study was the first to assess the clinical and humanistic outcomes of MMR service for asthmatic patients in Jordan and abroad. MMR service conducted led to TRPs identified through reviewing reliever/controller medication use patterns, evaluating patients' inhaler use skills through assessing administration technique, detecting patient's non-adherence to therapy, and assessing patient's knowledge concerning their diseases and medications. Results were documented and analyzed by utilizing SOAP (subjective, objective, assessment, plan) note format. Subjective data including history of present illness (date of asthma onset,

symptoms and exacerbations patterns, asthma medications), family history, if any chronic or hereditary diseases existed, past medical history and medication history were collected to help in studying each individual case properly. Objective data was also collected by reviewing patients' medical reports and doing spirometry testing.

A total number of 959 TRPs were identified, and every patient in this study was found to suffer from at least six TRPs. This is somewhat higher than the similar studies conducted in Turkey, in order to address TRPs and pharmacists' interventions concerning patients with asthma and COPD, as TRPs identified equaled to 1.3 TRPs per patient [26]. Moreover, 4.6 TRPs per patient was identified by the study conducted in Norway [27], and 1.93 TRPs per patient was identified by a study conducted in Australia [28].

A previous study in Jordan did identify a high number of TRPs, even higher than what was detected in this study (7.4 TRPs per patient) [18]. The difference in the number of problems between studies may be due to different terms that was used, some assessing TRPs while others assessing DRPs. In our study "treatment related problems" term was used instead of "drug related problems" term so all aspects of patient's management can be assessed. This may be explained by the low number of DRPs identified by some similar international studies in contrast with studies that used the term TRPs [18]. Furthermore, differences of socio-demographic characteristics could also play a factor, since the majority of this study population had a low education level and low income, as a result, non-adherence to therapy and inappropriate pharmacological and non-pharmacological knowledge were the highest among TRPs categories.

In this study, the majority of TRP categories were inappropriate knowledge, since high percent of patients were lacking pharmacological and non-pharmacological therapy knowledge. Almost all patients had misconceptions concerning either their asthma or its medications. For example, "asthma medication can cause addiction", all inhalers are called (preventer medications) so either preventers or relievers should be used every day, even if all is well, using preventer medications in cases of exacerbations, believing that their asthma is an infectious disease and could be treated with antibiotics, furthermore, some patients were neither aware of their comorbid diseases nor its medications, particularly that for the exacerbation of asthma. Inappropriate adherence problems were found similar to previous study findings, which was conducted in Turkey [26].

Moreover, 61.0% of patients of another similar study were non-adherent to non-pharmacological therapy [18]. Moreover, 55.0% of patients were using unnecessary drug (drug used without an indication 52.0% of patients were taking antibiotics on a routinely pattern to treat their asthma, while 27.0% of patients were taking antihistamine medication in order to relieve their asthma symptoms. This is similar to a local study, which reports that antihistamines are being used extensively in Jordan by asthmatic patient [8]. Yet, it has been shown that antihistamines and ketotifen are ineffective in this case [1, 29]. Also, since most of infections that trigger asthma attack are viral infections, antibiotics that are routinely prescribed are not indicated, in several studies, early wheezing and asthma has been associated with antibiotics use. One suggested explanation for this association is antibiotics change of bowel flora, which leads to immunologic stimulation [29].

Concerning safety, 48.0% of patients were facing problems related to drug contraindication or were using drugs that are unsafe, which should be monitored or replaced. This result was comparable to the results of a previous study, where 32.0% of the population experienced ADRs after taking their medications [30]. Significant decrease in the number of TRPs identified among the intervention group, participants as a result of MMR service that was provided was noted. Good physicians' acceptance rate of pharmacist's recommendation was noticed, as a result of this acceptance, preventing, improving and resolution of 284 identified TRPs happened.

This study was successful in reducing the inappropriate knowledge of TRPs category by 100% for the intervention group. 'Unnecessary drug therapy' TRP category was reduced by 60.0% because of the intervention provided. The 'untreated condition' category was also 100% resolved.

These findings confirm the important role pharmacists can play in improving the clinical outcomes for asthma patients through MMR service.

### **Asthma Control**

Since global initiative for asthma signaled a new philosophy of asthma management, which based on asthma control rather than symptoms or severity, good asthma control has turned to be a crucial goal. Yet asthma control is sub-optimal either worldwide or in Jordan. Numerous explanations exist for this sub-optimal control, for example issues linked to either health care system" unavailability or unaffordability of controllers" or physician-patient relationship, "inadequate time or unwillingness to make a discussion with patients", may led to poor knowledge, non-adherence and poor asthma control.

In order to assess asthma control, ACT questionnaire, which was utilized and published by [21], was used in this study. Baseline assessment for both groups revealed that mean ACT score was  $13.880 \pm 4.950$  somewhat higher than similar study [22].

### **Inhaler Technique**

This study comes to shed light on the pharmacist's role in educating asthmatic patients on inhaler technique, but for the first time, as an integrated part of MMR service. Patients' skills in performing correct inhaler technique were tested by utilizing published nine-point checklists specific for each device. Three devices were evaluated: pMDI, TH, and ACC.

Assessment of patients' inhaler technique at baseline revealed that most of the patients had poor technique. Unfortunately, patients were not aware of the fact that every inhaler must be used in a technique, which may differ than other inhalers. Errors such as shaking both TH and MDI before use or exhaling forcefully and deeply when both MDI and TH are used were common. Each patient in the intervention group received the educational intervention regarding inhaler technique specifically essential steps, since if they were done incorrectly no drug or low dose could reach the lungs. Some steps were requiring respiratory tract anatomical explanation, to enhance patients understanding the importance of the following step" keeping the head upright or slightly tilted". However, 72.0% of total patients were using MDI incorrectly, their score mean was 5.98 out of nine, which was significantly improved for the intervention group upon pharmacist's intervention and education to reach 7.97 at three months follow-up.

Data concerning the TH device showed that out of 77 patients, 23 (29.9%) demonstrated correct TH technique at baseline. At follow-up, an improvement in intervention group skills was noticed, score mean has changed from six to 8.6. Furthermore, 60.0% of ACC users demonstrated incorrect technique at baseline, score's mean equaled to seven out of nine, while data at follow-up has revealed a significant improvement in intervention group score's mean reaching a score of nine out of nine. The study that carried out by [22] to evaluate the role of pharmacist in inhaler technique education, showed results, which are comparable to our study. TH score out of nine was 5.5 at baseline, which improved by pharmacist intervention to reach 7.4. The same issue was noticed for MDI users, as out of nine at baseline, the score was 5.3, while at end of the study it became 6.9.

### Patients' Satisfaction

Fortunately, high patients' satisfaction rate toward MMR service was gained through this study, which may be reflected through the emerging need for such service; patients were very satisfied with the clarity and quality of information they got.

### Strengths & Limitations of This Study

Strengths involve rigorous assessment of inhaler technique using published checklists, which provide reproducible scores, in addition to the use of 'show-and-tell' inhaler technique education, a brief and simple educational intervention that is feasible and takes few minutes. The use of a validated measure of asthma symptom control and treatment related by a researcher blinded to the participants' randomization group, with confirmation of inter-rater reliability prior to study start. Limitations include that this study was conducted in one hospital and various health centers in Amman only. Other cities in Jordan and rural areas were not involved, limiting the generalizability of the results to all of Jordan.

## CONCLUSIONS

This randomized controlled study has shown the benefits of MMR service delivered to asthmatic patients in Jordan. Moreover, has been discovered the actual necessity of MMR service since a high number of TRPs have been identified. In addition to the noteworthy role of pharmacists, which was brought to light, such well-qualified pharmacists, particularly in respiratory medicine, were capable of employing their knowledge and skills in the management of asthma. Pharmacists' interventions in the field of asthma monitoring, inhaler technique assessment and education, optimizing drug use and adherence, instructing patients to achieve a healthy lifestyle were helpful in controlling asthma, decreasing the occurrence of exacerbations and improving patients' satisfaction. Patients were thankful for pharmacist's interventions, stated that they were reassured; felt valued and cared for thus very satisfied of MMR service delivered.

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Ministry of Health. Written consent was obtained from all participants during their enrollment in this study from 2018 to 2019.

**Declaration of interest:** No conflict of interest is declared by the authors.

**Data sharing statement:** Data supporting the findings and conclusions are available upon request from the corresponding author.

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