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Assessment of Knowledge on self-management among Asthmatic patients: A prospective cohort study

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Abstract

Objectives: Despite the many advancements in diagnosis and wide accessibility of numerous treatment options which are effective, still most of the patients have poorly controlled asthma. This can be significantly attributed to the lack of knowledge about disease management, its triggering agents and when to seek health-care provider among many other issues. The purpose of our study was to assess the knowledge of disease self-management among patients suffering from asthma.

Setting: A prospective cohort study design was used and ambulatory asthmatic patients were recruited through a convenient sampling method.

Participants: Questionnaires used enquired about 1) Patients' sociodemographic details, 2) Knowledge of disease self-management and were filled in via one-on-one interview with the patient. Asthma Self-Management Knowledge Questionnaire (ASMQ) was used and knowledge was assessed through summed ASMQ score.

Results: Low level of underlying disease self-management knowledge is reported when measured by asthma self-management questionnaire (ASMQ), with an average raw ASMQ score of 4.1 (max 14); which equals to transformed score of 29.34 (max 100). Of all the participants, 55% did not know that asthma cannot be cured, only 26.3% knew that one should inhale slowly while using the inhaler and approximately 87% were ignorant about the fact that getting a flu vaccine annually is the main method to prevent asthma flare-up. Overall, at baseline 83.3% of the participants showed poor knowledge with only 13.3% having adequate knowledge which after educational counseling showed improvement in the treatment group from mean ASMQ score of 4.20 to 9.77.

Conclusions: Low level of knowledge of asthma self-management greatly emphasizes the need

to impart self-management education in structured patient care, which can ultimately enhance patient outcomes in terms of their disease comprehension, self-esteem and standards of living apart from reducing number of hospital and emergency room visits as well as days off work.

Keywords: Asthma self-management, knowledge of asthma, asthma self- management education, asthmatic patients, asthma awareness.



Strengths and limitations of this study

- Strategies designed specifically targeting the deficit areas in patients' self-management knowledge can be a cost-effective approach.
- Evidence generated can attract policy makers to design and expand educational programs to meet each patient needs in achieving better disease control.
- Significance of improving patient's self-management knowledge can be manifested through asthma control, compliance, inhaler technique or quality of life.
- Multicenter study is needed so that the results can be generalizable.
- Scarcity of tools to measure the asthma self-management allowed one with very few opportunities to select ASMQ.

INTRODUCTION

Asthma has become one of the major health concerns affecting many millions of people (Wireklint et al., 2021). It is defined as a chronic, non-communicable inflammatory disorder of the airways, that is reported to affect 334 million people worldwide with an alarming prediction of an increase of 100 million more by the year 2025 (Farzandipour et al., 2019). Considering the most leading causes of disease burden, asthma ranks 28th, causing approximately 1000 people to die every day around the globe and 16th among the leading cause of years of life lived with disability with its prevalence still rising in underdeveloped countries (Asthma, 2018).

Globally asthma is the growing contributor to increased morbidity and mortality, thus imposing a significant burden in terms of reducing productivity, not only on the patients but also on their families and health care systems (Farzandipour et al., 2019). Genetic predisposition and exposure to numerous environmental substances including dust mites, pet dander, pollens as well as stress or sedentary lifestyle collectively account for various risk factors of asthma (Subbarao *et al.*, 2009).

Despite the fact that many advancements have been made in the management of asthma including its diagnosis and treatment yet worldwide it is poorly controlled with its prevalence still increasing (Sabar $et\ al.$, 2018). One of the previous studies reported as low as \leq 1% of asthmatic patients with controlled asthma (Nguyen $et\ al.$, 2018). Various reasons for such a low asthma control includes either health-care system related issues (unaffordability or unavailability of medications) or physicians related issues (incorrect or misdiagnosis, lack of proper diagnostic facilities, insufficient time to discuss matters with the patients, absence of reassessment of inhaler technique or lack of proper follow-up measures) or patient related issues (non-compliant behaviors due to lack of knowledge about their disease and its management) (Nguyen $et\ al.$, 2018). Apart from non-

adherence to medication regimen, lack of proper education or routine follow-ups, incorrect use of inhalers and lack of inhaler technique assessment at patients visit besides others also play a significant role in increasing the overall prevalence of asthma in different populations (Sabar *et al.*, 2018). Asthma being a controllable disease requires long-term therapy and thus can be sufficiently controlled if education is provided about the disease and correct use of medications ultimately improving treatment adherence, optimizing therapeutic benefits and enhancing the patients' well-being as alarmingly increased morbidity and mortality as well as worsening of disease states is reportedly associated with non-compliance in asthma (Irfan *et al.*, 2017, Nguyen *et al.*, 2018).

Patients' general knowledge about asthma includes pathophysiology of disease, purpose of treatment regimen, recognition and management of exacerbations/disease triggers and correct inhaler use and is quite different from patients' knowledge about self-management (Nguyen *et al.*, 2018). As self-management is defined as beliefs or confidence of an individual to uptake behaviors or to make decisions for managing their chronic conditions and it requires efficient communication about patients' condition with their family members, companions and healthcare professionals (Holley et al., 2018). Asthma self-management involves actions undertaken by the patients to monitor their disease symptoms in order to avoid exacerbations (Mancuso *et al.*, 2010). Asthma self-management education, when made a part of regular and planned care, not only improve patient outcomes in terms of disease comprehension, control and patients' well-being but also reduce number of hospital and emergency room visits and work absences (Farzandipour et al., 2019). Variability of asthma disease (i-e change in asthma over time) implies that exacerbations can possibly occur even if a patients' asthma is well controlled. Therefore, patients should have the knowledge about their disease management and recognition

of how and when to seek help from health professionals when confronted with exacerbations (Nguyen *et al.*, 2018).

Despite much evidence showing the significance of asthma self-management programs in terms of cost-effectiveness, their implementation in clinical practice is still low (Farzandipour et al., 2019, Wireklint et al., 2021). Extremely low knowledge of asthma self-management is reported in several countries and requires specific educational programs that can lead to better asthma control (Nguyen *et al.*, 2018).

As to the best of our knowledge, data regarding the asthma self- management knowledge is lacking, therefore, the current study intended to determine the knowledge of disease self-management among the asthmatic population.

METHODOLOGY

Study setting and design

The study follows a prospective cohort design and is conducted at the pulmonary department (OPD) of Pakistan Institute of Medical Sciences (PIMS), a tertiary care hospital. Eligible participants include ambulatory asthmatic patients recruited between May to Sep 2019. The Quasi experimental design was used consisting of a non-equivalent control group. Members of the control and treatment group possess almost similar characteristics with the only difference being that participants to control group were not randomly assigned. At baseline patients' sociodemographic characteristics as well as knowledge of asthma self-management were assessed via a face-to-face interview. Educational counseling was provided by the research scholar (pharmacist) to the treatment group at baseline and to the control group during follow-up.

Inclusion and exclusion criteria

Inclusion criteria include patients of age ≥18 years already diagnosed with asthma, already

followed up at this hospital and who were willing to give consent.

Exclusion criteria include 1) patients with cognitive disability and communication issues; 2) did not give consent; 3) having any other illness with asthma related symptoms; 4) have COPD, TB or congestive heart failure.

Data collection tools

The data collection form was structured to obtain the patient socio-demographic details for which information was obtained from the patients' medical records and through a one-on-one interview with the patient. The Asthma Self-management questionnaire (ASMQ), a prevalidated tool was used and was filled in by the researcher.

The ASMQ is used to assess the asthmatic patients' knowledge on their disease self-management. This questionnaire contained 16 multiple choice questions including preventive measures, use of inhalers, medications and peak flow meters and can be completed in 8-10 minutes through an interview (Mancuso et al., 2009). Tool scores are calculated as each preferred response is given one point, then all answers are summed up to generate a raw ASMQ score ranging from 0-14 and then finally transformed between 0-100 range with more asthma self-management knowledge indicated by higher ASMQ transformed scores (Nguyen *et al.*, 2018). Two questions related to the peak flow meters have been omitted because of their minimum use in developing countries for example, in India, patients who were prescribed peak flow meters reported to be only 2% of the total (Kotwani *et al.*, 2012). Occupational status was categorized according the ISCO categories into not working including students, housewives, currently not working or retired, blue collars workers which includes doing manual work and white-collar workers includes desk workers (Razzaq *et al.*, 2018).

Data compilation and statistical analysis

IBM SPSS Statistic version 21 was employed for data analysis. Descriptive statistics was used to summarize the mean and standard deviations of the demographics of both groups i-e Treatment and Control groups. Categorical variables were analyzed using the Chi-square test. For intra-group comparisons, Wilcoxon matched-pair test was used. A p-value of ≤ 0.05 was labeled statistically significant.

Patient and public involvement

No patient involved.

RESULTS

Approximately 265 adult asthmatic patients aged ≥18 years were approached out of which 240 gave consent to participate in the study. The majority 47.5% of the participants belonged to 36-55 years age group with 56.7% of participants being males, 15.4% had a history of allergy while 25.4% had a positive family history of the disease. **Table 1** lists some of the other characteristics.

Table 1. Socio-demographics of study participants

Characteristics	Categories	CG	TG	p-value
Age		39.46±13.5	39.70±13.99	0.892
Age categories	18-35	27	32	0.881
	36-55	54	60	
	>56	39	28	
Gender	Male	61	75	0.068
	Female	59	45	
Residence	Rural	75	66	0.597
	Urban	45	54	
Occupation	Not working	61	53	0.827
(ISO Categories)	Blue collar worker	25	22	

	White collar worker	34	45	
Educational	Illiterate	20	24	0.870
Status	Primary	36	40	
	Secondary	37	27	
	Graduate	27	29	
Family history	Disease	30	26	0.846
	Allergy	22	15	
	Both	30	35	
	None	38	44	
Smoking status	Ex-smokers	22	27	0.927
	Current-smokers	33	38	
	Never-Smoke	65	55	
Disease duration	≤2	47	51	0.978
Categories	2-5	45	34	
	>5	28	35	

Pre and post ASMQ raw and transformed score are presented in **Table 2.** Wilcoxon matched-pair test is used to calculate the p-value. A p-value of .487 in pre and post ASMQ raw and transformed scores shows non-significant changes in control group while p-value of 0.00 (i-e ≤ 0.05) in the pre and post ASMQ raw and transformed scores shows significant changes in the treatment group as a result of counseling.

Table 2. Pre and post ASMQ categories, ASMQ raw and transformed scores in control and treatment group

	Control group	T	reatment group
ASMQ Raw score	Pre	Post	p-value
Control group	4.01 ± 3.32	3.89 ± 2.92	.487
Intervention group	4.20 ± 3.03	9.77 ± 2.58	<.001
ASMQ Transformed score	Pre	Post	p-value
Control group	28.69 ± 23.75	27.76 ± 20.86	.487
Treatment group	30 ± 21.64	69.83 ± 18.42	<.001

Table 3. represents responses to different question choices at baseline. Incorrect responses to questions highlight a lack of patient knowledge about the underlying disease.

Table 3. Frequency of false responses to questions of ASMQ at baseline

	46 (19.2%)
<u> </u>	33 (13.8%)
	71 (29.6%)
	40 (16.7%)
Same as taking four puffs once a day	05 (2.1%)
Arranged in any way as long as you take a total of	58 (24.2%)
four puffs a day	
Your lungs are not sensitive to irritants	18 (7.5%)
It's ok to skip some doses of medicine	64 (26.7%)
You are probably cured of asthma	32 (13.3%)
Don't need to be taken everyday	51 (21.3%)
Make you breathe better right after you take them	87 (36.3%)
Can only be taken in pill form	13 (5.4%)
Help prevent future flare-ups	74 (30.8%)
Have no side effects	20 (8.3%)
Do not cause you to become tolerant to medicine	11 (4.6%)
Take shallow breaths	16 (6.7%)
Inhale quickly	113 (47%)
	22 (9.2%)
	57 (23.8%)
	11 (4.6%)
	6 (2.5%)
	44 (18.3%)
	69 (28.7%)
	21 (8.8%)
o o mar and y o o mar and a mar and	(0.0,0)
Is really not harmful	28 (11.7%)
	59 (24.6%)
	17 (7.1%)
	19 (7.9%)
	21 (8.8%)
	62 (25.8%)
	(20.070)
	83 (34.6%)
	42 (17.5%)
	7 (2.9%)
	77 (32.1%)
,	29 (12.1%)
	29 (12.1%)
	19 (7.9%)
	50 (20.8%)
	30 (20.670)
	5 (2 10/)
	5 (2.1%)
	46 (19.2%)
Drinking plenty of water to stay hydrated Avoiding foods with sulphites, such as dried fruit	25 (10.4%) 15 (6.3%)
	Arranged in any way as long as you take a total of four puffs a day Your lungs are not sensitive to irritants It's ok to skip some doses of medicine You are probably cured of asthma Don't need to be taken everyday Make you breathe better right after you take them Can only be taken in pill form Help prevent future flare-ups Have no side effects Do not cause you to become tolerant to medicine

Figure 1 shows that number of patients possessing good knowledge improved from 3 to 47 and those possessing adequate knowledge improved from 15 to 42 in the treatment group.

Figure 1

Figure 2 shows that question 7 (About hold of breadth after use of an inhaler for several seconds) has the highest percentage of correct answers i.e. 47.9%. Only 32.1% of the participants knew that asthma is an incurable disease. Item 9 (About patients' increased need for maintenance medicines in case he/she is using more rescue medications than are prescribed) was frequently answered to be unknown (47.1%).

Figure 2

Figure 3 shows distribution of raw ASMQ score at baseline. 0-14 is the total possible range with higher scores resulting in higher ASMQ transformed scores and thus indicating good asthma self-management knowledge. This underlying distribution of ASMQ raw score indicates poor disease management knowledge among the study participants.

Figure 3

DISCUSSION

The major conclusions of the current study conducted to analyze the knowledge on disease self-management among asthmatic patients illustrate a low level of knowledge with an average raw ASMQ score of 4.1 [4.1/14] that equals to 29.34 transformed score [29.34/100] at baseline (Table).

Overall, at baseline 83.3% of patients have poor knowledge with only 13.3% having adequate knowledge. These results are consistent with the results from similar studies. For example, study conducted by Nguyen *et al* in Vietnam reported low knowledge with mean raw ASMQ score of 4.3 which equals to the transformed score of 30 (Nguyen *et al.*, 2018). Another observational study conducted in the Kingdom of Saudi Arabia reported an average ASMQ score of 3.5 [3.5/14] (AI et al., 2017). The format of both of these studies was similar to that of the present study (two items related to the peak flow meter removed) as use of peak flow meter is not common in developing countries (Nguyen *et al.*, 2018). Apart from baseline ASMQ score, follow up ASMQ score was also recorded in the present study suggesting the significance of educational counseling by a pharmacist for the patient, as the mean ASMQ score got significantly increased from 4.20/14 to 9.77/14 [transformed score 69.83/100] in the treatment group as compared to no significant increase in the control group, from 4.01/14 to 3.89/14.

Al *et al* found that patients with more than 50% correct responses were 4% while in our study this percentage is 16.7% which is quite close to that reported by Nguyen *et al* (Al *et al.*, 2017, Nguyen *et al.*, 2018). The number of patients with greater than 50 ASMQ scores has been significantly increased up to 89 patients at follow-up in the treatment group. This is in agreement with the results of an interventional study in which a full version of ASMQ was used (i-e all 16 items) reporting an average score of 4.49/16 (transformed 28.6/100) in the intervention group at baseline and 3.91/16 (transformed score 24.4/100) in the control group and also reported an improvement in the ASMQ average scores only in intervention group when compared to control group as a result of an educational intervention, highlighting the fact that better ASMQ score involves better asthma control test score (Hiral *et al.*, 2013). Significant improvement in patients asthma knowledge resulting in increased adherence level and asthma control score after 3 months follow-up with 60%

of the patients having achieved better control and 18% well-controlled asthma has also been reported by another study emphasizing the need for effective educational programs (Kovačević et al., 2018).

Although data about the knowledge on asthma self-management is limited but on the contrary various studies have been conducted to assess the general knowledge about the diseases. For example, a study conducted in Sri Lanka reported that only 34% of the patients were knowledgeable about their disease and medications (Nguyen *et al.*, 2018). A multicenter study in China reported a low level of disease awareness among the parents of asthmatic children (Zhao *et al.*, 2013). Another study illustrated that 62.7% of asthmatics have poor, 12% have good and only 25.3% possess adequate knowledge (Abbas *et al.*, 2019). Another study showed that although the patients have a positive attitude towards the disease, yet patients' specific disease knowledge was low (Shamkuwar *et al.*, 2016). Similarly, a lower score for knowledge apart from attitude and practices has been reported by a KAP study (Werthmann *et al.*, 2021). Another KAP study targeting caregivers of asthmatic children illustrates that different educational and management programs related to asthma have room for improvement (Beshah, 2018).

Thus, targeting patients to enhance their knowledge can improve disease outcomes and is supported by various studies, e-g cognition improvement of a patient through self-management education, ultimately enhancing patients' confidence to adopt healthy lifestyles, improving their medication adherence and quality of life has been demonstrated (Chavannesa *et al.*, 2009).

Despite the significance of inhaler therapy in the management of asthma, incorrect use of inhaler devices including the MDI (meter dose inhaler) is mostly reported (Nguyen *et al.*, 2018). This study shows that 47.9% of asthmatic patients have knowledge about holding of breadth after inhaling for few seconds, while 23.8% agreed about the misconception about consecutively taking

the second puff as soon as after the first one is taken. Only 26.3% knew that they should inhale slowly while using their inhaler and 63% responded incorrectly about the correct use of inhaler. So, there's a need for patient education through health-care providers on correct use of inhalation technique as deficiency in health education and absence of regular follow-up visits are reported to be the significant predictors of incorrect inhaler use which have significant association with poor asthma control (Al-Jahdali et al., 2013). Significant improvement through education at follow-ups (p=0.000) in the inhalation technique through assessing and demonstrating the correct inhaler technique to study participants has been reported by another study (Hiral et al., 2013). Therefore, health care providers should regularly demonstrate and re-evaluate the patients' inhaler technique at each visit to opt out the chances for errors in the inhalation technique (Nguyen et al., 2018). Although, asthma is confirmed to be an incurable disease, yet most of the patients are ignorant about this fact (Nguyen et al., 2018). In this study, only 32.1% of participants knew that asthma cannot be cured with 55% having the view that it can be cured by taking regular medicines and avoiding triggers. These findings are consistent with the results from other studies. For example, misconception about asthma being a curable disease was reported by 52% of participants through a study conducted in Vietnam and 40% by a study conducted in Saudi Arabia (Nguyen et al., 2018, Donques et al., 2017). In addition, there is a lack of knowledge about control and rescue medications: for example, 36.3% answered that breathing becomes better immediately after taking the maintenance medicines and 30.8% thought that future flare-ups can be prevented by using rescue medicines. These misconceptions and lack of knowledge were also reported by Al et al stating that only 22% and 16.6% of the participants had correct knowledge about controller and rescue medicines and Nguyen et al, in his study conducted in Vietnam, mentioning that only 15.8% and 17.1% answered correctly about the use of maintenance and rescue medicines (Al et al., 2017, Nguyen et al., 2018).

In the current study, a response regarding what to do when having asthma symptoms and not knowing the cause, only 23.3% answered correctly of changing one's immediate environment. In general, large gaps in patients' knowledge of asthma self-management have been highlighted in this study. It is hoped that study findings will help to design and expand educational programs specifically aiming at knowledge gap areas, which are still rare and this all will ultimately help the patient to achieve better control of their disease by decreasing the frequency of exacerbations and hospital readmissions which will in return improve treatment compliance, optimize therapeutic benefits and ultimately aid the patients to lead a normal healthy life.

As far as according to our knowledge, this is probably the first study in our region targeting the patients' knowledge of asthma self-management with the aim of highlighting important areas of the knowledge gap. However, it should be noted that it is a single-center study, so the results are not generalizable. The strength of our study is that as asthma is one of the ignored diseases in our country, so our study results highlighting the low level of asthma self-management knowledge helps to create a dire need for future research in this area along with emphasizes on the need for educational programs based on identified knowledge gaps. In short, various public health plans based on knowledge of medications, disease states, strategies to control the exposures to triggering agents and ensuring the correct use of inhaler techniques are needed.

CONCLUSION

Assessment of patients' self-management knowledge provides room for designing specific programs aiming at the areas where knowledge deficits are evident thus providing a cost-effective approach which otherwise is impossible because of resource and time limitations. The reported low level of asthma self-management knowledge emphasizes the need for designing and

implementation of educational programs, ongoing monitoring and regular follow-ups in such a way to fit all patient needs even including the less educated ones. Moreover, regular and repeated assessment of inhaler technique if made necessary will optimize the therapeutic benefits and help to achieve better disease control.

Abbreviations

ASMQ: Asthma self-management questionnaire; OPD: Out-patient department; TB: Tuberculosis; COPD: Chronic obstructive pulmonary disease; ISCO: International Standard Classification of Occupations; MDI: Metered dose inhaler; SPSS: Statistical package for social sciences.

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Data Availability Statement

All relevant data are within the paper and its supporting information files.

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Ethical approval and participant's consent

This study was approved by the Bioethics Committee of Quaid-i-Azam University, Islamabad and Institutional review board of PIMS [F.1-1/2019 (EC) PIMS]. Informed consent was also obtained from all participants after explaining them the purpose and nature of the study.

Competing interests

The authors declare that they have no competing interests.

Author's Contribution: All authors (SSS, AK, RA, KUS, AB, SSs) have conceptualized and designed the study. SSS and RA collected the data. SSS, AK and KUS have contributed to the data acquisition and analysis. SSS drafted the manuscript and AK, KUS, AB and SSs have reviewed the manuscript critically. All authors read and have approved the final manuscript. The study is supervised by AK & KUS.

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Figure Legends

Figure 1 Pre and Post ASMQ categories in the control and treatment group

Figure 2 Responses to 14 items of ASMQ at baseline

Figure 3 Distribution of raw ASMQ score at baseline. 0-14 is total possible range with higher scores resulting in higher ASMQ transformed score and thus good asthma self-management knowledge



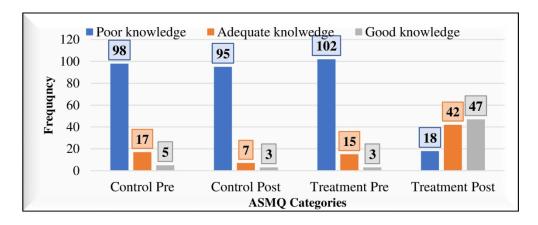


Figure 1. Pre and Post ASMQ categories in the control and treatment group

Figure 1. Pre and Post ASMQ categories in the control and treatment group $140x66mm\;(300\;x\;300\;DPI)$

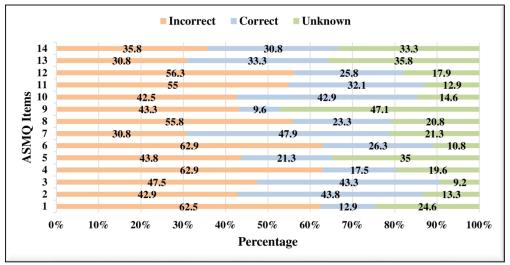


Figure 2. Responses to 14 items of ASMQ at baseline

Figure 2. Responses to 14 items of ASMQ at baseline $165 \times 90 \, \text{mm} \, (300 \times 300 \, \text{DPI})$

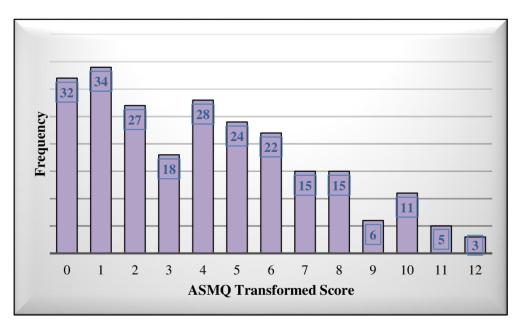


Figure 3. Distribution of raw ASMQ score at baseline

Figure 3. Distribution of raw ASMQ score at baseline $128x84mm (300 \times 300 DPI)$

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the	1-2
		abstract	
		(b) Provide in the abstract an informative and balanced summary of what was	
		done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being	4
		reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of	6
		recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of	6-7
		participants. Describe methods of follow-up	
		(b) For matched studies, give matching criteria and number of exposed and	
		unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and	7
		effect modifiers. Give diagnostic criteria, if applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	7
measurement		assessment (measurement). Describe comparability of assessment methods if	
		there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,	7
		describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for	7-8
		confounding	
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	
		(d) If applicable, explain how loss to follow-up was addressed	
		(\underline{e}) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially	88
•		eligible, examined for eligibility, confirmed eligible, included in the study,	
		completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social)	8
-		and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	9

Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-12
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	12- 16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	16
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12- 16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16- 17
Other informati	on		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

^{*}Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

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Assessment of knowledge on self-management among Asthmatic patients: The effects of an educational intervention

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Assessment of knowledge on self-management among Asthmatic patients: The effects of an educational intervention
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Abstract

- **Objectives:** Despite many advancements in diagnosis and wide accessibility of numerous
- 3 treatment options which are effective, still most of the patients have poorly controlled asthma. This
- 4 can be significantly attributed to the lack of knowledge about disease management, its triggering
- 5 agents and when to seek the advice from health-care provider among many other issues. The
- 6 purpose of our study was to assess the knowledge of disease self-management among patients
- 7 suffering from asthma.
- **Setting:** A Prospective cohort study design was used and ambulatory asthmatic patients were
- 9 recruited through convenient sampling method.
- **Participants:** Questionnaires used enquired about 1) Patients' sociodemographic details, 2)
- 11 Knowledge of disease self-management and were filled in via one-on-one interview with the
- patient. Asthma Self-Management Knowledge Questionnaire (ASMQ) was used and knowledge
- was assessed through summed ASMQ score.
- **Results:** Low level of underlying disease self-management knowledge is reported when
- measured by ASMQ, with an average raw ASMQ score of 4.1 (max 14); which equals to
- transformed score of 29.34 (max 100). Of all the participants, 55% did not know that asthma
- cannot be cured, only 26.3% knew that one should inhale slowly while using the inhaler and
- approximately 87% were ignorant about the fact that getting a flu vaccine annually is the main
- method to prevent asthma flare-up. Overall, at baseline 83.3% of the participants showed poor
- 20 knowledge with only 13.3% having adequate knowledge which after an educational intervention
- showed improvement in the treatment group from mean ASMQ score of 4.20 to 9.77.
- **Conclusions:** Low level of knowledge of asthma self-management at baseline greatly

- emphasizes the need to impart self-management education in structured patient care, which can
- 2 ultimately enhance patient outcomes in terms of their disease comprehension, self-esteem and
- 3 standards of living apart from reducing number of hospital and emergency room visits as well
- 4 as days off work.
- **Keywords:** Asthma self-management, knowledge of asthma, asthma self- management education,

6 asthmatic patients, asthma awareness.

Strengths of this study

• Strategies designed specifically targeting the deficit areas in patient's self-management

- knowledge can be a cost-effective approach.
- Evidence generated can attract policy makers to design and expand educational programs to meet each patient needs in achieving better disease control.
- Significance of improving patient's self-management knowledge can be manifested through asthma control, enhanced compliance, correct inhaler technique and improved quality of life.

Limitations

- Multicenter study is needed so that the results can be generalized.
- Scarcity of tools to measure the asthma self-management knowledge allowed one with very few opportunities to select ASMQ.

INTRODUCTION

Asthma has become one of the major health concerns affecting many millions of people (1). It

is defined as a chronic, non-communicable inflammatory disorder of the airways, that is reported to affect 334 million people worldwide with an alarming prediction of an increase of 100 million more by the year 2025 (2). Considering the most leading causes of disease burden, asthma ranks 28th, causing approximately 1000 people to die every day around the globe and 16th among the leading cause of years of life lived with disability with its prevalence still rising in underdeveloped countries (3). Globally, asthma is the growing contributor of increased morbidity and mortality, thus imposing a significant burden in terms of reducing productivity, not only on the patients but also on their families and health care systems (2). Genetic predisposition and exposure to numerous environmental substances including dust mites, pet dander, pollens as well as stress or sedentary lifestyle collectively accounts for various risk factors of asthma (4). Despite the fact that many advancements have been made in the management of asthma including its diagnosis and treatment yet worldwide it is poorly controlled with its prevalence still increasing (5). One of the previous studies reported as low as $\leq 1\%$ of asthmatic patients with controlled asthma (6). Various reasons for such a low asthma control includes either health-care system related issues (unaffordability or unavailability of medications) or physicians related issues (incorrect or misdiagnosis, lack of proper diagnostic facilities, insufficient time to discuss matters with the patients, absence of reassessment of inhaler technique or lack of proper follow-up measures) or patient related issues (non-compliant behaviors due to lack of knowledge about their disease and its management) (6). Apart from non-adherence to medication regimen, lack of proper education or routine follow-ups, incorrect use of inhalers and lack of inhaler technique assessment at patients visit besides others also play a significant role in increasing the overall prevalence of asthma in different populations (5). Asthma being a controllable disease requires long-term therapy

and thus can be sufficiently controlled if education is provided about the disease and correct use of medications ultimately improving treatment adherence, optimizing therapeutic benefits and enhancing the patients' well-being as alarmingly increased morbidity and mortality as well as worsening of disease states is reportedly associated with non-compliance in asthma (6, 7). Patients' general knowledge about asthma includes pathophysiology of disease, purpose of treatment regimen, recognition and management of exacerbations/disease triggers and correct inhaler use and is quite different from patients' knowledge about self-management (6). As selfmanagement is defined as beliefs or confidence of an individual to uptake behaviors or to make decisions for managing their chronic conditions and it requires efficient communication about patients' condition with their family members, companions and healthcare professionals (8). Asthma self-management involves actions undertaken by the patients to monitor their disease symptoms in order to avoid exacerbations (9). Asthma self-management education, when made a part of regular and planned care, not only improve patient outcomes in terms of disease comprehension, control and patients' well-being but also reduce number of hospital and emergency room visits and work place absences (2). Variability of asthma disease (i-e change in asthma over time) implies that exacerbations can possibly occur even if a patient's asthma is well controlled. Therefore, patients should have the knowledge about their disease management and recognition of how and when to seek help from health professionals when confronted with exacerbations (6). Despite much evidence showing the significance of asthma self-management programs in terms of cost-effectiveness, their implementation in clinical practice is still low (1, 2). Extremely low knowledge of self-management among asthmatic patients is reported in several countries and requires specific educational programs that can lead to better asthma control (6).

- 1 As to the best of our knowledge, data regarding the asthma self- management knowledge is
- 2 lacking as no such studies have been conducted in Pakistan so far, therefore, current study intended
- 3 to determine the knowledge of disease self-management among the asthmatic population and
- 4 effects of an educational intervention.

METHODOLOGY

Study setting and design

- 7 The study follows a prospective cohort design and is conducted at the pulmonary department
- 8 (OPD) of Pakistan Institute of Medical Sciences (PIMS), a tertiary care hospital. Eligible
- 9 participants include ambulatory asthmatic patients recruited between May to Sep 2019. The
- 10 Quasi experimental design was used consisting of non-equivalent groups. Members of the
- 11 control and treatment group possess almost similar characteristics while only one of the group
- members experiences the treatment. At baseline patients' socio-demographic characteristics as well
- as knowledge of asthma self-management were assessed via a face-to-face interview.
- 14 Educational material includes specifically designed pamphlets. The research scholar
- 15 (pharmacist) provides the educational counselling and evaluates the inhaler technique of each
- treatment group patient at baseline and then at follow-up while educational counselling is
- provided to the control group patients at follow-up only along with evaluation of their inhaler
- technique by the same research scholar. Time for counselling varied according to each patients'
- 19 apprehension and previous knowledge.

Inclusion and exclusion criteria

- Inclusion criteria include patients of age ≥ 18 years diagnosed with asthma through spirometry,
- already followed up at this hospital and who were willing to give consent.
- 23 Exclusion criteria include 1) patients with cognitive disability and communication issues; 2) did

1 not give consent; 3) having any other illness with asthma related symptoms; 4) have COPD, TB

2 or congestive heart failure.

Data collection tools

4 The data collection form was structured to obtain the patient socio-demographic details for

5 which information was obtained from the patients' medical records and through a one-on-one

interview with the patient. The Asthma Self-management questionnaire (ASMQ), a pre-

validated tool was used and was filled in by the researcher.

8 The ASMO is used to assess the asthmatic patients' knowledge on their disease self-

management. This questionnaire contained 16 multiple choice questions including preventive

measures, use of inhalers, medications and peak flow meters and can be completed in 8-10

minutes through an interview (10). Tool scores are calculated as each preferred response is given

one point, then all answers are summed up to generate a raw ASMQ score ranging from 0-16

and then finally transformed between 0-100 range with more asthma self-management

knowledge indicated by higher ASMQ transformed scores (6). Two questions related to the peak

flow meters have been omitted because of their minimum use in developing countries for

example, in India, patients who were prescribed peak flow meters reported to be only 2% of the

total (11). After omission of these peak flow meter related two questions, generated ASMQ raw

score will range from 0-14 and then will be converted into transformed score, so that it can

further be categorized into poor, adequate and good knowledge categories accordingly.

Occupational status was categorized according the ISCO categories into not working including

students, housewives, currently not working or retired, blue collars workers which includes doing

22 manual work and white-collar workers includes desk workers (12).

Data compilation and statistical analysis

- 1 IBM SPSS Statistic version 21 was employed for data analysis. Descriptive statistics was used
- 2 to summarize the mean and standard deviations of the demographic variables of both groups i-e
- 3 Treatment and Control. Categorical variables were analyzed using the Chi-square test. For intra-
- 4 group comparisons, Wilcoxon matched-pair test was used. A p-value of ≤ 0.05 was labeled
- 5 statistically significant.

Patient and public involvement

8 Patients were not involved in the design and conduct of this study.

RESULTS

- 11 Approximately 265 adult asthmatic patients aged ≥18 years were approached out of which 240
- gave consent to participate in the study. The majority 47.5% of the participants belonged to 36-55
- years age group with 56.7% of participants being males, 15.4% had a history of allergy while
- 14 25.4% had a positive family history of the disease. **Table 1** lists some of the other characteristics.

Table 1. Socio-demographics of study participants

Characteristics	Categories	CG	TG	p-value
Age		39.46±13.5	39.70±13.99	0.892
Age categories	18-35	27	32	0.881
	36-55	54	60	
	>56	39	28	
Gender	Male	61	75	0.068
	Female	59	45	
Residence	Rural	75	66	0.597
	Urban	45	54	
Occupation	Not working	61	53	0.827
(ISO Categories)	Blue collar worker	25	22	

a result of educational intervention.

	White collar worker	34	45	
Educational	Illiterate	20	24	0.870
Status	Primary	36	40	
	Secondary	37	27	
	Graduate	27	29	
Family history	Disease	30	26	0.846
	Allergy	22	15	
	Both	30	35	
	None	38	44	
Smoking status	Ex-smokers	22	27	0.927
	Current-smokers	33	38	
	Never-Smoke	65	55	
Disease duration	≤2	47	51	0.978
Categories <u>(yrs)</u>	2-5	45	34	
	>5	28	35	

Pre and post ASMQ raw and transformed score are presented in **Table 2.** Wilcoxon matched-pair test is used to calculate the p-value. A p-value of .487 in pre and post ASMQ raw and transformed scores shows non-significant changes in control group while p-value of 0.00 (i-e ≤ 0.05) in the pre and post ASMQ raw and transformed scores shows significant changes in the treatment group as

1 Table 2. Pre and post ASMQ categories, ASMQ raw and transformed scores in control and treatment group

	Control group	Tı	reatment group
ASMQ Raw score	Pre	Post	p-value
Control group	4.01 ± 3.32	3.89 ± 2.92	.487
Intervention group	4.20 ± 3.03	9.77 ± 2.58	<.001
ASMQ Transformed score	Pre	Post	p-value
Control group	28.69 ± 23.75	27.76 ± 20.86	.487
Treatment group	30 ± 21.64	69.83 ± 18.42	<.001

Figure 1 shows that number of patients possessing good knowledge improved from 3 to 47 and

those possessing adequate knowledge improved from 15 to 42 in the treatment group. Patients'

knowledge was categorized on the basis of transformed score as good (>75), adequate (50-75)

4 and poor (<50).

5 6 Figure 1

8 Figure 2 shows that question 7 (About hold of breadth after use of an inhaler for several seconds)

9 has the highest percentage of correct answers i.e. 47.9%. Only 32.1% of the participants knew

that asthma is an incurable disease which emphasizes the need for patients' education about the

regular uptake of medications to achieve disease control. Item 9 (About patients' increased need

for maintenance medicines in case he/she is using more rescue medications than are prescribed)

was frequently answered to be unknown (47.1%).

Figure 2

Figure 3 shows distribution of raw ASMQ score at baseline. 0-14 is the total possible range with higher scores resulting in higher ASMQ transformed scores and thus indicating good asthma self-management knowledge. This underlying distribution of ASMQ raw score indicates poor

22 Figure 3 23

disease management knowledge among the study participants.

DISCUSSION

27 The major conclusions of the current study conducted to analyze the knowledge on disease self-

28 management among asthmatic patients illustrate a low level of knowledge with an average raw

ASMQ score of 4.1 [4.1/14] that equals to 29.34 transformed score [29.34/100] at baseline (Table). Overall, at baseline 83.3% of patients have poor knowledge with only 13.3% having adequate knowledge. These results are consistent with the results from similar studies. For example, study conducted by Nguyen et al in Vietnam reported low knowledge with mean raw ASMQ score of 4.3 which equals to the transformed score of 30 (6). Another observational study conducted in the Kingdom of Saudi Arabia reported an average ASMQ score of 3.5 [3.5/14] (13). The format of both of these studies was similar to that of the present study (two items related to the peak flow meter removed) as use of peak flow meter is not common in developing countries (6). Apart from baseline ASMQ score, follow up ASMQ score was also recorded in the present study suggesting the significance of educational intervention by a pharmacist for the patient, as the mean ASMQ score got significantly increased from 4.20/14 to 9.77/14 [transformed score 69.83/100] in the treatment group as compared to no significant increase in the control group, from 4.01/14 to 3.89/14. Al et al found that patients with more than 50% correct responses were 4% while in our study this percentage is 16.7% which is quite close to that reported by Nguyen et al (6, 13). The number of patients with greater than 50 ASMQ scores has been significantly increased up to 89 patients at follow-up in the treatment group. This is in agreement with the results of an interventional study in which a full version of ASMQ was used (i-e all 16 items) reporting an average score of 4.49/16 (transformed 28.6/100) in the intervention group at baseline and 3.91/16 (transformed score 24.4/100) in the control group and also reported an improvement in the ASMQ average scores only in intervention group when compared to control group as a result of an educational intervention, highlighting the fact that better ASMO score involves better asthma control test score (14). Significant improvement in patients asthma knowledge resulting in increased adherence level and

asthma control score after 3 months follow-up with 60% of the patients having achieved better control and 18% well-controlled asthma has also been reported by another study emphasizing the need for effective educational programs (15). Low level of knowledge is reported by various studies conducted to assess the general knowledge about management of asthma, thus highlighting the dire need for educational programs. For example, a study conducted in Sri Lanka reported that only 34% of the patients were knowledgeable about their disease and medications (6). A multicenter study in China reported a low level of disease awareness among the parents of asthmatic children (16). Another study illustrated that 62.7% of asthmatics have poor, 12% have good and only 25.3% possess adequate knowledge (17). Another study showed that although the patients have a positive attitude towards the disease, yet patients' specific disease knowledge was low (18). Similarly, a lower score for knowledge apart from attitude and practices has been reported by a KAP study (19). Another KAP study targeting caregivers of asthmatic children illustrates that different educational and management programs related to asthma have room for improvement (20). Thus, targeting patients to enhance their knowledge can improve disease outcomes and is supported by various studies, e-g cognition improvement of a patient through self-management education, ultimately enhancing patients' confidence to adopt healthy lifestyles, improving their medication adherence and quality of life has been demonstrated (21). Habib et al also demonstrated in a systematic review, the significance of various patient-tailored therapies including patient education that leads to their behavioral changes on long term basis ultimately causing health enhancement and better disease control (22). Despite the significance of inhaler therapy in the management of asthma, incorrect use of inhaler

devices including the pMDI (pressurized meter dose inhaler) is mostly reported (6). Assessment

of pMDI technique during this study shows that 47.9% of asthmatic patients have knowledge about holding of breadth after inhaling for few seconds, while 23.8% agreed about the misconception about consecutively taking the second puff as soon as after the first one is taken. Only 26.3% knew that they should inhale slowly while using their inhaler and 63% responded incorrectly about the correct use of inhaler. So, there's a need for patient education through health-care providers on correct use of inhalation technique as deficiency in health education and absence of regular followup visits are reported to be the significant predictors of incorrect inhaler use which have significant association with poor asthma control (23). Significant improvement through education at followups (p=0.000) in the inhalation technique through assessing and demonstrating the correct inhaler technique to study participants has been reported by another study (14). Therefore, health care providers should regularly demonstrate and re-evaluate the patients' inhaler technique at each visit to opt out the chances for errors in the inhalation technique (6). Although, asthma is confirmed to be an incurable disease, yet most of the patients are ignorant about this fact (6). In this study, only 32.1% of participants knew that asthma cannot be cured with 55% having the view that it can be cured by taking regular medicines and avoiding triggers. These findings are consistent with the results from other studies. For example, misconception about asthma being a curable disease was reported by 52% of participants through a study conducted in Vietnam and 40% by a study conducted in Saudi Arabia (6, 24). These misconceptions highlight the dire need for patient's education about the incurable nature of asthma and to clarify their concepts about the term cure that it cannot be equated with cure. In addition, there is a lack of knowledge about control and rescue medications: for example, 36.3% answered that breathing becomes better immediately after taking the maintenance medicines and 30.8% thought that future flare-ups can be prevented by using rescue medicines. These

misconceptions and lack of knowledge were also reported by Al et al stating that only 22% and 16.6% of the participants had correct knowledge about controller and rescue medicines and Nguyen et al, in his study conducted in Vietnam, mentioning that only 15.8% and 17.1% answered correctly about the use of maintenance and rescue medicines (6, 13). In the current study, a response regarding what to do when having asthma symptoms and not knowing the cause, only 23.3% answered correctly of changing one's immediate environment. As far as according to our knowledge, this is probably the first study in our region assessing the patient's self-management knowledge of asthma and effect of educational intervention specifically targeting those knowledge gaps with the hope that these will ultimately help the patient to achieve better control of their disease by decreasing the frequency of exacerbations and hospital readmissions and will improve treatment compliance, optimize therapeutic benefits and ultimately aid the patients to lead a normal healthy life. Designing of such an educational program even for General Physician (GPs) is also recommended by a study highlighting high educational need for conditions that are commonly encountered in primary care such as asthma, allergies etc so that coordinated and harmonized patient care can be provided as primary care skills and development of sustainable GPs knowledge levels are also necessary for the success of any health care initiative (25). With the shift of modern treatment goals to early detection and prevention of exacerbations, effective strategies can include either broad commitments and interactive educational sessions at different levels of healthcare systems as health centers are the first contact points of patients when referring to their disease symptoms or counselling of patients during drug purchase about the proper medication use and inhalation technique (26). Specifically organized educational programs for asthma control can not only

reduce morbidity but also enhance patient's health realted quality of life and can save health-care

- system resources and thus can be a cost-effective approach for under-developed countries (27).
- 2 As asthma is one of the ignored disease in our country, our study results will help to attract the
- 3 attention of countries health authorities for further research in this area along with greater
- 4 emphasizes on the need for targeted educational programs. In short, the present study tried to
- 5 enlighten the significance of educational intervention for conditions commonly encountered in the
- 6 health care settings such as asthma in front of relevant authorities so that better disease control can
- be achieved cost-effectively in a developing country like Pakistan through reducing health related
- 8 costs and improving quality of life of asthmatic patients.

CONCLUSION

- 11 Low level of asthma self-management knowledge emphasizes the need for designing and
- implementation of educational programs, ongoing monitoring and regular follow-ups in such a
- way to fit all patient needs even including the less educated ones. Assessment of patient's self-
- management knowledge provides room for designing specific programs aiming at the areas where
- 15 knowledge deficits are evident thus providing a cost-effective approach which otherwise is
- impossible because of resource and time limitations. Moreover, regular and repeated assessment
- of inhaler technique, if made necessary, will optimize the therapeutic benefits and help to achieve
- 18 better disease control.

Abbreviations

- 20 ASMQ: Asthma self-management questionnaire; OPD: Out-patient department; TB: Tuberculosis;
- 21 COPD: Chronic obstructive pulmonary disease; ISCO: International Standard Classification of
- Occupations; MDI: Metered dose inhaler; SPSS: Statistical package for social sciences.

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- 10 Ethical approval and participant's consent
- 11 This study was approved by the Bioethics Committee of Quaid-i-Azam University, Islamabad and
- 12 Institutional review board of PIMS [F.1-1/2019 (EC) PIMS]. Informed consent was also obtained
- from all participants after explaining them the purpose and nature of the study.
- 14 Competing interests
- 15 The authors declare that they have no competing interests.
- Author's Contribution: All authors (SSS, AK, RA, KUS, AB, SSs) have conceptualized and
- designed the study. SSS and RA collected the data. SSS, AK and KUS have contributed to the data
- acquisition and analysis. SSS drafted the manuscript and AK, KUS, AB and SSs have reviewed
- 19 the manuscript critically. All authors read and have approved the final manuscript. The study is
- 20 supervised by AK & KUS.

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Figure Legends

- 3 Figure 1 Pre and Post ASMQ categories in the control and treatment group
- 4 Figure 2 Responses to 14 items of ASMQ at baseline
- Figure 3 Distribution of raw ASMQ score at baseline. 0-14 is total possible range with higher scores resulting in higher ASMQ transformed score and thus good asthma self-management knowledge



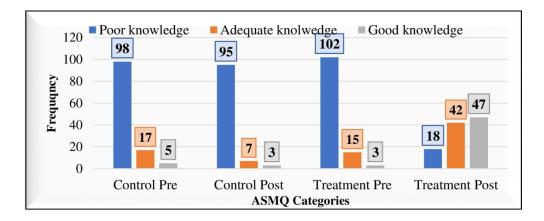


Figure 1. Pre and Post ASMQ categories in the control and treatment group

Figure 1. Pre and Post ASMQ categories in the control and treatment group $140x66mm\;(300\;x\;300\;DPI)$

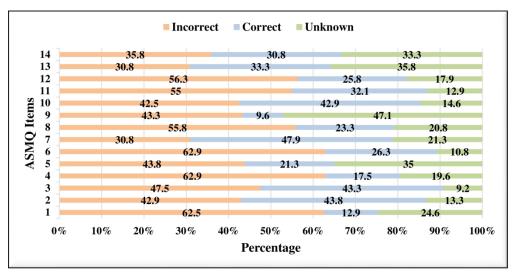


Figure 2. Responses to 14 items of ASMQ at baseline

Figure 2. Responses to 14 items of ASMQ at baseline $165 \times 90 \text{mm}$ (300 x 300 DPI)

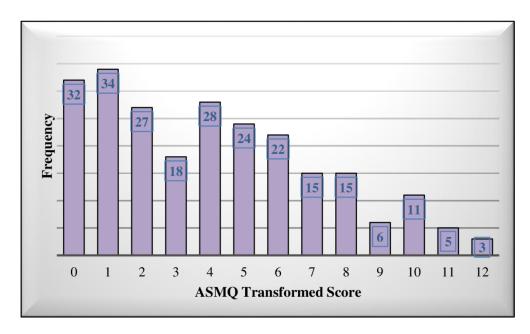


Figure 3. Distribution of raw ASMQ score at baseline

Figure 3. Distribution of raw ASMQ score at baseline $128x84mm (300 \times 300 DPI)$

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the	1-2
		abstract	
		(b) Provide in the abstract an informative and balanced summary of what was	
		done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being	4
		reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of	6
		recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of	6-7
		participants. Describe methods of follow-up	
		(b) For matched studies, give matching criteria and number of exposed and	
		unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and	7
		effect modifiers. Give diagnostic criteria, if applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	7
measurement		assessment (measurement). Describe comparability of assessment methods if	
		there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,	7
		describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7-8
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	
		(d) If applicable, explain how loss to follow-up was addressed	
		(e) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially	88
1 w. w. pwins	10	eligible, examined for eligibility, confirmed eligible, included in the study,	
		completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social)	8
- F	-	and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	9

Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-12
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a	
		meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	12- 16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision.	16
		Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,	12-
_		multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16-
			17
Other informati	on		
Funding	22	Give the source of funding and the role of the funders for the present study and, if	17
		applicable, for the original study on which the present article is based	

^{*}Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

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Assessment of knowledge on self-management among Asthmatic patients: The effects of an educational intervention

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Assessment of knowledge on self-management among Asthmatic patients: The effects of an educational intervention
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Abstract

- **Objectives:** Despite the availability of effective diagnosis and treatment strategies, asthma is still
- 3 poorly controlled in majority of patients. This could be partly due to the patients' lack of
- 4 knowledge about the disease management, its triggering agents and when to seek the advice from
- 5 health-care provider. The purpose of our study was to assess the knowledge of disease self-
- 6 management among the established asthma patients.
- 7 Setting: This was a prospective cohort study carried out among conveniently enrolled
- 8 established asthmatic patients at the outpatient department of PIMS.
- **Methods:** Via one-on-one interview with the enrolled patients, the questionnaires used enquired
- about 1) patients' sociodemographic details and 2) knowledge of disease self-management by
- using Asthma Self-Management Knowledge Questionnaire (ASMQ). The level of knowledge
- was assessed through summed ASMQ score.
- **Results:** The analysis of the gathered data revealed low level of underlying disease self-
- management knowledge with an average raw ASMO score of 4.1 (max 14); which equals to
- transformed score of 29.34 (max 100). More than half of study participants (55%) did not know
- that asthma cannot be cured. Only 26.3% of the participants knew that one should inhale slowly
- while using the inhaler, and an overwhelming majority (87%) were ignorant about the fact that
- getting a flu vaccine annually is the main method to prevent asthma flare-up. At baseline visit,
- only 13.3% had adequate knowledge of asthma self-management. The administration of
- 20 educational intervention resulted in an improved level of knowledge of asthma self-management
- in the treatment group (mean ASMQ score from 4.20 to 9.77).
- 22 Conclusions: On the baseline visit, patients had poor knowledge about asthma self-

management. Educational intervention had a positive impact on improving patients' knowledge about disease self-management. This advocates that imparting self-management education in

structured patient care could result in achieving optimal asthma control and improve patients

health related quality of life.

Keywords: Asthma self-management, knowledge of asthma, asthma self-management education, asthmatic patients, asthma awareness.

Strengths and limitations of this study

- Adherence to clearly defined inclusion and exclusion criteria.
- Educational program resulted in significant improvement in self-management knowledge.
- Comparison with a parallel control group signifies the impact of an educational intervention.
- Participants recruited only from a single centre.
- Scarcity of tools to measure the asthma self-management knowledge.

INTRODUCTION

Asthma has become one of the major health concerns affecting many millions of people (1). It is defined as a chronic, non-communicable inflammatory disorder of the airways, that is reported to affect 334 million people worldwide with an alarming prediction of an increase of 100 million more by the year 2025 (1, 2). Considering the most leading causes of disease burden, asthma ranks 28th, causing approximately 1000 people to die every day around the globe and 16th among the leading cause of years of life lived with disability with its prevalence still rising in underdeveloped countries (3). Globally, asthma is the growing contributor of increased morbidity and mortality, thus imposing a significant burden in terms of reducing productivity, not only on the patients but also on their families and health care systems (2). Genetic predisposition and exposure to numerous environmental substances including dust mites, pet dander, pollens as well as stress or sedentary lifestyle collectively accounts as contributing factors for developing and high prevalence of poorly controlled asthma (4). Despite the availability of effective diagnosis and treatment strategies, asthma is still poorly controlled in majority of patients and its incidence is on rise (5, 6). Various reasons for such a low asthma control includes either health-care system related issues (unaffordability or unavailability of medications) or physicians related issues (incorrect or misdiagnosis, lack of proper diagnostic facilities, insufficient time to discuss matters with the patients, absence of reassessment of inhaler technique or lack of proper follow-up measures) or patient related issues (non-compliant behaviors due to lack of knowledge about their disease and its management) (5). In addition to non-adherence to medication regimen, lack of proper education or routine follow-up, incorrect use of inhaler and lack of inhaler technique assessment at patient visit also play a significant role in the suboptimal

control of asthma (6). Being a controllable disease, asthma requires a prolonged guidelines compliant therapy along with patient education about the correct use of medications and disease self-management (5, 7). The patients' general knowledge about asthma includes pathophysiology of disease, purpose of treatment regimen, recognition and management of exacerbations/disease triggers and correct inhaler use (5). On the contrary, self-management is defined as beliefs or confidence of an individual to uptake behaviors or to make decisions for managing their chronic conditions, it requires efficient communication about patients' condition with their family members, companions and healthcare professionals (8). Asthma self-management involves actions undertaken by the patients to monitor their disease symptoms and avoid exacerbations (9). The existing published literature signifies that asthma self-management is conditional on education because education improves patients understanding of their treatment rationale and monitoring and when made a part of regular and planned care, not only improves asthma control and patients' quality of life but also reduces the healthcare costs by decreasing the frequency of hospital and emergency room visits and absentees in the work places (2). Variability of asthma disease (i-e change in asthma over time) implies that exacerbations can possibly occur even if a patient's asthma is well controlled. Therefore, patients should have the knowledge about their disease management and recognition of how and when to seek help from health professionals when confronted with exacerbations (5). Despite the well documented evidence of positive impact of asthma self-management programs in achieving the desired patient outcomes and reducing healthcare costs, it is still rarely

23 Despite the sixth most populous country in the world and harboring a high burden of asthma

implemented in the routine clinical practice (1, 2, 5).

- patients, there is a scarcity of published information regarding the patients' knowledge and
- 2 impact of educational intervention on knowledge about asthma self-management from Pakistan.
- 3 Therefore, the current study was conducted with the objective to evaluate the knowledge of
- 4 disease self-management among established asthmatic patients and the impact of an educational
- 5 intervention.

METHODOLOGY

Study setting and design

This was a prospective cohort study carried out at the pulmonology outpatients department (OPD) of Pakistan Institute of Medical Sciences (PIMS), a tertiary care hospital located in the capital territory of Islamabad Pakistan. Those established asthmatic patients through spirometry. who were at-least 18 years old, visited the study site from May to September 2019 and were willing to participate in the study by given a written consent were included in the study. Those patients who were unable to communicate, had cognitive abnormality or any other disease with asthma related symptoms like chronic obstructive pulmonary disease, tuberculosis and heart failure were not included. The Quasi experimental design was used. The study participants were arbitrarily assigned to control and treatment groups. Both groups were roughly similar in terms of sociodemographic characteristics and asthma self-management knowledge on baseline visit. The educational intervention was administered to the treatment group. On baseline patients' socio-demographic characteristics as well as knowledge of asthma self-management were assessed via a face-to-face interview. Educational material included specifically designed pamphlets. The principal author (SSS) provided the educational counselling and evaluated the inhaler technique of each patient in the treatment group at baseline and follow-up visits. Whereas educational counselling is provided to the control group patients on follow-up visit only along

- with evaluating their inhaler technique. Time for counselling varied according to each patients'
- 2 comprehension and previous knowledge.

Data collection tools

- 4 A purpose developed data collection form was used to obtain the patients' sociodemographic
- 5 characteristics from their medical records and in one-on-one interview with the patient. In order
- 6 to evaluate patients' knowledge about self-management of asthma, the principal investigator
- 7 administered ASMQ to the patients.
- 8 ASMQ contained 16 multiple choice questions about preventive measures, use of inhalers,
- 9 medications and peak flow meters (10). Tool scores were calculated by giving one point to each
- 10 preferred response. For generating raw ASMQ scores, all answers were summed up and
- transformed to a score ranging between 0-100. Higher transformed score on ASMQ signified
- higher knowledge about self-management of asthma (5). Two questions related to the peak flow
- meters were omitted because of their minimum use in developing countries, generated ASMQ
- raw score then ranged from 0-14 (11).

Data compilation and statistical analysis

- 16 IBM SPSS Statistic version 21 was employed for data analysis. Descriptive statistics was used
- to summarize the mean and standard deviations of the demographic variables of both groups i-e
- 18 Treatment and Control. Categorical variables were analyzed using the Chi-square test. For intra-
- group comparisons, Wilcoxon matched-pair test was used. A p-value of ≤ 0.05 was labeled
- 20 statistically significant.

Patient and public involvement

22 Patients were not involved in the design and conduct of this study.

RESULTS

- 2 Approximately 265 adult asthmatic patients aged ≥18 years were approached. Among them a
- total of 240 patients gave consent to participate in the study. The majority of participants (47.5%)
- 4 belonged to the age group of 36-55 years, 56.7% were males, and 15.4% had a history of allergy
- 5 while 25.4% had a positive family history of asthma (table 1). 47.5% were categorized as not
- 6 working and 32.9% as white collar workers according to ISCO categories for occupational status
- 7 (12).

Table 1. Socio-demographics of study participants

Characteristics	Categories	CG	TG	p-value
Age		39.46±13.5	39.70±13.99	0.892
Age categories	18-35	27	32	0.881
	36-55	54	60	
	>56	39	28	
Gender	Male	61	75	0.068
	Female	59	45	
Residence	Rural	75	66	0.597
	Urban	45	54	
Occupation	Not working	61	53	0.827
(ISO Categories)	Blue collar worker	25	22	
	White collar worker	34	45	
Educational	Illiterate	20	24	0.870
Status	Primary	36	40	
	Secondary	37	27	
	Graduate	27	29	
Family history	Asthma	30	26	0.846
	Allergy	22	15	
	Both	30	35	
	None	38	44	
Smoking status	Ex-smokers	22	27	0.927

	Current-smokers	33	38	
Disease duration Categories(<u>vrs.)</u>	Never-Smoke	65	55	
	≤2	47	51	0.978
	2-5	45	34	
	>5	28	35	

2 Pre and post intervention ASMQ raw and transformed scores are presented in Table 2. No

3 statistically significant difference in ASMQ raw and transformed scores was observed in control

group (p-value=0.487). However, as a result of educational intervention, there was a statistically

significant change in these scores in the treatment group (p-value <0.001).

6 Table 2. Pre and post ASMQ categories, ASMQ raw and transformed scores in control and treatment group

	Control group	•	Treatment group
ASMQ Raw score	Pre	Post	p-value
Control group	4.01 ± 3.32	3.89 ± 2.92	.487
Treatment group	4.20 ± 3.03	9.77 ± 2.58	<.001
ASMQ Transformed score	Pre	Post	p-value
Control group	28.69 ± 23.75	27.76 ± 20.86	.487
Treatment group	30 ± 21.64	69.83 ± 18.42	<.001

Figure 1 shows that as a result of educational intervention the number of patients possessing
good knowledge improved from 3 to 47 and those possessing adequate knowledge improved
from 15 to 42 in the treatment group. Patients' knowledge was categorized on the basis of
transformed score as good (>75), adequate (50-75) and poor (<50).
Figure 1
Figure 2 shows that question 7 (About hold of breath after use of an inhaler for several seconds)
has the highest percentage of correct answers i.e 47.9%. Only 32.1% of the participants knew
that asthma is an incurable disease which emphasizes the need for patients' education about the
regular uptake of medications to achieve disease control. Item 9 (About patients' increased need
for maintenance medicines in case he/she is using more rescue medications than are prescribed)
was frequently answered to be unknown (47.1%).
Figure 2

Figure 3 shows distribution of raw ASMQ score at baseline. 0-14 is the total possible range with higher scores resulting in higher ASMQ transformed scores and thus indicating good asthma self-management knowledge. This underlying distribution of ASMQ raw score indicates poor disease management knowledge among the study participants.

Figure 3

DISCUSSION

To the best of our knowledge, this is probably the first study from Pakistan which assessed the patient's self-management knowledge of asthma and impact of an educational intervention. The findings of the current study signify that at baseline visit, majority of the study participants (83.3%) were poorly aware about the self-management of asthma and their knowledge was significantly improved after an educational intervention. Likewise, findings regarding the patients' poor knowledge about asthma self-management have been reported by studies conducted elsewhere. For example, a study conducted by Nguyen et al in Vietnam reported low knowledge with mean raw ASMQ score of 4.3 which equals to the transformed score of 30 (5). Similarly, another observational study conducted in the Kingdom of Saudi Arabia reported an average ASMQ score of 3.5 [3.5/14] (13). The format of both of these studies was similar to that of the present study (two items related to the peak flow meter removed) as use of peak flow meter is not common in developing countries (5). Likewise, a study conducted in Sri Lanka reported that only 34% of the patients were knowledgeable about their disease and medications (5). A multicenter study in China reported a low level of disease awareness among the parents of asthmatic children (14). Another study illustrated that 62.7% of asthmatics have poor, 12% have good and only 25.3% possess adequate knowledge (15). Similar studies showed that although the patients have a positive attitude towards the disease, yet patients' specific disease knowledge was low (16, 17). In our study the proportion of patients (16.7%) who correctly answered more than 50% questions was greater than that reported by Al et al., (4%) but similar to that reported by Nguyen et al (16.5%) (5, 13). Despite the significance of correct use of inhaler devices including the meter dose inhaler (MDI) in optimal control of asthma, there have been reports of its incorrect use (5). We found that only

47.9% of the current study participants had the knowledge about holding of breath after inhaling for few seconds, and 23.8% agreed with the misconception about consecutively taking the second puff as soon as after the first one is taken. Only 26.3% knew that they should inhale slowly and 63% did not know about the correct use of the inhaler. So, there's a need for patient education through health-care providers on correct use of inhalation technique. Lack of health education and regular follow-up visits has previously been reported as the predictors of incorrect inhaler use and poor asthma control (18). Significant improvement through education at follow-ups (p=0.000) in the inhalation technique through assessing and demonstrating the correct inhaler technique to study participants has been reported by another study (19). Therefore, health care providers should regularly demonstrate and re-evaluate the patients' inhaler technique at each visit to opt out the chances for errors in the inhalation technique (5). Despite being an incurable disease, 55% of the current study participant were of the opinion that it can be cured thus equating control with cure. Similar findings regarding the patients' misconception that asthma is curable have been reported by studies conducted in Vietnam and Saudi Arabia (5, 20). Furthermore, there was a lack of knowledge about control and rescue medications: for example, 36.3% of the current study participants answered that breathing becomes better immediately after taking the maintenance medicines, and 30.8% thought that future flare-ups can be prevented by using rescue medicines. These misconceptions and lack of knowledge were also reported by Al et al stating that only 22% and 16.6% of the participants had correct knowledge about controller and rescue medicines. Similar poor knowledge about the correct use of maintenance and rescue medicines has been reported from Vietnam (5, 13). In the current study, a response regarding what to do when having asthma symptoms and not knowing the cause, only 23.3% answered correctly of changing one's immediate environment.

Low level of patients' knowledge of asthma self-management found in the current study and studies conducted elsewhere emphasize on the educational programs among asthma patients. In the current study, the pharmacist administered educational intervention in the treatment group significantly increased the mean ASMO score from 4.20/14 to 9.77/14 [transformed score 69.83/100]. On the contrary, no significant increase in these scores was observed in the control group. In the current study, educational intervention increased the number of patients with >50 ASMQ score up to 89 in the treatment group. This is in agreement with the results of an intervention study in which a full version of ASMQ (i-e all 16 items) was used. The study reported a statistically significant increase in ASMQ score in the group of patients who received an educational intervention (19). Similar positive impact of an educational intervention on patients' self-management knowledge of asthma, medication adherence and asthma control (60% better control and 18% well-controlled) has also been reported (21). Likewise positive impact of patient-tailored educational interventions on knowledge about disease self-management, better disease control, treatment outcomes and patients' health related quality of life has been reported by studies conducted elsewhere (18, 21-25). Especially with the shift of modern treatment goals to early detection and prevention of exacerbations, effective strategies can include either broad commitments and interactive educational sessions at different healthcare levels and can be a cost-effective approach for under-developed countries (26, 27).

CONCLUSION

Low level of asthma self-management knowledge and the positive impact of educational intervention in the reducing the knowledge gaps emphasize the need for designing and implementation of educational programs, ongoing monitoring and regular follow-ups in such a way to fit all patient needs even including the less educated ones. Assessment of patient's self-

- 1 management knowledge provides room for designing specific programs aiming at the areas where
- 2 knowledge deficits are evident thus providing a cost-effective approach which otherwise is
- 3 impossible because of resource and time limitations. Moreover, regular and repeated assessment
- 4 of inhaler technique, if made necessary, will optimize the therapeutic benefits and help to achieve
- 5 better disease control.

6 Abbreviations

- 7 ASMQ: Asthma self-management questionnaire; OPD: Outpatient department; TB: Tuberculosis;
- 8 COPD: Chronic obstructive pulmonary disease; ISCO: International Standard Classification of
- 9 Occupations; MDI: Metered dose inhaler; SPSS: Statistical package for social sciences.

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Data Availability Statement

All relevant data are within the paper and its supporting information files.

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- been received for the research.

20 Ethical approval and participant's consent

- 21 This study was approved by the Bioethics Committee of Quaid-i-Azam University, Islamabad and
- 22 Institutional review board of PIMS [F.1-1/2019 (EC) PIMS]. Informed consent was also obtained
- from all participants after explaining them the purpose and nature of the study.

Competing interests

- 2 The authors declare that they have no competing interests.
- 3 Author's Contribution: All authors (SSS, AK, RA, SSs, AB, NA, SMu, SM, KUS) have
- 4 conceptualized and designed the study. SSS, RA and SSs collected the data. SSS, AK, SMu and
- 5 KUS have contributed to the data acquisition and analysis. SSS drafted the manuscript and AK,
- 6 NA, AB and SM have reviewed the manuscript critically. All authors read and have approved the

7 final manuscript. The study is supervised by AK & KUS.

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Figure Legends

- Figure 1 Pre and Post ASMQ categories in the control and treatment group
- 4 Figure 2 Responses to 14 items of ASMQ at baseline
- Figure 3 Distribution of raw ASMQ score at baseline. 0-14 is total possible range with higher scores resulting in higher ASMQ transformed score and thus good asthma self-management knowledge



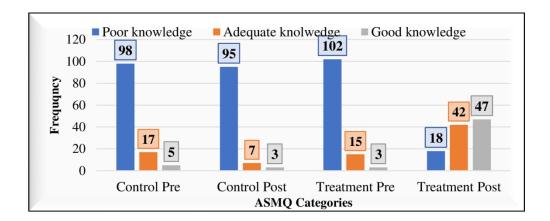


Figure 1. Pre and Post ASMQ categories in the control and treatment group

Figure 1. Pre and Post ASMQ categories in the control and treatment group $140x66mm\;(300\;x\;300\;DPI)$

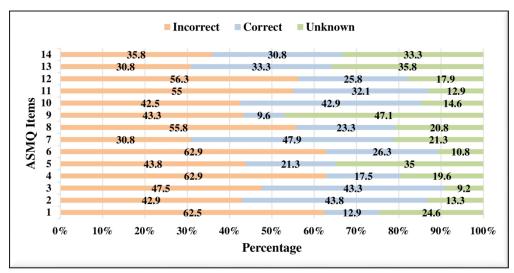


Figure 2. Responses to 14 items of ASMQ at baseline

Figure 2. Responses to 14 items of ASMQ at baseline $165 \times 90 \text{mm}$ (300 x 300 DPI)

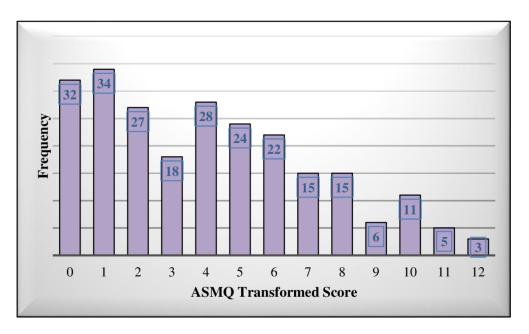


Figure 3. Distribution of raw ASMQ score at baseline

Figure 3. Distribution of raw ASMQ score at baseline $128 \times 84 \text{mm} (300 \times 300 \text{ DPI})$

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the	1-2
		abstract	
		(b) Provide in the abstract an informative and balanced summary of what was	
		done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being	4
		reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of	6
-		recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of	6-7
•		participants. Describe methods of follow-up	
		(b) For matched studies, give matching criteria and number of exposed and	
		unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and	7
		effect modifiers. Give diagnostic criteria, if applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	7
measurement		assessment (measurement). Describe comparability of assessment methods if	
		there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,	7
		describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for	7-8
		confounding	
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	
		(d) If applicable, explain how loss to follow-up was addressed	
		(e) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially	88
T di tio ipanto	15	eligible, examined for eligibility, confirmed eligible, included in the study,	
		completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social)	8
pv uuu		and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	

Main results 16		(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a	
		meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	12- 16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision.	16
		Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,	12-
		multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16-
			17
Other informati	on		
Funding	22	Give the source of funding and the role of the funders for the present study and, if	17
		applicable, for the original study on which the present article is based	

^{*}Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

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Impact of Pharmacist-led educational intervention on knowledge of self-management among Asthmatic patients: A prospective cohort study

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Impact of Pharmacist-led educational intervention on knowledge of selfmanagement among Asthmatic patients: A prospective cohort study Shahzadi Sidra Saleem¹, Amjad Khan^{1*}, Rubina Aman², Shahzadi Sadia Saleem³, Ayesha Bibi^{1,4}, Nafees Ahmad⁵, Saima Mushtaq⁶, Saifullah Mehsud⁷, Ivan R. Green⁸, Sheikh Abdur Rashid⁹, Ahmad Khan¹, Kifayat Ullah Shah^{1*} ¹Department of Pharmacy, Quaid-i-Azam University, Islamabad, Pakistan ²Department of Pulmonology, Pakistan Institute of Medical Sciences, Islamabad, Pakistan ³King Edward Medical University, Lahore, Pakistan ⁴Usher Institute for Population Health Sciences and Informatics, University of Edinburgh, Edinburgh, UK ⁵Department of Pharmacy Practice, Faculty of Pharmacy and Health Sciences, University of Balochistan, Quetta, Pakistan ⁶Department of Healthcare Biotechnology, Atta-ur-Rahman School of Applied Biosciences, National University of Sciences and Technology, Islamabad, Pakistan ⁷Department of Pharmaceutical Sciences, Abbottabad University of Science and Technology, Havelian, Abbottabad, Pakistan ⁸Department of Chemistry and Polymer Science, University of Stellenbosch, Matieland, South Africa ⁹Gomal Center of Pharmaceutical Sciences, Faculty of Pharmacy, Gomal University, D.I.Khan, Pakistan *Corresponding authors: Amjad Khan & Kifayat Ullah Shah Department of Pharmacy, Quaid-i-Azam University Islamabad, 45320, Pakistan +92-051 9064 4128 amjadkhan@gau.edu.pk, kushah@gau.edu.pk **Short title:** Self-management among asthmatic patients Email addresses of Authors: shahzadisidra93@gmail.com, amjadkhan@gau.edu.pk, rubinaaman7@gmail.com, shahzadisadia98@gmail.com, a.bibi@sms.ed.ac.uk, nafeesuob@gmail.com, smushtaq.phdab13asab@asab.nust.edu.pk, drsaifmehsud@aust.edu.pk, irg@sun.ac.za, sheikhabdurrashid11@gmail.com, akhan@qau.edu.pk, kushah@qau.edu.pk

Abstract

- **Objectives:** Poor control of asthma in the majority of patients could be partly due to their lack of
- 3 knowledge concerning disease management, its triggering agents, and when to seek advice from
- 4 the health-care provider. This study aims to assess the impact of pharmacist-led educational
- 5 intervention on knowledge of self-management among asthmatic patients.
- **Design:** A pre-post cohort study.
- 7 Setting: Outpatient department of a tertiary care hospital affiliated with Quaid-i-Azam
- 8 University, Pakistan.
- 9 Participants: Approximately 265 adult asthmatic patients selected through a spirometry
- process, aged ≥18 years were approached. 240 patients gave consent to participate in the study
- and were divided into control and treatment groups.
- **Interventions:** The educational intervention consisted of individual patient counselling using
- educational material with time varied according to each patient's comprehension and previous
- 14 knowledge.
- **Primary and secondary outcome measures:** Assessment consisted of a 14-item Asthma Self-
- 16 Management Knowledge Questionnaire (ASMQ) quantifying a patient's self-management
- 17 knowledge through an ASMQ score and its change following an educational intervention.
- **Results:** Disease self-management knowledge was low with an average raw ASMQ score of 4.1
- 19 (max 14); which equates to a transformed score of 29.34 (max 100) and the proportion of patients
- who correctly answered more than 50% of questions were 16.7% preintervention. More than
- 21 half of the participants (55%) did not know that asthma cannot be cured. The administration of

to 9.77).

- educational intervention protocols resulted in significantly improved level of knowledge of asthma self-management (<.001) in the treatment group (mean ASMQ score improved from 4.20
- 4 Conclusion: On baseline visit, patients possessed a poor knowledge about asthma self-
- 5 management. Educational intervention protocols had a positive impact on improving patients'
- 6 knowledge about disease self-management. This would suggest that education and self-
- 7 management skills should be seen as an integral component of asthma management and should
- 8 be incorporated in structured patient care to achieve optimal asthma control.
- **Keywords:** Asthma self-management, knowledge of asthma, asthma self-management education, asthmatic patients, pharmacist-led educational intervention.

Strengths and limitations of this study

- Adherence to clearly defined inclusion and exclusion criteria.
- A cohort study using a parallel control group for comparison.
 - An appropriate sample size consisting of representative asthmatic patients.
 - Participants were recruited only from a single center.
 - Scarcity of tools to measure the asthma self-management knowledge.

INTRODUCTION

Asthma has over many years become one of the major health concerns affecting millions of people (1) and is defined as a chronic, non-communicable inflammatory disorder of the airways which affects 334 million people worldwide with an alarming prediction of an increase of 100 million more by the year 2025 (1, 2). Considering the most leading causes of disease which burdens society, asthma ranks 28th, causing approximately 1000 people to die every day around the globe. In addition, it ranks 16th among the leading causes of years of life lived with a disability and its prevalence is still rising in underdeveloped countries (3). Globally, asthma is becoming a growing contributor of increased morbidity and mortality and thus imposing a significant burden in terms of reducing productivity, not only of the patients but also on their families and health care systems (2). Genetic predisposition and exposure to numerous environmental substances including dust mites, pet dander, pollens as well as stress or sedentary lifestyle collectively accounts as contributing factors for developing and high prevalence of poorly controlled asthma (4). Despite the availability of effective diagnostic and treatment strategies, asthma is still poorly controlled in the majority of patients and its incidence is on the rise (5, 6). Various reasons for such a low asthma control includes either health-care system related issues (unaffordability or unavailability of medications) or physicians related issues (incorrect or misdiagnosis, lack of proper diagnostic facilities, insufficient time to discuss matters with the patients, absence of reassessment of inhaler technique or lack of proper follow-up measures) or patient related issues (non-compliant behaviors due to lack of knowledge about their disease and its management) (5). In addition to non-adherence to the proper medication regimen, lack of proper education or routine follow-up, incorrect use of inhaler and lack of inhaler technique assessment during the patient

1 visit also play a significant role in the suboptimal control of asthma (6). Being a controllable

disease, asthma requires a prolonged guidelines compliant therapy along with patient education

about the correct use of the prescribed medications and disease self-management (5, 7).

4 The patients' general knowledge about asthma includes that of the pathophysiology of the

disease, the purpose of the specific treatment regimen, recognition and management of

exacerbations/disease triggers and especially, correct use of the inhaler (5). Self-management

is defined as the ability of an individual to apply the appropriate guidelines or make informed

decisions for managing their chronic conditions. This requires the efficient communication

about patients' condition with their family members, companions and healthcare professionals

(8). Asthma self-management furthermore involves actions undertaken by the patients to

monitor their disease symptoms and avoid exacerbations (9). The existing published literature

signifies that asthma self-management is conditional on the education received by the patients

since this improves their understanding of their treatment rationale and monitoring thereof and

when made a part of their regular and planned care, not only improves asthma control and their

quality of life but also reduces the healthcare costs by decreasing the frequency of hospital and

emergency room visits and absenteeism from the work places (2). Variability of asthma disease

(change in asthma over time) implies that exacerbations can possibly occur even if a patient's

asthma is well controlled. Therefore, patients should have the knowledge about their disease

management and recognition of factors to indicate when to seek help from health professionals

when confronted with such exacerbations (5).

Despite well documented evidence of the positive impact of asthma self-management programs

in achieving the desired patient outcomes and reducing healthcare costs, it is unfortunately rarely

implemented in routine clinical practice (1, 2, 5).

- 1 Despite being the sixth most populous country in the world and harboring a high burden of
- 2 asthma patients, there remains a scarcity of published information regarding the patients'
- 3 knowledge and impact of the educational intervention about asthma self-management in
- 4 Pakistan. Therefore, the current study was conducted with the objective to evaluate the
- 5 knowledge of disease self-management among established asthmatic patients and the impact of
- 6 an educational intervention might illustrate to address this finding.

METHODOLOGY

Study setting and design

The cohort study was carried out at the pulmonology outpatient's department (OPD) of the Pakistan Institute of Medical Sciences (PIMS), a tertiary care hospital located in the capital territory of Islamabad Pakistan. All asthmatic patients were selected through a spirometry process and were at least 18 years old. These patients visited the study site from May to September 2019 and were willing participants by giving their written consent. Those patients who were unable to communicate adequately, had a cognitive abnormality or any other disease with asthma related symptoms such as chronic obstructive pulmonary disease, tuberculosis or a weak heart, were excluded. The Quasi experimental design was used. Participants in the study group were arbitrarily assigned to control and treatment groups. Both groups were roughly similar in terms of sociodemographic characteristics and asthma self-management knowledge resulting from a baseline visit. The educational intervention was provided to the treatment group. The baseline patients' socio-demographic characteristics as well as knowledge of asthma self-management were assessed via a face-to-face interview. Educational material included specifically designed pamphlets. The principal author (SSS) provided educational counselling and evaluated the inhaler technique of each patient in the treatment group at baseline and follow-

- 1 up visits. All educational counselling was provided to the control group patients on follow-up
- 2 visits only along with evaluating their inhaler technique. Time allocated for counselling varied
- 3 according to each patients' comprehension and previous knowledge of their condition.

4 Data collection tools

- 5 A purpose developed data collection form was used to obtain the patients' sociodemographic
- 6 characteristics from their medical records and in one-on-one interviews with the patient. In order
- 7 to evaluate a patients' knowledge about what self-management of asthma meant, the principal
- 8 investigator administered ASMQ forms to the patients.
- 9 The ASMQ contained 16 multiple choice questions about preventive measures, use of inhalers,
- medications and peak flow meters (10). Tool scores were calculated by giving one point to each
- preferred response. For generating raw ASMQ scores, all answers were summed up and
- transformed to a score ranging between 0-100. Higher transformed scores on ASMQ signified a
- higher knowledge about self-management of asthma (5). Two questions related to the peak flow
- meters were omitted due to their minimum use in developing countries. This process generated
- an ASMQ raw score which ranged from 0-14 (11).

Data compilation and statistical analysis

- 17 IBM SPSS Statistic version 21 was employed for data analysis. Descriptive statistics was used
- 18 to summarize the mean and standard deviations of the demographic variables of both groups
- 19 viz., Treatment and Control. Categorical variables were analyzed using the Chi-square test. For
- intra-group comparisons, the Wilcoxon matched-pair test was used. A p-value of ≤ 0.05 was
- 21 labeled statistically significant.

Patient and public involvement

23 Patients were not involved in the design and conduction of this study.

RESULTS

- 2 Approximately 265 adult asthmatic patients aged ≥18 years were initially approached. Among
- 3 them a total of 240 patients gave their consent to participate in the study. The majority of
- 4 participants (47.5%) belonged to the age group of 36-55 years of which 56.7% were males, and
- 5 15.4% had a history of an allergy while 25.4% had a positive family history of asthma (Table
- 6 1). 47.5% of the study group were categorized as not working and 32.9% as white collar workers
- 7 according to the ISCO categories for occupational status (12).

Table 1. Socio-demographics of study participants

Characteristics	Categories	CG	TG	p-value
Age		39.46±13.5	39.70±13.99	0.892
Age categories	18-35	27	32	0.881
	36-55	54	60	
	>56	39	28	
Gender	Male	61	75	0.068
	Female	59	45	
Residence	Rural	75	66	0.597
	Urban	45	54	
Occupation	Not working	61	53	0.827
(ISO Categories)	Blue collar worker	25	22	
	White collar worker	34	45	
Educational	Illiterate	20	24	0.870
Status	Primary	36	40	
	Secondary	37	27	
	Graduate	27	29	
Family history	Asthma	30	26	0.846
	Allergy	22	15	
	Both	30	35	
	None	38	44	
Smoking status	Ex-smokers	22	27	0.927

	Current-smokers	33	38	
	Never-Smoke	65	55	
Disease duration	≤2	47	51	0.978
Categories (yrs.)	2-5	45	34	
	>5	28	35	

Pre and post intervention ASMQ raw and transformed scores are presented in **Table 2.** No statistically significant difference in the ASMQ raw and transformed scores was observed in control group (p-value=0.487). However, as a result of educational intervention, there was a

statistically significant change in these scores in the treatment group (p-value <0.001).

Table 2. Pre and post ASMQ categories, ASMQ raw and transformed scores in control and treatment group

	Control group Treatment group		Treatment group
ASMQ Raw score	Pre	Post	p-value
Control group	4.01 ± 3.32	3.89 ± 2.92	.487
Treatment group	4.20 ± 3.03	9.77 ± 2.58	<.001
ASMQ Transformed score	Pre	Post	p-value
Control group	28.69 ± 23.75	27.76 ± 20.86	.487
Treatment group	30 ± 21.64	69.83 ± 18.42	<.001

Figure 1 illustrates that as a result of the educational intervention, the number of patients
possessing a good knowledge improved from 3 to 47 and those possessing adequate knowledge
improved from 15 to 42 in the treatment group. Patients' knowledge was categorized on the
basis of a transformed score as: good (>75), adequate (50-75) and poor (<50).

5 6 Figure 1

Figure 2 illustrates that question 7 (the holding of breath after use of an inhaler for several seconds) has the highest percentage of correct answers i.e 47.9%. Only 32.1% of the participants knew that asthma is an incurable disease which emphasizes the need for a comprehensive patients' education about the regular uptake of medications to achieve disease control. Item 9 (patients' increased need for maintenance medicines in case he/she is using more rescue medications than are prescribed) was frequently answered to be unknown (47.1%).

Figure 2

Figure 3 illustrates the distribution of the raw ASMQ score at baseline. 0-14 is the total possible range with higher scores resulting in higher ASMQ transformed scores and thus indicating a better asthma self-management knowledge. This underlying distribution of ASMQ raw scores indicates a poor disease management knowledge among the study participants.

22 Figure 3

DISCUSSION

To the best of our knowledge, this is probably the first study conducted in Pakistan to assess the patient's self-management knowledge of their asthma condition and the impact of an educational intervention might have to manage this condition. The findings of the current study signify that at the baseline visit the majority of the study participants (83.3%) were poorly educated about the self-management of asthma and their knowledge was significantly improved after an educational intervention. Likewise, findings regarding the patients' poor knowledge about asthma selfmanagement have been reported by studies conducted elsewhere. For example, a study conducted by Nguyen et al in Vietnam reported a poor knowledge with a mean raw ASMQ score of 4.3 which equates to the transformed score of 30 (5). Similarly, another observational study conducted in the Kingdom of Saudi Arabia reported an average ASMQ score of 3.5 [3.5/14] (13). The format of both of these studies was similar to that of the present study after the two items related to the peak flow meter were similarly removed (5). Likewise, a study conducted in Sri Lanka reported that only 34% of the patients were knowledgeable about their disease and medications (5). A multicenter study in China reported a low level of disease awareness among the parents of asthmatic children (14). Another study illustrated that 62.7% of asthmatics have poor, 12% have good and only 25.3% possess an adequate knowledge of their condition (15). Similar studies showed that although the patients have a positive attitude towards the disease, their specific disease knowledge was low (16, 17). In our study the proportion of patients (16.7%) who correctly answered more than 50% of the questions was greater than that reported by Al et al., (4%) but similar to that reported by Nguyen et al (16.5%) (5, 13). Despite the significance of the correct use of inhaler devices, including the meter dose inhaler (MDI) in optimal control of asthma, there have been reports of its incorrect use (5). We found that

only 47.9% of the participants in the current study had the correct knowledge about the holding of breath after inhaling for several seconds, and 23.8% agreed with the misconception about consecutively taking the second puff as soon as possible after the first. Only 26.3% knew that they should inhale slowly and 63% did not know about the correct use of the inhaler. This strongly suggests that there is a need for patient education through health-care providers on the correct procedure of the inhalation technique. Lack of health education and regular follow-up visits has previously been reported as the predictors of incorrect inhaler use and poor asthma control (18). Significant improvement through education at follow-ups (p=0.000) in the inhalation technique through assessing and demonstrating the correct inhaler technique has been reported by another study (19). Therefore, health care providers should regularly demonstrate and re-evaluate the patients' inhaler technique at each visit to prevent or reduce the chances for errors in the inhalation technique (5). Despite being an incurable disease, 55% of the current study group were of the opinion that it can be cured thus equating control with cure. Similar findings regarding the patients' misconception that asthma is curable have been reported by studies conducted in Vietnam and Saudi Arabia (5, 20). Furthermore, there was a lack of knowledge about control and rescue medications: for example, 36.3% of the current study participants answered that breathing becomes better immediately after taking the maintenance medicines, and 30.8% thought that future flare-ups can be prevented by using rescue medicines. These misconceptions and lack of knowledge were also reported by Al et al stating that only 22% and 16.6% of the participants had correct knowledge about controller and rescue medicines. Similar poor knowledge about the correct use of maintenance and rescue medicines has been reported from Vietnam (5, 13). In the current study, a response regarding what to do when manifesting asthma symptoms and not knowing their cause,

only 23.3% answered correctly to change one's immediate environment.

The low level of patients' knowledge of asthma self-management found in the current study and studies conducted elsewhere, emphasize the importance of educational programs among asthma patients. In the current study, the pharmacist administered educational intervention in the treatment group significantly increased the mean ASMQ score from 4.20/14 to 9.77/14 [transformed score 69.83/100]. On the other hand, no significant increase in these scores was observed in the control group. In the current study, educational intervention increased the number of patients with >50 ASMQ score up to 89 in the treatment group. This is in agreement with the results of an intervention study in which a full version of ASMQ (all 16 items) was used. The study reported a statistically significant increase in the ASMQ score for the group of patients who received an educational intervention (19). A similar positive impact of an educational intervention on patients' self-management knowledge of asthma, medication adherence and asthma control (60% better control and 18% well-controlled) has also been reported (21). Likewise, the positive impact of patient-tailored educational interventions on knowledge about disease self-management, better disease control, treatment outcomes and patients' health related quality of life has been reported by studies conducted elsewhere (18, 21-25). This specifically applies to the shift of modern treatment goals to early detection and prevention of exacerbations, effective strategies including either broad commitments and interactive educational sessions at different healthcare levels and a cost-effective approach for under-developed countries (26, 27).

CONCLUSION

The low level of asthma self-management knowledge and positive impact of educational intervention in reducing current knowledge gaps, emphasize the need for designing and implementation of educational programs, ongoing monitoring and regular follow-ups in such a

- way to fit all patient needs especially including the less educated ones. Assessment of patient's
- 2 self-management knowledge provides room for designing specific programs aimed at the areas
- 3 where knowledge deficits are evident thus providing a cost-effective approach which otherwise is
- 4 impossible because of resource and time limitations. Moreover, regular and repeated assessment
- of inhaler technique, if made necessary, will optimize the therapeutic benefits and help to achieve
- 6 better disease control.

7 Abbreviations

- 8 ASMQ: Asthma self-management questionnaire; OPD: Outpatient department; TB: Tuberculosis;
- 9 COPD: Chronic obstructive pulmonary disease; ISCO: International Standard Classification of
- Occupations; MDI: Metered dose inhaler; SPSS: Statistical package for social sciences.

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- period.

Data Availability Statement

All relevant data are within the paper and its supporting information files.

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- been received for the research.

21 Ethical approval and participant's consent

- 22 This study was approved by the Bioethics Committee of Quaid-i-Azam University, Islamabad and
- 23 Institutional review board of PIMS [F.1-1/2019 (EC) PIMS]. Informed consent was also obtained

from all participants after explaining them the purpose and nature of the study.

Competing interests

- The authors declare that they have no competing interests.
- Author's Contribution: All authors (SSS, Amjad Khan, RA, SSs, AB, NA, SMu, SM, IRG, SAR,
- AK, KUS) have conceptualized and designed the study. SSS, RA and SSs collected the data. SSS,
- Amjad Khan, SMu and KUS have contributed to the data acquisition and analysis. SSS drafted the
- manuscript and Amjad Khan, NA, AB, SM, SAR and AK have reviewed the manuscript critically.
- IRG attended to the English language used in the manuscript. All authors read and have approved
- the final manuscript. The study is supervised by Amjad Khan & KUS.

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Figure Legends

- Figure 1 Pre and Post ASMQ categories in the control and treatment group
- 4 Figure 2 Responses to 14 items of ASMQ at baseline
- Figure 3 Distribution of raw ASMQ score at baseline. 0-14 is total possible range with higher scores resulting in higher ASMQ transformed score and thus good asthma self-management knowledge



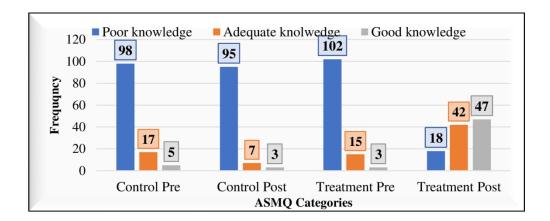


Figure 1. Pre and Post ASMQ categories in the control and treatment group

Figure 1. Pre and Post ASMQ categories in the control and treatment group $140x66mm\;(300\;x\;300\;DPI)$

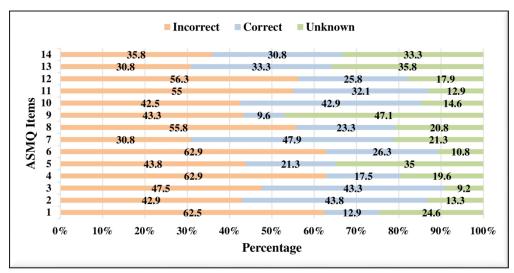


Figure 2. Responses to 14 items of ASMQ at baseline

Figure 2. Responses to 14 items of ASMQ at baseline $165 \times 90 \text{mm}$ (300 x 300 DPI)

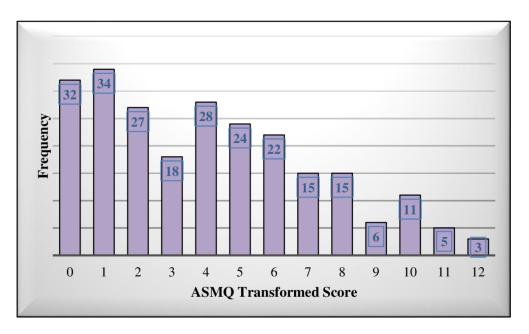


Figure 3. Distribution of raw ASMQ score at baseline

Figure 3. Distribution of raw ASMQ score at baseline $128 \times 84 \text{mm} (300 \times 300 \text{ DPI})$

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the	1-2
		abstract	
		(b) Provide in the abstract an informative and balanced summary of what was	
		done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being	4
		reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of	6
-		recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of	6-7
•		participants. Describe methods of follow-up	
		(b) For matched studies, give matching criteria and number of exposed and	
		unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and	7
		effect modifiers. Give diagnostic criteria, if applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	7
measurement		assessment (measurement). Describe comparability of assessment methods if	
		there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,	7
		describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for	7-8
		confounding	
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	
		(d) If applicable, explain how loss to follow-up was addressed	
		(e) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially	88
T di tio ipanto	15	eligible, examined for eligibility, confirmed eligible, included in the study,	
		completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social)	8
pv uuu		and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	

Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-12
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a	
		meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	12- 16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision.	16
		Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,	12-
_		multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16-
			17
Other informati	on		
Funding	22	Give the source of funding and the role of the funders for the present study and, if	17
		applicable, for the original study on which the present article is based	

^{*}Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.