ROLE OF SMARTPHONE BASED INHALER TEACHING TECHNIQUE IN ASTHMA CONTROL- A RANDOMISED CONTROL STUDY

Thesis

Submitted to

All India Institute of Medical Sciences, Jodhpur

In partial fulfillment of the requirement for the degree of

Doctor of Medicine (DM)

Pulmonary, Critical Care and Sleep Medicine

July 2020-23 **Dr. Saumya Shishir**

AIIMS, Jodhpur

DECLARATION

I hereby declare that the thesis titled "Role of Smartphone based inhaler teaching technique in asthma control- A randomised control study" embodies the original work carried out by the undersigned in All India Institute of Medical Sciences, Jodhpur.

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CERTIFICATE

This is to certify that the thesis titled **"ROLE OF SMARTPHONE BASED INHALER TEACHING TECHNIQUE IN ASTHMA CONTROL- A RANDOMISED CONTROL STUDY"** is the bonafide work of **Dr. Saumya Shishir** carried out under my guidance and supervision, in the Department of Pulmonary Medicine,, All India Institute of Medical Sciences, Jodhpur.

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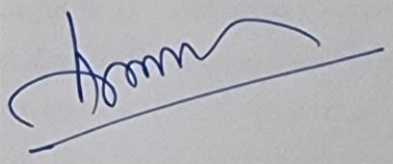
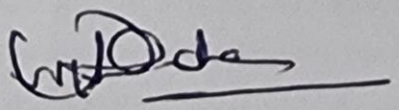
Dr. M K Garg Professor & Head Department of General Medicine & Pulmonary Medicine AIIMS Jodhpur	
Dr. Nishant Kumar Chauhan Additional Professor, Department of Pulmonary Medicine, AIIMS, Jodhpur	

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This thesis is a culmination of the effort of many people without who's direct or indirect involvement, this document would not have seen the light of the day.

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Dr Saumya Shishir

LIST OF ABBREVIATIONS

ACT	Asthma Control Test
BDR	Broncho Dilator Reversibility
BMI	Body Mass Index
CAD	Coronary Artery Disease
CBC	Complete Blood Count
CI	Confidence Interval
CKD	Chronic Kidney Disease
CT	Computed Tomography
CXR	Chest X-ray
ED	Emergency Department
FEV1	Forced Expiratory Volume in 1 sec
IQR	Inter Quartile Range
KFT	Kidney Function Tests
LFT	Liver Function Tests
SD	Standard deviation
TLC	Total Leucocyte counts

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SUMMARY

Background

Education regarding the use of inhaler devices is a critical step for the management of asthma. Adherence and correct technique are associated with better control of symptoms and less number of exacerbations. In this modern digital era, the use of smartphone apps is increasing rapidly and reaching almost all aspects of our life, including health promotion and patient education on asthma self-management. The study evaluated the impact of video-assisted teaching of inhaler devices in addition to face-to-face teaching on asthma symptoms, adherence and rate of exacerbation.

Methods

This was a randomised, open label study done from 01 January 2021 to 31st May 2022 in our institution. Spirometry or Clinician diagnosed asthma patients with access to smart phone were enrolled in the study and randomized in two groups. The intervention arm received video regarding inhaler education at 15 days interval in addition to face-to-face teaching at monthly interval, whereas the control arm received only face-to-face education at monthly interval. All patients were followed up to 12 weeks from enrolment. The primary outcome measures was to compare asthma control in both the groups by Asthma Control Test (ACT) scores. The secondary outcomes measures were to assess reduction in rate of exacerbation, assess adherence to inhaler devices and identify errors in inhalation techniques.

Results

A total 128 patients were randomised to two arms. A total of 61 patients in intervention arm and 59 patients in control arm completed 12 weeks follow-up. There was significant improvement in ACT scores, adherence and FEV_1% predicted in both the arms at the end of 12 weeks follow-up. However, the difference in median ACT score between 1st visit and 12th was significantly more in intervention arm compared to the control group [9.0 (IQR 7.75-11.0) vs 5.0 (IQR 3.0-8.0), ($p<0.0001$)]. The difference in adherence between 4th week and 12th week was also more in intervention group compared to control group. [10.0% (IQR 4.0-18.0) vs. 5.0% (IQR 0.0-15.5), ($p=0.0125$)]. On comparing the median difference in FEV_1% predicted between 1st visit and 12th week, improvement was more in intervention group compared to control

group [7.0% (IQR 2.0-21.0) vs. 3.0% (IQR -1.0 – 6.7), (p=0.0036)]. The patients who underwent exacerbation during follow-up period were significantly less in intervention arm compared to control arm. (4.9% vs 18.6%, p=0.001)

Conclusion

There is better control of asthma symptoms, lung function improvement, decreased rate of exacerbation and better rate of adherence to inhalers in the group receiving both face-to-face teaching and video teaching compared to group receiving only face-to-face education. The video education along with face-to-face teaching has a beneficial synergistic effect which is higher than face-to-face teaching in asthmatic patients.

INTRODUCTION

Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms such as wheezing, shortness of breath, chest tightness, and cough that vary over time and in intensity, together with variable expiratory airflow limitation. It is a common, chronic respiratory disease affecting 1-18% of the population in different countries [1].

To date, asthma is a treatable disease of the respiratory system, but it is not entirely treatable. The high burden of illness leads to hospitalization due to exacerbation of the disease. Despite eff

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ective treatment options and evidence-based guidelines, disease control is not optimal in patients with asthma.

There are numerous reasons for the lack of control of disease. One of the most important is the incorrect use of inhaler devices which is associated with worsened health outcomes, such as the increased risk of hospitalization [2][3]. Inhalation medication plays a cornerstone in the treatment of asthma. The inhalational route of administration delivers drugs directly to the airways. A high drug concentration can be achieved locally with a decreased risk of systemic side eff ects [1]. However, there are several sequential steps necessary to accomplish the correct application of inhaler devices. Incorrect performance of one or more steps can drastically decrease the delivery of the administered drug and consequently decrease the eff icacy of the medication [4] [5].

Numerous studies have demonstrated that many asthma patients have an ineff ective or poor inhaler technique which range from 20-90% [6] [7] [8] [9] [10]. Even health care providers make multiple errors in using inhalers. In a study from Gujrat involving medical interns, only 34% could properly use pMDI [11]. It is recommended to show the inhaler technique to patients and at every opportunity it should be checked should be checked [1]. Inhaler reminders, either proactively or for missed doses, are associated with improved rate adherence and helps decrease the rates of exacerbations. [10][11]. Directly observed controller medicine with telemedicine oversight is associated with better control of asthma symptoms and fewer urgent visits than usual care.[1]

In recent years, the usage of multimedia in the healthcare industry has grown. There are several factors that indicate the usefulness of video education and video instructions, little research regarding the efficacy of this educational system exists. This study aims to investigate the eff ect of video demonstration of inhaler technique at regular intervals in addition to usual care to patients and to determine the eff ect on asthma control.

AIMS AND OBJECTIVES

Aim-

To evaluate the utility of video demonstration of inhaler techniques as an additional method of providing inhaler education compared to usual care in asthma

Objective-

Primary

1. To compare asthma control in both the groups by Asthma Control Test (ACT) scores.

Secondary

2. To assess Reduction in rate of exacerbation
3. To assess Compliance to inhaler devices
4. To identify errors in inhalation technique at hospital visits

REVIEW OF LITERATURE

Cook et al., studied a cohort of 60 asthma patients, with the use of smartphone use for 4 months, they found an improvement in asthma control test score from 16.6 to 20.5 over study period, and a 7.9% absolute increase in FEV1 [12].

Park et al., studied the impact of video teaching on inhaler technique in a study in South Korea. They had a study cohort of 184 individuals with asthma patients, who were either well- or partially controlled. Randomization was used to assign subjects to either video education or in-person instruction. After 12 weeks, the control group's FEV_1 had dramatically improved. After correction, the study group's FEV_1 improvement was not noticeably worse than that of the control group. The secondary outcome measures, such as change in FEV_1 at 4 weeks, ACT score, and other inhaler device and satisfaction indicators at 4 and 12 weeks, did not show any discernible differences between the two groups. [13]

Schantz et al., investigated the use of video tutorials in patient education programmes promoting proper dry powder inhaler technique. The 31 inhaler naive patients were enrolled. After watching of each of the four inhalers' instructional videos, the participants practised using the inhaler. They moved on to the following inhaler. It was observed that DPI users responded better to non-verbal movies compared to others when instruction on inhaler technique was given [14].

Gregoriano et al., studied 165 patients with asthma and COPD. Depending on the inhaler type, the percentage of incorrect inhalation technique ranged from 0 to 53%. Patients with COPD who applied their devices incorrectly had higher CAT total scores than those who applied them correctly ($p=0.2$). Patients with COPD who applied the device incorrectly experienced increased symptoms. Patients with COPD who correctly applied their devices had a significantly better mean FEV_1% predicted at baseline compared to those who applied their devices incorrectly ($p=0.04$), whereas there was no significant difference detected in asthma patients [15].

Merchant et al have linked digital education with decreased use of rescue inhalers and increased controller drug adherence. The intervention included electronic medication monitors (EMMs) that monitored the use of rescue and controller inhalers as well as a

digital health platform that informed patients and healthcare professionals on medication use and the state of their asthma control. In 224 trial participants, the number of asthma-related ED visits and combined ED and hospitalisation events fell significantly from 11.6 to 5.4 visits (p 0.05) and 13.4 to 5.8 events (p 0.05), respectively, 365 days prior to and 365 days following enrolment in the intervention. The number of hospitalisations and emergency room visits due to asthma were decreased because of this digital health intervention, which was successfully implemented into standard clinical practise. [16]

Chan et al. investigated the impact of an electronic monitoring device with an audio-visual reminder function on asthmatic children's school attendance and adherence to inhaled corticosteroids. To a total of 220 patients, 110 were randomly allocated to the intervention group and 110 to the control group. In the intervention group, the median percentage of adherence was 84% (10th percentile 54%, 90th percentile 96%), as opposed to 30% (8%, 68%) in the control group (p 0.0001). With a reduction of 2 points from a mean baseline score of 9 (3 SD) to 7 (3 1) in the intervention group, compared to a reduction of 1 point from a baseline of 9 (2 5), the change in asthma morbidity score from baseline to 6 months was significantly greater in the intervention group than in the control group.[17]

Press et al. studied 90 patients with COPD or asthma, virtual teach-to-goal adaptive learning of inhaler technique. One session using a V-TTGTM metered-dose inhaler with customised rounds of narrated demonstration and self-assessments was completed by eligible people with asthma or COPD. The proportion of individuals misusing inhalers post-versus pre-V-TTGTM was the primary outcome, and supplementary analyses looked at mastery, self-efficacy, and perceived versus actual inhaler abilities. Misuse was substantially lower post-than-pre-V-TTGTM among participants who completed both pre- and post-V-TTGTM (n = 83; 24% vs. 83%; P .001). When comparing post- to pre-V-TTGTM, mastery and confidence both showed a considerable improvement (46% vs 7%, P 0.001; 83% vs 67%, P .001). Greater congruence between perceived and real inhaler skills was observed after V-TTGTM (P .01). [18]

MATERIAL AND METHODS

Study setting - Department of Pulmonary Medicine at All India Institute of Medical Sciences, Jodhpur

Study design - Randomised open label study. Randomisation was be done by computed generated random numbers.

Study participant - All asthmatic patients presenting to pulmonary medicine in outpatient and inpatient department of AIIMS Jodhpur from 01 January 2021 to 31st May 2022 were enrolled after satisfying following inclusion criteria. Follow -up periods ranged from 1ST April 2021 to 31st July 2022.

Study duration - 18 months

INCLUSION CRITERIA:

1. Spirometry or Clinician diagnosed asthma patients.
2. Use of own internet-enabled and compatible mobile phone

EXCLUSION CRITERIA:

1. Other clinically significant coexisting respiratory disease e.g. fibrosis, bronchiectasis, malignancies
2. Patients who do not give consent

SAMPLE SIZE CALCULATION

- FORMULA-
- $N = \frac{(r+1)\,(Z\alpha + Z_{1-\beta})^2\,\sigma^2}{rd^2}$
- Where, Z is normal deviate at 5% level of significance= 1.96
- $Z_{1-\beta}$ is normal deviate at 1- β % level of significance where β= type 2 error for power 80%
- r= ratio of sample size of two population= 1
- σ = pooled standard deviation of two groups = 4.6 , as per study of Cook et al [16]
- d= mean difference of ACQ between two groups = 2.5
- $= \frac{(1+1)\,(1.96+0.89)^2\,4.6^2}{1*2.5^2} = 54$
- Hence, we planned to take 54 subjects in study group and 54 as control with the total sample of 108.

METHODOLOGY

Scientific Committee and institute ethics committee approval were taken prior to the commencement of the study. All patients satisfying the inclusion criteria during the study period were enrolled under the study. A written informed consent was taken from all the participants as per proforma.

Patients were randomised to study and control group by computed generated random numbers. Data was collected using the predesigned structured proforma which included chief complaints, history of allergy, family history of asthma, age since diagnosis of asthma, addiction and other comorbidities. Asthma control test (ACT) score was calculated using the questionnaire given to the patients. Spirometry was performed in all patients. All patients were demonstrated the technique of using inhaler device according to the checklist.

The patients in the intervention group were sent video regarding the inhaler technique via smart phone every 2 weeks from the day of enrolment. Control group received usual care without any video. All patients were followed up at 1,2 and 3 months. Inhalation techniques were evaluated for every patient in every visit using pre-determined checklist. Asthma control was assessed with ACT questionnaire.

Check list for MDI-

1. Remove inhaler cap
2. Hold inhaler upright and shake well
3. Breathe out gently, away from the inhaler
4. Put mouthpiece between teeth without biting and close lips to form a good seal
5. Breathe in slowly through the mouth and, at the same time, press down firmly on canister
6. Keep breathing in slowly and deeply and hold breath for about 5 seconds or as long as comfortable
7. While holding breath, remove inhaler from mouth
8. Breathe out gently, away from the inhaler
9. If an extra dose is needed, repeat steps 2 to 8
10. Replace cap

Check list for MDI with spacer-

1. Prepare the spacer
2. Remove inhaler cap
3. Hold inhaler upright and shake well before inserting into spacer
4. Put mouthpiece between teeth without biting and close lips to form a good seal
5. Breathe out gently, into the spacer
6. Hold spacer level and press down firmly on inhaler canister once 7
7. Single breath: Breathe in slowly and deeply and hold breath for around 5 seconds or as long as comfortable. Take spacer out of mouth while holding breath OR Tidal breath: Breathe in and out normally for 3 or 4 breaths before removing spacer from the mouth
8. Breathe out gently
9. Remove inhaler from spacer ,If an extra dose is needed, repeat steps 3 to 9
10. Replace cap on inhaler

Check list for DPI-

1. Remove cap
2. Flip mouthpiece to open
3. Remove capsule from blister and place in chamber
4. Close mouthpiece until it clicks
5. Press side buttons in once and release (do not shake)
6. Breathe out gently, away from inhaler
7. Put mouthpiece between teeth without biting and close lips to form good seal
8. Breathe in quickly and steadily, so capsule vibrates
9. Hold breath for about 5 seconds, or as long as comfortable
10. While holding breath, remove inhaler from mouth
11. Breathe out gently, away from inhaler
12. Open mouthpiece and remove capsule
13. If more than one dose is needed, repeat steps 3 to 12
14. Close mouthpiece and cap

Asthma Control Test (ACT): Score ranges from 5-25 (higher is better). Scores of 20-25 are classified as well-controlled; 16-19 as not well-controlled; and 5-15 as very poorly controlled asthma. The ACT has four symptom/reliever questions plus patient self-assessed. Steps involved in ACT score calculations are as follows-

1. In the past 4 weeks, how much of time did your asthma keep you from getting as much done at work, school or at home?
   All the time (1) Most of the time (2) Some of the time (3) A little of the time (4) None of the time (5)
2. During the past 4 weeks, how often you had shortness of breath?
   More than once a day (1) Once a day (2) 3 to 6 times a week (3) Once or twice a week (4) Not at all (5)
3. During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you at night or earlier than usual in the morning?

4 or more nights a week (1) 2 to 3 nights a week (2) Once a week(3) Once or twice (4) Not at all (5)

4. During the past 4 weeks, how often you used your rescue inhaler or nebuliser medication?
   3 or more times per day(1) 1 to 2 times per day (2) 2 or 3 times per week (3) Once a week (4) Not at all (5)
5. How would you rate your asthma control during the past 4 weeks?
   Not controlled at all(1) Poorly controlled (2) Somewhat controlled(3) Well controlled(4) Completely controlled (5)

SCORE Total ……..

Spirometry- It was done in all patients using Spiroair spirometer in pulmonary function laboratory of the institute, according to the recommendations by the American Thoracic Society [20]. Daily calibration was performed before measuring pulmonary function.

Laboratory investigation- Complete blood count, absolute eosinophilic count and serum total immunoglobulin (IgE) was measured for every patient at baseline.

Treatment- All the patients were given combination of Inhaled corticosteroids and long acting beta-agonist (ICS + LABA) as controller and reliever medication. The medication was given in form of MDI/MDI with spacer/DPI. The type of inhaler prescribed was a joint decision by treating physician and patient's preference.

Video regarding the inhaler was sent to the patients in the intervention group at 15 days interval starting from the day of enrolment via. WhatsApp by the phone available in the department.

Asthma exacerbation- It was defined as acute or sub-acute worsening in symptoms of shortness of breath, cough, wheezing or chest tightness requiring change in treatment.

Data was analysed for the following parameter:

a) Change in ACT score in both groups at 1,2 and 3 months was analysed and compared.
b) Rate of asthma exacerbation in both groups were compared.
c) Change in FEV1 at third month from baseline was compared.
d) Adherence in subjects using MDI and MDI with spacer was analysed using digital dosimeter and by counting capsules in DPI users at every visit. Adherence rate % was calculated as the percentage of medication doses taken relative to the number of doses prescribed.
e) The steps with error in inhalation technique in both groups were analysed and steps with maximum errors were identified.

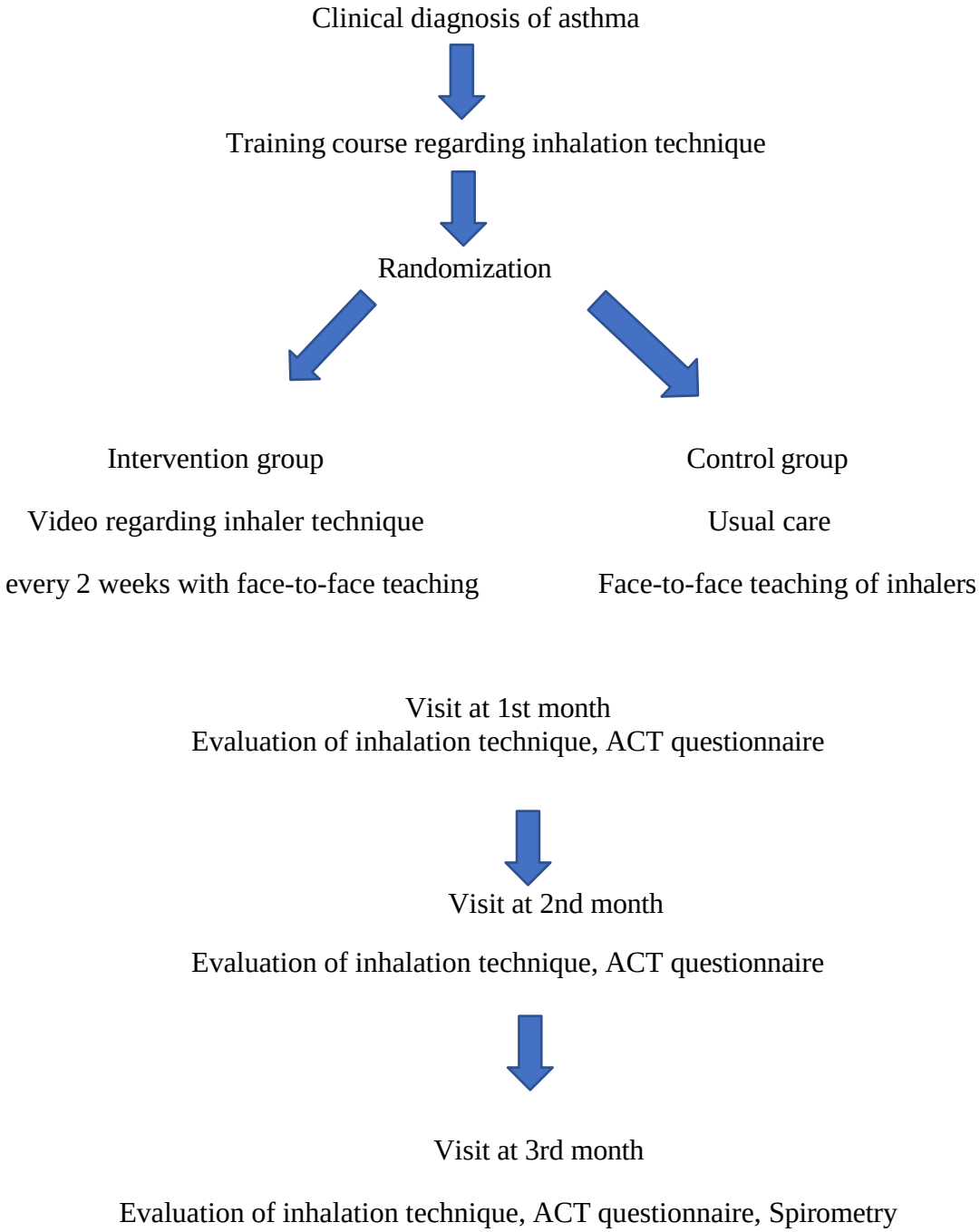

Fig.1. Study design

Statistical analysis:

Statistical analysis was done using Med Calc Version 20.115. All variables were checked for normality of distribution by Kolmogorov method. Those variables found not to have normal distribution, underwent Wilcoxon or Mann Whitney test as applicable. For the other variables, student t test was used. Chi square test used for categorical variables. The degree of significance in this study is taken to be below 0.05 ($P<0.05$ was considered significant).

Ethical Consideration

Once approved by the Research committee, the protocol was submitted to the Institute Ethics Committee for ethical clearance. A written informed consent was taken from all eligible participants. Participants were fully informed about the study and its utility.

RESULTS

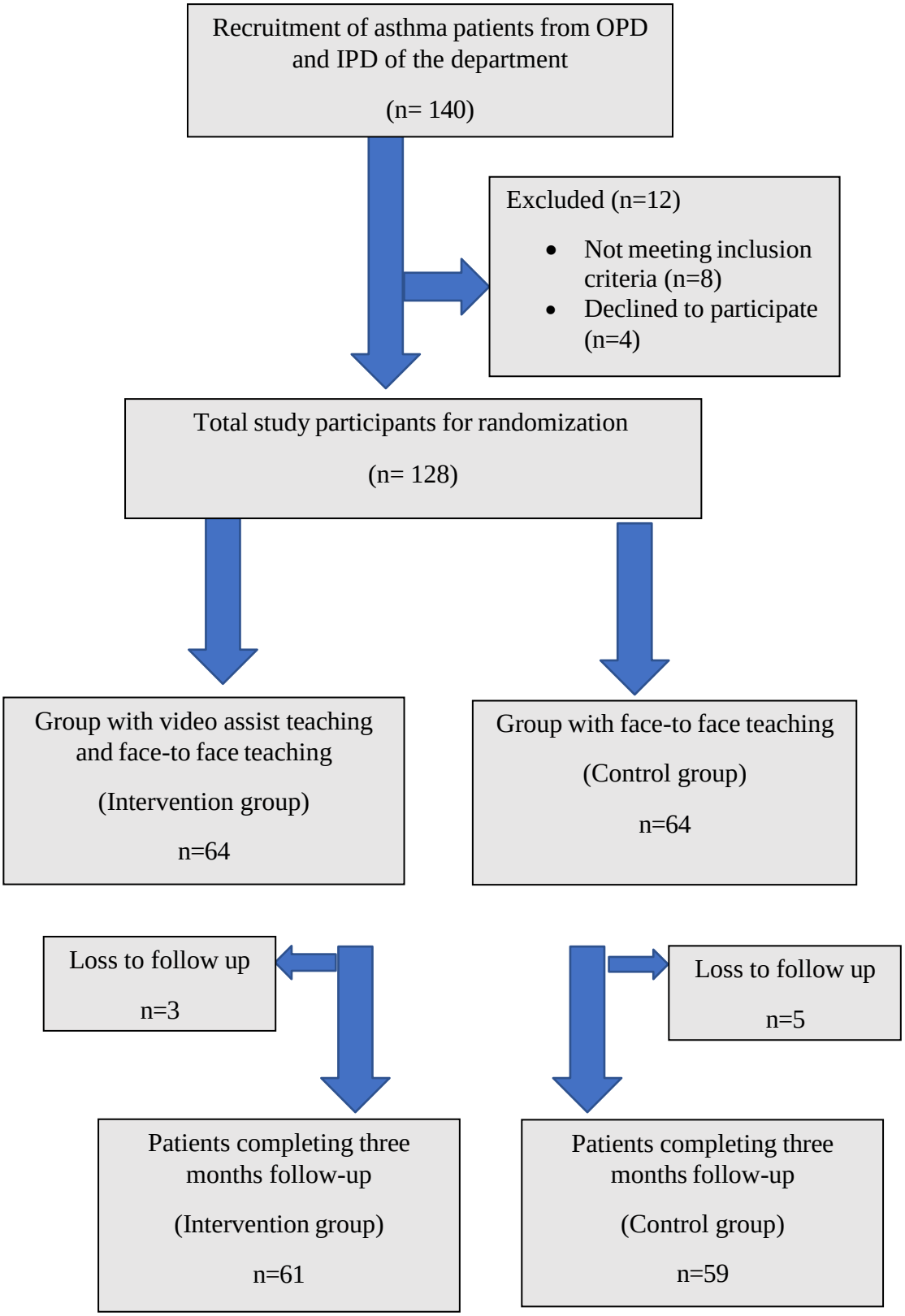

Fig.2 Flow chart of the study

Demographics data

In our study, 61 patients were included in the intervention arm who received video assistance in addition to face-to-face teaching. Fifty-nine patients in the control arm received face-to-face teaching during each visit. The median age in the intervention and control groups were 26.0 years (IQR 22.0-38.0) and 29.0 years (IQR 23.0-42.0), respectively . The majority of patients were male in both groups, 61% in intervention and 55.9% in the control group (Fig.3). The median BMI was 21.0 kg/m^2 (IQR 19.7-24.0) and 20.8 kg/m^2 (IQR 18.8-26.8) in both arms, respectively. The majority of the subjected were educated up to high school, 34,4% in intervention arm and 32.2% in control arm. Tobacco chewing was the most common addiction present in 19.7% of intervention and 23.7% control group respectively. Smoking was present in 8.1% of intervention and 10.1% of the control arm. The most common comorbidity was GERD present in 18% of intervention and 22.1% of the control arm. It was followed by obesity, diabetes, and hypertension. The demographic data is represented in Table 1.

Table 1. Demographics of the intervention and control group.

		Intervention group (N=61)	Control group (N=59)	*p* value	Method
Age (years) Median, IQR		26.00 (22.00-38.00)	29.00 (23.00– 42.00)	0.378	Mann whitney
Sex n (%)	Male	37 (60.66%)	33 (55.93%)	0.682	Chi-square test
	Female	24 (39.34%)	26 (44.06%)		
BMI (Kg/m^2) Median, IQR		21.00 (19.75-24.00)	20.80 (18.75-26.67)	0.8562	Mann whitney
Education n (%)	Not educated	11 (18.1%)	13 (22.1%)	0.744	Chi-square test
	Elementary school	10 (16.4%)	8 (13.6%)		
	Middle school	7 (11.5%)	8 (13.6%)		
	High school	21 (34.4%)	19 (32.2%)		
	Graduate	12 (19.7%)	11 (18.6%)		
Addiction n (%)	Smoking (yes)	5 (8.1%)	6(10.1%)	0.842	Chi-square test
	Alcohol (yes)	7(11.5%)	7(11.8%)		
	Tobacco chewing (yes)	12 (19.7%)	14 (23.7%)		
Comorbidities n (%)	GERD	11 (18%)	13 (22.1%)	0.744	Chi-square test
	Obesity	8 (13.11%)	11 (18.6%)		
	Hypertension	4 (6.5%)	6 (10.1%)		
	Diabetes	5 (8.2%)	4 (6.7%)		

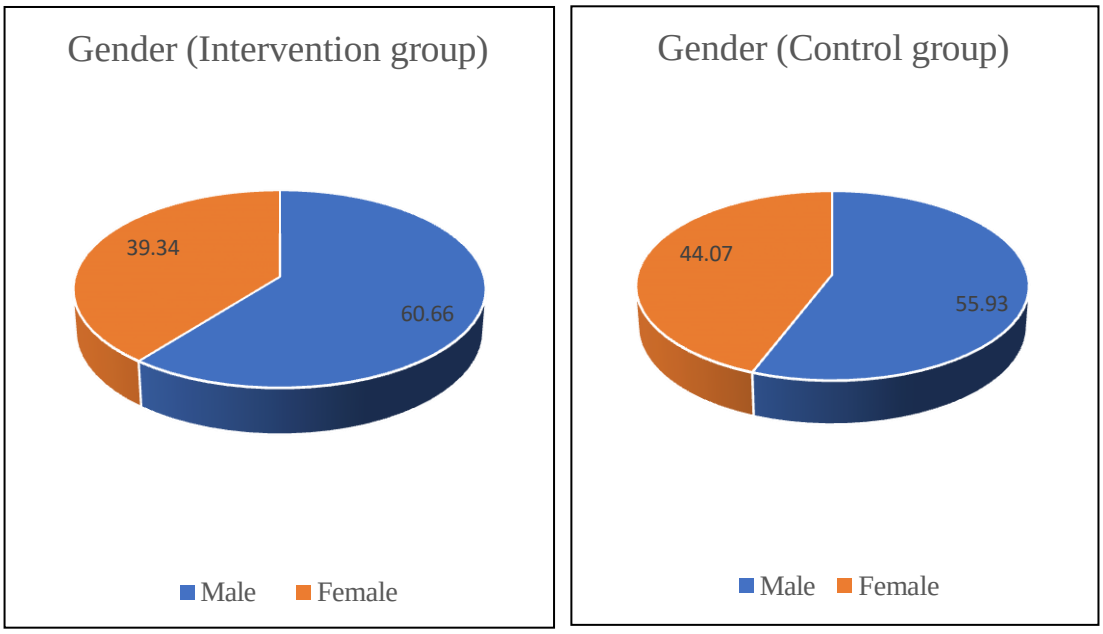

Fig.3. Pie graph showing the gender distribution in two groups

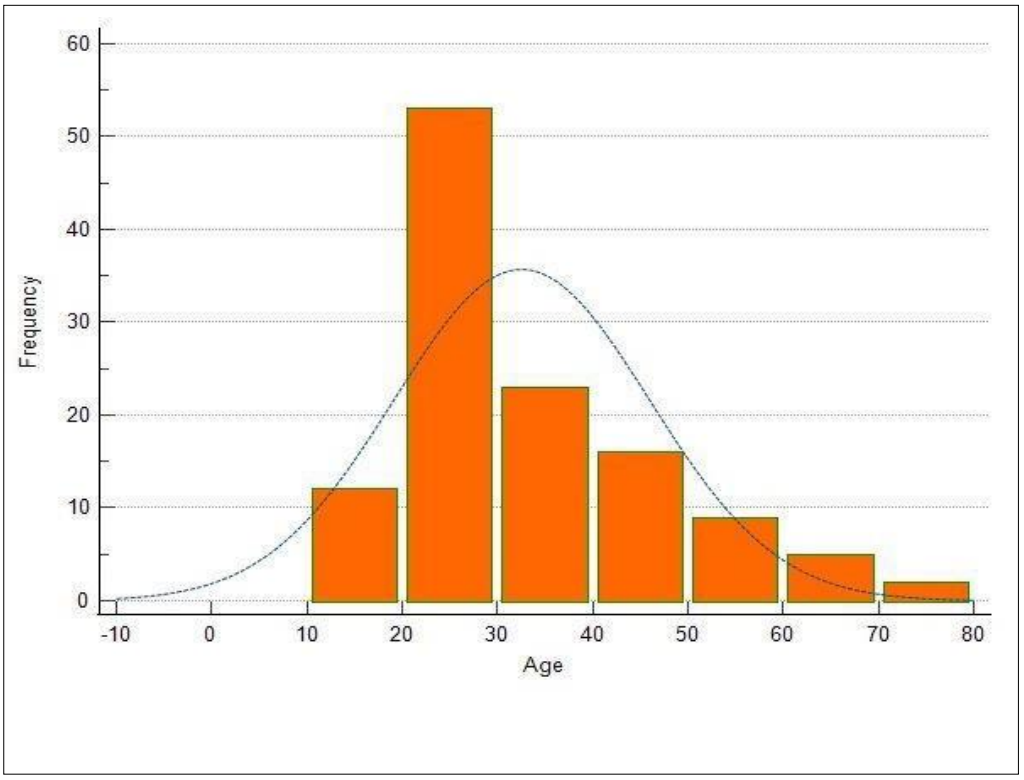

Fig 4. Histogram depicting the age distribution of the study cohort

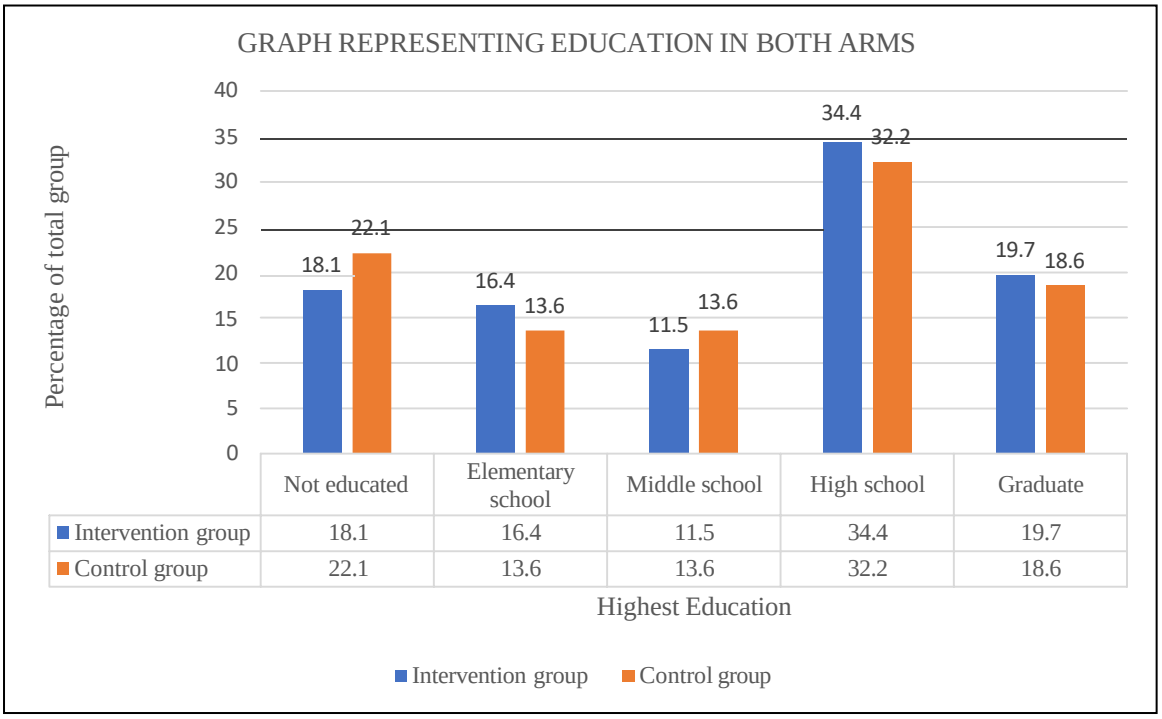

Fig 5. Bar graph depicting education in both groups

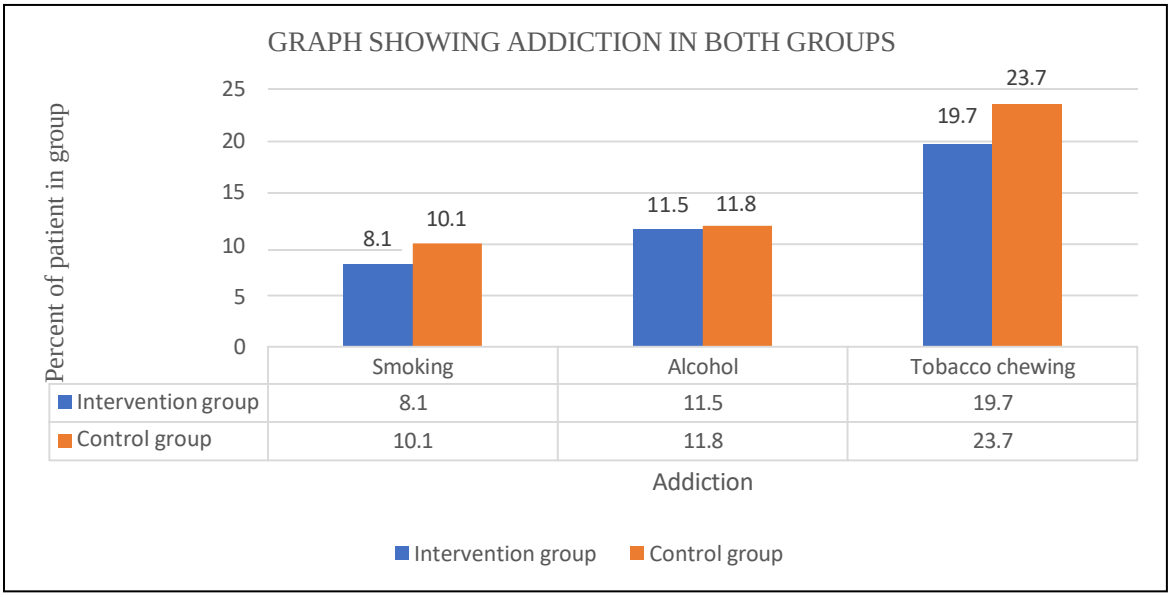

Fig 6. Bar graph depicting addiction in both groups

Symptomology and asthma control at baseline

The most common presenting symptom was cough in both groups, present in 48 (78.7%) subjects of the intervention group and 43(72.9%) subjects of the control group. It was followed by wheezing, present in 47 (77.0%) and 41 (69.5%) patients of each group, respectively. Chest tightness was present in 40 (65.6%) and 39 (66.1%) patients. Shortness of breath was the presenting complaints in 34 (55.8%) patients of intervention group as compared to 38 (64.5%) in the control group. The Asthma Control test (ACT) score was calculated at baseline to see the asthma result. The median ACT score was 15.0 (IQR 10.0-16.0) in the intervention arm and the score was 15.0 (IQR 12.0-19.0) in the control group. The median duration of symptoms was 24.0 months (IQR 24.0-60.0) in former group whereas it was 36.0 months (13.5-60.0) in the control group. There was history of allergy in 36% of intervention and 32.2% of the control group. There was family history of asthma in 29.5% of intervention and 28.8% of the control group. (Table. 2)

Table 2. Symptomology and asthma control of the intervention and control group at baseline

		Intervention group N=61	Control group N=59	P value	Method
Symptoms N (%)	Cough	48 (78.7%)	43 (72.9%)	0.344	Chi-square test
	Chest tightness	40 (65.6%)	39 (66.1%)	0.284	Chi-square test
	Shortness of breath	34 (55.8%)	38 (64.5%)	0.422	Chi-square test
	Wheezing	47 (77.0%)	41 (69.5%)	0.447	Chi-square test
ACT Score (Baseline) Median (IQR)		15.0 (10.0- 16.0)	15.0 (12.0-19.0)	0.190	Mann whitney
Asthma control	Uncontrolled (<16)	32 (52.5%)	34 ((57.6%)	0.446	Chi-square test
	Partially controlled (16-19)	20 (32.7%)	13 (22.0%)		
	Controlled (>20)	9 (14.7%)	12 (20.3%)		
Duration of asthma (months) (Median, IQR)		24.0 (24.0-60.0)	36.0 (13.5-60.0)	O.779	Mann whitney
Family history of asthma N (%)		18 (29.5%)	17 (28.8%)	0.19	Chi-square test
History of allergy N (%)		22 (36.0%)	19 (32.2%)	0.21	Chi-square test

Lab parameters and spirometric values at baseline

The median value of Absolute Eosinophil Count (AEC) was 240.0 (IQR 135.0-343.0) in the intervention group and 282.0 (IQR 205.0-475.0) in the control group. The median value of serum total Immunoglobulin E (IgE) was 264.0 (IQR 175.0-520.0) in the intervention group and 200.0 (IQR 126.8-337.8) in the control group. The baseline median value of predicted Forced Expiratory Volume in one second % (FEV_1) in the intervention group at first visit was 86.0% (IQR 69.0-93.0) with bronchodilator reversibility (BDR) present in 42.6% patients. The baseline median value of FEV_1% in the control was 85% (IQR 67.2-99.0) with bronchodilator reversibility present in 42.4% patients. (Table 3)

Table 3. Lab parameters and Spirometric values of the intervention and control group at baseline

	Intervention group N=61	Control group N=59	P value	Method
Absolute Eosinophil count Median (IQR)	240.0 (135.0- 343.0)	282.0 (205.0-475.0)	0.432	Mann whitney
Serum total IgE Median (IQR)	264.0 (175.0-520.0)	200.0 (126.8- 337.8)	O.232	Mann whitney
Predicted FEV_1% Median (IQR)	86.0 (69.0-93.0)	85.0 (67.2-99.0)	0.874	Mann whitney
BDR present N (%)	26 (42.6%)	25 (42.4%)	0.684	Chi-square test

ACT improvements after 4,8 and 12 weeks in the intervention and control groups

In the intervention group there were improvements in median ACT score from baseline 15.0 (IQR 10.0-16.0), at 4 weeks 20.0 (IQR 16.0-22.0), 8th week 22.0 (IQR 18.0-24.0) and 12 weeks 24.0(IQR 22.0-25.0). (Table 4). On comparison of change of ACT score from baseline to 12th week, increase was statistically significant (*p* <0.001). (Table 5). In the control group there were improvements in ACT from baseline 15.0 (IQR 12.0-19.0), at 4 weeks 18.0 (16.0-22.0). However there was no change at 8th week 18.0 (IQR 16.0-22.0) from 4th month. There was improvement at 12th week 19.0 (IQR 18.0-24.0) from 8th week. (Table.4). On comparison change of ACT from the baseline to 12th week, increase was statistically significant (p=0.001) in the control group. (Table 5)

Table 4. ACT scores at follow-up visits in intervention and control group

	Baseline (At first visit)	Follow up (4th Week)	Follow up (8th Week)	Follow up (12th Week)
Intervention group N=61	15.0 (10.0-16.0)	20.0 (16.0-22.0)	22.0 (18.0-24.0)	24.0 (22.0-25.0)
Control group N=59	15.0 (12.0-19.0)	18.0 (16.0-22.0)	18.0 (16.0-22.0)	19.0 (18.0-24.0)

Table 5. Comparison of ACT scores at 12th Week and baseline in intervention and control group

	Baseline (At first visit)	Follow up (12 weeks)	p value	Test used
Intervention group N=61	15.0 (10.0-16.0)	24.0 (22.0-25.0)	<0.001	Paired Wilcoxon test
Control Group N=59	15.0 (12.0-19.0)	19.0 (18.0-24.0)	0.001	Paired Wilcoxan test

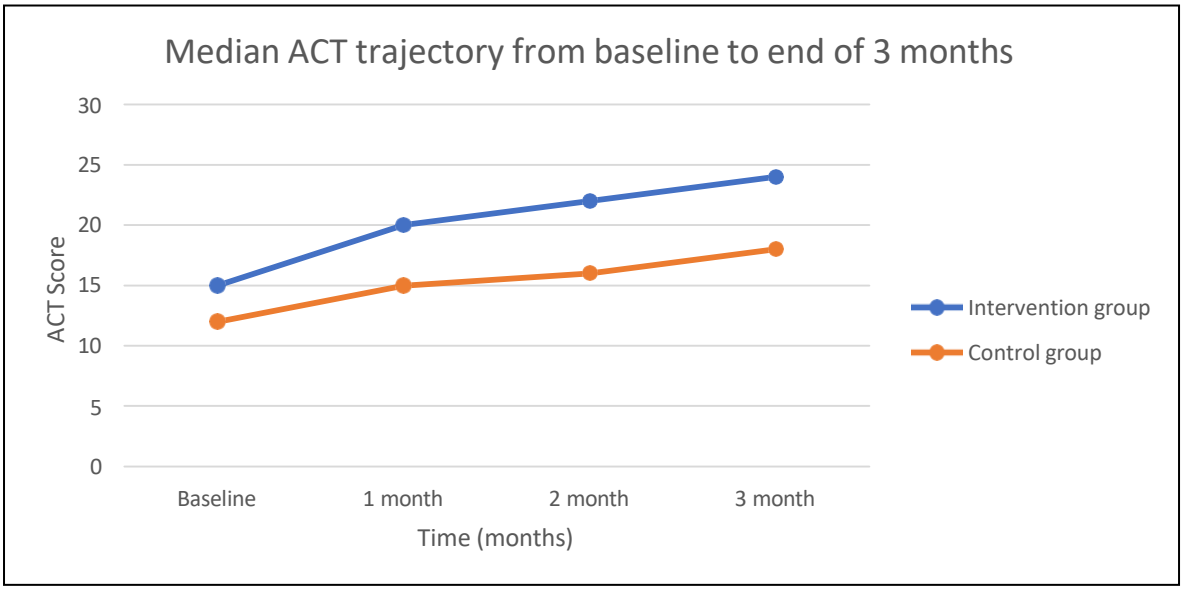

Fig 7. Line graph depicting the Median ACT score trajectory in both arms

FEV_1 improvement after 12 weeks in the control and intervention group

The median value of predicted FEV_1% was significantly improved in the intervention group from baseline, 86.0% (IQR 69.0-93.0) to 92.0 %(88.0-98.0) ; p<0.001 at the end of 12 weeks in the follow-up. It also improved significantly in control group from 85.0% (IQR 67.2-99.0) to 90.0% (74.0-99.5), p=0.003 at the end of 12 weeks.

Table 6. Comparison of FEV_1 % from baseline (1^{st} visit) to 12 weeks in intervention and control group

	Baseline (1^{st} visit)	Follow up (12^{th} Week)	*p* value	Test used
Intervention group N=61	86.0 (69.0-93.0)	92.0 (88.0-98.0)	<0.001	Paired Wilcoxon test
Control Group N=59	85.0 (67.2-99)	90.0 (74.0-99.5)	0.003	Paired Wilcoxon test

Improvement in adherence to inhalers at 4,8 and 12 weeks in the intervention and control groups

In the intervention group there was improvement in Adherence% from 4th week 88.0% (IQR 80.0-94.3), at 8 weeks 98.0% (IQR 92.0-100.0) and 12th week 100% (98.0-100.0). On comparison of Adherence % from 4th to 12th week, improvement was statistically significant (p <0.001). In the intervention group there was also improvement in adherence % from 4th week 85.0% (IQR 74.0-97.3), at 8 weeks 88.0% (IQR 78.5-99.7) and 12th week 90% (80.5-100.0) . On comparison of Adherence % from the baseline to 12th week, improvement was statistically significant (p=0.001) in the control group.

Table 7. Adherence% to inhalers at follow-up visits

	Follow up (4th Week)	Follow up (8th Week)	Follow up (12th Week)
Intervention group N=61	88.0 (80.0-94.3)	98.0 (92.0-100.0)	100.0 (98.0-100.0)
Control group N=59	85.0 (74.0-97.3)	88.0 (78.5-99.7)	90.0 (80.5-100.0)

Table 8. Comparison of Adherence% to inhalers from baseline to follow-up visit at 12th Week

	Baseline (At first visit)	Follow up (12th weeks)	*p* value	Test used
Intervention group N=61	88.0 (80.0-94.3)	100.0 (98.0-100.0)	<0.001	Paired Wilcoxan test
Control group N=59	85.0 (74.0-97.3)	90.0 (80.5-100.0)	<0.001	Paired Wilcoxan test

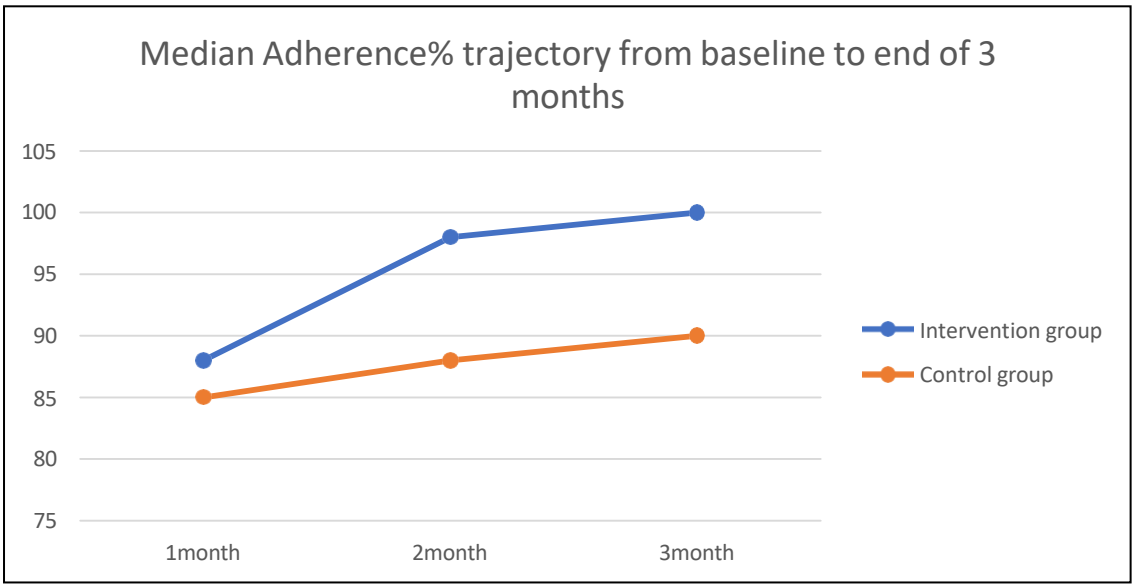

Fig 8. Line graph depicting the adherence rate trajectory in both arms

Difference in ACT Score, Adherence %, FEV1% and exacerbations from baseline to 12th week follow-up between intervention and control groups

The difference in median ACT score between 1st visit and 12th week was 9.0 (IQR 7.75-11.0) in the intervention group and 5.0 (IQR 3.0-8.0), the difference between the groups was statistically significant (*p*<0.0001). The difference in median Adherence % between 4th week and 12th week was also more in intervention group 10.0% (IQR 4.0-18.0) compared to control group 5.0% (IQR 0.0-15.5), it was also statistically significant (*p*=0.0125). On comparing the median difference in FEV1% between 1st visit and 12th week, difference was more in intervention group 7.0% (IQR 2.0-21.0) compared to the control group 3.0% (IQR -1.0 – 6.7), the difference between the group was also statistically significant (p=0.0036). Three patients (4.9%) in the intervention arm underwent exacerbation during the follow-up period while thirteen patients (18.6%) had exacerbations in the control group, the difference between the two groups was statistically significant (*p*=0.001).

Table 9. Difference in ACT scores, adherence%, FEV1% and rate of exacerbation at 12th week follow-up from baseline in intervention and control group

	Intervention group N=61	Control Group N=59	*p* value	Test used
Difference in ACT between 12th Week and baseline Median (IQR)	9.00 (7.75-11.0)	5.00 (3.0-8.0)	<0.0001	Paired Wilcoxon test
Difference in adherence% between 12th and 4th week Median (IQR)	10.0 (4.0-18.0)	5.0 (0.0-15.5)	0.0125	Paired Wilcoxan test
Difference in FEV_1 % between 12th week and baseline Median (IQR)	7.0 (2.0-21.0)	3.0 (-1.0- 6.7)	0.0036	Paired Wilcoxon test
Number of exacerbations in the follow-up period N (%)	3 (4.9%)	11 (18.6%)	0.001	Chi-square test

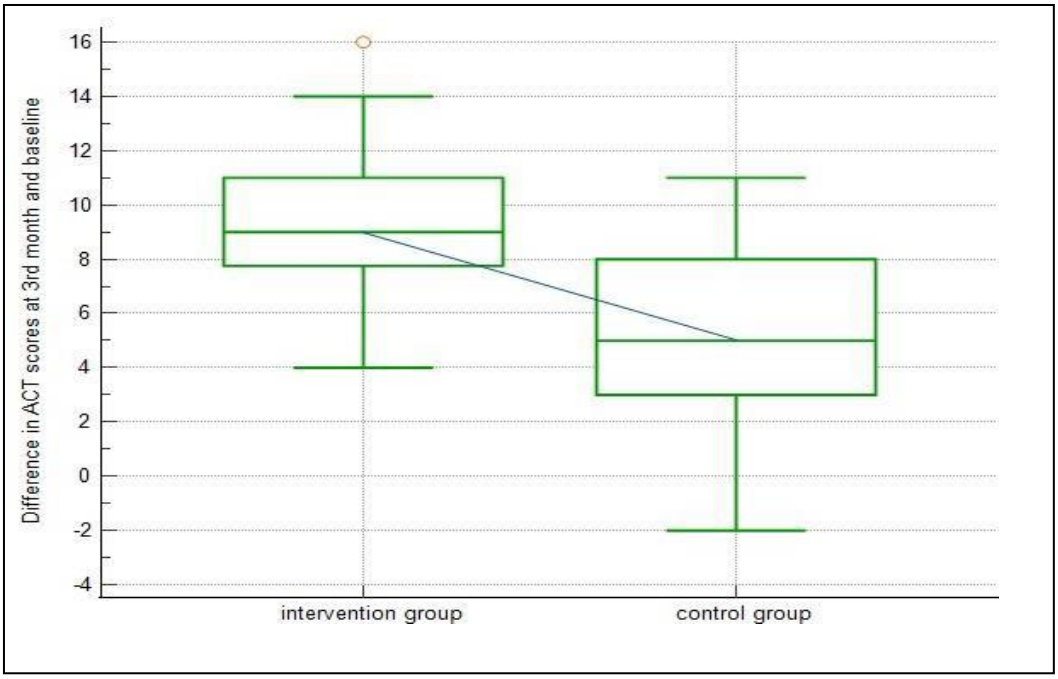

Fig 9. Box plot showing difference of ACT scores at 3rd month and baseline in intervention and control group

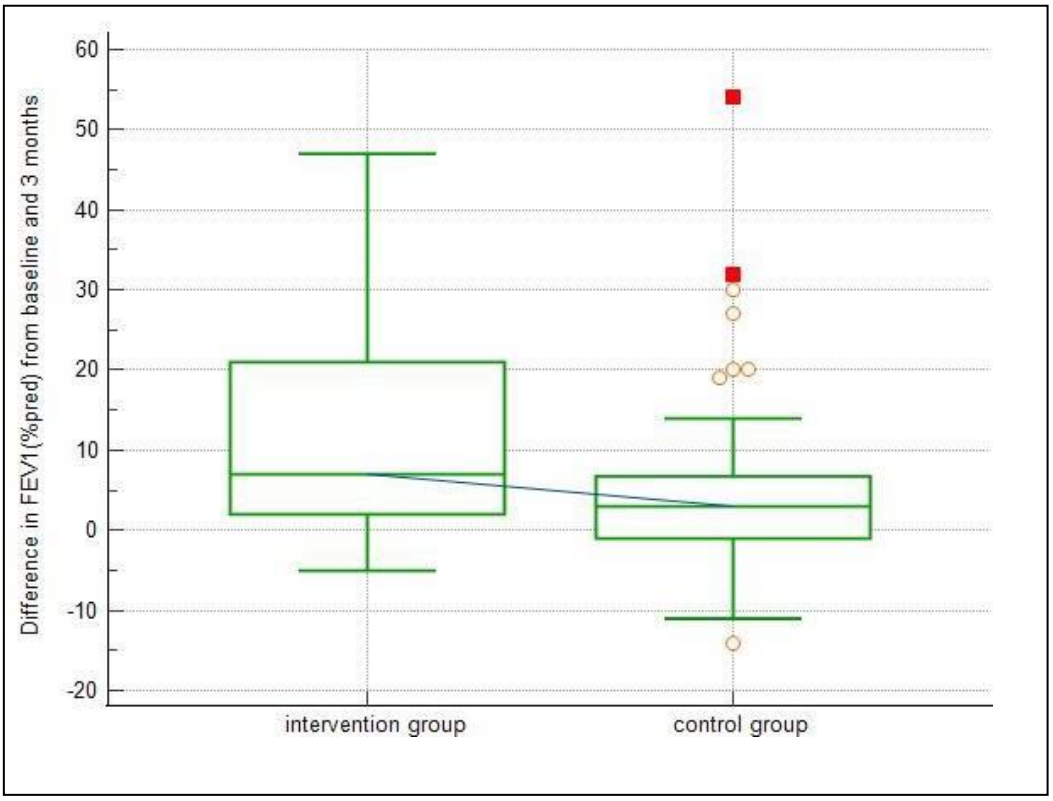

Fig 10. Box plot showing difference of predicted FEV_1% at 3rd month and baseline in intervention and control group

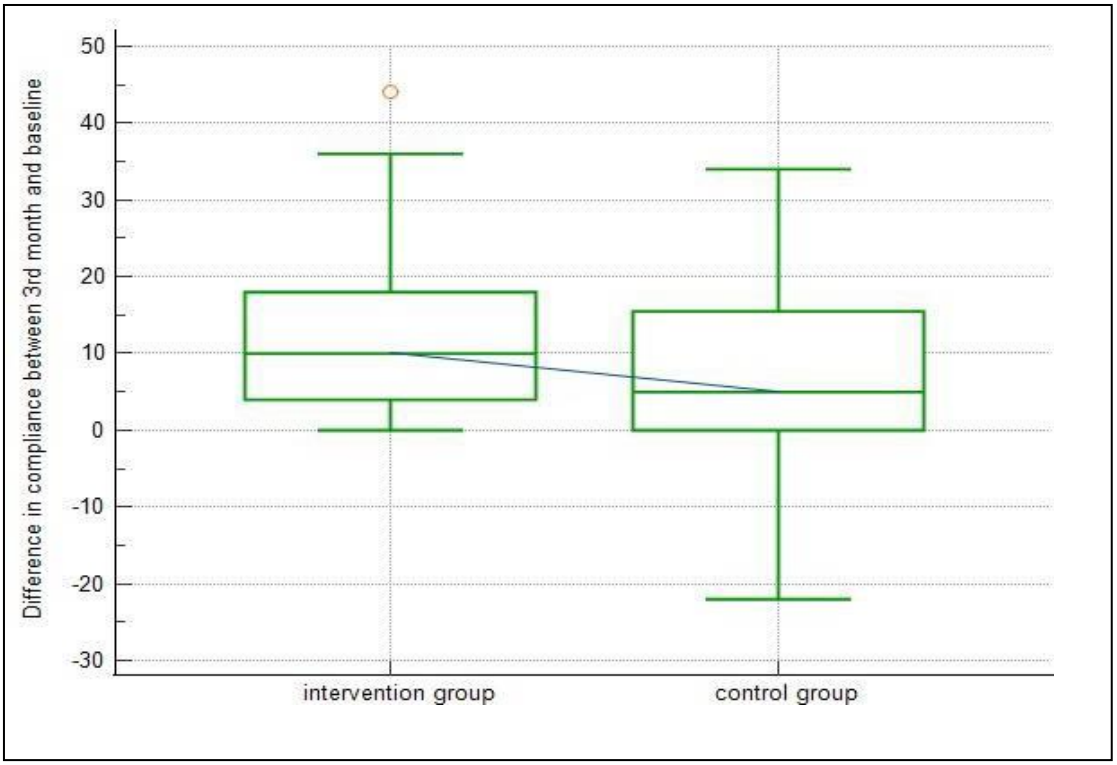

Fig 11. Box plot showing difference of rate of adherence at 3rd month and baseline in intervention and control group

Step with maximum errors in various types of inhalers

MDI

Twenty seven patients in the intervention group and twenty four patients in the control group were started in MDI treatment. The step in which maximum error was done was step 6, where patient had to breathe in slowly and hold the breath for 5 sec/as long as possible. The error was present in 59.2% of intervention and 66.7% of control group. However, in subsequent visits the error decreased and was present in 18.5% and 33.3% of both groups respectively.

MDI with spacer

Eleven patients each in the intervention group and control group were started in MDI treatment. The step in which maximum error was performed was step 7, where patient had to breathe in slowly and hold the breath for 5 sec/as long as possible/tidal breath with spacer. The error was present in 63.6% of intervention and 72.7% of control group. However, in subsequent visits the error decreased and was present in 18.5% and 33.3% of both groups respectively.

DPI

Twenty-three patients in the intervention and twenty-four in the control group were started on DPI treatment. The step with maximum error was performed was step 9, where patient had to breathe in slowly and hold the breath for 5 sec/as long as possible/tidal breath with spacer. The error was present in 56.5% of intervention and 62.3 % of control group. However, in subsequent visits the error decreased to 8.6% and 8.3% of both groups respectively.

Table 10. Errors present in various steps of MDI inhaler

	Follow up (4th Week)		Follow up (8th Week)		Follow up (12th Week)	
	Intervention group N=27	Control group N=24	Intervention group N=27	Control group N=24	Intervention group N=27	Control group N=24
1. Remove inhaler cap	0	0	0	0	0	0
2. Hold inhaler upright and shake well	3 (11.1%)	5 (20.8%)	1 (3.7%)	0	0	0
3. Breathe out gently, away from the inhaler	5 (18.5%)	5 (20.8%)	1 (3.7%)	1 (4.1%)	0	0
4. Put mouthpiece between teeth to form a good seal	9 (33.3%)	10 (41.6%)	2 (7.4%)	4 (16.6%)	1 (3.7%)	2
5. Breathe in slowly through mouth and the same time, press firmly on canister	11 (40.7%)	12 (50.0%)	6 (22.2%)	8 (33.3%)	4 (14.8%)	4 (16.6%)
6. Keep breathing in slowly and hold breath for 5 sec/as long as comfortable	16 (59.2%)	16 (66.7%)	11 (40.7%)	13 (54.1%)	5 (18.5%)	6 (33.3%)
7. Remove inhaler from inhaler while holding breath	4 (14.8%)	8 (33.3%)	2 (7.4%)	3 (12.5%)	1 (3.7%)	1 (4.1%)
8. Breathe out gently, away from the inhaler	4 (14.8%)	6 (25.0%)	3 (11.1%)	5 (20.8%)	1 (3.7%)	4 (16.6%)
9. If extra dose is needed, repeat steps 2 to 8	0	0	0	0	0	0
10. Replace cap	0	0	0	0	0	0

Table 11. Errors present in various steps of MDI inhaler with spacer

	Follow up (4th Week)		Follow up (8th Week)		Follow up (12th Week)	
	Intervention group N=11	Control group N=11	Intervention group N=11	Control group N=11	Intervention group N=11	Control group N=11
1. Prepare the spacer	1 (9.1%)	2 (18.2%)	0	1 (9.1%)	0	0
2. Remove inhaler cap	0	0	0	0	0	0
3. Hold inhaler upright and shake well before inserting in to spacer	1 (9.1%)	3 (27.3%)	0	2 (18.2%)	0	0
4. Put mouthpiece between teeth to form a good seal	2 (18.2%)	3 (27.3%)	1 (9.1%)	1 (9.1%)	0	1 (9.1%)
5. Breath out gently, in to the spacer	3 (27.3%)	4 (36.3%)	1 (9.1%)	2 (18.2%)	1 (9.1%)	1 (9.1%)
6. Hold spacer level and press down firmly on inhaler canister	5 (45.5%)	5 (45.5%)	2 (18.2%)	3 (27.3%)	2 (18.2%)	2 (18.2%)
7. Breathe in slowly and deeply and hold breath for 5 sec/as long as comfortable/Tidal breath with spacer	7 (63.6%)	8 (72.7%)	4 (36.3%)	6 (54.5%)	2 (18.2%)	4 (36.3%)
8. Breathe out gently	2 (18.2%)	3 (27.3%)	1 (9.1%)	1 (9.1%)	0	0
9. Remove inhaler from spacer, if extra dose is needed, repeat steps 3 to 9	0	0	0	0	0	0
10. Replace cap on inhaler	0	1 (9.1%)	0	0	0	0

Table 12. Errors present in various steps of DPI

	Follow up (1st month)		Follow up (2nd month)		Follow up (3rd month)	
	Intervention group N=23	Control group N=24	Intervention group N=23	Control group N=24	Intervention group N=23	Control group N=24
1. Remove cap	0	0	0	0	0	0
2. Flip mouthpiece to open	2 (8.6%)	3 (12.5%)	1 (4.3%)	0	0	0
3. Remove capsule from blister and place in chamber	4 (17.4%)	6 (25.0%)	1 (4.3%)	2 (8.3%)	0	0
4. Close mouthpiece until it clicks	2 (8.6%)	4 (16.7%)	1 (4.3%)	3 (12.5%)	0	1 (4.2%)
5. Press side buttons in once and release	6 (26.1%)	8 (33.3%)	4 (17.4%)	5 (20.8%)	2 (8.6%)	1 (4.2%)
6. Breath out gently, away from inhaler	4 (17.4%)	6 (25.0%)	3 (13.1%)	3 (12.5%)	1 (4.3%)	2 (8.3%)
7. Put mouthpiece between teeth to form good seal	6 (26.1%)	6 (25.0%)	3 (13.1%)	4 (16.7%)	1 (4.3%)	1 (4.2%)
8. Breathe in quickly and steadily, so capsule vibrates	9 (39.1%)	7 (29.2%)	3 (13.1%)	4 (16.7%)	2 (8.6%)	2 (8.3%)
9. Hold breath for 5 seconds/as long as comfortable	13 (56.5%)	15 (62.3%)	7 (30.4%)	11 (47.8%)	4 (17.4%)	6 (24.9%)
10. While holding breath, remove inhaler	4 (17.4%)	6 (25.0%)	3 (13.1%)	5 (20.8%)	1 (4.3%)	4 (16.7%)
11. Breathe out gently, away from mouth	4 (17.4%)	5 (20.8%)	2 (8.6%)	2 (8.3%)	0	0
12. Open mouthpiece and remove capsule	2 (8.6%)	1 (4.2%)	0	0	0	0
13. If more than one dose needed, repeat steps 3 to 12	0	0	0	0	0	0
14. Close mouthpiece and cap	0	0	0	0	0	0

DISCUSSION

This randomized controlled open-label trial was conducted to investigate the eff ect of video demonstration of the inhaler technique at regular intervals in addition to regular face-to-face teaching in patients with asthma and to determine its on asthma control in comparison to the usual care. A total of 61 patients in the intervention arm received a video regarding the inhaler technique at 15 days intervals in addition to the monthly face-to-face follow-up up to 12 weeks. The control arm with 59 patients received the usual care of face-to-face inhaler device training at monthly follow-up. The two groups were comparable as per demographics, symptoms, lung functions, and severity of asthma. The median age of intervention and control group was 26.0 years (IQR 22.0-38.0) and 29.0 years (IQR 23.0-42.0), respectively comparable to the study by Schantz et al. in which subjects were aged 25-34 years. Males compromised 60.66% of the intervention and 55.93% of the control group.

In our study, 55% of the patients had uncontrolled asthma, results comparable to prior studies by Guenette et al. and Cook et al. where it was present in 48% and 59% of the patients, respectively [12] [21]. There was a history of asthma in the family in 29.5% patients in the intervention arm and 29.5% of patient in the control arm. Similar findings were present in the study cohort by Park et al. with a family history of asthma in 23.8% and 21.8% of the control and study, respectively [13]. In our study, 36.0% of patients in the intervention arm and 32.2% of patients in the control arm had a history of allergy comparable to the study by Gregoriana et al. [22].

The median value of FEV_1 % at baseline was 86.3% (IQR 69.3-93.0) in the intervention and 85.0% (IQR 67.2-99.0) in the control group. Bronchodilator reversibility was present in 42.6% and 42.4% of the two groups, respectively. In the study by Park et al. the mean value of FEV_1% at baseline was 84.8 ± 1.6% in the control and 85.3 ± 1.7% in the study group, comparable to our study [13]. The median value of absolute eosinophilic count was 240.0 (IQR 135.0-343.0) and 282.0 (IQR 205.0-475.0) in the intervention and control group, respectively. The median value of total serum IgE was 264.0 (IQR 175.0-520.0) and 200.0 (IQR 126.8-337.8) in the two groups.

The outcomes of the study included lung function (FEV_1) and symptoms (ACT), which are crucial indicators for managing asthma. The Asthma Control Test (ACT) is an asthma management tool that has been scientifically proven to be effective in identifying the severity of asthma, predicting FEV_1, and used to modify the medication dosage. [19]. There was an improvement in ACT scores in both groups in the follow-up visits. In the intervention arm, the increase in ACT score from the baseline 15.0 (IQR 10.0-16.0) to 24.0 (IQR 22.0-25.0) at 12 weeks, was statistically significant ($p < 0.001$). Similarly, an increase was present in the control group from baseline 15.0 (IQR 12.0-19.0) to 19.0 (IQR 18.0-24.0), which was also statistically significant ($p = 0.001$). The minimum clinically important difference in ACT is 3 points which was present in both groups [23] Significant improvement was also seen by Park et al. from baseline 19.6 ±0.3 to 22.3 ± 0.3 at the end of 12 weeks in the group receiving face-to-face education and improvement from 19.9 ±0.3 to 22.2 ± 0.3 in the group receiving video assist teachings.[13]. Cook et al. also reported an improvement in ACT score from 16.6 to 20.5 in asthma patients receiving smartphone inhaler teaching techniques [12]. However, on comparison of the difference of increase of ACT from baseline to 12th week, between the two groups in our study, 9.0 (7.75-11.0) in the intervention group and 5.00 (3.0-8.0), the difference was statistically significant ($p<0.001$). There have been studies utilizing the use of phone app for asthma inhaler teaching. Burbank et al. and Mosnaim et al. utilised these features and found increase of ACT of 3.9 and 3.0 in their studies, respectively [24] [25]. In our study we found that clinically significant ACT improvement of 3 points were seen in both arms [23]. This is because of the regular physical follow up which were undertaken in both groups. But the greater ACT improvement in the intervention arm can only be attributed to the training videos. This videos in the patients' mobiles were a handy reckoner to which the patients could always go back and check their techniques, a distinct advantage with respect to the physical follow-up.

The improvement in FEV_1% at the end of the 12th week were significant in both groups. The median value of FEV_1% in the intervention group improved from baseline 86.0% (IQR 69.0-93.0) to 92.0 % (IQR 88.0-98.0) at the end of 12 weeks in the follow-up was significant ($p<0.001$). It also improved in the control group from 85.0% (IQR 67.2-99.0) to 90.0% (74.0-99.5) at the end of 12 weeks ($p=0.003$). Park et al. also reported improvement in FEV_1 in the study group receiving video-assist

teaching (from 84.8 ±1.6% to 89.2 ±1.5%; $p< 0.01$) and the control group receiving face-to-face teaching (from 85.3 ± 1.7% to 88.7 ± 1.6%; $p<0.01$) [13]. There was a mean increase of 7.9 in FEV_1 percent predicted ($p=0.03$) in the study population by Cook et al. [12]. On comparing the improvement between the groups in our study, the FEV_1% difference at the end of the follow-up period was 7.0% (IQR 2.0-21.0) in the intervention group and 3.0% (IQR -1.0 - 6.7) in the control arm, the difference was statistically significant ($p=0.0036$). However, Park et al did not find any difference in FEV_1 between the two groups ($p=0.60$) [13].

There was a significant improvement in adherence with inhalers in both groups. In the intervention group, there was an improvement in adherence rate from the 4th week, 88.0% (IQR 80.0-94.3), to the 12th week, 100% (98.0-100.0). There was also a statistically significant improvement in the control arm from the 4th week, 85.0% (IQR 74.0-97.3), to the 12th week, 90% (80.5-100.0). Park et al. found an adherence rate of 90.4 ± 16.3 in the group receiving face-to-face care compared to 95.1 ± 15.3 in the group receiving video education [13]. In an observation study by Jochman et al., improvement across a range of asthma control measures was seen in children with ≥80% adherence, however, no improvement was seen in those whose monitored adherence was <60%.[26]. In our study, patients in both groups had an adherence rate >80%, with improvement in asthma control measures. The increase in adherence in subsequent visits could be due to improved control with good adherence, which would help to initiate behaviour change in the patients. However, the increase in adherence from the 4th week to the 12th week was more in the intervention arm, 10.0% (IQR 4.0-18.0) compared to the control group 5.0% (IQR 0.0-15.5), (p=0.0125). The intervention arm received videos at 15 days intervals, which were reminders in addition to the monthly monitoring done in both groups. The study by Chan et al. found that children in the intervention group provided with an audio-visual reminder function showed a median percentage adherence of 84% compared with 30% in the control group receiving usual care ($P < 0.0001$) [27].

The asthma exacerbation rate was significantly less in the intervention arm compared to the control (4.9% vs 18.6%, p=0.001). Poor asthma control and poor adherence to medication have been implicated in the disease's flare [28]. In our study, better asthma control (ACT score), lung function and inhaler adherence in the intervention arm

compared to control led to less exacerbation compared to control arm. In the study by Halterman et al., the School-based telemedicine-enhanced asthma management group that received video teaching had fewer emergency department visits or hospitalization for asthma than usual care (7% vs. 15%, OR, 0.52; CI, 0.32-0.84) [29]. Lin Y et al. studied video-based telehealth (VBT) in school children with asthma found a decrease of exacerbation requiring oral steroids from 68%, before enrolment to 9.5% in 6 months follow-up (p=0.001) [30]. Cook et al. observed decrease in the number of courses of systemic steroids per person due to exacerbation from 0.5 to 0.3 after mobile-based teaching but did not have statistical significance (p=0.046); 45% of their cohort had FEV<80% at baseline had required most courses [12].

We identified the most common errors performed during inhaler device use in all the follow-up visits. Errors related to the inspiratory effort were frequent in all three devices cohorts. In the MDI group, breathing and holding breath was the most common error in 56.5% and 62.3% of subjects in the intervention and control groups at 4-week follow-up, respectively. The error decreased to 17.4% and 24.9% in both groups, respectively. In the cohort of MDI with spacer, the step of breath holding or tidal breathing was most common, seen in 63.6% and 72.7% of intervention and control groups at 4 weeks, reduced to 18.2% and 36.3% in each group at 12 week end, respectively. With DPI, breathing in and holding the breath was the most common step, with errors seen in 59.2% and 66.7% of the intervention and control group and improved to 18.5% and 33.3% in the respective groups. Similar to our work, the authors of the CRITIKAL study, one of the largest studies to examine the inhaler technique in a global population, noted that inspiratory effort mistakes were widespread. Patients who used DPI devices inhaled too slowly and forcefully, including 32.1% of Turbuhaler users, 38.4% of Diskus users, and 47.2% of patients who used MDI devices [31]. Studies done previously by Park et al. and Munteanu et al. also demonstrated improved inhaler technique with video instructions to better control the disease [13] [32]. There is a deterioration of the inhaler technique over time, as little as 2-3 months.[33]. Inhaler handling training must occur regularly to achieve and maintain the correct technique. In both groups of our study, inhaler techniques were checked at a monthly visit, leading to improved technique. The intervention arm receiving videos could watch the same on their phone repeatedly,

which promoted better recall on inhaler use and less error, same is supported by Wilson et al [34].

Our study showed that the group who received educational videos regarding inhaler technique in addition to regular face-to-face visits had better asthma control with a statistically and clinically significant improvement in ACT score compared to the face-to-face teaching group. We also found a statistically significant difference in FEV_1 % between the two groups at the end of three months follow-up. There was also better adherence to inhalers and less exacerbation in the intervention group compared to the group receiving the regular face-to-face visit. Although many studies have compared video teaching with traditional face-to-face, our study is the first of a kind to combine both methods in the intervention arm. We believe that video education along with face-to-face teaching has a beneficial synergistic effect which is higher than the individual techniques in isolation. Inhalational drugs have become the cornerstone for the management of asthma. To achieve the desired therapeutic effects of an inhaler, the correct dosage with technique and adherence is crucial for asthma control. Notably, adequate inhalation education is not fully practiced due to a lack of medical staff, time constraints, and associated financial costs. There is a growing interest among the healthcare fraternity in the adaption of mobile technology to assist in managing chronic diseases. It is evident by the rising number of available smartphone apps of education and monitoring of respiratory illness. There has been an evolution in the innovations, starting from increasing adherence by using short messaging services (SMS) text messages to smartphone apps that monitor compliance of inhalers, calculate ACT scores and tabulate peak expiratory flow rate. [35] [36]. Video education has practical applications. It doesn't need expensive machinery, sophisticated software or a big financial investment. These video-assisted lessons can change the management of asthma from a hospital-centric strategy to one that is patient-centric. Patients in distant locations with limited access to specialised medical facilities and trained professionals will find it to be a helpful option.

LIMITATIONS

1. The study was single-centered.
2. Patients in both arms were young, and the majority were educated. The use of video assistance teaching in the older population with sometimes limited knowledge of smartphone needs further investigation.
3. There was no provision in the program where patient's query could be resolved after sending the video. It could only be resolved when patient came for physical visit. It might have led to delay in query resolution during which patient could have continued with incorrect technique.
4. The sample size was small due to time constraints.

CONCLUSION

There is better control of asthma symptoms, lung function improvement, decreased rate of exacerbation and better rate of adherence to inhalers in the group receiving both face-to-face teaching and video teaching compared to group receiving only face-to-face education. The video education along with face-to-face teaching has a beneficial synergistic effect which is higher than face-to-face teaching in asthma patients.

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ANNEXURE -1
All India Institute of Medical Sciences
Jodhpur, Rajasthan

Informed Consent Form

Title of Thesis/Dissertation: Role of smartphone based inhaler teaching technique in asthma control- A randomised control study

Name of DM Student : Dr Saumya Shishir, Tel. No. 8527048244

Patient/Volunteer Identification No. : _____

I, _____S/o or D/o _____

R/o

_____

give my full, free, voluntary consent to be a part of the study "_____", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from _____ (Company Name) or from regulatory authorities. I give permission for these individuals to have access to my records.

Date: _____ _____

Place: _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date: _____ _____

Place: _____ Signature of DM Student

1. Witness 1

_____
Signature

Name: _____

Address: _____

2. Witness 2

_____
Signature

Name: _____

Address: _____

ANNEXURE -2

अखिर भारतीय चिकित्सा विज्ञान स्स थान

जोधनरु , राजस्थान

सचित सहमचत्रानत्र

थीचसस/चनबधिाशीर् : अस्थभा नास्र ण भें इनहेरय निंण तकनीक नय आधारयत ि

स्भार्टपोन की बनभका- एक माद्दच्छिक ननमत्रण अध्ममन

डीएभ ि्ात्र का नाभ: डॉ सौम्म निनिय भोफाइर नफय: 8527048244

योगी / स्वमसेवीकीनहचान._____

भैं, _____पनता/भाो _____
अध्ममन का एक हहस्सा फनने के नरए भेयी नण ट्स्वत्र ,स्वच्ै छि कसहभनतव्मक्त कयता हूॉ।
थीनसस / ननफध का "अस्थभा नास्र ण भें इनहेरय निंण तकनीक नय आधारयत ि्रीक

स्भार्टपोन की बनभका- एक माद्दच्छिक ननमत्रण अध्ममन

च्ि प्रहिमा औय प्रकृ नत को भझ े अनी न्यू ी पि के नरए अनी बार्ा भें सभझामा गमा सत

है भैं नपि कयता हूॉ हक भझे प्रश्न न्निने का अवसय नभरा है।

भैं सभझता हूॉ हक भेयी बागीदायी स्वच्छिक है औय भझे हकसी बी कायण हदए पफना हकसी बी सभम अध्ममन से फाहय ननकरने के भेये अनधकाय की ि्ानकायी है।

भैं सभझता हूॉ हक भेये भयीि औय भेये भयीि के भेहडकर रयकॉडट के फाये भें एक पत्रत की गई ि्ानकायी को अच्ि बायतीम नचहकत्सा पवा्ान सस्थान से च्ि्भेदाय व्मपक्त द्वाया देि्ा ि्ा सकता है। भैं इन व्मपक्तमों को अनने अनबरेि्ोों तक नहोच के नरए अनभनत देता हूॉ तायीि : _____ _____

ि्गह: _____ हस्ताय / फाऐॉअग ठेकाि्ान

मह प्रभाच्णत कयने के नरए हक भेयी उनच्स्थनत भें उनयोक्त सहभनत प्राप्त की गई है

तायीि : _____

स्थान: _____

डीएभ ि्ात्र के हस्ताय।

1. गवाह 1
हस्ताय :
नाभ: _____
नता: _____
_____

2. गवाह 2
हस्ताय:
नाभ: _____
नता : _____
_____

ANNEXURE -3
Patient information sheet (ENGLISH)

Title of Thesis/Dissertation: Role of smartphone-based inhaler teaching technique in asthma control- A Randomised control study

You are invited to take part in this research study. Before you decide whether or not to take part it is important for you to understand why the research is being done and what will it involve. Please take your time to read the information and then decide. Queries if any will be addressed. This study aims to compare the effectiveness of smartphone based inhaler teaching technique in asthma control

1) Why have I been chosen to take part in the study?

You have been chosen to take part in the study because you have ASTHMA. Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity, together with variable expiratory airflow limitation

2) What is the purpose of the study?

Video education and its use among healthcare personals has been increasingly used in recent years. This study aims to investigate the eff ect of video demonstration of inhaler technique at regular intervals in addition to usual care to patients and to determine the eff ect on asthma control.

3) Do I have to take part in the study?

It is up to you to decide whether to take part. In case you decide to take part, you will be given the information sheet and will be asked to sign the consent form. If you decide to take part, you can still withdraw your consent anytime in the study without giving any reasons.

4) What will happen to me if I take part in the research?

You will be involved in this research for 3 months. You will be randomised to either study or control group by computed generated random numbers. Study group will be sent video regarding the inhaler technique via smart phone every 2 weeks from the

day of enrolment. Control group will receive usual care without any video. All patients will be followed up at 1,2 and 3 months

5) What do I have to do?

You will have to give consent for the study. You will be randomized to either study or control group by computer generated random numbers. The study group will be sent a video regarding the inhaler technique via smart phone every 2 weeks from the day of enrolment. Inhalation techniques will be evaluated for every patient in every visit using pre-determined checklist. Asthma control will be assessed with an ACT questionnaire. Spirometry will be repeated at the end of 3 months

6) What are the possible benefits of taking part in the study?

Your follow-up will be more systematic, and the additional investigations performed as per the study protocol will help in better treatment.

7) Will my data be kept confidential?

Your medical records and demographic data will be disclosed only to the researcher, treating physician, and concerned authorities.

For further information / questions, the following personnel can be contacted:

Dr. Saumya Shishir,
DM fellow,
Department of Pulmonary Medicine,
All India Institute of Medical Sciences,
Jodhpur, Rajasthan.
Ph: 8527048244

ANNEXURE - 4

अखिऱभारतीयचिकित्साविज्ञानसस् थान

जोधऩरु , राजस्थान

रोगीसिनाऩत्रि

थीचसस/चनबधिाशीर् : अस्थभा नम्न ण भें इनहेरय निंण तकनीक ऩय आधारयत स्भार्टपोन ि

की बनभका- एक माद्दच्छिक ननमत्रण अध्ममन।

आऩको इस ि्ोध अध्ममन भें बाग रेने के नरए आभपत्रत हकमा ि्ाता है। मह तम कयने से ऩहरे हक आऩ बाग रेना चाहते हैं मा नहीॊ, मह सभझना आऩके नर एभहत्वऩणट है हक ि्ोध क्मों हकमा ि्ा यहा है औय इसभें क्मा ि्ानभर होगा। कृ ऩमा ि्ानकायी ऩढ़ने के नरए अऩना

सभमरें औय हपय ननणमरें। प्रश्नों को सपोनधत हकमा ि्ाएगा। इस अध्मम नका रक्ष्म भयीि्ोॊ की साभान्म देि्बार के अरावा ननमनभत अतयार ऩय इनहेरय तकनीक के वीहडमो प्रदिन के प्रबाव की ि्ाॊच कयना औय अस्थभा ननमत्रण ऩय प्रबाव ननधारयत कयना है।

1) अध्ममन भें बाग रेने के नरए भझे क्मों चुना गमा है**?**

आऩको अध्ममन भें बाग रेने के नरए चुना गमा है क्मोंहक आऩके ऩास अस्थभा है। अस्थभा एक पवर्भ फीभायी है, ि्ो आभतौय ऩय ऩयानी वामभागट **सिन** द्वाया पवित्ता है। मह श्वसन के रंणों ि्ैसे हक घयघयाहर्, साॊस की तकरीप, सीने भें ि्कड़न औय ि्ाॊसी के रूऩ भें ऩरयबापर्त हकमा गमा है ि्ो सभम के साथ औय तीव्रता भें नबन्न होता है, साथ भें

ऩरयवतनिीर वामु प्रवाह सीभा ।

2) अध्ममन का उद्देश्म क्मा है**?**

हार केवर्ोॊ भें स्वास््म निंा के ेत्र भें वीहडमो निंा औय इसके उऩमोग भें ते ि्ी से उऩमोग हकमा गमा है। इस अध्ममन का उद्देश्म योनगमों की साभान्म दे ि्बार के अरावा ननमनभत

अतयार ऩय इनहेरय तकनीक के वीहडमो प्रदिन के प्रबाव की ि्ाॊच कयना औय अस्थभा ननमत्रण ऩय प्रबाव ननधारयत कयना है।

3) क्मा भझे अध्ममन भें बाग रेना है**?**

मह तम आऩको कयना है हक आऩ बाग रेना चाहते हैं मा नहीॊ। महद आऩ बाग रेने का पै सरा कयते हैं तो आऩको सचना ऩत्र हदमा ि्ाएगा औय सहभनत प्रऩत्र ऩय

हस्तांय कयने के नरए कहा ाएगा। महद आऩ बाग रेने का पै सरा कयते हैं तो आऩ पफना हकसी कायण फताए अध्मभन भें कबी बी अऩनी सहभनत वाऩस रे सकते हैं।

4) अगय भैं ि◌ोध भें बाग रेता हो तो भेये साथ क्मा होगा**?**

आऩ इस ि◌ोध भें 3 भहीने तक ि◌ानभर यहेंगे। गणना हकए गए माओं के आधाय ऩय भाऩच्छिक सख्

आऩको अध्ममन मा नाभ ण सभह केनरए भाऩच्छिक हकमा ि◌ाएगा। अध्ममन को नाभाॉकन के सभह

हदन से हय 2 सप्ताह भें स्भार्ट पोन के भाध्मभ से इनहेरय तकनीक के फाये भें वीहडमो बेि◌ा ि◌ाएगा। नाभ ण सभह को पफना हकसी वीहडमो के साभान्म देि◌ाय प्राप्त होगी। सबी योनगमों को 1,2 औय 3 भहीने तक ि◌ाॉच हकमा ि◌ाएगा

5) भझेक्माकयनाहै**?**

अध्ममन केनरए आऩको सहभनतदेनी होगी। गणना हकए गए भाऩच्छिक सख्माओं के आधाय ऩय आऩको अध्ममन मा नाभ ण सभह केनरए भाऩच्छिक हकमा ि◌ाएगा। अध्ममन सभह को नाभाॉकन के हदन से हय 2 सप्ताह भें स्भार्ट पोन के भाध्मभ से इनहेरय तकनीक के फाये भें वीहडमो बेि◌ा ि◌ाएगा। ऩवट ननधारयत चेकनरस् का उऩमोग कयके प्रत्मेक मात्रा भें प्रत्मेक योगी के नरए साॉस रेना तकनीक का भलमाॉकन हकमा ि◌ाएगा। एसीर्ी प्रश्नावरी के साथ अस्थभा ण का भलमाॉकन हकमा ि◌ाएगा। च्स्ऩयोभेट्री को 3 भहीने के अत भें दोहयामा ि◌ाएगा ।

6) अध्ममन भें बाग रेने के सबापवत राब क्मा हैं **?**

आऩका अनवती अध्ममन अनधकत्म वच्स्थत होगा औय अध्ममन भर नरपऩके अनसाय हकए गए अनतरयक्त ि◌ाॉच आऩकी अस्थभा की च्स्थनत के पवस्तत भलमाॉकन भें सहामता क्मोंि◌

7) क्मा भेया डेर्ा गोऩनीम यिा ि◌ा एगा**?**

आऩके भेहडकर रयकॉडट औय ि◌नसाॉच्छमकी मडेर्ा के वर नचहकत्सक औय नैधत अनधकारयमों सपके इरादि के नरए ि◌ोधकताट कोही प्रकर् हकमा ि◌ाएगा।

अनधकानकायी / प्रश्नोंके नरए ननम्ननरच्ितकनभम ों से सम्पकट हकमा ि◌ासकताहै:

डॉ सौम्म ननिय
डीएभ ि◌ात्र
ऩरभोनयीभेहडनसनपवबाग,

अच्ि◌रबायतीमआमपवां Ph: 8527048244

ानसस्थान, िोधऩयु ,
याि स्थान।

ANNEXURE - 5

PROFORMA FOR DATA COLLECTION

Name- …… Age-…… Gender……

Contact no- …… Occupation……

Marital status…….. Educational qualification …….

Symptoms and duration-

Cough-

Chest tightness- Chest pain- Fever-

Wheezing-

Running nose-

Others-

Previous history of medical illness (Asthma/Diabetes/hypertension/others):-

……

History of addiction(smoking/tobacco/alcohol/opium/others) , if yes please mention with duration:-

……

Year of diagnosis of asthma:- ……

Hospital/Clinic where diagnosis was made: - ……

Was inhaler device prescribed (Yes/NO): - ……. …….

Type of inhaler device (MDI/MDI with spacer/DPI): - …….

Name of medication with frequency: - ……. ……..

Who taught the technique of inhaler (Doctor/Nurse/Pharmacist/None)……

Were you taking inhaler on regular basis (Yes/NO):- ……..

If not taking the inhaler, please mention the reason:- ……...

Did the inhaler relieve the symptoms(Yes/NO) :- ……...

Did you follow up with your treating physician :- ……

If yes, frequency of follow up visit:- …….

Was inhaler technique checked at follow up visit(yes/no) :- ……

General examination:

Pulse rate……..

BP……..

RR……..

SpO2…….

Auscultatory findings : ……. .

ACT Score : ……

Diagnosis ……

Medication prescribed ……..

Type of inhaler prescribed …….

Technique of inhaler checked (Yes/No) ……

Follow up appointment date ……..

Signature……

FOLLOW UP (1 MONTH) **Date ……..**

Symptoms, if any: ……

Are you taking the medication regularly (Yes/No) :……..

If no, please specify the reason: …….

Inhaler technique checked (Yes/No) :…….

If technique is incorrect, the steps which are incorrect:

….……

MDI dosimeter reading/No. of capsules used in the month in DPI ……

Asthma control test score : ……..

Next appointment date: ……

Signature……

FOLLOW UP (2 MONTH) **Date ……..**

Symptoms, if any: ……

Are you taking the medication regularly (Yes/No) :……..

If no, please specify the reason: …….

Inhaler technique checked (Yes/No) :…….

If technique is incorrect, the steps which are incorrect: ….

……

MDI dosimeter reading/No. of capsules used in the month in DPI ……..

Asthma control test score : …….

Next appointment date: ……..

Signature……

FOLLOW UP (3 MONTH) **Date ……..**

Symptoms, if any: ……

Are you taking the medication regularly (Yes/No) :……..

If no, please specify the reason: …….

Inhaler technique checked (Yes/No) :…….

If technique is incorrect, the steps which are incorrect: ….

……

MDI dosimeter reading/No. of capsules used in the month in DPI ……..

Asthma control test score : …….

Signature……

Name …….

Date……..

ANNEXURE – 6
Institutional Ethics Committee Certificate

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2021/3461 **Date: 12/03/2021**

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2021/3296**

Project title: **"Role of smartphone based inhaler teaching technique in asthma control-A randomised control study"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**D.M. Dissertation**
Student Name:	**Dr. Saumya Shishir**
Guide:	**Dr. Ramniwas**
Co-Guide:	**Dr. M.K.Garg, Dr. Naveen Dutt & Dr. Nishant Kumar Chauhan**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation.

If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member Secretary
Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Basni Phase-2, Jodhpur, Rajasthan-342005; **Website:** www.aiimsjodhpur.edu.in; **Phone:** 0291-2740741 Extn. 3109
E-mail : ethicscommittee@aiimsjodhpur.edu.in; ethicscommitteeaiimsjdh@gmail.com