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# Effect of adjuvant yoga therapy for asthma control: A randomized controlled trial

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ARTICLE INFO	A B S T R A C T
Keywords: Asthma Randomized-controlled trial Asthma control test Yoga exercise	Background: Asthma is a chronic respiratory disease with symptoms of attacks of wheezing, shortness of breath, & tightness in the chest. Even with pre-existing treatment exacerbations go uncontrolled. <i>Objective:</i> This study compared asthma control in yoga intervention versus non-yoga intervention group using Asthma Control Test. <i>Methods:</i> In this randomized controlled trial, participants were allocated into two groups in 1:1 ratio - yoga intervention versus non-yoga intervention. Only outcome assessor was blinded. Sample size of 200 was calculated. Individuals between 18 and 60 years of age, diagnosed with mild to moderate asthma with no exacerbation in past one month were screened and enrolled. Per-protocol analysis was done to assess the outcomes of Asthma Control Test and expenditure.(CTRI/2020/02/023534) <i>Results:</i> A total of 192 participants enrolled, 165 completed this study who were considered for final analysis. A significant difference (p < 0.001) was found between yoga and non-yoga exercise group at 13 weeks. Expenses were more in non-yoga exercise group. <i>Conclusion:</i> Our findings confirm that yoga exercise with routine medical care reduces exacerbations and improves asthma control.

### 1. Introduction

Asthma as defined by Global Initiative for Asthma (GINA 2022) as a "common, chronic respiratory disease characterized by variable symptoms of wheeze, shortness of breath, chest tightness and/or cough, and by variable expiratory airflow limitation" [1]. Asthma exacerbations lead to emergency visits and unwarranted hospital admissions that increase the cost of asthma-related care.

Asthma control test is a self-administered tool which is used for identification of person(s) with poor asthma control. It was developed by Robert A Nathan and colleagues [2]. There are 5 items in this tool that are assessed by recall method after four weeks of treatment. Test-re-test reliability of this method was found to be 0.77 [3,4]. ACT has been validated after correlating it with specialist's rating of asthma control based on history, physical examination and FEV1. The recall method assesses symptoms and daily function of asthmatic individual.

Scoring of each question is based on a scale of 1–5. These five items are assessed on five-point scale where a score of one means no control of symptoms or asthma and a score of five indicates complete control. Thus, a minimum score will be 5 and maximum score will be 25. Overall score more than 19 points indicates well controlled asthma. A three-point difference between groups is required to consider change in score as meaningful [5]. A pediatric version of ACT is also validated and used for childhood asthma [4].

Yoga is a tradition and part of daily practices in Indian culture as well as a part of integrative medicine. Amalgamation of different techniques of yoga with allopathic medicines aims to improve asthma control to reduce exacerbations.

In this study, we aimed to compare effect of yogic intervention and non-yogic intervention.

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#### Table 1

Yoga intervention Protocol.

Structured yogic intervention		
Yoga techniques	Frequency	Duration
Gomukhasana (cow face pose) Bhujangasana (cobra pose) Ardhamatsyendrasana (half spinal twist) Dhanurasana (bow Pose) Tadasana (mountain standing pose) Shavasana (relaxing asana) Bhastrika Pranayama Nadishodhan Pranayama Om sheming	2 rounds 2 rounds 2 rounds 2 rounds 2 rounds - 20 strokes 10 rounds 7 10 anudo	2 min 2 min 2 min 2 min 2 min 5 min 2 min 5 min 2 min
Meditation Total duration	- -	5 min 30 min

## 2. Methodology

#### 2.1. Study design

This study was designed as a randomized controlled trial to compare asthma control and expenditure in yoga intervention versus non-yoga intervention group using asthma control test. Only outcome assessor was blinded. Participants were allocated into two groups in 1:1 ratio. This study was conducted after receiving approval from Institute Ethics Committee of All India Institute of Medical Sciences, Rishikesh (Ethics number). The study was registered on Clinical Trial Registry of India (CTRI/2020/02/023534)

#### 2.2. Sample size calculation

Sample size was calculated to compare means of two-independent groups with an effect size of 0.57, alpha error = 0.05 and power of study = 0.95. A sample size of 158 participants was calculated by G\*Power version 3.1, which was adjusted for 20% attrition. Thus, a final sample size of 200 was considered for this study.

### 2.3. Inclusion and exclusion criteria

Patients between age of 18 years–60 years who were diagnosed with mild to moderate asthma as per Global Initiative for Asthma (GINA) guidelines, with no exacerbation in past one month were screened and enrolled. As per the exclusion criteria of this study, hose with musculoskeletal disorder, cervical, back pain; history of arthritis, hypertension or any other major disease like history of myocardial infarction, stroke, end stage renal disease; and those unwilling to provide written informed consent were excluded from the study.

#### 2.4. Randomization, allocation and baseline measure

192 participants were found to be eligible after screening and they were randomized (1:1) into yoga (n = 99) or non-yoga (n = 93) exercise groups. Randomization was done by computer generated random numbers and sequentially numbered opaque sealed envelopes were used for allocation concealment. ACT was performed from one week onwards and expenditure at baseline was estimated for both groups.

#### 2.5. Yoga exercise and non-yoga exercise groups

A 30 min structured yoga exercise (Table 1) was delivered everyday by a qualified yoga instructor through a virtual platform for six days every week with one day off for a total duration of three months. For ease of performing yoga, recorded sessions were made available and also, pictorial depictions of yoga steps were provided. Non-yoga exercise included joint loosening exercises which were self-practiced at home for six days every week with one day off for three months. Both groups



Fig. 1. CONSORT Diagram of study.

received standard medical care during the period of this study. Asthma Control Test was performed at one week after enrolment and then every week till 13 weeks. Weekly scores were calculated for each group and ACT outcomes were compared at 5 weeks, 9 weeks and 13 weeks.

#### 2.6. Statistical analysis

An independent samples t-test compared mean outcomes between yoga and non-yoga exercise groups in a per-protocol analysis. At baseline, ACT was performed by all participants and was later compared to scores at 5 weeks, 9 weeks and 13 weeks respectively using a generalized linear model repeated measures analysis of variance (RM-ANOVA). Continuous variables were analyzed using independent sample *t*-test. Between and within -group comparisons were also made to determine if change in one group was significantly greater compared to the other groups. A p-value of less than 0.05 was considered significant.

## 3. Results

During this trial, a total of 192 participants were allocated to either yoga exercise (n = 99) group or non-yoga exercise (n = 93) group. Out of 192 participants, 27 participants dropped from both arms during the

#### Table 2

Demographics and baseline values.

	Yoga (N = 99)	Control (N = 93)	
Age in years (mean $\pm$ SD)	$\textbf{37.52} \pm \textbf{11.23}$	$\begin{array}{c} \textbf{39.14} \pm \\ \textbf{12.71} \end{array}$	p = 0.348
Total duration of asthma in	81.34 (±	87.56 (±	<b>p</b> =
months (mean $\pm$ SD)	99.13)	86.93)	0.644
Sex % (n)			
Male	44.4 % (44)	49.6 % (46)	100 %
Formala			(99)
Feiliale	55.0 % (55)	50.5 % (47)	(03)
Height in $cm$ (mean $+$ SD)	163 40 +	161 01 +	(93) n —
Height in the (mean $\pm 3D$ )	103.40 ±	13.26	P 0 314
Weight in kg (mean $+$ SD)	10.40 65 13 $\pm$ 11 15	$62.01 \pm 9.58$	n –
Weight in kg (mean $\pm$ 5D)	$05.15 \pm 11.15$	$02.01 \pm 9.50$	P 0.056
Occupation $\%$ (n)			0.050
Not working	4%(4)	43%(4)	n —
Work at home	41.4 % (41)	36.6 % (34)	0.900
Work outside home	22.2 % (21)	21.5 % (20)	
Student	18.2 % (18)	17.2 % (16)	
Service	11.1 % (11)	17.2 (16)	
Business	3 % (3)	3.2 % (3)	
Smoking % (n)			
Smoker	5.1 % (5)	4.3 % (4)	<b>p</b> =
Non-smoker	82.8 % (82)	86.0 % (80)	0.828
Ex-smoker	12.1 % (12)	9.7 % (9)	
Alcohol % (n)			
Alcoholic	9.1 % (9)	5.4 % (5)	<b>p</b> =
Non-alcoholic	83.8 % (83)	88.2 % (82)	0.595
Ex-alcoholic	7.1 % (7)	6.5 % (6)	
Other addiction(s) % (n)			
No	93.9 % (93)	95.7 % (89)	$\mathbf{p} =$
Yes	2 % (2)	3.2 % (3)	0.828
In past	4 % (4)	1.1 % (1)	
History of medical illness % (n)			
Yes	21.2 % (21)	19.4 % (18)	$\mathbf{p} =$
No	78.8 % (78)	80.6 % (75)	0.858
On medications % (n)			
Yes	13.1 % (13)	12.9 % (12)	$\mathbf{p} =$
No	86.9 % (86)	87.1 % (81)	0.963
Asthma Control Test (n) 1 week	$12.90\pm3.98$	$\textbf{9.90} \pm \textbf{2.68}$	p <
	(83)	(82)	0.001

## Table 3

Mean ACT scores at different time points (week 1, 5, 9 and 13) during the study are given in table below.

Group	Week 1	Week 5	Week 9	Week 13
Yoga exercise	12.90 ± 3.98	14.94 ± 3.26	$18.18 \pm 2.77$	21.45 ± 2.64
(n=83)	(13.64,	(15.56,	(18.73,	(21.96,
	12.16)	14.31)	17.62)	20.95)
Non-yoga	$9.90 \pm 2.68$	$11.61 \pm 2.46$	$13.85\pm2.33$	$15.65 \pm 1.92$
exercise	(10.64, 9.16)	(12.24,	(14.41,	(16.16,
(n=82)		10.97)	13.29)	15.15)
Mean	$3\pm0.52$	$3.33\pm0.45$	$4.32\pm0.39$	$5.79 \pm 0.36$
difference $\pm$	(4.04, 1.95)	(4.22, 2.44)	(5.11, 3.53)	(6.51, 5.08)
SD				

All mean values are reported with standard deviation and upper and lower bound of 95 % confidence interval.

second wave of corona virus disease. Eight patients expressed their inability to participate (Fig. 1). 83 participants in yoga exercise arm and 82 participants in non-yoga exercise arm completed the study and were included in final analysis.

## 3.1. Demographics and baseline data

At baseline, both yoga intervention and control group had similar demographic profile. The demographic and baseline values are outlined in Table 2.

#### Table 4

Pairwise comparison	of ACT	scores at	week 5	, 9	and	13.
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Week A – Week B	Mean difference	Significance (P)	95 % Confidence interval for difference
Week 5 – Week 1	1.827	<0.001	2.330, 1.413
Week 9 – Week 1	4.614	<0.001	5.164, 4.065
Week 9– Week 5	2.742	<0.001	3.149, 2.336
Week 13 – Week 1	7.155	<0.001	7.790, 6.520
Week 13 – Week 5	5.283	<0.001	5.777, 4.790
Week 13 – Week 9	2.541	<0.001	2.920, 2.162

The mean difference was significant at p < 0.005.

#### 3.2. Asthma control test

In yoga exercise group and non-yoga exercise group, a slow decline in ACT scores of participants was observed. This decline reached a meaningful value of score more than 19 points at week 13 (Table 3). A similar declining trend was observed in the non-yoga exercise group; however, participants could not achieve a meaningful ACT score (Table 3 and 4). The assumption using Mauchly's test of Sphericity was not met (p < 0.001). The results of Greenhouse-Geisser (df = 5) = 0.75, p < 0.001 and Huynh-Feldt (df = 5) = 0,0.765, p < 0.001 were found to be significant. A repeated measures ANOVA test was run and a significant difference (F = 539.72, df = 1.1618; p=<0.001) was found between ACT scores at different time points (Figure). On multivariate analysis, a significant time effect was found in the yoga group. Wilk's lambda (F = 335.844, df = 3) = 0.138 and Pilai's trace (F = 335.844, df = 3) = 0.862, partial eta squared = 0.862 were found to be significant (p < 0.001). Mean response were adjusted for both groups and marginal means (Figs. 2 and 3) show the difference in the weekly mean responses of ACT in both groups. The results of ANOVA for time effect - within subject effect and between-subjects were found to be statistically significant. Greenhouse-Geisser effect (F = 23.028, df = 2.249, p < 0.001) and Huynh-Feldt (F = 572.855, df = 2.296, p < 0.001), partial eta squared = 0.124 were found to be significant. Also, tests of betweensubject effects of yoga exercise improved with time at a p < 0.001, F (1) = 119.284 and partial eta squared = 0.423. Thus, yoga intervention had a significant impact on symptoms and asthma control among asthmatics with time. A 13 weeks voga exercise with standard of care provides a clinically significant exacerbation control.

## 3.3. Comparison of expenditure at week 13

In this study we compared the expenditure of asthmatics on medications during past one month at the end of study. Yoga exercise group spent 2171.68  $\pm$  561.53 Indian rupees (INR). Non-yoga exercise group spent 3180.24  $\pm$  490.72 INR. Expenses in each group were compared using *t*-test, which yielded a significant mean difference in their expenditure on asthma medications using a two-tailed hypothesis. Mean difference was 1008.55 $\pm$  82.13 (846.36, 1170.75), p < 0.001.

#### 3.4. Exacerbations in yoga exercise and non-yoga exercise groups

More participants reported no exacerbations from yoga exercise group (47) while lesser participants reported at least one episode of exacerbation from same group compared to non-yoga exercise group. However, higher number of participants reported more than 2 exacerbations from yoga exercise group. Overall, higher number of exacerbations were observed in non-yoga exercise group (42) than yoga exercise group (36). The association between exercise and exacerbation was statistically not significant (p = 0.224).



Fig. 2. Mean weekly Asthma Control Test scores (Red dots) in yoga exercise and non-yoga exercise groups.



Fig. 3. Mean Asthma Control Test scores (Red dots) at week 1, week 5, week 9 and week 13 in yoga exercise and non-yoga exercise groups.

### 3.5. Expenditures by mild and moderate asthmatics

Expenditure between two groups was compared at baseline and at the end of study. Participants were divided into subgroups of mild asthma and moderate asthma. Out of 68 mild asthmatics, 36 were in yoga exercise group and 32 in non-yoga exercise group. Out of 97 moderate asthmatics, 47 were in yoga exercise group and 50 in non-yoga exercise group. Mean expense in mild asthmatics yoga exercise group was  $2258.33 \pm 492.22$  INR and  $3243.75 \pm 474.97$  INR in non-yoga ex-

ercise group. Mean expense in moderate asthmatics yoga exercise group was  $2105.31\pm 605.96$  INR and  $3139\pm 501.01$  INR in non-yoga exercise group. Mean difference between yoga and non-yoga exercise groups in mild asthmatics was statistically significant F(1) = 70.135, p < 0.001 and partial eta squared was 0.575. Mean difference between yoga and non-yoga exercise groups in moderate asthmatics was statistically significant F(1) = 84.343, p < 0.001 and partial eta squared was 0.47.

#### 4. Discussion

In this randomized controlled trial, we compared impact yoga versus non-yoga exercises on Asthma Control Test and expenditure at the end of study. Blinding wasn't not possible due to the nature of the yoga and non-yoga exercises, thus the participants remained unblinded. One of the investigators was a yoga trainer. Drop-outs of the study has been reported with reasons (Fig. 1).

Asthma Control Test was used in this study. Although, other questionnaires like Asthma Control Questionnaire (ACQ), Childhood Asthma Control Test (C-ACT), Asthma therapy Assessment Questionnaire (ATAQ), Asthma Quality of Life Questionnaire (AQLQ) and the Asthma Control Scoring System (ACSS) are validated for use in asthma patients we employed ACT for this study [6,7]. Since, information was collected telephonically, ACT was perceived easy for self-administration in this study.

An increment in ACT score by more than 19 points is meaningful in asthma control. In this study, although groups were significantly different at baseline, none of the groups had score more than 13 points as odds of having asthma control increase with baseline values of less than 13 [8]. Moreover, it was observed that a meaningful ACT score was attained in yoga exercise group only after 9 weeks of yoga exercise (Fig. 2). Yoga exercise at 13 weeks yielded scores that were comparable to ACT score in other studies [9,10]. Non-exercise group participants did not reach this cut-off of 19 points by 13 weeks. Exacerbation rates differed, with fewer observed in the yoga group. Thus, it can be

#### A. Yadav et al.

suggested that yoga exercise imparts better asthma symptom and exacerbation control.

### 5. Conclusion

Yoga exercises improves asthma control with a difference of more than 5 points at 13 weeks in yoga exercise group compared to non-yoga exercise group with additional benefit of decreasing exacerbation related-expenses.

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### **CRediT** author statement

Anshu: Conceptualization, project administration, data curation, analysis; Khushboo Bisht: Writing original draft, review and editing; Girish Sindhwani: Conceptualization, resources, methodology, validation, final draft review and supervision; Ranjeeta Kumari: supervision.

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