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The efficacy of lifestyle changes based on the principles of yoga in the management of bronchial asthma

Submission date	Recruitment status	[_] Prospectively registered
08/10/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/10/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/08/2009	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N-581

Study information

Scientific Title

Effect of yoga on pulmonary function, mast cell activation and quality of life in bronchial asthma: a randomised controlled trial

Study objectives
There are several studies suggesting that yoga has a favourable effect on the frequency and severity of attacks, pulmonary functions, dependence on medication and quality of life in bronchial asthma. Nevertheless, very few of the previous studies are randomised controlled trials (RCT), and none of them have investigated any immunological mechanisms by which yoga might work in bronchial asthma.

Bronchial asthma is characterised by hyperreactivity of airways leading to airway obstruction, and is aggravated during stressful periods. Therefore yoga, which leads to improvement in respiratory function as well as stress reduction, is likely to be useful in the management of bronchial asthma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of All India Institute of Medical Sciences (AIIMS) for human studies approved the original protocol of the study on 9th February 2001 and amendments were approved on 7th January 2004.

Study design
Parallel-group randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bronchial asthma

Interventions
Group I (yoga group) was given an integrated course on lifestyle based on the principles of yoga for 2 weeks while continuing with the conventional treatment. At the end of the 2-week training, participants were asked to continue the practice at home for an additional 6 weeks. Parameters were recorded at regular intervals (0 weeks, 2 weeks, 4 weeks and 8 weeks). During the follow-up period, the patients were expected to continue the yoga practice daily. Their compliance was monitored by a diary, which they brought at each visit.

Group II (control group) was a wait-listed control group. For the first 8 weeks, the patients in Group II did not receive any yogic intervention but they continued to receive conventional treatment. The parameters were recorded at regular intervals as in Group I. At the end of 8 weeks, the patients in Group II were also offered yoga intervention as for Group I, i.e. a two-week course.

Parameters from both the groups are recorded at regular intervals at 0 weeks, 2 weeks, 4 weeks and 8 weeks, although the last timepoint for recording parameters was not equally separated,

taking our patients convenience and continued compliance into consideration, we have kept 4 week separation for last study visit.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Spirometric indices of pulmonary function
2. Eosinophilic cationic protein as a marker of the course of the disease
3. The degree of exercise-induced bronchoconstriction as percentage of fall in FEV1 with exercise challenge
4. Urinary concentration of the prostaglandin D2 metabolite, 11 beta-Prostaglandin F2a (11 beta-PGF2a), before and after the exercise challenge as a marker of mast cell activation

Recorded at regular intervals at 0 weeks, 2 weeks, 4 weeks and 8 weeks.

Key secondary outcome(s))
1. Asthma quality of life: quality of life was measured by using a self-administered Asthma Quality of Life Questionnaire (AQLQ) which is available in bilingual form, i.e. English and Hindi (local Indian language)
2. Frequency of rescue medication

Recorded at regular intervals at 0 weeks, 2 weeks, 4 weeks and 8 weeks.

Completion date
28/02/2006

Eligibility

Key inclusion criteria
The potential subjects (adults of either sex) went through a step-wise screening procedure which consisted of satisfying the following criteria:
1. Clinical history of episodic airway obstruction
2. Forced expiratory volume of one second (FEV1), or peak expiratory flow rate (PEFR) less than 80 percent of predicted normal and more than 10% or at least 200 mL increase in FEV1 15 minutes after administration of two puffs of salbutamol
3. Presence of at least two clinical criteria of mild or moderate bronchial asthma for at least 6 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Any respiratory tract infection during the past 4 weeks
2. On systemic or oral corticosteroid therapy
3. Smokers (any one who had smoked during the last one year was considered a smoker)
4. Concomitant major illness such as coronary heart disease, renal disease or diabetes
5. Practiced yoga or any other similar discipline during 6 months preceding the study

Date of first enrolment
19/04/2002

Date of final enrolment
28/02/2006

Locations

Countries of recruitment
India

Study participating centre
Department of Physiology
New Delhi
India
110029

Sponsor information

Organisation
Central Council for Research in Yoga & Naturopathy (CCRYN) (India)

ROR
https://ror.org/02h2r8882

Funder(s)

Funder type
Research organisation

Funder Name
Central Council for Research in Yoga & Naturopathy (CCRYN) (India)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/07/2009		Yes	No
Abstract results		25/05/2007		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes