

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

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

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.

Primary study design

Interventional

Study design

Parallel-group randomised controlled trial

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