The Integrated Approach of Yoga Therapy for Irritable Bowel Syndrome (IAYT-IBS) study

Submission date	Recruitment status	Prospectively registered
24/11/2013	No longer recruiting	[_] Protocol
Registration date	Overall study status	[] Statistical analysis plan
31/12/2013	Completed	[_] Results
Last Edited 31/12/2013	Condition category Digestive System	Individual participant data
		[_] Record updated in last year

Plain English summary of protocol

Background and study aims

We are carrying out a study of therapeutic effect of yoga in patients with irritable bowel syndrome (IBS) (gut disorder). Our goal is to find if yoga is a viable alternative treatment option to be included for IBS patients. The studys findings should help to include yoga as therapy for IBS patients and to enhance the quality of life in IBS patients.

Who can participate?

All adults 18 years of age and older with IBS within the southern California region to enroll in the study.

What does the study involve?

The present study involves postures, breathing control and meditation on physical and emotional symptoms in adults, suffering from IBS. All the participants will be divided randomly into three groups, yoga group, combination group and wait listed control group. All participants will participate in the three assessments at the start (0 week), mid (end of 6 weeks) and the end (end of 12 weeks). Every participant will be in the program for 12 weeks. At the end of the study, we will compare the IBS symptoms severity and quality of life between the groups, specifically yoga and combination groups against the control group.

What are the possible benefits and risks of participating?

Besides gaining relief from the symptoms of IBS, participants will be learning to better manage these symptoms and causes in the future as the changes comes from within oneself through yoga practices. Participants will be adding to the knowledge about a new long-term approach of IBS management. We hope that this new approach can help in finding a way to reduce the prevalence of IBS. It will also help to reduce the amount of medication to control the symptoms of IBS. The risks are none, when Yoga postures are done correctly. The principal researcher and the team will take every precaution to avoid any kind of wrong postures.

Where is the study run from?

This study is run from the White Memorial Medical Center (WMMC), Los Angeles, USA.

When is the study starting and how long is it expected to run for? Recruitment started in late 2012 and is expected to run for 2 years.

Who is funding the study? Vivekananda Yoga Research Foundation- Los Angeles (VYASA-LA) is funding the project.

Who is the main contact? Dr Senthamil Selvan, senthamils59@gmail.com Vijaya Kavuri, vijaya_kavuri@yahoo.com

Contact information

Type(s) Scientific

Contact name Dr Senthamil Selvan

Contact details 11722 Farina St Norwalk United States of America 90650

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers IAYT-IBS-001

Study information

Scientific Title

A randomized controlled study to determine whether the integrated approach of yoga therapy is effective in managing/reducing the symptoms of irritable bowel syndrome patients

Acronym IAYT-IBS

Study objectives

It is hypothesized that the integrated approach of yoga therapy will benefit the irritable bowel syndrome (IBS) patients in reducing the severity of IBS symptoms and improving quality of life compared to a wait-list control group.

Null hypothesis: there will be no difference in the severity of IBS symptoms and quality of life in the yoga and combination groups compared to the wait-list control group.

Ethics approval required

Old ethics approval format

Ethics approval(s) White Memorial Medical Center Institutional Review Board, 02/06/2012, ref: IAYT-IBS-001-VYASA-LA/WMMC

Study design Three groups, three time assessments, randomized controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Irritable bowel syndrome

Interventions

The study will involve 75 IBS patients aged 18 and older, female/male, to complete the study. They will be randomized into one of the three groups: Yoga group, Combination group and Waitlisted Control group. Participation will be for 3 months (12 weeks).

Yoga group: will participate in three, one hour long, yoga classes a week, for 12 weeks. They are also asked to voluntarily reduce their medication to three times a week.

Combination group: will participate in three, one hour long, yoga classes a week for 12 weeks. They can take their medication as directed by their physician.

Wait-listed Control group: will continue with their medication and are encouraged to walk three times a week.

All groups will come for three assessments: baseline (before starting the study period, 0 week), mid assessment (end of 6 weeks) and post assessment (end of 12 weeks).

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

1. Irritable Bowel Syndrome Symptom Severity Score (IBS-SSS)

2. Irritable Bowel Syndrome Quality of Life (IBS-QOL)

Time points of measurements: 0 weeks (base line), 6 weeks (mid) and 12 weeks (end).

Secondary outcome measures

- 1. Hospital Anxiety and Depression Scale (HADS)
- 2. Autonomic Nervous System Symptom Score (ANS-SS)
- 3. Body Mass Index
- 4. Physical Flexibility hip and trunk
- 5. Physical Flexibility shoulder
- 6. ANS Sympathetic Reactivity Hand Grip test (4 minutes)
- 7. ANS Sympathetic Reactivity Mental Math test (5 minutes)
- 8. ANS Parasympathetic Reactivity Deep Breathing test (3 minutes)
- 9. ANS Parasympathetic Reactivity 30:15 (standing from a lying down position)

Time points of measurements: 0 weeks (base line), 6 weeks (mid) and 12 weeks (end).

Overall study start date

01/11/2012

Completion date

31/10/2014

Eligibility

Key inclusion criteria

- 1. IBS patients, male and female adults 18 years of age and older
- 2. Consent to participate in the study
- 3. Not enrolled in any other alternative medical program
- 4. Not practiced yoga in the last 6 months

Participant type(s)

Patient

Age group

Adult

Lower age limit 18 Years

Sex Both

Target number of participants

75 IBS patients to complete the study (not including dropouts)

Key exclusion criteria

1. Physical disability that prevents the patient from doing yoga

- 2. Pregnancy
- 3. Mental disability that prevents the patient from doing yoga
- 4. Any organic bowel disease

Date of first enrolment 01/11/2012

Date of final enrolment 31/10/2014

Locations

Countries of recruitment United States of America

Study participating centre 11722 Farina St Norwalk United States of America 90650

Sponsor information

Organisation

90650

Vivekananda Yoga Research Foundation - Los Angeles (Vivekananda Yoga Anusandhana Samsthana - Los Angeles) (USA)

Sponsor details 11722 Farina Street Norwalk United States of America

Sponsor type Research organisation

Website http://vivekanandayoga.org

Funder(s)

Funder type Other

Funder Name

Vivekananda Yoga Research Foundation - Los Angeles (Vivekananda Yoga Anusandhana Samsthana - Los Angeles) (USA)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary Not provided at time of registration