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

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

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
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Contact information

Type(s)
Scientific

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

Sponsor details
11722 Farina Street
Norwalk
United States of America
90650

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