

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Meditation and Yoga for Irritable Bowel Syndrome: Study Protocol for a Randomized Clinical Trial (MY-IBS Study)
AUTHORS	D'Silva, Adrijana; Marshall, Deborah; Vallance, Jeffrey; Nasser, Yasmin; Rajagopalan, Vidya; MacKean, Gail; Raman, Maitreyi

VERSION 1 – REVIEW

REVIEWER	Sugaya, Nagisa Yokohama City University, School of Medicine
REVIEW RETURNED	20-Dec-2021

GENERAL COMMENTS	<p>This paper describes the background and methods in detail. I look forward to seeing the results of the intervention. Some points that I would like you to consider are as follows.</p> <p>In the abstract, please describe what "MY" in "MY-YOGA" means.</p> <p>In the Methods section, please describe the gender ratio of the participants for this study.</p> <p>Can you assess the participants' proficiency in yoga or the mediating variables in the mechanisms that yoga affect the outcomes in this study?</p>
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REVIEWER	Desai, Geetha Department of Psychiatry, National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore
REVIEW RETURNED	05-Feb-2022

GENERAL COMMENTS	<p>I think the study appears to be a feasibility RCT. It may be better to mention the same.</p> <p>The age range is wide and it may be possible that many may have comorbid medical conditions, in which some of the postures (not all) are contraindicated. How will account for that? Do you think yoga is an add on therapy for IBS? as both groups are likely to be on treatment. Good to use the term Upa yoga rather Hatha Yoga. Who will be conducting the assessments? would the person be blind to the intervention? There are multiple secondary outcomes. It may be difficult to have any meaningful interpretations with this sample size. Do you include any advice related to diet as part of upa yoga (satvik, frequency of meals? Often IBS is comorbid with other FSS. How will you account for the same?</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Nagisa Sugaya, Yokohama City University

Comments to the Author:

This paper describes the background and methods in detail. I look forward to seeing the results of the intervention. Some points that I would like you to consider are as follows.

We thank the Reviewer for their positive comments and constructive review.

In the abstract, please describe what "MY" in "MY-YOGA" means.

We apologize for this oversight and thank the reviewer for bringing it to our attention. We have now changed the statement in the introduction section of the abstract from: "The primary aim of the MY-IBS randomized controlled trial..." to "The primary aim of the Mind and Yoga for IBS (MY-IBS) randomized controlled trial..."

In the Methods section, please describe the gender ratio of the participants for this study.

Thank you for this suggestion. We have changed the following statement to include variables used to randomize participants. The following statement: "A statistician blinded to the randomization key will create a computer-generated REDCap randomized sequence to allocate participants." now reads "A statistician blinded to the randomization key will create a computer-generated REDCap randomized sequence to allocate participants based on gender (1:1:1 male:female:other) and depression (1:1 depression:no depression)."

Can you assess the participants' proficiency in yoga or the mediating variables in the mechanisms that yoga affect the outcomes in this study?

Participants will be asked if they have previous experience with yoga, and if they are currently practicing yoga prior to study participation. Proficiency of their practice will be assessed by the yoga facilitator who will observe the participants' practice during the yoga visits. Practice corrections will be supplied during each virtual visit. With this study design, the effectiveness of the intervention on various clinical outcomes can be evaluated, however, the mechanisms for the effectiveness (should we demonstrate any) cannot be inferred. Future directions would include an assessment of mechanisms (brain imaging, heart rate variability, gut microbiome brain interactions, etc.).

Reviewer: 2

Dr. Geetha Desai, Department of Psychiatry, National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore

Comments to the Author:

We thank the Reviewer for their positive comments and constructive review.

I think the study appears to be a feasibility RCT. It may be better to mention the same.

We agree that feasibility is an important outcome of this study, however the study is powered to detect differences in the study primary outcome. Therefore, it may be better described in its current form as a traditional RCT.

The age range is wide and it may be possible that many may have comorbid medical conditions, in which some of the postures (not all) are contraindicated. How will account for that?

The Reviewer is correct in that some participants may not be able to perform some of the postures. In the Intervention section of the Methods we describe: "The yoga facilitator will provide participants with modifications for common challenges to support best practices and ensure safety." We agree that some participants may not be able to engage in some postures. The yoga facilitator will provide individualized modifications to participants to support safety and efficacy.

Do you think yoga is an add on therapy for IBS? as both groups are likely to be on treatment.

We agree with the Reviewer. In the Introduction, we describe: "Therapies focusing on mind-body interactions and stress reduction may be adjunctive treatments for IBS." In the Conclusion, we stated: "Study findings may aid in developing interventions and services tailored to patients with IBS." These statements were included because we agree yoga is an adjunctive therapy for IBS.

Good to use the term Upa yoga rather Hatha Yoga.

We thank the Reviewer for bringing this inconsistency to our attention. We changed the following sentence to say "Upa" rather than "Hatha" yoga in the Abstract. We refer to the intervention as Upa yoga in the remainder of the manuscript.

Who will be conducting the assessments? would the person be blind to the intervention?

We have added the following statement under Data Management in the Methods section to make this clearer: "Effectiveness outcome measures, program satisfaction, attendance, and adherence will be entered by the participants. Recruitment, attrition, and safety will be recorded by the study coordinator who is not blinded to the randomization."

There are multiple secondary outcomes. It may be difficult to have any meaningful interpretations with this sample size.

The study was powered based on the primary outcome measure (IBS Symptom Severity Score). We also ensured the sample size was adequate to demonstrate outcomes in the secondary measures of quality of life, depression, and anxiety. For the secondary outcome measures that we did not power, these are exploratory analyses.

Do you include any advice related to diet as part of upa yoga (satvik, frequency of meals?).

We recognize that many formal yoga programs include a dietary component to enhance the effectiveness of yoga outcomes. However, for this study, no recommendations about dietary practices were provided to participants. They were free to continue with their habitual diet.

Often IBS is comorbid with other FSS. How will you account for the same?

That is correct. We will ask participants to self-report on commonly diagnosed comorbidities in IBS patients such as IBD, GERD, functional dyspepsia, fibromyalgia, chronic fatigue syndrome, and alike. We will evaluate the IBS sub-group responders by comorbid status.

VERSION 2 – REVIEW

REVIEWER	Sugaya, Nagisa Yokohama City University, School of Medicine
REVIEW RETURNED	07-Apr-2022
GENERAL COMMENTS	Authors have responded to my comments sufficiently. Thank you.