

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

TITLE (PROVISIONAL)	Yoga therapy on elderly patients with fear of fall – An open label randomized controlled trial (YOFEAR trial)
AUTHORS	Kashyap, Kritartha; Dhar, Minakshi; Bisht, Khushboo; Bahurupi, Yogesh; Pathania, Monika

### VERSION 1 – REVIEW

REVIEWER	Franco, Marcia The George Institute for Global Health, Musculoskeletal Division
REVIEW RETURNED	17-Jan-2023

GENERAL COMMENTS	<p>Thank you for the opportunity to review this study protocol. It is a well-designed RCT evaluating the effect of a 12-week Yoga intervention among older people with fear of fall. The primary outcomes are fear of falling measured by FES-I and Berg balance scale. I have some comments, please see below.</p> <ol style="list-style-type: none"> <li>1. The exclusion criteria of patients with known psychiatric disorders and who are under current treatment for the same conditions needs more clarity about any specific cut off point and duration of treatment prior to recruitment. Depression, for instance, is a common psychiatric condition among the older population. Do authors are planning to exclude any participant diagnosed with depression? This could limit generalizability of the study results.</li> <li>2. Authors state that most of the yoga postures will be completed in sitting posture. This fact is likely to hinder significant improvements in balance and confidence while walking. I suggest authors to include more standing postures for better results.</li> <li>3. Please describe the maximum number of participants in each yoga session.</li> <li>4. Authors state that each session of yoga will last 30 minutes. Please clarify if aerobic or other types of exercise will be taken.</li> </ol>
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REVIEWER	Sivaramakrishnan , Divya The University of Edinburgh, Scottish Collaboration for Public Health Research and Policy
REVIEW RETURNED	04-Feb-2023

GENERAL COMMENTS	<p>Thank you for the opportunity to review this manuscript. It is great to see that this work is being undertaken. However, I think more detail needs to be provided within the protocol to ensure that it is robust. One concern is that the language, grammar and typos sometimes inhibit clarity and flow. Some sections lacked depth and nuance, with general statements, lacking appropriate citations.</p>
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	<p>Your background and rationale do not refer to the literature in the field. While you have attached the CONSORT checklist, several sections are incomplete (also because the trial is not yet complete). However, I would suggest using the SPIRIT checklist, which is more appropriate for protocols and recommended by BMJ open. More specific point given below:</p> <ol style="list-style-type: none"> <li>1. Please provide an aim or objective in the abstract.</li> <li>2. The strengths and limitations are vague (example: parameters being assessed are more relevant for this group of patients"). Could they be rewritten to be more specific and highlighting the methodological strengths and limitations clearly.</li> <li>3. Line 50, Page 4: "Huang et al defines fall as" - no reference provided for this. Please check the definition provided.</li> <li>4. Line 6, Page 5: "FOF is greatest fear among geriatric population and the prevalence is estimated to be around 40 to 73 percent in those with FOF"</li> </ol> <p>This does not make sense and the numbers are repeated (incorrectly) from the second sentence of introduction (Line 39, Page 4). Please correct the statement and avoid repetition.</p> <ol style="list-style-type: none"> <li>5. Line 13, page 5: "However, not many interventional studies have been till date"- International studies relating to what? It would be good to specify what literature is available on interventions relating to falls.</li> <li>6. Several section in the introduction do not have citations (Lines 14-23, Page 5)</li> <li>7. The introduction should have information on existing knowledge. No evidence relating to interventions on fear of falls have been provided. No evidence on yoga and fear of falls/balance/quality of life have been provided (what studies exist, effectiveness etc). Some information on this in the discussion section- please move this to the introduction. Please ensure that the introduction has a clear logical flow, describing the population, intervention, and outcomes.</li> <li>8. Outcomes- Information on outcomes is sparse. The objective includes the instrument (FES-I and BBS) rather than the outcome. More information on balance and quality of life required.</li> <li>9. Yoga intervention: Line 31, Page 8: "Participants will be asked to send a recorded video of their yoga sessions at home on a daily basis to the instructor."</li> </ol> <p>How will you ensure that older people have access to the technology, knowledge and skill to do this? How will this data be stored and used?</p> <ol style="list-style-type: none"> <li>10. Could the intervention section include a description of how the programme will be adapted for different abilities of participants. Will there be any measures to ensure that the programme and setting are appropriate for the population. Could information on the yoga instructor be provided.</li> <li>11. Since home based sessions are a part of the intervention, will any information be provided to participants on what to do in case of any adverse events?</li> <li>12. Table 2- please provide the full forms of the acronyms. Why are some of the data being collected when they are not going to be used in the trial (example- fasting lipid profile, TSH, T3, ECG etc)? Is this paper part of a bigger trial? How will the data collected be used, and if you are not using them, how would you ethically justify collecting this data.</li> <li>13. Data collection- demographic data is mentioned (Line 19, Page 11)- how will this be collected and stored?</li> <li>14. How will you account for aspects such as age and sex in your analysis?</li> </ol>
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	<p>15. Analysis of non parametric data is mentioned in the abstract but not the main text.          15. Line 23, Page 16: "In another study, by Catherine Woodyard(14), it was observed that"          Please state that this is a review article.          16. Please describe your plans for participant recruitment.          17. Reference list is incomplete and has only 15 references. In text citation is not appropriate in some cases (example: Narjes Nick MSc et al, Line 5, Page 16).</p>
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### VERSION 1 – AUTHOR RESPONSE

Author’s Reply to Comments to Reviewer 1, Miss Marcia Franco, The George Institute for Global Health

Comment 1: The exclusion criteria of patients with known psychiatric disorders and who are under current treatment for the same condition is valid for those on antidepressants, antipsychotics for more than 3 months as these medications require a period of three months to manifest their therapeutic effect. Also, patients on such medications need exclusion as these drugs have side effects (eg. dizziness, drowsiness, fatigue) that can affect their posture and balance during yoga. We agree that depression is prevalent amongst elderly, and yoga may benefit such patients. However, this becomes a limitation of our study. Also, we have planned and proposed a study to evaluate the effect of yoga in depressed elderly.

Comment 2: Yoga postures consist of sitting, standing and supine positions. Previously, we drafted the sentence regarding yoga postures mostly to be completed in sitting postures taking into account comfort of elderly patients. Additionally we have now provided a supplementary table indicating yoga postures that could be personalized on a case to case basis, if needed, during conduct of study.

Comment 3: Each yoga session consists of not more than 5 participants. This was based on the available area for the study.

Comment 4: We have now provided a supplementary table indicating yoga postures that could be personalized on a case to case basis, if needed, during conduct of study.

Author’s Reply to Comments to Reviewer 2, Dr Divya Sivaramakrishnan, The University of Edinburgh  
 As appropriately mentioned in the comments, the CONSORT checklist will be completed at the end of this trial.

Comment 1: The objective of the study is provided in the updated abstract.

Comment 2: Strength and limitations have been rewritten and provided in the abstract section.

Comment 3: Since there was discrepancy in “Huang et al defines fall..” reference, we have revised and provided the definition of fall as per Kellogg International Work Group (Reference 6)

Comment 4: As correctly pointed out by the reviewer, there was incorrect repetition in the data which we have revised and now we have provided the correct data on percentage of falls. (Reference 8)

Correct 5: We have elicited references related to interventional studies in falls in elderly and have provided them in references numbered 16-20.

Comment 6: Relevant citations in the introductions have been provided in the introduction.

Comment 7: As suggested by the reviewer, we have moved few informations regarding existing knowledge on fear of fall in elderly from discussion to introduction. We have given a clear description of our research question, mentioned the population and outcomes of interest and intervention planned for the study. We hope the introduction now has a clear logical flow mentioning the population, intervention and outcomes as asked by the reviewer.

Comment 8: The objectives were not framed in a grammatically correct manner and we missed to add the comparison part in the objectives. However, the scales mentioned in the objectives will be used to measure the outcomes. We have now reframed the objectives.

Comment 9: Since most of the postures in the study are comfortable for the participants (Table S1), We do not anticipate any major complications with the exercise. Modifications, if required, will be incorporated after discussion with yoga teacher (Miss Beena) and if done, such modifications will be reported in the results at the time of publication.

Also, if any major modification which will jeopardize the result of this study is required, then such a participant will be excluded. However, if such a participant wants to attend yoga session, they may be allowed after discussion with the treating physician in the interest of potential benefits that may be incurred (as per participants discretion) by yoga therapy.

Comment 10: Participants will be directed to visit emergency service of the hospital where further care or treatment will be provided.

Comment 11: Full forms of the acronyms have been provided at the end of the table. All the data will be collected at baseline and at 12 weeks except 2D Echocardiography, chest x-ray, electrocardiography, which were collected for screening. Based on the results of this study, if any significant difference will be established, we plan to go for a larger trial to explore benefits of yoga on those factors relevant to a particular disease. Table 2 has been updated accordingly.

Comment 12: A case record proforma has been provided in supplementary data as Table S2. This data will be stored in a file in a locker at the data storage facility of the department.

Comment 13: We will analyse and report sex-wise differences between yoga and control group. Age categories will be formed as 60-69 years, 70-79 years and more than equal to 80 years for analysis.

Comment 14: We have included analysis of non-parametric data in the main text as well.

Comment 15: "Another study" has been replaced by "A review article."

Comment 16: Plans of participant recruitment has been provided in section "Patient Enrollment"

Comment 17: Reference list has been revised citing all the relevant references.

#### VERSION 2 – REVIEW

REVIEWER	Franco, Marcia The George Institute for Global Health, Musculoskeletal Division
REVIEW RETURNED	20-Jun-2023

GENERAL COMMENTS	<p>I would like to thank the authors for the responses to my previous comments, which have been addressed satisfactorily. Please see below a few more comments.</p> <p>1) On page 6, authors state that their primary objective was “to compare the effect of yoga intervention therapy in elderly with fear of fall at 12 weeks from baseline on fall scores between the study group and control group assessed by FES-I and BBS.”</p> <p>2) Please explain what “falls scores” means, as FES-I assess fear of falling and BBS assess dynamic functional balance.</p> <p>3) On page 9, line 190, correct the word caregivers. Also, describe some examples of the interventions the control group participants will receive for their primary diseases as per the established respective guidelines.</p> <p>4) On page 11, describe what the abbreviation HMSE stands for.</p>
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### VERSION 2 – AUTHOR RESPONSE

Author’s Reply to Comments to Reviewer 1, Miss Marcia Franco, The George Institute for Global Health

Comment 1: We read the primary objective where ‘fall scores’ is mentioned in the primary objective.

Comment 2: Fall scores was an umbrella term for FES-I and BBS. As appropriately highlighted by your comment fall scores seem to be a confusing term. Hence, we have rectified and reframed primary objective without the term ‘fall scores.’

Comment 3: The word ‘Caregivers’ is corrected to ‘Caregiver.’ We have mentioned an example indicating intervention to be received by participants for their primary disease as per the respective established guidelines in India.

Comment 4: We have described the abbreviation HMSE.

### VERSION 3 – AUTHOR RESPONSE

All authors sincerely thank Editor and both reviewers who helped us in refining the manuscript with their invaluable comments.

### VERSION 4 – AUTHOR RESPONSE

Reply to reviewer 2

We thank you for your intriguing comment. We will analyze and compare baseline data and data retrieved at the end of trial for comparing the results between yoga and control group in elderly age groups and also in different sexes. Age and sex adjusted analysis will be performed using linear multiple regression. Same has been added in the manuscript.