Reviewer's report

Title: Post traumatic stress disorder and heart rate variability in Bihar flood survivors following yoga: a randomized controlled study

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Review for BMC psychiatry of manuscript: “Post traumatic stress disorder and heart rate variability in Bihar flood survivors following yoga: a randomized controlled study.”

The authors studied the efficacy of a seven days yoga-program on heart-rate variability and a few additional outcome measures in survivors of a flood in India. They found that his program did not have an effect on heart rate variability. However, the authors report that there was an effect on feelings of sadness and anxiety.

I found this manuscript to be well-written and interesting. I think the topic is original and culturally relevant. The authors systematically studied the efficacy of an intervention that has not frequently studied before using a randomized controlled design. However, I noticed a few serious methodological problems, with respect to the design, the data-analysis, and the reporting of the results. Below, I will describe my comments to this manuscript, which I hope may be of use in further adaptations of the manuscript.

1. General: The biggest problem of this study is the extremely small sample size (N=22; 11 participants per group). The authors do not find an effect of the yoga-program on their (?) main outcome measure i.e. heart rate variability. It is highly likely that the absence of this effect has been caused by a lack of power. In studies of early interventions after trauma, usually relatively large numbers of participants are needed, because there is a high rate of natural recovery during the first weeks after trauma (see also (Cuijpers, 2003).

Related to the point above, I noticed that in the methods section, the authors do not mention whether they performed a power analysis before they started the trial. If they have done so, they should describe the results of the power analysis in the methods section.

2. General: Another problem is the fact that only an immediate posttreatment assessment was done, but no follow assessment at -for example- 6 months after the flood. These follow-up assessments are important, because in some studies evaluating early interventions after trauma (debriefing studies and studies evaluating psychoeducation), harmful effects of these interventions were found. More specifically, participants who had received an intervention reported more symptoms of PTSD than participants who had not. In some studies these harmful
effects were more pronounced later after the trauma (i.e. after months or years) than in first month (Mayou et al., 2000; Bisson et al., 1997; Sijbrandij et al., 2006). I think this limitation should be mentioned and substantiated in the discussion section.

3. Title page: The title the authors chose, suggests that they studied posttraumatic stress disorder (PTSD) and heart rate variability. However, they did not make formal DSM IV diagnoses of PTSD, therefore the use of the term posttraumatic stress disorder in this context is inappropriate. Perhaps “posttraumatic stress symptoms” would be a better choice.

4. Introduction: On the first page of the introduction section, the authors mention previous studies finding positive effects of yoga on symptoms of PTSD, anxiety and depression (“Clinical studies suggest……, depression and anxiety [3,4, 5]”). Were these studies randomized controlled studies as well? In fact, what led the authors to undertake the current study? Perhaps in the current study certain aspects of the research methodology was improved or a different kind of yoga method was evaluated? I think this point should be elaborated further in the introduction section, since it is not clear what the current study adds to what is already known about the efficacy of yoga after trauma.

5. In the fourth paragraph (“Previously……., people”), the authors describe the results of a previous study conducted in their own research group in Tsununami survivors from the Andaman Islands. A minor detail is that for readers, who are not familiar with the region, it would perhaps be helpful to mention that these islands are located in the Bay of Bengal and belong to India. In addition, the authors do not mention whether this study had a control group, which is essential for interpreting the results.

6. Methods: In the Participants paragraph, the authors describe that the original sample consisted of 1089 participants, who were screened for an increased risk for PTSD. First, the information provided on the screening of participants (mentioned in the participants paragraph), is very limited. For example, how did the authors screen for risk for developing posttraumatic stress disorder? Which instrument was used and which cut-off score was applied? Did the 98% of the original 1089 participants who were not included score below this cut-off? How many participants were excluded for other reasons? All this should be described, preferably in a flow diagram (see: http://www.consort-statement.org/consort-statement/flow-diagram/).

7. Second, since only 2% of the original sample was included, I am worried how the final sample of N=22 compares to the people who were initially asked to participate. Do the authors have information about the original sample, so that they can compare characteristics and know to what extent participants in their sample are representative of Bihar flood survivors in general?

8. Methods: There is a lack of information on the final sample of 22 participants, and the distribution of characteristics across the two groups. The manuscript would be improved by an addition of a table with the most relevant baseline
characteristics for each treatment group, and a comparison between the two groups using independent t-tests and chi-square analyses on these characteristics.

Did the traumatic events the participants experienced in all participants fulfill the stressor A1 and A2 criteria of the PTSD diagnosis in the DSM IV (American Psychiatric Association, 1994)? How many participants had lost relatives or witnessed people dying or thought they were going to die themselves during the flood? In addition, how much time had passed –on average- between the flood and the inclusion in the study?

9. Methods: The authors should explicitly differentiate between their main outcome measure and their secondary outcome measures, to avoid the risks of multiple comparisons (Pocock, 1997).

Further, the authors did not use established and validated instruments to assess symptoms of PTSD or anxiety. How many VAS-scales did they administer? Did they administer a VAS scale for each separate DSM IV symptom? Did they add up the score on the VAS scales? I think the information concerning the psychological self-report scales used, is currently too limited.

10. Results: I wondered why the authors only compared pre- and post assessments within each group by using t-tests for paired data, where in fact one wants to know whether there were differences between the two groups across time. i.e. whether there was an interaction effect between group and time. Therefore, I suggest that the authors reanalyze their data using a two-factor ANOVA test or a similar procedure. Second, did the authors consider to analyze whether the efficacy of the yoga program was mediated by changes in heart rate variability? This would be interesting. Heart rate variability could be added as a covariate to the statistical model.

11. Results: I would advise the authors to follow the CONSORT guidelines in reporting their results. See: http://www.consort-statement.org/consort-statement/

12. Discussion: The finding that the control group experienced an increase in symptoms of anxiety during time is surprising, since most studies show that these symptoms decrease during the first weeks following a traumatic event (e.g. (Shalev et al., 1998). I think this issue deserves more attention in the discussion section.

13. The discussion section would perhaps be more interesting if the authors compare their results with results from studies on, for example, breathing relaxation techniques after trauma, as used in cognitive behavioural treatments, or with mindfulness-based stress relaxation techniques.

14. In addition, the authors only mention the small sample size very briefly in their discussion section, but refrain from explaining what consequences their small N might have had for their the results. Another limitations that should be mentioned are the lack of a follow-up assessment. Also, I would be interested to know whether the authors believe that there results may be generalized to the
whole population of trauma victims of the Bihar flood, or to other populations.

References


Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests.