Author's response to reviews

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

Authors:

Shirley Telles (shirleytelles@gmail.com)
Nilkamal Singh (naosekpamkamal@gmail.com)
Meesha Joshi (meeshie26@gmail.com)
Acharya Balkrishna (pyp@divyayoga.com)

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Author's response to reviews: see over
COMMENT 1: Introduction: Rather than describing the loss of life as "colossal" provide some government estimate of the actual number of lives lost.

RESPONSE 1: A detailed report by the Tata Institute of Social Sciences (Mumbai, India) states that 'the official death toll was 75 (Jha, Raghavan, 2008). However survivors claimed that thousands of people had died as they were washed away with floods, completely unaware and unanticipated. Given the conflicting reports we would prefer not to mention any actual figure as the government estimate of lives lost (i.e., 75) may not be accurate. We hope that this omission is understandable. We have removed the word ‘colossal’ from the sentence.

Reference:

COMMENT 2: Here or in the Discussion section, the authors could mention the study: Descilo T, Vedamurtachar A, Gerbarg PL, Nagaraja D, Gangadhar BNG, Damodaran B, Adelson B, Braslow LH, Marcus M, Brown RP. Effects of a Yoga-Breath Intervention Alone and in Combination with an Exposure Therapy for PTSD and Depression in Survivors of the 2004 Southeast Asia Tsunami. Acta Psychiatr Scand 2009 [in press]. The abstract is available online or through the National Library of Medicine Database.

RESPONSE 2: This reference has been cited in the Discussion section. The additional paragraph is as follows:

‘In a more recent report, a yoga breath intervention which included SKY, was found to relieve psychological distress in survivors of the 2004 South-East Asia tsunami (Descilo, Vedamurtachar, Gerbarg, Nagaraja, Gangadhar, Damodaram, Adelson, Brastow, Marcus, Brown, 2009). In this non-randomized study, 183 tsunami survivors with scores of 50 or
more on the post-traumatic checklist-17 (PCL-17) were assigned to three groups. The three groups were yoga breath intervention, yoga breath intervention followed by 3-8 hours of trauma reduction exposure technique or a wait-list control group. This assignment was for participants within different camp and hence was camp-based. Assessments for post-traumatic stress disorder and depression were performed at 6, 12 and 24 weeks. Scores for post traumatic stress disorder (based on the PCL-17) decreased in the group assigned to yoga breath and in the group with yoga breath with exposure, though it was more in the former group.

This study, unlike the present study had a large sample, a long duration of followup, and used validated instruments. Nonetheless, both reports suggest the benefits of a yoga program which emphasized breathing techniques in PTSD.’

COMMENT 3: How were the participants screened for the possibility of developing PTSD? Was this based on their being directly affected and having lost relatives and friends or property?

RESPONSE 3: Yes, the single criterion we used to screen participants to develop PTSD was their being directly affected by the floods and having lost relatives and friends or property. This is because trauma exposure is known to determine the development of PTSD (Maes, Delmeire, Mylle, Allamura, 2001). We did not use the DSM IV diagnostic criteria for PTSD and this is mentioned as a limiting factor of the study. Also, we did not attempt to assess other possible contributing factors such as the number of previous trauma exposures, which also determines the development of PTSD.

References:

COMMENT 4: Of the 1089 participants, how were the 28 subjects selected? Were there only 28 volunteers or was some other method used?

RESPONSE 4: The lack of clarity in describing how the 28 participants were selected is regretted. The study was restricted to males as the heart rate variability is known to differ
between the sexes, especially for the age group who formed the present sample (Sztajzel, Jung, Bayes De Luna, 2008). There were 544 males among the 1089 participants. Most of the flood survivors were keen to learn yoga and apart from the study, yoga sessions were conducted for the others in the camp. Among 544 males, 65 participants met the other inclusion criteria. These were: (i) normal health, (ii) not on medication, (iii) readiness to be present for all assessments and to be assigned to either yoga or control group and (iv) no prior knowledge of yoga. Many participants had to be excluded as they had a diagnosed illness and were taking prescribed medication. A fifth factor which further limited the number (from 65 who met the inclusion criteria, to 28) was as follows; considering that a month had elapsed after the floods, people were continuously being relocated to other temporary camps closer to the village from which they came. Among the 65 flood survivors who met all our inclusion criteria 28 of them were told that they would not be transferred to another camp during the period of study. Hence the main factor which determined the sample size (which is small), was whether participants would be re-located to another camp during the study, as part of the attempts to restore normalcy and rehabilitate the survivors. After 28 participants were recruited, it was found that 6 of them were to be transferred and hence the final number who took part in the study was twenty-two. The 22 participants were randomized as yoga and control groups (n = 11 each).

These details have been added to the revised manuscript and a consort diagram has also been given.

References:

COMMENT 5: Intervention. In the description of the breath intervention, it would be helpful to indicate the rate of breathing and the length of each of the practices because these are important factors affecting heart rate variability. Also, this information would help in comparing different breath practices to better understand their various observed effects.
RESPONSE 5: The breath rate for the high frequency yoga cleansing breathing (kapalabhati) was approximately 60 breaths per minute. For alternate nostril breathing (anulom-vilom pranayama) the breath rate was approximately 12 breaths per minute, whereas for the breathing practices involving exhalation with a sound (e.g., brahamari and udgheeth pranayamas), the breath rate was lower, approximately 8 breaths per minute.

In the present study the breath rate was not recorded while participants were practicing different yoga breathing techniques. The breath rates mentioned here are based on our unpublished data recorded in normal volunteers who were also novices to yoga and had a single session to learn the techniques.

These details have been added to the Methods section of the revised manuscript.

COMMENT 6: When were the autonomic respiratory variables measured in relation to the breath practices?

RESPONSE 6: The yoga session was in the morning between 6:00 and 7:00 hours. All recordings were taken between 10:00 and 12:00 noon and 15:30 and 18:30 hours. The time of recording for each participant was kept constant for the initial and final assessment.

COMMENT 7: Results. This study is particularly interesting because it showed not only a reduction in sadness in the yoga group, but also an effect of possibly preventing the development of anxiety. This is the first study in which a yoga intervention appears to prevent an increase in anxiety in trauma survivors.

COMMENT 8: Discussion. A more elaborate discussion of the differences in breath techniques as a possible explanation for the lack of change in HRV and respiratory rate in this study as compared to other studies of breath programs in disaster survivors would help to advance the development of more effective breath programs. Some studies consider 10-14 breaths per minute to be slow, whereas other studies show that rates of 5-6 breaths per minute optimize HRV and that small changes in breath rate have significantly different effects on HRV.
RESPONSE 8: The breath rate and heart variability (HRV) are closely related. Respiratory sinus arrhythmia (RSA) is a commonly employed non-invasive measure of cardiac vagal control (Wilhelm, Grossman, Coyle, 2004). Respiratory variables such as tidal volume and breath rate have been shown to change with no change in tonic vagal activity. Hence, concurrent monitoring of respiration and physical activity are considered likely to enhance HRV accuracy to predict autonomic control. This is supported by acute increases in low frequency and total spectrum HRV and in vagal baroreflex gain, which is corrected by slow breathing periods with biofeedback (Lehrer, Vaschillo, Vaschillo, Lu, Eckberg, Edelberg, Shih, Lin, Kuusela, Tahvanainen, Hamer, 2003). It was earlier shown that biofeedback training increased the amplitude of heart rate oscillations at approximately 0.1Hz (Lehrer, Vaschillo, Vaschillo, 2000). To achieve this, breathing is slowed to a point at which resonance occurs between respiratory-induced oscillations and oscillations which naturally occur at this rate. Previously, studies on the effects of specific yoga practices examined whether a decrease in breath rate could have influenced the HRV where an increase in LF power would be related to slower breathing rather than autonomic activity (Sarang, Telles, 2006). In contrast, fast breathing practices have been associated with both increased sympathetic nervous system activity [i.e., kapalabhati (Stancák, Kuna, Srinivasan, VishnuDEVananda, Dostálek, 1991)] as well as reduced sympathetic nervous system activity [i.e., anulom-vilom pranayama (Raghuraj, Telles, 2008)]. In the present study the intervention consisted of both fast and slow breathing practices. As a result the breath rate may not have changed, or reduced as much as in cases where the intervention consisted of slow breathing practices alone. The end result may have been no change in the heart rate variability. This explanation has been added to the Discussion in the revised manuscript.

References:
COMMENT 9: Discussion section paragraph 5. The sentence beginning with "In fact, the close connection between emotional states and breathing........" is not intelligible.

RESPONSE 9: The sentence in the Discussion section (paragraph 5, prior to revision) which begins with ‘In fact, the close connection between emotional states and breathing……’ has been modified. The sentence is now as follows: In fact, the close connection between emotional states and breathing has been demonstrated since six basic emotions have characteristically different sets of breathing patterns [Bloch, Lemeignan, Aguilera, 1991].

References:

COMMENT 10: Discussion section paragraph 6 indicates that the conditions in the camp limited the number of subjects to 28. Clarify how this affected the selection process described in the Methods section.

RESPONSE 10: There were 1089 flood survivors in the camp one month after the floods. The camp was located in the capital city of the state. The aid received was inadequate and even though the survivors’ homes had not been reconstructed, people were continuously being re-located to camps closer to the towns or villages, where they lived. The study was restricted to males as the heart rate variability and vulnerability to
develop PTSD vary with gender (Sztajzel, Jung, Bayes De Luna, 2008; Maes, Delmeire, Mylle, Altamura, 2001, respectively). This has been detailed under the response to Referee 1, Comment 4.

References:

COMMENT 11: The intent of the final sentence of the discussion section might be clearer by deleting "which are recurrent but none the less damaging to health." This last phrase speaks to the significance of this study and of efforts to develop effective interventions to relieve psychological distress in survivors of mass disasters. This point could be made more clearly in a separate sentence.

RESPONSE 11: In the revised manuscript the final sentence of the Discussion has been modified as follows: ‘Despite these limitations the present findings suggest that a week long yoga intervention can reduce self-rated sadness and may prevent an increase in anxiety in survivors of floods. This may be particularly important in developing countries and in the case of survivors of recurrent disasters, where the survivors would know the outcome and hence may have specific apprehensions, for example, that aid may be delayed or inadequate, based on their earlier experiences.’

COMMENT 12: References. The spelling of the name of the first author in reference number 12 should be Franzblau.

RESPONSE 12: The spelling has been corrected in revised manuscript, so that the reference is now: Franzblau SH, Echevarria S, Smith M, Van Cantfort TE: A preliminary investigation of the effect of giving testimony and learning yogic
breathing techniques on battered women’s feelings of depression. *J Interpers Violence* 2008, **23**: 1800-1808.

**References:**


**COMMENT 13:** Overall this study makes an important contribution to the growing literature on interventions to alleviate the psychological and physiological effects of mass disasters. It is particularly challenging to do studies in the aftermath of disasters, but such studies are much needed. The authors have acknowledged the limitations in the number of subjects. Although it is difficult to do longer follow-ups following mass disasters, future studies should attempt to determine whether the benefits of the intervention persisted beyond one week.

**RESPONSE 13:** In the revised manuscript two main limitations of the study have been mentioned in the Discussion. These are (i) the small sample size and (ii) the fact that participants in both groups were assessed after one week of the intervention with no follow up.

**Referee 2:**

**Reviewer’s report**

I’m pleased to see more research on yoga as a therapeutic modality by Shirley Telles and colleagues. I was particularly impressed that the authors were able to conduct this research in the setting in which it was done. Overall, I enjoyed reading this submission and have a number of comments that I hope will help improve the paper. My main general comment is that it would be good to increase the level of detail in the results section and to add to the discussion of the data in the discussion section. Please refer to the numbered comments below.
COMMENT 1: Did the participants practice yoga on their own in addition to the classes? Please add this detail to the paper.

RESPONSE 1: No, the participants practiced yoga only during the one hour yoga session and they were instructed not to practice yoga at other times of the day. The control group did not practice yoga till the study was complete, when they were given the option to learn yoga if they wanted to. These details have been added to the Methods section of the revised manuscript.

COMMENT 2: Add more detail in the results section including reference to the 2 tables.

RESPONSE 2: In response to comment 10 of the third reviewer the Results section has been expanded to include the results of a repeated measures analysis of variance, even though none of the changes were statistically significant. In the revised manuscript the Results section also includes reference to the two tables.

COMMENT 3: What were the results of between group comparisons for both VAS endpoints and heart rate variability?

RESPONSE 3: A repeated measures analysis of variance was performed. There were no significant differences between groups for the four VAS end points and heart rate variability.

COMMENT 4: In general, there should be more content in the discussion section discussing the results.

RESPONSE 4: In the revised manuscript we have attempted to add further details to the Discussion section. This includes possible reasons why there was no change in the heart
rate variability measures as well the main limitations of the study (viz., the small sample size and lack of a long duration follow-up), as well as other details.

**COMMENT 5:** Please add to the discussion section your explanation for the negative findings on VAS items for fear and disturbed sleep.

**RESPONSE 5:** Several details have been added to the revised manuscript.

‘In the present study the intervention focused more on voluntarily regulated yoga breathing than on yoga postures (*asanas*), since voluntarily regulated yoga breathing constituted 50 percent of the total time spent in yoga practice. In another study, the practice of yoga postures (along with guided relaxation) in the day time was associated with an increase in slow wave sleep and a decrease in REM sleep on the subsequent night (Patra, Telles, 2009). In this study, yoga postures were believed to act as a form of mild exercise and exercise is known to promote sleep (Patra, Telles, 2009). The effect of yoga voluntarily regulated breathing alone on sleep has not been studied. The lack of effect on sleep disturbances may hence be related to the fact that at least half the time was spent in yoga voluntarily regulated breathing rather than yoga postures, through the latter are known to have a favorable effect on sleep.

In the present study there was also no change in the level of fear based on a VAS. Among various levels of fear, possibly the most extreme is the fear of death. A one year longitudinal study of two groups [yoga, (emphasizing Buddhist principles of mindfulness, compassion and equanimity) and a control group], showed that the yoga group had decreased fear of death at the end of the year (Scherwitz, Pullman, Metlenry, Gao, Ostaseski, 2006). In the present study there was no attempt to add philosophical aspects of yoga, which include discussions of fear and how to deal with it (Taimini, 1986). This may be considered a limitation of the intervention. However, the philosophical principles of yoga are drawn from ancient texts, often associated with Hindu spiritual beliefs. Since the flood survivors belonged to different faiths some of these principles may not have been acceptable to them and hence we did not add them.’ These details have been added to the Discussion in the revised manuscript.
References:

COMMENT 6: Another limitation of the study is the lack of a control group that controls for attention. For example, did the yoga participants feel better just because someone spent time with them in the classes? Please discuss in the discussion section.

RESPONSE 6: There was a control group. The 22 participants were randomized as a yoga and wait list control group.
We regret if this was not clearly mentioned.

COMMENT 7: A CONSORT diagram should be added to results section. Were any participants lost to follow-up? Did all participants complete all measures?

RESPONSE 7: In the revised manuscript we have mentioned that all 22 participants who were assigned to two groups completed the study. Also, a CONSORT diagram has been added to the revised manuscript.

COMMENT 8: Please discuss how the specific pranayama, asana routine impacted on your findings.

RESPONSE 8: We have attempted to explain how the different yoga practices may have influenced the variables assessed.

‘Previous studies have shown that the practice of yoga postures interspersed with relaxation while supine reduced sympathetic nervous activity more than a comparable period of supine rest alone (Sarang, Telles, 2006). Also, the same combination of
postures and supine rest delayed the latencies of certain evoked potential components which are generated in the cerebral cortex (Subramanya, Telles, 2009). Apart from this, an hour of practicing yoga postures increased the levels of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA) compared to an equal duration of time spent reading (Streeter, Jensen, Perlmutter, Cabral, Tian, Terhune, Ciraulo, Renshaw, 2007). The individual effects of separate asanas have not been worked out.

Apart from yoga postures, loosening exercises (sithilikarana vyayama) were shown to increase flexibility and reduce musculoskeletal discomfort in professional computer users (Telles, Dash, Naveen, 2009).

The effects of yoga breathing practices have been assessed more individually. High frequency yoga breathing (kapalbhati) has been shown to increase the low frequency power of heart rate variability suggesting an increase in sympathetic nervous system activity (Lepicovská, Dostálek, Kovárová, 1990). In contrast alternate nostril yoga breathing (anulom-vilom pranayam; Raghuraj, Telles, 2008) reduced the systolic, diastolic, and mean pressure values suggestive of lower sympathetic nervous system activity. Hence there may have been no overall effect of yoga voluntarily regulated breathing (pranayama) on the sympathetic nervous system activity in participants, which may have been the reason why there was no change in the heart rate variability.’

References:
COMMENT 1: Paragraph 3 in the discussion includes reference to the *Sudarshan Kriya* research. Please correlate these findings to those in this paper.

RESPONSE 1: In the revised manuscript we have attempted to correlate the findings of the two papers as follows:

‘In a more recent report, a yoga breath intervention which included SKY, was found to relieve psychological distress in survivors of the 2004 South-East Asia tsunami (Descilo, Vedamurtachar, Gerbarg, Nagaraja, Gangadhar, Damodaram, Adelson, Brastow, Marcus, Brown, 2009). In this non-randomized study, 183 tsunami survivors with scores of 50 or more on the post-traumatic checklist-17 (PCL-17) were assigned to three groups. The three groups were yoga breath intervention, yoga breath intervention followed by 3-8 hours of trauma reduction exposure technique or a wait-list control group. This assignment was for participants within different camp and hence was camp-based. Assessments for post-traumatic stress disorder and depression were performed at 6, 12 and 24 weeks. Scores for post traumatic stress disorder (based on the PCL-17) decreased in group assigned to yoga breath and in the group with yoga breath with exposure, though it was more in the former group. This study, unlike the present study had a large sample, a long duration of follow-up, and used validated instruments. Nonetheless, both reports suggest the benefits of a yoga program which emphasized breathing techniques in PTSD.’

COMMENT 2: Please discuss the dose of the yoga intervention in the discussion section. Was the ‘dose’ provided in this study adequate? Would a higher dose produce different results?

RESPONSE 2:

Participants practiced an hour of yoga every day. While we have no proof for it, we believe that this duration was adequate. It was also the most practical duration as participants would not have been willing to have a longer duration of practice.
COMMENT 3: It would be helpful to add N values = for each group in Tables 1 and 2.
RESPONSE 3: We have added ‘N’ values in the two tables.

Referee 3:
Reviewer’s report
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.

COMMENT 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.

**RESPONSE 1:** The small sample size is a definite limitation of the study. One of the main reasons for this was that the flood survivors were constantly being relocated to camps elsewhere. We have mentioned this in the revised manuscript as a limitation of the study.

We did not perform a power analysis before the trial, but have done a post-trial (i.e., *post hoc*) analysis using the G power software [Buchner A, Erdfelder E, Faul F, 1996; Power analyses. In: E. Erdfelder, R Manusfeld, T Meiser, G Rudinger (Eds.), Handbook of quantitative methods (pp.123-136) Weinham, Germany: Psychologie Verlags Union]. Based on this, for each of the variables studied we have provided (i) the effect size, (ii) the critical 't' value, two tailed, and (iii) the power, where alpha = 0.05.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Heart Rate Variability</th>
<th>Yoga group (N=11)</th>
<th>Control group (N=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Effect size</td>
<td>Critical t value</td>
</tr>
<tr>
<td>1. LF(n.u)</td>
<td></td>
<td>0.0370</td>
<td>2.08</td>
</tr>
<tr>
<td>2. HF(n.u)</td>
<td></td>
<td>0.0375</td>
<td>2.08</td>
</tr>
<tr>
<td>3. LF/HF</td>
<td></td>
<td>0.4886</td>
<td>2.08</td>
</tr>
<tr>
<td>4. NN50</td>
<td></td>
<td>0.0554</td>
<td>2.08</td>
</tr>
<tr>
<td>5. pNN50</td>
<td></td>
<td>0.3730</td>
<td>2.08</td>
</tr>
<tr>
<td>6. TINN</td>
<td></td>
<td>0.5337</td>
<td>2.08</td>
</tr>
<tr>
<td>7. Breath rate (cpm)</td>
<td></td>
<td>0.2946</td>
<td>2.08</td>
</tr>
</tbody>
</table>
In the table given above it is clear that for both groups the power was low and there was a small effect size. This can be attributed to (i) the small sample size, and (ii) the considerable inter-subject variability in the measurements of HRV studied. This inter-subject variability is not rare and normally a larger sample size increases the effect size.

For the VAS variables, a similar table is given below:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Yoga group N = 11</th>
<th>Control group N = 11</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Effect size</td>
<td>Critical ‘t’ value</td>
</tr>
<tr>
<td>1. Fear</td>
<td>0.4941</td>
<td>2.08</td>
</tr>
<tr>
<td>2. Anxiety</td>
<td>0.4219</td>
<td>2.08</td>
</tr>
<tr>
<td>3. Sadness</td>
<td>0.3357</td>
<td>2.08</td>
</tr>
<tr>
<td>4. Disturbed sleep</td>
<td>0.1302</td>
<td>2.08</td>
</tr>
</tbody>
</table>

From these two tables it is apparent that after completing the trial, a post-hoc analysis showed that for all the variables studied the effect size was small. Given the sample size and effect size the power of the test (a two tailed t-test) was low.

The small effect size may be due to at least two factors. The most important is the small sample size which we recognize as a serious limiting factor of the study. The other factor could be that the follow-up period was one week. After a longer duration of yoga practice a greater magnitude of change may have occurred. There were two reasons why the duration of the follow-up period was kept as one week. The first reason was a practical reason. The flood survivors were continuously being relocated to other camps closer to the village from which they came. The second reason was that in an earlier study we had used a one week yoga intervention (which had almost the same yoga techniques but for slightly different durations), a month after the event, for tsunami survivors (Telles, Naveen, Dash, 2007). The symptoms of distress in the tsunami
survivors were assessed using the same visual analog scales as those used in the present study. We wanted to compare the two groups which had common features (e.g., being given a week of yoga practice a month after a natural disaster) as well as differences (e.g., the yoga program was different, the present study had a non-yoga group for comparison, in the present study the sample size was smaller, and the flood survivors regularly faced the trauma of the floods, as this happens every year, though the magnitude of the problem differs).

We have added these details to the revised manuscript.

In addition based on a study by Chivers-Wilson (2006) and by Cuijpers and others (2005), we have added certain points to the Introduction in the revised manuscript. These are mentioned below:

Following certain traumas (e.g., sexual assault), early intervention is considered critical as the level of distress immediately after the assault has a strong positive correlation with development of future pathologies and PTSD (Girelli, Resick, Marhoefer-Dvorak, Hutter, 1986). High distress levels at the time of assault significantly predicted increased levels of fear and anxiety in the following months (Girelli, Resick, Marhoefer-Dvorak, Hutter, 1986). The authors suggested that since the level of distress is strongly correlated to PTSD symptoms, an attempt to decrease distress immediately following the event may result in a more positive treatment outcome. However not all interventions can be considered useful, for example trauma debriefing in the initial period was found to possibly increase the risk of PTSD symptoms and certainly did not prevent the onset of PTSD (Cuijpers, Van Straten, Smit, 2005). Hence treatments should be continuously evaluated and modified.

References:

COMMENT 2: General: Another problem is the fact that only an immediate post treatment assessment was done, but no follow-up 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 psycho education), 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.

RESPONSE 2: This point has been noted. In the discussion we have mentioned that assessing the short term impact of an intervention does not give adequate information about its’ efficacy (Mayou, Ehlers, Hobbs, 2000). For example, when road traffic accident victims received psychological debriefing, the outcome assessed at three years showed that the intervention group had a significantly worse outcome in terms of general psychiatric symptoms, as well as other problems. In another report also, individual single-session psychological debriefing was shown to aggravate symptoms of PTSD at 6 weeks in those participants in the intervention group who had high baseline hyper arousal scores (Sijbrandij, Oiff, Reitsma, Carlier, Gersons, 2006). Hence in the present study it is a serious limitation that we were not able to follow-up the participants after 6 months or a year.

However we should mention that we did attempt to do so as the yoga institute which conducted the study has several branches in the affected state. Most of the survivors had to be reached by regular post as most of them did not have telephone access. In many cases the letters were returned as (i) the address noted at the time the
participants enrolled in the camp was inadequate, or (ii) the survivors had re-located to another address.

References:

COMMENT 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.

RESPONSE 3: We have altered the title in the revised manuscript as “Post traumatic stress symptoms and heart rate variability in Bihar flood survivors following yoga: a randomized controlled study”.

COMMENT 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.

RESPONSE 4: The references cited in the manuscript (Brown, Gerbarg, 2005; Brown, Gerbarg, 2005; Brown, Gerbarg, Muskin, 2009) described earlier studies on Sudarshan Kriya Yoga for depression In the revised manuscript we have elaborated on previous studies which shown that yoga is useful in the management of anxiety, depression, and PTSD, as follows:
The sentence ‘clinical studies of yoga suggest that a yoga breath intervention could modify the symptoms of post-traumatic stress disorder (PTSD), depression and anxiety’ has been removed from the Introduction. In the revised manuscript, in the Introduction, the details given below have been mentioned.

Sudarshan Kriya yoga (SKY) is a technique which involves rhythmic hyperventilation at different rates of breathing (Janakiramaiah, Gangadhar, Nagavenkatesha Murthy, Harish, Subbakrishna, Vedamurthachar, 2000). Forty-five consenting untreated patients with melancholic depression were randomized as three treatment groups (viz., SKY, electroconvulsive therapy and imipramine). After three weeks the SKY and imipramine groups had similar scores on Beck Depression Inventory and the Hamilton Rating Scale for depression. However the SKY group had higher scores than the ECT group at three weeks. The results hence suggest a possible antidepressant effect of SKY.

Apart from the yoga intervention which included SKY, another yoga program which was useful for depression and anxiety., is the Siddha Samadhi Yoga program, in which meditation is associated with yoga breathing (pranayama) (Kozasa, Santos, Rueda, Benedito-Silva, De Ornellas, Leite, 2008). There were 22 volunteers with complaints of anxiety who were assigned to two groups, viz., yoga (n=14) and a wait-list control group (n=8). After a month of yoga practice, the yoga group had lower scores on anxiety, depression, and tension, and increased scores for well-being compared to the control group.

In the studies cited above, all the yoga programs included yoga voluntary breath regulation (pranayama). A review article described breathing as fundamental for physical well-being as yoga breathing ‘can rapidly bring the mind to the present moment and reduce stress’ (Brown, Gerbarg, 2009).

Previously, a week of yoga practice which included loosening exercises, physical postures, voluntarily regulated breathing, and yoga based guided relaxation, was helpful for tsunami survivors in the Andaman islands, an archipelago in the Bay of Bengal (Telles, Naveen, Dash, 2007). The yoga intervention was given a month after the December 2004 tsunami. Following yoga there was a significant decrease in self-rated fear, anxiety, sadness, disturbed sleep, and in the breath rate. The main limitation of the study was that there was no control group (comparisons were made between mainland
settlers and people endogenous to the islands), where both categories of people had received yoga. Also, though there were recordings of the heart rate, breath rate, and skin resistance level. There was no objective measure to assess autonomic nervous system function, which is known to be associated with PTSD (Blechert, Michael, Grossman, Lajtman, Wilhelm, 2007).

The present study was designed to assess the effect of one week of yoga practice on survivors of floods in the Indian state of Bihar, a month after the floods, with three main differences compared to the study cited above. These were: (i) a control group, since participants were randomized as yoga and wait-list control groups, (ii) recording of heart rate variability as an objective measure of autonomic nervous system function, and (iii) using a yoga program which had similar components as the program used earlier (Telles, Naveen, Dash, 2007), though there was a slightly greater emphasis on yoga breathing. The details have been added to the Introduction in the revised manuscript.

References:


COMMENT 5: In the fourth paragraph (‘Previously’ people?), the authors describe the results of a previous study conducted in their own research group in Tsunami 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.

RESPONSE 5: The location of the Andaman islands (i.e., as an archipelago in the Bay of Bengal) has been added to the revised manuscript, under the Introduction. The study on tsunami survivors did not have a control group. We have mentioned this in the revised version of the manuscript, under the Introduction, mentioning this as one of the reasons why the present study was conducted. This was to see the effect of one week of yoga, using similar yoga techniques, and assessment tools, with the addition of heart rate variability, and with participants randomized as yoga and wait-list control groups.

COMMENT 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/).
RESPONSE 6: The lack of clarity in describing how the 28 participants were selected is regretted.

To begin with the study was restricted to males as the heart rate variability is known to differ between the sexes, particularly for the age group who formed the present sample (Sztajzel, Jung, Bayes De Luna, 2008). There were 544 males among the 1089 participants. Among 544 males, 65 participants met the inclusion criteria. These were (i) normal health, (ii) not on medication, (iii) readiness to be present for all assessments and to be assigned to either yoga or control groups, and (iv) no prior knowledge of yoga. Many participants had to be excluded as they had a diagnosed illness and were taking prescribed medication. There was a fifth factor which further limited the number (from 65 to 22). This was that the flood survivors were continuously being relocated from the main camp which was located in the state capital (in a city called Patna) to other, smaller camps closer to the villages in which they lived. Among the 65 flood survivors who met our inclusion criteria 28 of them were told that they would not be re-located to another camp during the period of the study. After the 28 participants were randomized as two groups another six participants were told that they were to be re-located as well. Fortunately the six participants were equally distributed (i.e., 3 each in the yoga and control groups). Hence the final number to participate in the study was 22 with 11 each in the yoga and in the control groups. These details have been given in the Methods section (Participants) and are provided in a CONSORT diagram.

Apart from this, all participants [the number was 1289 (with 645 female) and ages between 15 and 85 years] were assessed using The Screening Questionnaire for Disaster Mental Health (SQD), (Telles, Singh, Joshi, 2009). This questionnaire screens for PTSD (p scores) and depression (d scores) (Fujii, Kato, Maeda, 1995). The data were analyzed for different age groups and for both sexes. The sub-scales on PTSD (9 items) were summed up to evaluate the possibility of being affected by PTSD (i.e., p scores). Scores between 6 and 9 were categorized as severely affected, between 4 and 5 as moderately affected, and between 0 and 3 as slightly affected. The subscales on depression (i.e., d scores based on 6 items) were summed up to evaluate the possibility of having depression. Participants who scored between 5 and 6 were categorized as more likely to be depressed and those who scored between 0 and 4 as less likely to be depressed. In the
study in which we screened 1289 persons (Telles, Singh, Joshi, 2009), there were 457 males with ages between 21 and 50 years [they were subcategorized as those between 21 and 30 years (n= 253) and those between 31 and 50 years (n =204). The scores are given below in the form of a table to see how the present sample (n = 22) compared with the larger group, i.e., all persons in the camp of comparable age and gender.

<table>
<thead>
<tr>
<th>Age between 21 and 30 years</th>
<th>Age between 31 and 50 years</th>
<th>Yoga group (average age 32.1 ±9.3 years)</th>
<th>Control group (average age 30.8 ±5.5 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n 253</td>
<td>204</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>p scores 4.61± 2.12</td>
<td>4.14 ± 2.34</td>
<td>4.47 ± 3.63</td>
<td>4.53 ± 3.27</td>
</tr>
<tr>
<td>d scores 3.25 ± 1.40</td>
<td>3.14 ± 1.50</td>
<td>3.47 ± 1.88</td>
<td>3.23 ± 1.91</td>
</tr>
</tbody>
</table>

*PLEASE NOTE: There were 1289 participants here. By the time the present study began there were 1089 participants, as 200 had been re-located.*

Hence the p scores revealed that the participants in the present study were moderately affected, and their scores were comparable to those of the group as a whole. The d scores, showed that they were less likely to be depressed and these scores also were comparable for the participants of the present and the other survivors in the camp.

There was no attempt to (i) use the p or d scores as a basis for excluding or including participants in the study, and (ii) the screening Questionnaire for Disaster (SQD) was not repeated after one week, as the Questionnaire is best repeated after a minimum of one month.

Further details about how the participants were selected, their scores on the SQD, and a consort diagram have been provided in the revised manuscript.

References:


COMMENT 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?

RESPONSE 7: The 1089 participants who were in the camp at the time the present study was conducted as well as another 200 participants (making the total number 1289) were given the Screening Questionnaire for Disaster Mental Health (SQD) to determine the scores for post traumatic stress disorder and depression (Telles, Singh, Joshi, 2009). The SQD was administered to the participants 2 days before the present study as 2 days were required to screen the participants for the present study. Hence we have some idea how the present sample (n = 22; constituting approximately 2 percent of the total sample size) compared to the larger group. The group as a whole (as well as the 22 participants of the present study); (i) had all been directly affected by the floods, having lost their relatives, property, and friends, (ii) all of them had less than seven years of education, as after this most of them, particularly the males, had started learning job-related skills, (iii) most of them were self-employed (i.e., owning small shops or working as farmers), while most of the females were house wives.

These details have been added to the Methods section of the revised manuscript, under the sub-section for participants.

Reference:
COMMENT 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?

RESPONSE 8: The participants could not be said to meet the DSM IV, through they did meet some of criteria. The criteria which they met were: (i) Criterion A (1) (Stressor), as all of them had experienced or witnessed the actual flooding, which could have resulted in death or injury, and (ii) Criterion C (1) (Avoidant/Numbing) as at the start of the study most of them did appear reluctant to recollect and respond to questions about the trauma. However the participants were not screened for post traumatic stress disorder using the criteria mentioned in DSM-IV. This has been mentioned under the Methods section (subsection ‘participants) as a limiting factor.

The study was conducted a month after the trauma.

Also, in the revised manuscript we have added details about the two groups as follows:
Table 1

Table: 1

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yoga</td>
</tr>
<tr>
<td>Age (years)</td>
<td>32.1 ± 9.3</td>
</tr>
<tr>
<td>Years of education</td>
<td>6.4 ± 1.1</td>
</tr>
<tr>
<td>Number who had themselves been directly affected by the floods</td>
<td>11</td>
</tr>
<tr>
<td>Number who had lost Relatives or witnessed people dying</td>
<td>11</td>
</tr>
</tbody>
</table>

p>0.05, comparing ages and years of education of the two groups using independent t-tests

This table has been mentioned in the Methods section of the Revised manuscript. The two groups did not differ significantly with respect to their age, years of education, or the extent to which they were affected by the trauma (p>0.05; t test for unpaired data). This has been mentioned in the Results section of the revised manuscript.

COMMENT 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.

RESPONSE 9: Our main outcome measures were the symptoms of emotional distress based on visual analog scales. Our secondary outcome measures were the heart rate variability and breath rate, recorded using a polygraph.

We chose to use visual analog scales rather than validated questionnaires, even though it was considered a limitation of an earlier study published by us as we found it difficult to get accurate responses. For example, we did try to use the Impact of Event Scale (which has 15 items) and found that since the participants are required to respond to the questionnaire themselves, they found this difficult (n = 12, unpublished data). We then switched to the Screening Questionnaire for Disaster Mental Health (called the SQD) (which has 12 items and can be administered by people with no specific experience in mental health). An intensive effort using a large number of volunteers was required to administer this questionnaire (the SQD) to the flood survivors (n =1289, including the 22 who formed the present study sample) (Telles, Singh, Joshi, 2009, a reference which has been mentioned earlier). In order to get accurate responses from the participants, all of whom had less than 7 years of education, the volunteers had to spend considerable time with each participant. In contrast, the participants found the visual analog scales easy to understand. For the participants of the present study (n=22) it was decided to use visual analog scales (i) as we were more likely to get accurate information, and (ii) we wanted to make comparisons between the responses we obtained in the present study and compare them with those we obtained earlier using the same visual analog scales. However we do recognize that not using validated questionnaires is a definite limitation of the study.

In the revised manuscript we have mentioned that using visual analog scales instead of validated questionnaires was a limitation of the study. We have also attempted to explain our reasons for using the VAS, which (as described above), were two, viz, (i) the fact that the participants found them easier to understand, and (ii) this allowed us to
make comparisons with an earlier study conducted by us on tsunami survivors, in which the same VAS were used. We have added this to the Methods section under Assessments.

We have also added the following comparison of the two studies to the Discussion:

‘Previously a one week yoga program reduced self-rated fear, anxiety, sadness and disturbed sleep, as well as decreased heart and breath rates in tsunami survivors a month after the calamity (Telles, Naveen, Dash, 2007). The yoga program was for 60 minutes each day which was the same duration as the present study. In the case of the tsunami survivors the yoga program consisted of yoga postures (asanas, with 16 postures in 20 minutes), loosening exercises (for 10 minutes), yoga voluntarily regulated breathing (for 15 minutes, with four practices), and guided relaxation (for 15 minutes). In the present study the yoga program had the same components but with slight variations, as mentioned below. The program consisted of yoga postures (asanas with 12 postures in 20 minutes), loosening exercises for 10 minutes, yoga voluntarily regulated breathing (for 25 minutes with 3 practices) and guided relaxation for 5 minutes. It is unlikely that the difference (mainly an increase in the time spent on voluntarily regulated breathing and less time spent in guided relaxation) accounted for the differences in results. One of the main differences is that the present study had a considerably smaller sample size (n =11), compared to the earlier study (Telles, Naveen, Dash, 2007), where the sample size was 47. This is a serious limitation of the study and was mainly due to the fact that participants were continuously being re-located to other camps, elsewhere.

We have added the following details about the visual analog scales (VAS). Visual analog scales (VAS) were designed for participants to self-rate their (i) fear, (ii) anxiety, (iii) disturbed sleep, and (iv) sadness, as these are indicators of emotional distress commonly reported by disaster survivors (Silver, Iacono, 1984). Each analog scale was a 10 centimeter long doubly anchored scale, with one end (score = 10) of the scale indicating the highest intensity of a feeling of a symptom of distress, while the other end (score = 0) indicated the lowest intensity of feeling for the same symptom. There was a separate scale for each of the four symptoms. Participants were instructed to place a vertical mark on the horizontal line to indicate the level of their feelings. For each individual the score for a particular symptom was obtained by measuring the distance in millimeters from the end of the line where the score was ‘0’ upto the mark made by the
participants. All the analog scales were scored in one direction (i.e., with ‘0’ on the left), to make it easier to explain the method to the participants. Hence for each of the four symptoms (i.e., fear, anxiety, disturbed sleep, and sadness), separate scores were obtained as millimeters for each of the four VAS. These details have been added to the Methods sections under assessments.

References:

COMMENT 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.

RESPONSE 10: We had done a repeated measure ANOVA (with Groups as the Between Subjects factor and Assessments as the Within Subjects factor). There were no significant differences between Groups or pre-post Assessments, and the interaction between Groups and Assessments was also not significant, hence we did not attempt post-hoc analyses.

However we have provided the details of the ANOVA here for the reviewer’s reference:
**Table A:** Repeated measures analysis of variance for Fear assessed using a VAS:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Df</th>
<th>F value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Groups</td>
<td>1, 20</td>
<td>0.243</td>
<td>P &gt;0.05</td>
</tr>
<tr>
<td>Assessments (Pre, Post)</td>
<td>1, 20</td>
<td>0.065</td>
<td>P &gt;0.05</td>
</tr>
<tr>
<td>Interaction (Groups*Assessments)</td>
<td>1, 20</td>
<td>2.915</td>
<td>P &gt;0.05</td>
</tr>
</tbody>
</table>

**Table B:** Repeated measures analysis of variance for Anxiety assessed using a VAS:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Df</th>
<th>F value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Groups</td>
<td>1, 20</td>
<td>0.797</td>
<td>P &gt;0.05</td>
</tr>
<tr>
<td>Assessments (Pre, Post)</td>
<td>1, 20</td>
<td>0.798</td>
<td>P &gt;0.05</td>
</tr>
<tr>
<td>Interaction (Groups*Assessments)</td>
<td>1, 20</td>
<td>1.174</td>
<td>P &gt;0.05</td>
</tr>
</tbody>
</table>
Table C: Repeated measures analysis of variance for Disturbed sleep assessed using a VAS:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Df</th>
<th>F value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disturbed sleep</td>
<td>1, 20</td>
<td>0.061</td>
<td>P &gt;0.05</td>
</tr>
<tr>
<td>Groups</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessments (Pre, Post)</td>
<td>1, 20</td>
<td>2.560</td>
<td>P &gt;0.05</td>
</tr>
<tr>
<td>Interaction (Groups*Assessments)</td>
<td>1, 20</td>
<td>0.912</td>
<td>P &gt;0.05</td>
</tr>
</tbody>
</table>

Table D: Repeated measures analysis of variance for Sadness assessed using a VAS:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Df</th>
<th>F value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sadness</td>
<td>1, 20</td>
<td>0.571</td>
<td>P &gt;0.05</td>
</tr>
<tr>
<td>Groups</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessments (Pre, Post)</td>
<td>1, 20</td>
<td>3.486</td>
<td>P &gt;0.05</td>
</tr>
<tr>
<td>Interaction (Groups*Assessments)</td>
<td>1, 20</td>
<td>0.001</td>
<td>P &gt;0.05</td>
</tr>
</tbody>
</table>

The same was true for all the variables of heart rate variability. We believed that this was mainly due to the small sample size (n = 11, in each group). For this reason we did not attempt further analysis using heart rate variability as a covariate. The data were analyzed using t-test for paired data. The fact that the small sample size did not allow rigorous analysis to be done is mentioned in the Discussion of the revised manuscript as a limitation of the study.
COMMENT 11: Results: I would advise the authors to follow the CONSORT guidelines in reporting their results. See: http://www.consort-statement.org/consort-statement/

RESPONSE 11: We have referred to the CONSORT guidelines as suggested by the reviewer and attempted to modify the paper accordingly. We have also provided (i) the CONSORT check list, filled in, and (ii) a CONSORT diagram, both given below below.

CONSORT Statement 2001 Checklist

Items to include when reporting a randomized trial

<table>
<thead>
<tr>
<th>PAPER SECTION And topic</th>
<th>Item</th>
<th>Descriptor</th>
<th>Reported on Page #</th>
</tr>
</thead>
<tbody>
<tr>
<td>TITLE &amp; ABSTRACT</td>
<td>1</td>
<td>How participants were allocated to interventions (e.g., &quot;random allocation&quot;, &quot;randomized&quot;, or &quot;randomly assigned&quot;).</td>
<td>7</td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td>2</td>
<td>Scientific background and explanation of rationale.</td>
<td>4-5</td>
</tr>
<tr>
<td>Background</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>METHODS</td>
<td>3</td>
<td>Eligibility criteria for participants and the settings and locations where the data were collected.</td>
<td>6,9</td>
</tr>
<tr>
<td>Participants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interventions</td>
<td>4</td>
<td>Precise details of the interventions intended for each group and how and when they were actually administered.</td>
<td>10-12</td>
</tr>
<tr>
<td>Objectives</td>
<td>5</td>
<td>Specific objectives and hypotheses.</td>
<td>5</td>
</tr>
<tr>
<td>OUTCOMES</td>
<td>6</td>
<td>Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).</td>
<td>8-9</td>
</tr>
<tr>
<td>Sample size</td>
<td>7</td>
<td>How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.</td>
<td>7</td>
</tr>
<tr>
<td>Randomization --</td>
<td>8</td>
<td>Method used to generate the random allocation sequence, including details of any restrictions (e.g., blocking, stratification)</td>
<td>7,12</td>
</tr>
<tr>
<td>Sequence generation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Randomization -- Allocation concealment</td>
<td>Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.</td>
<td>7-8</td>
<td></td>
</tr>
<tr>
<td>Randomization -- Implementation</td>
<td>Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.</td>
<td>7-8</td>
<td></td>
</tr>
<tr>
<td>Blinding (masking)</td>
<td>Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.</td>
<td>7-8, 12</td>
<td></td>
</tr>
<tr>
<td>Statistical methods</td>
<td>Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>RESULTS</td>
<td>Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.</td>
<td>6, Figure 1</td>
<td></td>
</tr>
<tr>
<td>Participant flow</td>
<td>Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.</td>
<td>6, Figure 1</td>
<td></td>
</tr>
<tr>
<td>Recruitment</td>
<td>Dates defining the periods of recruitment and follow-up.</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Baseline data</td>
<td>Baseline demographic and clinical characteristics of each group.</td>
<td>7-8, Table 1</td>
<td></td>
</tr>
<tr>
<td>Numbers analyzed</td>
<td>Number of participants (denominator) in each group included in each analysis and whether the analysis was by &quot;intention-to-treat&quot;. State the results in absolute numbers when feasible (e.g., 10/20, not 50%).</td>
<td>7-8, Table 1</td>
<td></td>
</tr>
<tr>
<td>Outcomes and estimation</td>
<td>For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval).</td>
<td>14, Table 2, Table 3</td>
<td></td>
</tr>
<tr>
<td>Ancillary analyses</td>
<td>Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.</td>
<td>Nil</td>
<td></td>
</tr>
<tr>
<td>Adverse events</td>
<td>All important adverse events or side effects in each intervention group.</td>
<td>Nil, 12</td>
<td></td>
</tr>
<tr>
<td>DISCUSSION Interpretation</td>
<td>Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.</td>
<td>17-19</td>
<td></td>
</tr>
<tr>
<td>Generalizability</td>
<td>Generalizability (external validity) of the trial findings.</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Overall evidence</td>
<td>General interpretation of the results in the context of current evidence.</td>
<td>22</td>
<td></td>
</tr>
</tbody>
</table>

The Consort diagram

Assessed for eligibility \((n = 1089)\)

Excluded:
1. Based on gender \((n = 545)\)
2. Not meeting inclusion criteria \((n = 479)\)
3. Likelihood of being shifted during the trial \((n = 43)\)

Enrollment

Randomized & Allocated \((n = 22)\)

Allocated to yoga group \((n = 11)\)
Received yoga \((n = 11)\)

Allocated to waitlist control group
\((n = 11)\)
Did not practice yoga \((n = 11)\)

Analysis

Analyzed \((n = 11)\)

Analyzed \((n = 11)\)
COMMENT 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.

RESPONSE 12: A possible reason for increase in anxiety in the control group which did not occur in the yoga group could be related to the way in which the calamity was handled, and how survivors received aid. This has been described below, and added to the Discussion in the revised manuscript.

‘The increase in self-rated anxiety in the control group needs further explanation. This is particularly the case as previous studies have not demonstrated an increase in anxiety in untreated trauma survivors (Shalev, Sahar, Freedman, Peri, Glick, Brandes, Orr, Pitman, 1988) or have shown an actual reduction in those treated with anti-anxiety medication (Shalev, Bloch, Peri, Bonne, 1998) or group debriefing, as an immediate effect of the session (Shalev, Peri, Rogel-Fuchs, Ursano, Marlowe, 1998). A possible reason for the increased anxiety in the control group may be the fact that the survivors were not receiving the kind of assistance they needed with the necessary speed. Social scientists reported that in the initial phase the administration, civil society groups and the media kept seeing the disaster as an ‘annual flood’ which was nothing new for that part of the country (Jha, Raghavan, 2008). All possible sources of aid failed to recognize the magnitude of the calamity. Hence given their dissatisfaction with the way in which relief was being provided the control group may have shown an increase in anxiety, which possibly was prevented from happening in the yoga group by the practice of yoga. However the small sample size and consequently the use of less rigorous statistical analysis prevent us from making any definite conclusion.’
References


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

RESPONSE 13: In the revised manuscript we have attempted to compare the present results with those of previous studies which also used breath modification and relaxation for persons surviving a traumatic event, as given below, adding it to the Discussion in the revised manuscript.

‘In addition to yoga, other mind-body interventions have been found to be useful for trauma victims. One hundred and thirty-nine high school students in Kosovo participated in three separate programs which included several mind-body interventions spaced two months apart (Gordon, Staples, Blyta, Bytyqi, 2004). The interventions included meditation, biofeedback, autogenic training, guided imagery, movement, and breathing techniques. The adolescents showed significantly lower symptoms of post traumatic stress based on the Posttraumatic Stress Reaction Index, compared to the initial values.

In another study refugees and survivors of torture appeared to respond positively to the practice of qi gong and t’ai chi, based on observations made on four refugee survivors (Grodin, Piwowarczyk, Fulker, Bazazi, Saper, 2008).’
References:

COMMENT 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.

RESPONSE 14: In the revised manuscript in the Discussion we have mentioned two factors, viz., a small sample size (n = 11, in each group) and no follow-up beyond one week as limitations of the study. We have also attempted to answer the reviewers questions about generalizing the results to all trauma victims of the Bihar Floods, or to other populations, as follows:

‘Though the present results are based on a study performed on a very small sub-section of survivors of the Bihar floods in one of the camps (approximately 2 percent of the people in that camp), it is believed that the results may be applicable to most young and middle aged people who were healthy. Also, the findings may be applicable to survivors of a natural disaster in situations where for any reason, it is difficult for aid to reach the survivors in a way which is both timely and adequate.’

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.

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**Comments from the Associate Editor:**

**COMMENTS:** The reviewers had major concerns about methodological issues, which severely limit any ability to generalize from these results. The limitations also need to be acknowledged more in the manuscript. The small sample size and the lack of adequate explanation of how people were screened to result in this sample size must be explained in much more detail.

**RESPONSE:** We have attempted to address the concerns mentioned by the reviewers and to mention the limitations of the study in the Discussion.