Author's response to reviews

Title: Beneficial effects of treatment with sensory isolation in flotation-tank as a preventive health-care intervention - a randomized controlled pilot trial

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Author's response to reviews:

Reviewer JG

Discretionary Revisions

1. Title page, clinical trial registration. Why was the trial registered in New Zealand? Is this where the trial took place? Need to describe study location in the manuscript, per standardized reporting guidelines (see CONSORT checklist).

   Answer: We realize this can be confusing. Here is the explanation: The trial was registered in the Australian New Zealand Clinical Trials Registry (ANZCTR), since the ANZCTR is recognised as an ICMJE acceptable registry (ICJME is International commit of medical journal editors, http://www.icmje.org). There are few ICMJE acceptable registry that are free of charge – and since ANZTR is free we choose it. They register trials world-wide, and we correctly registered our trial as occurring in Sweden. So the trial took place in Sweden (as described in the method section).

2. References: Is reference 39 correct? The reference alludes to sleep and blood pressure, which does not appear to directly support the statement of fact in the text.

   Answer: Hypertension refers to blood pressure as stated in the text; so it is correct.

Minor Essential Revisions

3. Title: Add designation as RCT, per standardized reporting guidelines (CONSORT)

   Answer: We have include “randomized control pilot trial” in the title.

4. Abstract, Methods: designate control group as “wait-list control group”.

   Answer: We have included this in both the abstract and in the method section.

5. Background, second to last paragraph, final sentence: state one or two example of “other relaxation techniques” here.

   Answer: we have added three other techniques here (muscle relaxation, biofeedback, and meditation)
6. Background: No specific hypotheses are stated at the end of this section. Please add, per standardized reporting guidelines (CONSORT).

Answer: We added the sentence “Would it have beneficial effects on their health as proven in previous studies” – since this was exactly what we wanted to know.

7. Methods, Design: designate control group as wait-list control here.

Answer: Done!

8. Methods, Instruments: Add score ranges for all instruments to help reader interpret baseline scores, post-intervention scores, and the magnitude of intervention-related change on each scale.

Answer: Done!

9. Methods, Instruments: Add Cronbach alphas for this sample for each instrument.

Answer: Done!

10. Methods, Instruments: Add sample items of stress and energy scale to (a) help readers understand how/why this scale would correlate with the mindfulness scale [MAAS], and (b) how this scale differs from the HAD? Could significant correlations be due, in part, to item overlap?

Answer: We have added some sample items of the SE-scale. We have not specifically reported any correlation between MAAS, SE or HAD.

11. Methods, Instruments, HAD: Please cite reference for subscale cutoff score of 10. Other large-scale studies (Bjelland, Dahl, Haug, & Neckelmann, 2002, J Psychosom Res) have reported an optimal subscale cutoff score of 8.

Answer: We changed to cut-off = 8, and added this reference (and re-number all references after this). Thanks.

12. Methods, Instruments, EDN: Please provide 2 sample items that help reader understand why this scale would correlate with the MAAS.

Answer: We have added 2 items from EDN.

Major Compulsory Revisions

13. Abstract, Background: The rationale is unclear to me how flotation-REST can be framed as a “health-care intervention” when participants in this study are healthy, and hence not necessarily in need of any intervention. If the healthy participants in this trial were at risk of stress-related sick-leave and/or stress-related mental or medical disorders, then such risk needs to be described in the Methods and Participants sections of the paper.

Answer: The participants were normal healthy persons, not on sick-leave. We changed the title to include the word “preventive” health-care intervention. We have earlier done several studies involving persons on sick-leave, but this is the first time we study flotation-REST as a (hopefully) health promoting program. As far as we know, all persons may benefit from deep relaxation and maintain good health.
14. Abstract, Conclusions: Conclusion appears to go beyond the data. Specifically, the conclusion that flotation-REST intervention could decrease or prevent sick-leave from work does not derive from the present data, nor is there a convincing rationale that the subjects in this study were at-risk of stress-related absenteeism or disease.

Answer: We deleted that sentence from the abstract, and also made some small revisions in the conclusions section.

15. Background: It would help better establish the rationale for this study in healthy participants to (a) discuss what level of subthreshold symptoms increase the risk of sick-leave or stress-related ill-health among generally healthy working adults, (b) whether such levels of stress-related risk factors were observed (or not) in the present sample, and (c) whether the intervention produced clinically relevant changes in the stress-related outcome variables measured in this study.

Answer: We believe it is quite clearly described that stress is a contributing factor for ill-health, and that stress-reducing methods can have beneficial effects among healthy working adults. We made a few revisions in the background section.

16. Methods, Participants, first paragraph: Eligibility criteria and details of randomization procedure need to be added (see CONSORT checklist). What was the allocation ratio (i.e., why was randomization imbalanced across groups)?

Answer: the randomization was done by the participant, who threw a dice. If the dice showed 1, 2 or 3 they were allocated to "the flotation-REST" condition; number 4,5 and 6 was "waiting list". This is the reason for the imbalance between the groups.

17. Methods, Procedure: Please describe whether the three companies played any role in study design, recruitment, assessment, data collection, interpretation, and/or manuscript preparation.

Answer: The three companies had no part in any of the practical details regarding data collection, interpretation of results, study design etc. This is now explained in the participants section.

18. Methods, Procedure: Describe time period for recruitment enrollment, as well as physical/geographical site(s) for the trial.

Answer: The location is Deje, Värmland Sweden (described in the procedure section); the time period for everything was about 6 months.

19. Methods, Procedure: How was it determined that participants were “healthy?”

Self-report? History and physical exam by a nurse or physician? Medical record review?

Answer: "Healthy” was determined by not being on sick-leave (explained in procedure section).

20. Methods, Procedure: Describe whether written and/or verbal informed consent obtained prior to data collection?

Answer: Now described in procedure section.

21. Methods, Procedure: Were data collected by study staff who were blind to
treatment group assignment? Please describe, and report per CONSORT guidelines.
Answer; The data (questionnaires) gathered before the randomization process (throwing dice to the conditions), were a blind procedure since it was not yet established which group the participants belong to.

There was not a blind procedure after the randomization to conditions. For questionnaires that were administered after a floating session, the staff knew that the person had been floating. The “waiting list control group” went to the floating centre merely for filling out the questionnaires. All questionnaires (for all participants) were filled out in privacy in a separate room, and put in a closed box by the participants. The box was distributed un-opened to us at Karlstad university, so the staff at the floating centre never touched the questionnaires.

22. Methods, Procedure: Post-intervention assessment of mindfulness in the intervention group only precludes analysis of change and attribution of causality. Discussion of MAAS results must reflect this design element, and not imply that flotation-REST increased (or changed) levels of mindfulness.
Answer: We have now pointed out in the discussion section that further studies are needed for confirming such a causality.

23. Results: For each measure, add interpretation of baseline levels and interpretation of change by reporting effect sizes, such as Cohen’s d. Also, interpret eta2 values reported for MANOVA. Which effects are large, medium, or small? Then, describe clinical importance in Discussion.
Answer: We included one sentence about the large effect size for the MANOVA in the discussion section.

24. Results: For each outcome, report specific t-values, df, and p-values for paired-samples t-tests.
Answer: We have included this in the results section.

25. Results, Energy: Why would energy levels decrease (worsen), when all other outcomes improved, and energy levels are ostensibly correlated with other outcomes? Please raise this issue in Discussion/Limitations section.
Answer: We have added a few lines about that.

26. Results, Mindfulness and Altered States of Consciousness: Was this correlation hypothesized? Were any other correlations examined among outcome variables?
Answer: This was the only correlation that was examined, since we have earlier seen that the altered state of consciousness during relaxation in the tank (often described as a "here-and-now-state") seems to be very similar to a very mindful state. This is the first time we administer scales for these two variables (mindfulness/MAAS and degree of altered states of consciousness/EDN) together in the same study. So yes, we had some idea that it could be possible to find a connection here.

We believe that researchers interested in the concept of "mindfulness", probably not are aware of the research performed on "altered states of consciousness".
Since there seems to be so many similarities between these concepts, there is a great value investigate this. We are for the moment gathering data for another study, where these two variables are investigated in more detail.

27. Discussion, first paragraph: Need to verify or describe how study participants were deemed “healthy.”

Answer: we added "not being on sick-leave"

28. Discussion, second paragraph: Authors can test for correlation between decreased stress and improved sleep quality in order to empirically answer this question using the current dataset.

Answer: Ok, thanks. We added this in the discussion. We believe this is previously known general knowledge, and probably a little out of scope for the present study. We would prefer not to include this in the discussion (but now it is there anyway).

29. Discussion, second paragraph: Sleep quality and sleep quantity are two distinct measures, and are not always correlated. Speculating about implications for effects of sick-leave based on putative effects of flotation-REST on sleep quantity (i.e., sleep deprivation) goes beyond the data collected in this study.

Answer: We have removed this assumption.

30. Conclusions: Whereas the first sentence is accurate given the study design and enrolled sample (assuming participants were, in fact, “healthy”), speculation about possible effects on sick-leave need to be better substantiated by describing the extent to which the current sample was at-risk of stress-related absenteeism and/or disease. Yes, future research is warranted to investigate potential effects on sick-leave prospectively in at-risk employees.

Answer: Thank you for this comment. We have altered the text somewhat to clarify this. We conclude the potential beneficial effects. It seems REST can increase general health (by decreasing pain, anxiety etc) which might help prevent possible future sick leave - which we are all at risk of, healthy or not. We have also included a sentence about future research, as suggested.

Reviewer FB

I only have some minor essential revisions:

Methods:

p.5, l.10: "There were no significant differences regarding gender, age, cigarettes, snuff or alcohol between the two groups (independent samples t-tests, p = 0.256)." What does the p-value reflect? The mentioned t-tests should yield one p-value for each comparison.

Answer: Of course, thanks. We have changed into ps>0.256

p.6, l.12: To my knowledge, HAD should read HADS.

Answer: thanks. We have changed.

Results:

p.10, l.14: "(pair-samples t-tests, 5 % level)". Please explain "5% level". Does this
refer to the significance threshold?
Answer: Yes, it refers to significance threshold. We now also included values of t, df and p, for making it more clear.

p.12, "Mindfulness and Altered states of consciousness". The authors transform their continuous into a categorical variable here to be able to run an ANOVA. There are numerous and well known problems associated with this procedure. As they have found a significant correlation, it is ok to run such an analysis as a further evaluation. The results, however, do not add much to the correlation result and could be omitted. The authors should, however, add a scatter plot for EDN vs. MAAS.
Answer: We have included such a scatter plot as a Figure. We prefer to keep the ANOVA-analysis.

Table 1: This table should definitely contain the difference between the two groups. From my point of view, the total is much less informative and should be omitted.
Answer: We have omitted the "Total" from the tables.

It would also help a lot to have the results from Tables 1+2 in a plot. Probably, an interaction plots makes most sense or, better, an array of plots.
Answer: thank you for the suggestion. If necessary, we can include such plots, but we do prefer to keep it the way it is if possible.

Discussion:
Please discuss, why Energy levels were by the treatment. Is energy considered something negative in the questionnaire used?
Answer: We actually do not know. We have in earlier research with pain patients and burn-out depressed person seen the same (energy level decrease). A speculation could be that when they relax (and get stress-reduction) they finally realize how tired they are – and then recognize this as "lesser energy". But we do not know. We included in the manuscript that we do not know.

Please discuss, why a difference was found for worst but not normal pain.
Answer: We have included one sentence about this in the discussion section.

We wish to thank both reviewers for their valuable comments!