Reviewer’s report

Title: Beneficial effects of treatment with sensory isolation in flotation-tank as a health-care intervention

Version: 3 Date: 15 September 2013

Reviewer: Jeffrey Greeson

Reviewer’s report:

Overview
This concise, generally well written paper presents findings from a relatively small 2-arm RCT that compared flotation-REST (Restricted Environmental Stimulation Technique) with a wait-list control condition on a variety of self-reported psychosocial outcome measures pertinent to stress and risk of stress-related sick-leave and disease. There appears to be a solid track record of previous publications on the flotation-REST intervention. However, I am unable to fully evaluate the quality, substantive meaning, and clinical implications of this trial without being able to see a completed CONSORT checklist. Numerous standardized reporting details are missing in this report (e.g., statement of specific hypotheses, allocation ratio, eligibility criteria, setting and locations of data collection, dates defining period of recruitment and follow-up, sample size determination and power analysis, randomization method details, primary vs. secondary outcomes, estimates of effect sizes for specific outcome measures, and trial limitations). These omissions compromise the quality of the report as currently written, and must be included to facilitate a thorough and fully-informed review. Specific recommended revisions follow.

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).
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.

Minor Essential Revisions
3. Title: Add designation as RCT, per standardized reporting guidelines (CONSORT)
4. Abstract, Methods: designate control group as “wait-list control group”.
5. Background, second to last paragraph, final sentence: state one or two example of “other relaxation techniques” here.
6. Background: No specific hypotheses are stated at the end of this section. Please add, per standardized reporting guidelines (CONSORT).
7. Methods, Design: designate control group as wait-list control here.

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.

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

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?

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.

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

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.

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.

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.

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)?

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

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

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?

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

21. Methods, Procedure: Were data collected by study staff who were blind to treatment group assignment? Please describe, and report per CONSORT guidelines.

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.

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.

24. Results: For each outcome, report specific t-values, df, and p-values for paired-samples t-tests.

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.

26. Results, Mindfulness and Altered States of Consciousness: Was this correlation hypothesized? Were any other correlations examined among outcome variables?

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

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.

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.

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.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.