Reviewer's report

Title: Mindfulness-based therapy for the treatment of chronic tinnitus: a randomized controlled pilot study

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Reviewer: Hugo Hesser

Reviewer's report:

Review of manuscript entitled, “Mindfulness-based Therapy For the Treatment of Chronic Tinnitus: A Randomized Controlled Pilot Study”. This manuscript reports results from a small RCT comparing a treatment, consisting of various exercises focusing on increasing mindfulness, with a wait-list control over a time period of 24 weeks. The effects presented were of substantial magnitude. Results are also broadly in accordance with recent findings from clinical trials on treatment focusing on mindfulness-related processes in tinnitus. Methodology used is adequate for most part (validated measures, randomization). Thus, the study has merits.

However, the paper is also marked with some limitations that prevent it from being publishable in its current format. I have enumerated points below that I feel need to be addressed.

Major Compulsory Revisions

1. The authors state in the background that “Very recently mindfulness-based cognitive therapy has been proposed for the treatment of tinnitus”. This is the only rationale provided for the study in the introduction. It is important to acknowledge previous published work in the area. Several trials have been conducted on treatments for tinnitus that have included mindfulness-based interventions as integral parts of the treatment protocol [1-3]. Thus, a rationale for study ought to be provided in relation to previous work most relevant to current investigation.

2. More information on the recruitment of participants is needed.

3. Please provide inclusion and exclusion criteria that were used in the trial.

4. Similar, more information about the treatment ought to be provided. For example, information about the providers/therapists and the amount of contact with therapists throughout the trial should be provided. Did participants need to complete homework assignments? Were any data collected on whether participants worked with the treatment material?

5. Means and standard deviations should be provided for all measurements and assessment points.

6. LOCF is not a good way to handle missing data, as it will in most missing data scenarios inflate type 1 error rates and give inaccurate estimates of treatment effects [e.g., 4, 5]. There are several statistical approaches, including EM
imputation and full information maximum likelihood estimation (FIML; see e.g. the reference provided above), that will do a far better job of handling missing data in terms of power and estimates in the most common missing scenarios. In this scenario where few people were lost to follow-up, I would recommend the authors to use one of these missing methods or to rely solely on the participants who provided data at each assessment point, instead of using LOCF.

7. The authors evaluate the results using mixed RM ANOVAs. To gain more power in this randomized design the authors could use ANCOVA (instead of ANOVAs) with the postassessment/24 weeks follow-up as the dependent variable and pretreatment values as the covariate [see e.g. 6]. This would also mean that the authors could exclude the post-hoc tests from the paper. Another option is to use linear mixed-effects regression analyses to examine average trajectories of change across all measurements points (using FIML as missing method).

8. Analyses for all secondary outcomes should be included in the paper.

9. Include the proportion of participants who met the criterion for treatment response on the TQ at 24-weeks follow-up and compare proportions between treatment and control.

Minor Essential Revisions

1. In the abstract the authors state that "Since causal treatment options are scarce...". I am not sure what the authors mean. Please revise sentence to clarify this.

2. Please check language throughout. For example, commas are missing at places and wording is sometimes not clear enough (e.g., “mutual phone calls”).

Discretionary Revisions

1. Although the authors theorize about the potential neural mechanisms underling effective mindfulness training, I would appreciate if the authors could discuss the potential psychological processes of such training in tinnitus. For example, it has been proposed that mindfulness facilitates non-reactivity to distressing thoughts and feelings and increases mindfulness-related processes, such as acceptance and ability to distance, describe and observe internal events in a non-evaluative way. Similar ideas have been expressed in relation to how mindfulness and similar procedures can facilitate adaptive responses to tinnitus [see 1, 7].


6. Van Breukelen, GJP. ANCOVA versus change from baseline had more power in randomized studies and more bias in nonrandomized studies. Journal of Clinical Epidemiology 2006, 59: 920-925.


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

**Quality of written English:** Needs some language corrections before being published

**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