Author's response to reviews

Title: Simplified form of tinnitus retraining therapy in adults: a retrospective study

Authors:

Hashir H Aazh (hashir.aazh@nhs.net)

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Author's response to reviews: see over
**Reviewer:** Tobias Kleinjung  
**Reviewer's report:**

This is a retrospective study which is presenting a substantial reduction of THI score in tinnitus patients after a simplified version of Tinnitus Retraining Therapy (TRT), called Tinnitus Rehabilitation (TR). However there are some concerns which should be considered before publication.

**Major Compulsory revisions:**

In my opinion it is not necessary to introduce a new terminology (Tinnitus Rehabilitation, TR) for the author’s treatment strategy in tinnitus patients. It would be sufficient and much less confusing to call the method a “simplified form of TRT”. I would suggest using this terminology already in the title, as TRT is a standard procedure which is internationally well known. (I have replaced the term TR by simplified TRT)

The lack of a control group is only briefly mentioned in “Conclusions” (page 13). The inability of ruling out a placebo effect due to the absence of a control group or untreated comparison should be discussed. (Done)

It is not clear to me, if the follow up measurements were collected in a systematic way on clearly defined endpoints. (I have explained this in the methods. “The follow up appointments were arranged as required with 1 month, 2 months, 3 months, and 6 months intervals. The outcome measurement questionnaires were completed at the beginning of each session. The scores achieved in the last session, at the time of the data collection for this study, were compared with the pre-treatment scores.”)

Within in the group of patients there is obviously a large variability of symptoms, other clinical characteristics and length of treatment, which offers a potential for selection bias. Furthermore there is a division into 4 different treatment groups, where certain parts of the treatment program were only administered after specific demand of the patient. The question arises, if all patients can be summarized in one group, which is implicated in the abstract. (That is true. However, due to the limited number of patients, I had to summarize them in one group instead of reporting the results separately. However, at the end I have compared the improvement between patients who used/ did not use SGs, HAs and WSGs. I have now mentioned this in the discussions as one of the limitations of this study)

The duration of tinnitus seems to be a very important factor in most tinnitus therapy outcome studies. The discussion should focus in more detail on the fact that there was no significance of this factor for TR. (I have added scatterplots to show the correlation between duration of tinnitus and the decline on THI. In addition, I replaced the term “no correlation” with “no linear correlation”.)
Regarding the duration of the treatment, in this study I have not compared the improvement of the individual scores over time (e.g. THI scores at 1, 3, 6, 12-months times). If I would have done so, I could have found a relationship between the length of the treatment and improvement on the THI scores. Using the overall decline scores in testing the linear or nonlinear correlation will not give us much information regarding the effect of the duration of treatment. For this reason, I have deleted the section devoted to correlation between duration of treatment and decline on the THI scores.)

The sustained therapy outcome with a decline of 39.4 points in THI score seems to be very effective, even more effective than standard TRT or other therapeutic efforts in tinnitus patients. This should be discussed in more detail, additional literature of therapy effects of TRT should be related to the results of this study. (Done)

Are there any patients with negative results or worsening of their tinnitus? (THI score reduced (improved) in all of the patients after 3-23 months of treatment. VAS of tinnitus loudness increased (got worse) in 4 patients. VAS of tinnitus annoyance and effect on life increased (got worse) in 1 patient. I have added this to the result section)

Minor Essential Revisions:
It would be more appropriate to present the results in a figure instead of a table. (I have added the scatterplots. I was not able to transform the tables to a figure. I needed to report p value etc)
The text is consisting of a lot of abbreviations. A table would be suitable. (Done)

The international literature and especially Pawel Jastreboff usually provides the term “hyperacusis” in combination with tinnitus. I would suggest to use this term instead of DST. (I am more comfortable in using the term DST with my patients. I think that the term DST is more self explanatory in comparison with hyperacusis. Jastreboff used this term too. Jastreboff PJ, Jastreboff MM. Tinnitus retraining therapy for patients with tinnitus and decreased sound tolerance. Otolaryngol Clin North Am. 2003 Apr;36(2):321-36. Review.)

Discretionary Revisions:
The paragraph on “Subjects and Sample Size” might easier be presented in a table. (Done. I have summarised the tinnitus descriptions in a table)

Reviewer: CARLOS HERRAIZ
This manuscript is a retrospective study to assess the efficacy of a different approach for tinnitus management. This method, called Tinnitus Rehabilitation (TR) by the authors, is based on Tinnitus Retraining Therapy (TRT). The main difference between both of them is related to the subjects and shorter duration of the counseling in TR. This fact seems to be interesting for the medical practice because the 90-minute TRT counseling is not possible to be applied in the majority of our crowded hospitals. During the fifteen years since the first description of the TRT method, the professionals have adapted the counseling to the characteristics of the patient (age, cultural level), tinnitus
annoyance (mild or severe) and available time per patient. This manuscript demonstrates that a 30-minute counseling can be also effective for tinnitus relief. (I have added the following sentences to the background: Since the first description of TRT in 1990s, clinicians have modified and customised the method of TRT in order to match to their practice and their patients [3-5].)

The other difference between TR and TRT is referred to sound therapy. According to TR, white sound generators are not mandatory for category 1 patients. Due the fact that two patients decided to be fitted with these instruments, I would not consider any difference in the principles of sound therapy between both treatments. (WSG’s were not mandatory or recommended. But as you pointed out most of the patients in our sample size were hearing aid candidate not WSG’s)

The manuscript defines the issue posed (tinnitus rehabilitation) in a correct way. The title and the abstract convey the conclusions of the work. The method is appropriate and well described. The paper adheres to the relevant standards for reporting and data deposition. The discussion and conclusions are well balanced and adequately supported by the data. The limitations of the work are clearly stated. The authors seem to acknowledge the works upon they have built their paper. The quality of written English is acceptable. The statistics does not need to be reviewed by a statistician. (Thanks)

The manuscript could be accepted, although I would suggest some discretionary revisions:

ABSTRACT
1- Background: It should be included the description of the TR sound therapy applied for category 1 patients (“white noise generators were not mandatory or recommended”) (Done)
2- Results: It should be included the statistical value (p= ) after the scores for THI and VAS after the treatment. (Done)

METHODS
3- The second and third paragraph should be included in RESULTS instead of METHODS. The description of the data obtained from the subjects (age, duration, hearing loss; type of tinnitus, etc.) is not previously designed. It has been gotten after the study. (Done)
4- Tables usually show the information in a faster and more comprehensive way. I recommend changing paragraph 3 (type of tinnitus) into a table. (Done)

RESULTS / DISCUSSION
5- I recommend the use of a table for the presentation of the first paragraph of “decline in THI Score and VAS after TR” (Done)
6- Although it is discussed afterwards, the comparison of the results when using the SGs could be confusing. It should be described the causes to reject the use of SGs. If the patient has not sleeping problems or he cannot hear the SG because of his hearing loss, he will not acquire the device. (Done)
To compare the efficacy of SGs, the groups should be homogeneous (similar sleeping and hearing difficulties) (That is correct. However, I was not able to apply this to the current study. I have added this to the discussions though)
7- It has been concluded that the use of hearing aids (HA) is not crucial for
Tinnitus relief through TR. As it is argue in the discussion, all the patients that reject the hearing aids had only slight hearing loss. The group fitted with the HA included all degrees of hearing impairment. I would recommend comparing the efficacy of TR considering two groups with slight hearing loss, one with HA and the other one without it. The conclusion of this comparison could be interesting due the fact that nowadays, there is a tendency to use open-fit HA for slight hearing loss and tinnitus patients. (That is a good point. However, due to the small number of patients at this group (only seven), the conclusion should be interpreted with caution. I think it is better just to express the need for further research in this area.)

8- We cannot get any conclusion about the efficacy of White Sound Generators and Jastreboff’s category 1, because the sample is too small (only 2 patients were fitted with WSGs) (I accept this and discussed it in the paper)

CONCLUSION
9- The first paragraph, related to the absence of a control group (without treatment) has to be included in the DISCUSSION. It has not been commented in any part of the manuscript so it cannot be included in the conclusions. (That’s true. I have explained this in the discussions now)

10- It should be included the statistical value of “p= ” after the scores of THI and VAS. (Done)

Reviewer: Pawel Jastreboff
Tinnitus Rehabilitation in Adults: a Retrospective Study; Hashir Aazh
This interesting and well written manuscript presents results of use of simplified version of Tinnitus Retraining Therapy (TRT). The author obviously is familiar with TRT, recognizes and presents differences with full method. There are a few points which need clarification.

General:
The main results are pretty strong and clear, however, secondary findings are unclear and weak, perhaps due to small number of subjects in subgroups. I suggest that all data are reanalyzed using proper statistics, i.e., ANOVA with repetitions followed by paired test (for comparisons before-after) and with uncorrelated test for between subgroups comparisons. (I have reanalysed the data after adjusting the sample size based on your comment regarding excluding the patients with less than 3 months of TR. The result of ANOVA is as follow:

To assess the statistical significance of the effect of SGs, one-way analysis of variance (ANOVA) was conducted. The effect of SGs on decline in THI was significant; \( F=12.17, p < 0.005 \). One-way ANOVA shows no significant effect of SGs on the mean decline of VAS of tinnitus loudness (\( F=1.1, p=0.31 \)), tinnitus annoyance (\( F=0, p=0.99 \)), and effect on life (\( F=2, p=0.16 \)).

On-way ANOVA shows that the effect of HAs on the mean decline of THI was not statistically significant (\( F=0.05, p=0.81 \)). On-way ANOVA shows no significant effect of HAs on the mean decline of VAS of tinnitus loudness (\( F=0.77, p=0.39 \)), tinnitus annoyance (\( F=0.11, p=0.74 \)), and effect on life (\( F=0.01, p=0.94 \)).

The result of ANOVA is consistent with my findings using unrelated t test (uncorrelated test). I did not include the results of ANOVA to the paper.
because it might confuse my readers. Adding the ANOVA results may confuse them because I had only 2 groups to compare and ANOVA is usually used in order to compare 3 or more groups.

One figure with scatter diagrams and nonlinear regression will be helpful as well (see specific comments). (Done) Note, when providing statistical information always present number of degrees of freedom. (Done)

Presented material is very similar to submitted previously manuscript. The main difference is in time of data collection (from Feb 2006 in previous manuscript). One of the groups seems to be obtained using identical methodology as in this manuscript. Was it any particular reason not to include it in present data? If possible it would increase total number by 12 subjects. Visual inspection of means and SD create impression that results are indeed very similar. (They were already included)

Specific:
- Two months are too short time for evaluation due to placebo effect. I would suggest removing subjects who were in treatment for shorter time than 3 months. (Done)
- Please provide clear cut-off score for THI for acceptance patients to the analysis. (Done)
- From description (pager 6) it is not clear whether one or two wearable sound generators were used (Now explained)
- Provide a figure with three scatter diagrams for relations between decline in THI as a function of age, duration of tinnitus, and duration of the treatment. Calculate nonlinear regression checking whether there is improvement of R2 and provide values of R2 and its significance. Lack of correlation (i.e., linear dependence) does not preclude existence of dependence and can be misleading without visual inspection of the data or advance statistical analysis. As conclusion regarding importance of treatment duration is important, it need to be explored properly. (That is true. I have added the scatter diagrams for age and duration of tinnitus and corrected my sentences regarding “lack of correlation”. Now I have mentioned that there was no “linear correlation” between them.
I have omitted the section devoted to the correlation between the duration of TR and the decline on THI. This is because I have realized that in order to investigate such relationship I should have assessed the THI scores over time, not only pre-and post-treatment scores.)

- Conclusion regarding usefulness of WSG use is not justified as sample size was too small for any statements. Specifically, it is stated (page 11) that decline of 30% and 74% was observed for patients who did not use WSG decrease and who used them, respectively. However there were only two patients in group who use WSG and obviously, even in spite of large difference in extent of decrease, it was not significant. Providing number of cases in each group and number of degree of freedom are essential. Statements about significance or lack of it cannot be made when smaller group is not at least 6 (preferably 10). (I accept this and I have reworded this section. Given the small number of patients in this group and other limitations of this study it was impossible to conclude anything regarding the efficacy of
WSGs. Therefore, I have tried to avoid focusing on this issue and I have just briefly explained the condition in this group.)