Author's response to reviews

Title: Physical Therapy Treatment in Patients Suffering from Cervicogenic Somatic Tinnitus: Study Protocol for a Randomized Controlled Trial.

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Author's response to reviews: see over
Dear editor,

We would like to thank you and the reviewer for your interest in the paper we submitted. Your comments and critiques have been very useful to improve the manuscript.

All the changes the reviewer requested were carried out and are highlighted in the manuscript. An overview of the changes made is also listed in this document.

We hope our paper now meets all the criteria to be accepted for publication in ‘Trials’.

Kind regards,

Sarah Michiels
The changes made to adapt the paper to the reviewer’s critique are highlighted in the manuscript. An overview of the changes made is also listed below.

1. **Reviewer’s comments**

   **Comment 1:**

   *Abstract: the description of the outcome assessment points could be stated more clearly. As it is written, I was not sure whether the first and second mention of "six weeks" were referring to the same time point.*

   **Answer to the reviewer:**

   To clarify the outcome assessment points, the following changes were made:

   The original text:

   ‘Next, patients will be treated with a structured physical therapy with a maximum of 12 sessions of 30 minutes for a six weeks program. All measurements are provided before the start of the therapy, at the end of the therapy, 6 weeks and 3 months after the therapy, secondary outcome measures will be repeated 6 weeks after the therapy.’

   Was replaced by:

   ‘Patients will receive physical therapy with a maximum of 12 sessions of 30 minutes for a six weeks program. **Data from the TFI and NBQ will be collected at baseline (week0), at the start of therapy (week0 or 6), at the end of therapy (week6 or 12), 6 weeks after therapy (week12 or 18) and 3 months after therapy (week18 or 24). Secondary outcome measures will be collected at baseline and 6 weeks after the therapy (week12 or 18), as the maximal therapy effect on the cervical spine dysfunctions is expected at that moment.**’

   **Comment 2:**

   *Abstract, last sentence, it is not clear why secondary outcomes are measured at a different time point from the primary outcome(s).*

   **Answer to the reviewer:**

   The primary outcome measures (TFI and NBQ) are collected at each assessment point, to assess the effect of the treatment on tinnitus and cervical spine dysfunctions. The secondary outcome measures, mainly cervical spine assessment, are only collected at baseline and 6 weeks after the end of the therapy (week 12 for the direct treatment group and week 18 for the delayed treatment group), as the maximal effect of the cervical spine treatment is to be expected at this moment.

   The following sentence was added to clarify this statement:

   ‘**Secondary outcome measures will be collected at baseline and 6 weeks after the therapy (week12 or 18), as the maximal therapy effect on the cervical spine dysfunctions is expected at that moment.**’
The last sentence of the abstract was changed to:

This study is the first to investigate the effect of a standardized physical therapy treatment protocol on somatic tinnitus with a prospective comparative delayed design and **with blinded evaluator for baseline, end of the therapy and 6 and 12 weeks after therapy**.

Comment 3:

*Introduction, 1st sentence beginning "For instance" is not a complete sentence.*

Answer to the reviewer:

The original text:

‘Other recent studies in humans, found that in some patients, tinnitus could be evoked or modulated by input from the somatic system. For instance: by forceful muscle contractions of the head, neck and limbs and pressure on myofacial triggerpoints.’

Was replaced by:

‘Other recent studies in humans, found that in some patients, tinnitus could be evoked or modulated by input from the somatic system, for instance: by forceful muscle contractions of the head, neck and limbs and pressure on myofacial triggerpoints.’

Comment 4:

*Outcome measures section, what is meant by the "effect size" being a 13 point reduction for the TFI. Does this mean the threshold for clinically relevant improvement? Same question for similar statement at the end of the paragraph for NBQ.*

Answer to the reviewer:

The “effect size” being a 13 point reduction for the TFI is indeed the threshold for clinically relevant improvement.

The original text:

‘The effect size was a 13-point reduction.’

Was replaced by:

‘The clinically relevant reduction was a 13-point reduction.’

The “effect size” of the NBQ on the other hand is calculated using Cohen’s d, which represents the way the NBQ responds to changes in cervical spine complaints.

The original text:

‘The effect size was found to be high (Cohen’s d: 1.67).’

Was replaced by:
The effect size was found to be high (Cohen’s d: 1.67), which indicates that the NBQ is highly responsive to changes in cervical spine complaints.

Comment 5:

I did not understand the rationale for the primary (null) hypothesis. The active period for the treatment group is 6 weeks, then they are "inactive" from 6-12 weeks. The wait list group has been active at the end of end of 12 weeks. So, if I understand correctly, the null hypothesis is that there is no difference between 2 groups who received the PT, one of which just received it & one of which received it 6 weeks earlier. I was expecting the primary comparison point to be at 6 week, comparing an active vs. untreated group.

Answer to the reviewer:

This is indeed a good remark, the null hypothesis should be that there is no difference between the group that received the treatment and the group that did not receive the treatment at week 6.

The original text:

\[ H_0: \text{Change in TFI-baseline to TFI-12 weeks (treated) = Change in TFI-baseline to TFI-12 weeks (waiting list)} \]

\[ \text{Change in NBQ-baseline to NBQ-12 weeks (treated) = Change in NBQ-baseline to NBQ-12 weeks (waiting list)} \]

The primary outcome is a change in the scores on the TFI and NBQ after 12 weeks. The mean change in TFI and NBQ-baseline and TFI and NBQ-12 weeks follow up scores will be calculated.

Was replaced by:

\[ H_0: \text{Change in TFI-baseline to TFI-6 weeks (treated) = Change in TFI-baseline to TFI-6 weeks (waiting list)} \]

\[ \text{Change in NBQ-baseline to NBQ-6 weeks (treated) = Change in NBQ-baseline to NBQ-6 weeks (waiting list)} \]

The primary outcome is a change in the scores on the TFI and NBQ after 6 weeks. The mean change in TFI and NBQ-baseline and TFI and NBQ-6 weeks follow up scores will be calculated.
The same adjustments were made in other parts of the text:

A repeated measures ANOVA and post hoc tests will be used to compare the mean changes of the treatment and waiting list population at 6 weeks and secondary at baseline, 12 and 18 weeks follow up.

Comment 6:

It is not necessary to list both H0 and HA.

Answer to the reviewer:

HA was removed in the revised text.

Comment 7:

The TFI is initially stated as the primary outcome, then later in the methods it is stated that the "primary outcome is a change in the scores of the TFI and NBQ." These should be made concurrent.

Answer to the reviewer:

To make the text more concurrent, both TFI and NBQ are now stated as primary outcome from the start.

The original text:

‘The primary outcome measure, the TFI,...’

Was replaced by:

‘The primary outcome measures are the TFI and NBQ.’

Comment 8:

The discussion seemed to end abruptly. The statements about feasibility of recruitment may be better placed earlier, and the authors may want to consider a more general concluding paragraph.

Answer to the reviewer:

The statements about feasibility of recruitment were placed earlier as requested, and the following general concluding paragraph was added:

This study is the first to investigate the effect of a standardized physical therapy treatment protocol on somatic tinnitus with a prospective comparative delayed design and with blinded evaluator for baseline, end of the therapy and 6 and 12 weeks after therapy.
Please include an additional file title and legend section after your figure legend.

The following section was added after the figure legend:

Additional files:

Figure 1.pdf:
  Title: Delayed treatment design
  Description: figure explaining the delayed treatment design used in this study

Figure 2a.pdf:
  Title: Craniocervical flexion exercise in supine position (starting position)
  Description: picture of the starting position of a craniocervical flexion exercise

Figure 2b.pdf:
  Title: Craniocervical flexion exercise in supine position (end position)
  Description: picture of the end position of a craniocervical flexion exercise

Figure 3.pdf:
  Title: Craniocervical flexion exercise in sitting position
  Description: picture of a craniocervical flexion exercise in sitting position