

FINAL REPORT

STSM: Comparing Auditory Stimulation Effects in Different Tinnitus Subtypes

TABLE OF CONTENTS:

- 1. DESCRIPTION OF THE WORK CARRIED OUT DURING THE MISSION**
 - 1.1 AUDITORY STIMULATION**
- 2. RESULTS**
 - 2.1 POSITIVE POINTS**
 - 2.2 DRAWBACKS**
 - 2.3 STATISTICAL ANALYSIS RESULTS**
- 3. FUTURE COLLABORATION WITH THE HOST INSTITUTION.**
- 4. CONFIRMATION BY THE HOST INSTITUTION OF THE EXECUTION OF THE STSM**

1. DESCRIPTION OF THE WORK CARRIED OUT DURING THE MISSION

We conducted a small pilot study to evaluate a new tinnitus therapy which is based on auditory stimulation. The therapy is meant to produce immediate inhibitory effects. Each session lasted about 1.5 hours, including explanations plus stimulation. The duration of the study was three weeks.

There were 9 participating patients: Mr. S1., Mr. W1., Mr. H., Mr. W2., Mr. V., Mr. M., Mr. K., Mr. S2., and Ms. K. We used numeric rating scales to evaluate the degree of tinnitus distress at the following moments: just before the therapy session, just after the therapy session, 6 hours after the session and the day after the session. The Tinnitus Sample Case History Questionnaire (TSCHQ) was used before treatment to assess patients' details.

We used the following equipment:

- Software: Max 6 audio programming environment.
- Hardware controller: PDC-08B by Power Dynamics.
- Headphones: Sennheiser HDA 200.

A translator was needed for the communication between the researcher and the patients in their native language (German). The following picture shows the lab setting.

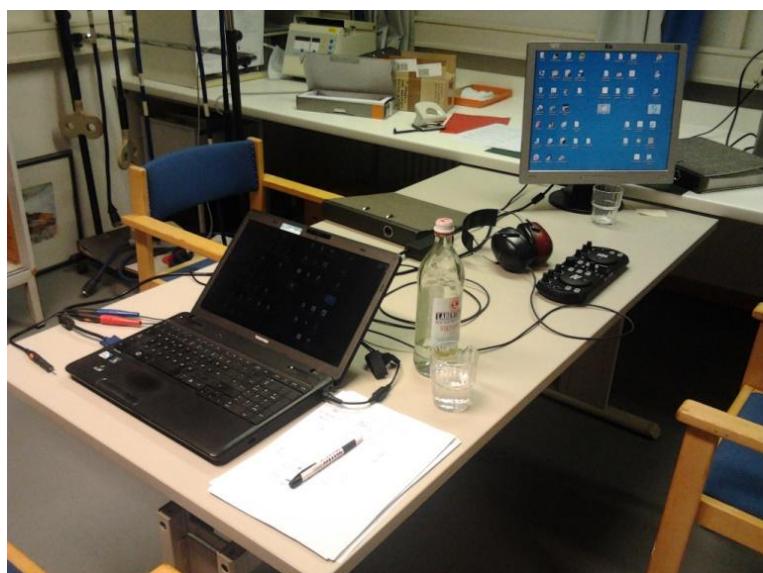


Figure 1: Lab setting

Regarding tinnitus subtypes we asked the following questions to all the patients:

- Is your tinnitus a pure tone or a band-pass noise?
- Do you hear only a tone or is it accompanied by an amalgam of other noises?
- Was tinnitus onset sudden or it developed gradually?
- Is your tinnitus always the same or does it change often?
- Do you prefer silent or sound-enriched environments? Or, when your tinnitus is bad, do you prefer silent or sound-enriched environments?
- Does your tinnitus react to external sounds?

1.1 AUDITORY STIMULATION

I developed this therapy as a result of an empirical research experimenting with my own tinnitus and many types of acoustic and electronic sounds during three years. My tinnitus consisted of a permanent high pitch tone accompanied by an amalgam of whistles. The therapy uses an interactive band-pass noise generator. The method consists of two stages. The first stage aims to globally eliminate the amalgam of whistles. At the end of this stage the tinnitus used to be typically reduced to only the permanent tone. The second stage aims to individually remove such a tone.

With this therapy I experienced long lasting tinnitus inhibition. In every therapy session I managed to eliminate all the tones and whistles that formed the tinnitus. At the end of every session, it typically remained a residual broad band noise without a predominant pitch, so it was not bothersome.

With time, the tone and whistles used to reappear, which is why the therapy had to be applied on a regular basis, typically once a day, usually just before going to sleep. Continuing with the treatment, the tone disappeared permanently and the whistles used to take longer to reappear and with lower intensities. Therefore, the therapy is needed less and less often, typically every four or five days after three months of treatment. After six months of treatment the therapy was needed every one-to-three months. It was after approximately one year of treatment when the therapy was last applied and currently, it has been more than four years without the need of another session.

2. RESULTS

In summary, we had positive results even though the patients showed a lack of ear training to match their tinnitus frequency precisely. Without a precise pitch matching, the principles of many therapies, not only this one, may not come into play at all. Even though, some other aspects of the therapy gave positive results.

Also, the possibility of offering personalised treatments proved to be very convenient. By means of bespoke audio programming, we had the opportunity to try certain variations and make tailored adaptations of the therapy for some patients. We also implemented and tried a new therapy approach successfully with one patient.

2.1 POSITIVE POINTS

- One patient went home with no tinnitus at all on two different days. This inhibition lasted for several days.
- Interactivity: in general, the patients used to like playing with the device. The feeling of having full control over the sound generator seemed to be good for them. During the therapy they could monitor their tinnitus very often and could stop the sound and quit the therapy at any moment.
- Most of the patients wanted to repeat sessions. The only one who did not show interest in repeating was Mr H. He, however, reported at the end of the therapy session that his tinnitus "definitely experienced changes, clearly for the better". The reason why he did not want to repeat

could be because in a psychological therapy group he was trained not to be hopeful for any new therapy.

- A number of patients experienced immediate beneficial effects. Some found the 1st stage of the therapy beneficial, like Mr. W2, 2nd session of Mr V.... Some others found the 2nd stage beneficial like Mr. K. who reported the bandwidth of his tinnitus was narrower. Also, Mr M. was very excited to experience some sort of Residual Inhibition (RI) maybe for the first time. Not to mention Mr. S1. who went home with no tinnitus at all on two occasions.
- Ms K. clearly noticed how her tinnitus was reacting to certain sounds of the therapy. Although her tinnitus loudness did not improve significantly, she scored very positively on the questionnaires.
- Some patients found the pitch matching method better than others they have tried before, like Mr. K. and Mr. M.
- Thanks to repeating sessions we could make tailored adaptations of the therapy to some patients, like Mr. W2.
- We implemented with successful results a new approach suggested by Winfried Schlee. It is based on adding modulations (AM plus FM) to the original stimulation protocol.

2.2 DRAWBACKS

- The main problem we identified is the lack of ear training, on the part of the patients, to match their tinnitus frequency with precision. This handicap was identified with a game specifically programmed for this study; the game uses a virtual tinnitus tone to assess the capability of the patient for frequency matching. This is a crucial step that can make the principles of the therapy not brought into play at all if it is not done correctly. We have started a collaboration with a technical department of the University of Ulm to implement an ear training software specifically designed for tinnitus patients. This might be useful also for other existing therapies.
- Also the patients may need more time to practice with the interactive controller in order to get more results, as Mr. M. expressed himself.
- Some patients used to be quiet stressed in the first session because they were facing something new. This level of stress led to an increase of tinnitus distress in some patients, like Mr. V. In the subsequent sessions this problem diminished.
- Three patients reported their tinnitus was worse after 6 hours, but then, the day after, it recovered to normal levels. We tried not to overexpose the patients to the sounds by not extending the stimulation for more than one hour.
- Maybe we did not get more results with the 1st Stage because it is meant to treat an amalgam of whistles or other noises that accompany the main tone. Not any patient reported having such amalgam. Only Mr. K. reported to have a soft whistle accompanying his strong band-pass pitched noise, and after the 1st Stage he reported that the whistle was “hardly heard”.

2.3 STATISTICAL ANALYSIS RESULTS

With only 9 participants in 16 treatment sessions the number of observations was very low. Also, in the pilot study, it was only possible to assess short-term effects. Even so, a statistical analysis was performed. As can be expected with such an underpowered study, the resulting p-values were all above the significance threshold of $p=.05$. The more important value of the pilot study can be found in the test of feasibility and the case reports. Nevertheless, the short-term results are encouraging to perform a long-term study with similar auditory stimulations.

Statistical testing has been performed with mixed models ANOVAs using "nlme" library running under the open source R statistical software (www.r-project.org).

Assessment	Result	Comment
Reactions of the tinnitus	in 100% of individuals	Reactions in different directions. One patient reacted only in the second session after several adjustments.
Tinnitus Annoyance	mean reduction: 0.81 (14%) $F(1,8) = .09, p > 0.7$	Tinnitus Annoyance has been assessed with a 11-point numeric rating scale.
Tinnitus Loudness	mean reduction: 0.38 (6.6 %) $F(1,8) = .86, p > 0.3$	Tinnitus Loudness has been assessed with a 11-point numeric rating scale.

Furthermore, a subset of patients with hyperacusis has been compared with a subset of patients without symptoms of hyperacusis. The time x group interaction did not reveal any significant effect for the loudness scale ($F(1,7) = 0.34, p > 0.5$) and the annoyance scale ($F(1,7) = 1.2, p > 0.3$)

It needs to be mentioned that the long-term effects were better in the case of the therapy author himself, despite his hyperacusis.

3. FUTURE COLLABORATION WITH THE HOST INSTITUTION.

As mentioned above, we have started a collaboration to develop a pitch-matching training software. Eventually, the software will be available to patients. Then, it would be interesting to conduct another study that includes a training programme using this software.

It would be also interesting to conduct a brain imaging study with those patients that report a significant loudness reduction, like Mr. S. (This patient, however, has only mild to moderate tinnitus and perhaps the contrast in the scan would not be sufficient). Such study could give new insights for a better understanding of the neural mechanisms behind this therapy.

Along the same lines, single-subject studies with those patients reporting good results would be both interesting and necessary since the literature in this field reports a lack of this kind of studies.

4. CONFIRMATION BY THE HOST INSTITUTION OF THE EXECUTION OF THE STSM

A letter by the host institution is attached to this report.