2pPPb25. Intervention for restricted dynamic range and reduced sound tolerance: Clinical trial using a Tinnitus Retraining Therapy protocol for hyperacusis

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Hyperacusis is the intolerance to sound levels that normally are judged acceptable to others. The presence of hyperacusis (diagnosed or undiagnosed) can be an important reason that some persons reject their hearing aids. Tinnitus Retraining Therapy (TRT), a treatment approach for debilitating tinnitus and hyperacusis, routinely gives rise to increased Loudness Discomfort Levels (LDLs) and improved sound tolerance. TRT involves both counseling and the daily exposure to soft sound from bilateral noise generator devices (NGs). We implemented a randomized, double-blind, placebo-controlled clinical trial to assess the efficacy of TRT as an intervention for reduced sound tolerance in hearing-aid eligible persons with hyperacusis and/or restricted dynamic ranges. Subjects were assigned to one of four treatment groups (2x2): Devices: NGs or placebo NGs and Counseling: Yes or No. They were evaluated at least monthly on a variety of audiometric tests, including LDLs, the Contour Test for Loudness for tones and speech, and word recognition measured at each session's comfortable and loud levels. Eighty percent of the participants who received full treatment benefited significantly; whereas the other treatment groups demonstrated ≤ 45% treatment efficacy. Treatment dynamics and examples of improved word recognition post-treatment will be described. Supported by NIH R01 DC04678.
INTRODUCTION

Hyperacusis is an intolerance to the loudness of sounds that most individuals deem to be tolerable. Hyperacusis can occur with or without hearing loss, and is sometimes associated with tinnitus. The focus of our current research is on persons who have sound intolerance, nominally hyperacusis and hearing loss. These individuals often need amplification to compensate for their hearing loss, but find prescribed amplification of sounds via hearing aids too loud to tolerate. Consequently, they may either reject hearing aids, assume that they cannot tolerate hearing aids and never try them, or they may attempt to use amplification sub-optimally. For this group of patients to be fitted successfully with hearing aids, they may require large amounts of compression, inordinate decreases in the maximum output level, or diminished prescriptive target gains, each of which are less-than-optimum strategies for hearing aid fittings.

Our primary goal was to establish whether Tinnitus Retraining Therapy (TRT), which has been used with some success to treat tinnitus and hyperacusis for almost two decades, can be helpful to hearing-impaired patients with limited sound tolerance. There have been reports that Loudness Discomfort Levels (LDLs) rise in many tinnitus patients during their TRT treatment [1,2,3]. This finding led to modifications of the TRT protocol to manage patients with hyperacusis [4]. The purpose of this project was to conduct a controlled clinical investigation of modified TRT that might ultimately be implemented as an intervention for hearing-impaired persons with sound tolerance complaints and/or limited dynamic ranges that restrict their use of amplified sound from hearing aids.

METHODS

How is Hyperacusis Treated with TRT?

The intervention under trial in this study is based on a modified TRT protocol, which has been used with considerable success for treating hyperacusis patients. Classical TRT uses directive counseling to initiate habituation of the tinnitus percept, and sound therapy from ear-level noise generators to facilitate the habituation process. TRT is used in this study to treat sound intolerance as the primary complaint, with the focus of the counseling session on the sound intolerance problem rather than on tinnitus.

Clinical Trial Design

Our investigation was designed as a randomized, placebo-controlled, clinical trial. Nine participants were assigned to each of four treatment groups: 1) full treatment, which included bilateral noise generators (NGs) and counseling; 2) placebo NGs and counseling; 3) NGs alone; and 4) placebo NGs alone. This design allowed us to assess the effects of full treatment as well as the effects of sound therapy, provided by the NGs, separately from the effects of counseling.

Test Session

Subjects were evaluated repeatedly over intervention periods of 5 to 12 months in a series of tests, including repeated measures of air-conduction thresholds, LDLs for tones and white noise, and categorical loudness judgments for FM pulsed tones and recorded spondaic words measured per the Contour Test of Loudness [5]. Also included were repeated measures of NU-6 word recognition scores for sound levels reported as “comfortable” and “loud, but OK” for the Contour Test using speech stimuli. Electrophysiological measures of auditory brainstem (ABR) and middle latency (MLR) responses also were recorded across repeated sessions, but these data are not considered here.
RESULTS

Changes in Loudness Discomfort with Treatment

The primary aim of the study was to assess the validity and efficacy of the TRT intervention, as modified to treat sound intolerance as the primary complaint. Secondary aims were to evaluate and parse the partial treatment effects of directive counseling and sound therapy (i.e., the two main components of the intervention).

We observed early on in the study that when LDLs improved over the course of an intervention, these treatment-related shifts generally were apparent within the first 4 months of the intervention. An initial early shift in the LDLs was observed, which plateaus around 6 months after the onset of full treatment with counseling and use of NGs. This observation led us to modify the treatment period to finish each intervention after 6 months and, subsequently, allow participants who were not assigned to the full treatment group to cross over and receive full treatment for an additional 6 months.

The LDL for 1000 Hz (hatched bars) and the average level for “Uncomfortably Loud” reported on the Contour Test for 500 and 2000 Hz (open bars) are shown in Fig. 1 for each participant in their treatment group. Initial results measured at baseline before the start of each treatment (shown with unfilled bars) are shown alongside the results measured after 6 months of treatment (shown with filled bars). The participants’ results are marked with a large asterisk if the change with treatment for either the LDL or the Contour 7 judgment increased by more than 10 dB. The treatment success rate was 80% for the NGs with Counseling group, 25% for the placebo NGs with Counseling group, 45% for the NGs without Counseling group, and 43% for the placebo NGs without Counseling group. Thus, the full treatment, combining Counseling and NG, yielded the greatest positive treatment benefit.

![Graph showing changes in LDL and Contour Test results for different groups.](https://example.com/graph.png)

**FIGURE 1.** Change in LDL (1000 Hz) and “Uncomfortably Loud” for the Contour Test (averaged over 500, 2000, 4000 Hz) for individual subjects over the course of each treatment. Large asterisks denote a change of more than 10 dB. Defects in the sensing mechanism caused some early placebo units to behave as conventional NG devices over some portion of the treatment period. These failures are marked with a cross on the participant number shown along the x-axis label, and these participants are presented in the as-treated groups with NGs instead of placebo NGs.

Changes in Loudness Growth with Treatment

Consistent with the changes in the LDL and categorical judgements of “Uncomfortably Loud” are the positive treatment-related changes in loudness growth. These changes are most evident for Group 1, the full-treatment group, between baseline assessment and the end of treatment, calculated as the average of the last two study visits. Note the clear separation of the functions for loudness judgements “Comfortable” and louder, and the shallower and extended growth function measured at the end of treatment. Group 3, which was assigned to NGs without counseling, also showed a nominally positive treatment effect, on a smaller scale than for Group 1; whereas, Groups
2 and 4 showed little or no differences in loudness growth as a consequence of treatment at 500 Hz. The results for 2000 and 4000 Hz are similar to those shown here for 500 Hz.

FIGURE 2. Group mean loudness growth functions for a pulsed 500-Hz warbled tone measured prior to treatment, at baseline, and at the end of treatment as calculated by the average of the level for each categorical loudness judgement at the last two study visits.

Group Treatment Dynamics

The dynamics of the group treatment effects as a function of months of treatment are shown in Fig. 3 for changes in the “Uncomfortably Loud” categorical judgements for 500, 2000 and 4000 Hz. Within each group, the results are similar across frequency. A significant treatment effect over time is observed only for Group 1 and is on the order of 10-12 dB for the “Uncomfortably Loud” judgements. This dynamic treatment effect is on the order of 7 dB and is significantly different from the treatment dynamics of the other treatment groups when the categorical judgements for “Comfortable, but Loud”, “Loud”, “Uncomfortably Loud” are considered together as determined by a two-way mixed effects ANOVA (p<0.02).

FIGURE 3. Group average treatment effects over time for changes in the “Uncomfortably Loud” category as measured by the Contour Test for Loudness. Shown are linear fits to changes from baseline for individual subjects over time for 500, 2000 and 4000 Hz.

DISCUSSION

The TRT protocol for hyperacusis can be used as a treatment to help persons with sound intolerance improve their conditions prior to being fitted with hearing aids. Furthermore, Group 1 participants, who received full
treatment (i.e., NGs + counseling), achieved significantly better results than any of the partial treatment groups considered in this study with 80% of the participants achieving at least 10 dB improvement in level for “Uncomfortably Loud” by 6 months of treatment. In contrast, the partial treatment (Groups 2 and 3) or no treatment (Group 4) groups had no more than 45% of participants meet this criterion.

There was a positive treatment-related change in loudness growth for Group 1 at all frequencies. “Comfortable” and louder sounds were judged at a higher level after the treatment. A nominal positive treatment effect was also seen for Group 3, the group with NGs without counseling.

The improvement in tolerance of “Uncomfortably Loud” sounds was similar in magnitude for 500, 2000 and 4000 Hz sounds. While the time course varied across participants, any improvements were generally observed by 2-4 months with stable results by 6 months of treatment.

At the conclusion of the study, many of the participants were better able to tolerate amplified sounds from their hearing aids. Future research will extend the principles and theories in the current study to practical applications in hearing aids to minimize the need for compression, enhance the dynamic range for aided sound, and optimize hearing aid benefit.

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REFERENCES


