

## **Title: Clinical Validation of a Novel Combination Hearing Aid and Tinnitus Therapy Device**

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**MeSH words:** Tinnitus, Tinnitus Treatment, Hearing Aids

**Objectives.** Chronic tinnitus is the persistent sensation of a sound that exists only inside the head. It is at the present time an incurable auditory disorder. Hearing loss, either the result of age or noise-exposure, is closely associated with tinnitus, and patients who suffer from both are in need of management techniques that address both disorders. Auditory stimulation can be an effective form of therapy for tinnitus sufferers, and digital technology has allowed for features such as masking noise to be integrated into hearing aid devices. This noise is shaped to the hearing aid user's specifications so that the greatest amount of tinnitus masking (or tinnitus relief) is achieved. Starkey Hearing Technologies, Inc. has created an ear-level combination instrument that offers both amplified sound and shapeable noise. The objective of this research project is to conduct a pilot study to determine whether use of the shapeable noise with Starkey combination instruments provides significant relief from tinnitus for hearing impaired individuals who also suffer from bothersome tinnitus.

**Plan.** This single-site pilot study used both an experimental group and a control group to evaluate whether the noise-generating feature on Starkey combination instruments provides significant relief from tinnitus for individuals suffering from both hearing impairment and bothersome tinnitus. Thirty subjects were enrolled and randomized to one of the two groups. Each subject participated for 3-4 months, and all data collected over a 6-month period.

**Methods.** Interested callers were screened over the telephone to ensure as much as possible that they are suitable candidates. The Tinnitus and Hearing Survey (THS) was administered during this call; those who reported "clinically significant" tinnitus as determined by the questionnaire were invited to attend an appointment for consenting and further testing. During Visit 1, candidates completed the consenting process, underwent additional screening measures, and completed questionnaires. Those who qualified for the study returned 1-2 weeks later to be fitted with the combination instruments. During this visit, participants were also counseled on how sound can be used to make tinnitus less of a problem, as described in pages 31-64 of the "Progressive Tinnitus Management: Counseling Guide." Participants were randomized to either the experimental or control group. Those in the experimental group had the noise portion of their combination instruments turned on and adjusted to achieve the greatest degree of relief from tinnitus. The control group did not have the noise portion turned on. Participants returned 1-3 weeks after fitting to check on use and performance of the combination instruments, with adjustments and counseling provided as necessary. They returned 3-4 months after fitting for final outcome assessments. Participants were allowed to keep the Starkey combination instruments following their successful completion of all four study visits.

**Findings to Date.** Thirty individuals with hearing impairment were enrolled into this study, and all were fitted with bilateral hearing aids. Both groups revealed significant improvement, as indicated by reductions in mean TFI index scores. Differences between groups at 3 months were not statistically significant. However, the experimental group showed a mean reduction in the TFI score that was 6.4 points greater than that for the control group. Results of this study suggest that the use of hearing aids alone or hearing aids plus the use of sound generators both provide significant benefit with respect to alleviating effects of tinnitus. Average hours of daily use were excellent for both groups. Data collection for this study is complete, and additional data analysis is pending.

**Relevance to VA's Mission.** Tinnitus is the most common of all the service-connected disabilities for military Veterans. By the end of Fiscal Year 2011, a total of 840,865 Veterans were service connected for tinnitus. The focus of this study is to determine whether a combination hearing aid and tinnitus masker device by Starkey can provide relief for these Veterans.