

Title: Multi-Site Evaluation of Progressive Tinnitus Management

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Objectives: Tinnitus prevalence increases with age, and exposure to high levels of noise is the most commonly reported cause of tinnitus. Veterans are especially at risk for incurring tinnitus—they tend to be older than the general population, and their military experience often involves hazardous-noise exposure. Although tinnitus is a significant and escalating problem for Veterans and for the VA healthcare system, the VA has not implemented a standardized method of tinnitus management. Our efforts have focused on developing tinnitus management methodologies for Veterans, culminating in the study “Progressive Intervention Program for Tinnitus Management” (RR&D C4488R). As a result of this pilot study we have developed a defined methodology referred to as Progressive Tinnitus Management (PTM), which consists of five levels of care: (1) Triage; (2) Audiologic Evaluation; (3) Group Education; (4) Interdisciplinary Evaluation; (5) Individualized Support. The goals of this study are to (a) determine the program’s benefit to Veterans and (b) perform a qualitative program evaluation to determine the appropriateness of PTM for utilization as a standard tinnitus management program for VA medical centers.

Plan: Building on accomplishments thus far, the study will: refine PTM, assure the protocol can be introduced and maintained in various VA settings, add psychological management components to the protocol, and evaluate patient outcomes for the modified protocol. The design of the study is a two-group multi-site randomized clinical trial. One group will receive “usual care” for their tinnitus. The second group will receive PTM.

Methods: At each of the two study sites there will be no advertising or recruiting that would affect normal clinical function. Patients will come to the audiology clinic as they normally do. If they complain of tinnitus during the appointment, then the attending audiologist will inform them about the study and give them a recruitment flyer. Following basic audiology services, patients who are interested will meet with the Research Assistant who will explain the study, conduct screening, perform informed consent, and administer baseline questionnaires. Enrolled participants will be randomized to receive either “immediate PTM” or “usual care” (wait-list control). The immediate-PTM cohort will attend the next series of Level 3 Group Education workshops. The usual care group will wait 6 months before starting the Level 3 workshops. Participants in both cohorts will receive the same Level 3 workshops and they all will have the opportunity to progress to Levels 4 and 5 as needed. Outcomes will be compared between groups during the 6-month control period.

Findings to Date: This study continues work that was completed during the pilot study. The present study is in the planning and setup stage, and subjects will be recruited starting in February 2011.