Project Title: Randomized Controlled Trial of a Novel Device for Acoustic Treatment of Tinnitus During Sleep
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Abstract

Objective
The purpose of this research is to compare three different methods of using sound during sleep and evaluate if these sounds offer relief from bothersome tinnitus.

Plan
Everyone who qualifies for this research will receive a device that produces sound. This is a randomized clinical trial and eligible participants will be assigned to one of three treatment groups. All of the groups will listen to sound from their respective device while they sleep. Two of the groups will listen to sound through custom-fit earbuds and the third group will listen to sound from a bedside/tabletop sound generator.

Methods
Sixty adults meeting all inclusion criteria will be enrolled and randomized to one of three groups. The initial appointment will determine eligibility and which group participants will be randomized into. All eligible participants will return 2 weeks after the initial appointment to receive their respective devices. Participants will use the devices for approximately 3 months at which time they will return and complete the final outcome measures. The Tinnitus Functional Index is the primary outcome instrument. Participants will be allowed to keep their devices after completing all study requirements.

Clinical Relevance and Relevance to VA's Mission
Tinnitus is the most prevalent service-connected disability for Veterans (Veterans Benefits Administration, 2013) and currently there is no "cure." Data generated from this research will help to assess the relative effectiveness of different methods of using sound during sleep compared to other methods of tinnitus management in providing tinnitus relief for Veterans and millions of people who have bothersome tinnitus.

MeSH Terms: Tinnitus, Evaluation Studies, Outcome Assessment (Health Care)