

**Project Title: Clinical Trial of Transcranial Magnetic Stimulation for Relief of Tinnitus**  
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**Project Summary/Abstract**

Repetitive transcranial magnetic stimulation (rTMS) is a non-invasive intervention that involves delivering electromagnetic pulses through a coil to the subject's scalp. Ultimately, some of this energy is transmitted through the skull and affects the activity of underlying neural tissue. Because tinnitus is associated with superfluous neural activity in the central auditory system, rTMS has the potential to reduce patients' perception and severity of tinnitus. Several investigators have used rTMS successfully on relatively small populations of tinnitus patients.

**Objective:** Our *long-range goal* is to develop a safe, practical, effective and cost-effective treatment for chronic tinnitus. The *objective of this proposal*, the next step toward attaining our long-range goal, is to conduct a well-designed, placebo-controlled clinical trial of rTMS in a large sample of tinnitus sufferers.

The *central hypothesis* of the proposed research is that rTMS can reduce the perception of tinnitus for prolonged periods of time with minimal adverse side effects. Our hypothesis has been formulated on the basis of supportive preliminary studies.

**Specific Aims:** We will test our central hypothesis and accomplish the objective of this application by pursuing the following two *specific aims*:

- 1. Conduct a double-blinded, randomized, placebo-controlled clinical trial of low frequency (1 Hz) repetitive transcranial magnetic stimulation (rTMS) in a large sample of people who experience chronic tinnitus.**

We hypothesize that application of 2000 pulses of 1 Hz rTMS daily for 10 successive work days will result in statistically and clinically significant reductions in tinnitus loudness and severity for the treatment group compared to the placebo group.

- 2. Track the progress of subjects who participated in the clinical trial for six months post-treatment.**

We hypothesize that improvements in tinnitus loudness and severity experienced by the treatment group will be sustained during the follow-up period. The placebo group will not experience significant changes in tinnitus loudness and severity during the follow-up period.

**Study Design:** This will be a prospective, randomized, subject and clinician/observer blind, placebo-controlled parallel-group clinical trial of rTMS involving a sample of 168 people who experience tinnitus. Subjects will receive either active or placebo rTMS therapy on 10 consecutive work days. Outcomes will be measured prior to the start of treatment, immediately before and after each therapeutic session. Follow-up evaluations will be conducted 1, 2, 4, 13 and 26 weeks after the last treatment session. The target population (to whom the study findings will be generalized) for this investigation includes people who experience bothersome, chronic tinnitus.

**Impact:** At the conclusion of the study, protocols will be identified and developed that maximize the efficacy of rTMS to reduce tinnitus severity. Clinicians will then be able to administer rTMS therapy to tinnitus patients in the most effective ways to reduce the severity of their condition.