

Title & Abstract Level 1 Screening Form Help Sheet

2. Is this an animal research study?
Yes [stop] -- <i>i.e., the research participants are not human, implication of findings are not sufficient to retain citation in our search. If yes, submit this form now.</i>
No/Unclear

3. What is the age group of the research participants?
Under 18 years [stop] <i>-- i.e., a teenage or pediatric population. If yes, submit this form now.</i>
18 years of age or older/Unclear

4. Is the research limited to a focus on pulsatile tinnitus only?
Yes [stop] -- <i>please note: Pulsatile Tinnitus may be referred to as "PT" or "objective tinnitus". Pulsatile tinnitus can be heard by a doctor using a stethoscope (like a pulse), an audible sound emanates from the patient's ears. The sound may have an identified cause.</i> <i>If yes, submit form now.</i>
No/Unclear

5. Does the research address any of the following:
a) Tinnitus symptoms b) Tinnitus diagnosis; or diagnostic instruments/tests c) Tinnitus treatments/interventions
Yes/Unclear -- any or all of these subjects themes are considered a) Symptoms – ringing, buzzing in the ears, qualification of the sound perceived (e.g., pitch, volume) b) Diagnosis, diagnostic instruments/tests – i.e., evaluation of the perception of sound, source of sound, and/or impact on patient's daily life (e.g., physical exam, questionnaires, hearing test, CT scan, MRI) c) Treatments/interventions – i.e., medical/surgical (e.g., Pharmacological, Laser, TMJ and Complementary/Alternative Medicine therapies or treatments), technological (e.g., sound maskers, hearing aids, etc.), psychological (e.g., Tinnitus Retraining therapy, Cognitive Behavioral Therapy, etc.); alternative medicine; or combinations thereof
No [stop] -- <i>None of the above are addressed or Tinnitus is a result of another pathology (e.g., a symptom or outcome of another illness/disease/drug, i.e., brain tumor, hypertension, drug side effect/interaction). If so, submit this form now</i>

6. What is the research study design?
RCT or CCT (Randomized control trial, clinical control trial, other research that has been randomized)

Randomized Controlled Trial RCT: A controlled clinical trial that randomly (by chance) assigns participants to one of two or more groups. There are various methods to randomize study participants to their groups. Identifying words: – randomization; Open trials; Single blind trials; Double blind trials; Triple and quadruple-blind trials; explanatory trial. *Example:* An example is a *randomized controlled trial* (RCT) to understand whether calcium tablets work to prevent broken bones in women with low bone density. Women with low bone density are randomly assigned to one of two groups. One group receives calcium and the control group receives a placebo (inactive substance). The number of women who suffer fractures in each group are compared to find out whether calcium works. **Controlled Clinical Trial CCT:** A type of clinical trial comparing the effectiveness of one medication or treatment with the effectiveness of another medication or treatment. In many controlled trials, the other treatment is a placebo (inactive substance) and is considered the “control”. *Example:* An example of a *controlled clinical trial* is one in which people who took a particular anti-depressive drug were compared with people who did not take the drug to determine its effectiveness in lowering blood pressure.

Observational study (cohort, case-control, case-series)

Cohort Study: A clinical research study in which people who presently have a certain condition or receive a particular treatment are followed over time and compared with another group of people who are not affected by the condition. *Example:* For example, a study that measures effects of tinnitus on quality of life in the same group of men and women with different blood pressure levels over a long period of time.

Case-control study (also called a retrospective study): A study that compares two groups of people: those with the disease or condition under study (tinnitus) and a very similar group of people who *do not* have the disease or condition. Researchers study the medical and lifestyle histories of the people in each group to learn what factors may be associated with the disease or condition. For example, in the case of tinnitus, they may look at environmental noise influences, current drugs being taken, etc.

Case Series (also known as a *clinical series*): a medical research observational study that tracks patients with a known exposure given similar treatment or examines their medical records for exposure and outcome. (Example: 100 patients with tinnitus using a masking device – impact of tinnitus is measured prior to use of device and after; or 100 active-duty soldiers exposed to noise with outcome of tinnitus treated with....). It can be retrospective or prospective and usually involves a smaller number of patients than more powerful case-control studies or randomized controlled trials. Case series may be *consecutive* or *non-consecutive*, depending on whether all cases presenting to the reporting authors over a period of time were included, or only a selection. Case series studies do **not** make comparisons *between* groups.

Systematic review or meta-analysis

Systematic Review: A summary of the clinical literature. A systematic review is a critical assessment and evaluation of all research studies that address a particular clinical issue. The researchers use an organized method of locating, assembling, and evaluating a body of literature on a particular topic using a set of specific criteria. A systematic review typically includes a description of the findings of the collection of research studies. The systematic review may also include a quantitative pooling of data, called a meta-analysis. *Example:* Scientists collect all the published studies that compare types of treatment for hypertension. They compile the results of these studies, using in-depth statistical methods (a comparative effectiveness review which is a type of *systematic review*.)

Narrative or descriptive review [stop] Submit form now

Case study [stop] Submit form now

Case Study Like a case series, but focused only a single case. WE ARE NOT INTERESTED IN SINGLE CASE STUDIES

Unclear – another type of design is mentioned or the citation does not discuss research design