Reviewer’s report

Title: Protocol for a multi-centre randomised controlled stand-alone feasibility trial to assess effectiveness and cost effectiveness of digital hearing aids in patients with tinnitus and hearing loss (The HUSH Trial)

Version: 0 Date: 10 Nov 2019

Reviewer: Lawrence Mbuagbaw

Reviewer's report:

The investigators report the protocol for a randomized feasibility trial of hearing aids and treatment as usual versus treatment as usual for people with tinnitus. Feasibility, acceptability and economic outcomes will be assessed.

The background is clear and well written.
In the methods section the bullets look like the letter O. See line 160 and others.
The choice of feasibility outcomes is appropriate.

There are two major concerns:

1. The feasibility outcomes are not operationalised. What proportion of eligible participants would indicate that a larger trial is feasible? Please report a threshold for all the feasibility outcomes. How will the data from other outcomes be used: proportion recruited and randomized, trial retention, completeness of collected data etc.

2. The sample size estimation is removed from feasibility. It is based on estimates of quality of life which are reported as a primary endpoint but are only listed third among the patient reported outcome measures.
   a. Sample size could be determined based on the primary feasibility measure: recruitment
   b. It is unclear how 800-1000 number was achieved and why 100 over 12 months will indicate feasibility.
   c. A sample size of 100/12 months is reported as what will indicate feasibility. This does not tie with the feasibility outcome reported above - a proportion. What proportion does 100 represent.
       The statistical analyses section does not indicate how the feasibility outcome measures will be interpreted.

The investigators are invited to use resources to improve the clarity of the decisions made in designing and interpreting the study.

Sample size for pilot studies: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4876429/
General information on pilot studies: https://www.ncbi.nlm.nih.gov/pubmed/20053272
Level of interest
Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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