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: 09 Oct 2019

Reviewer: Michael Campbell

Reviewer's report:

This is a well described protocol for a clinical trial in tinnitus.

A few minor points

1) The intervention and outcomes are well described, but I assume this is an external pilot trial, and so the results of this trial will not be included in the main trial? This could be stated in the title.

2) The sample size for the main trial is indicated as between 800 and 1000 patients, (line 245) and the authors state that if they can recruit 100 patients over 12 months in 5 centres they would proceed to a main trial. They might also use the results of the pilot to help the sample size for the main trial (eg estimates of the variance of the outcome measure and the correlation between baseline and outcome) They could state definitively how low below this target would they have to go before the main trial is abandoned.

3) Have they got any other stop/go criteria (eg proportion of people who refused to enter the trial, total lack of evidence of efficacy or patients who did not accept the control if they were randomised to it

4) The authors could state that they would consider the CONSORT statement for pilot trials when the report the results.1

5) will all the outcome measures in the pilot be used in the main trial, What is the primary one, or will this be decided by the pilot?

1 Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, Lancaster GA on behalf of the PAFS consensus group. CONSORT 2010 statement: extension to randomised pilot and feasibility trials BMJ 2016;355;i5239
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