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Hearing Aids for Tinnitus with Hearing Loss (HUSH)

Submission date	Recruitment status	[X] Prospectively registered
30/07/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/08/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/11/2022	Ear, Nose and Throat	

Plain English summary of protocol

Background and study aims
In the UK, about one in ten people experience tinnitus, which is hearing a sound (like a buzzing, ringing or whooshing) without any external source. The sound may be in one or both ears, or in the head. The most common help people get for tinnitus is being given advice about tinnitus and taught strategies to live better with tinnitus. Some patients also have counselling, if needed. This is called standard care because it is the treatment that everyone gets in clinics in the UK because it is known to help. If someone has hearing loss as well as tinnitus, some audiologists might give a hearing aid in addition to standard care to see if it helps the tinnitus. They think the hearing aid could make the sounds people do want to hear louder, making the tinnitus sound quieter over time. However, it is not known whether hearing aids help in this way. A large trial is needed to find out if giving hearing aids in addition to standard care would help improve tinnitus. Before running this large trial the aim of this study is to check that there are enough patients and audiologists interested in taking part.

Who can participate?
Patients aged 18 or over with tinnitus and hearing loss

What does the study involve?
During their first appointment for tinnitus with an audiologist, participants answer questions about their tinnitus and are randomly allocated to either receive standard care, or to receive standard care and also be fitted with a hearing aid. After 12 weeks participants are sent a questionnaire in the mail to see how their tinnitus is. Some participants are also asked to take part in an optional interview to share their experiences of having tinnitus and being in the trial.

What are the possible benefits and risks of participating?
It is not known whether using a hearing aid in addition to other tinnitus management strategies provides any benefit for the treatment of tinnitus above and beyond the benefits of management strategies alone. This study will help to determine whether or not it will be possible to run a larger study to try to answer this question. The information collected in this study will help improve the understanding of what current practice is and the interviews will

provide more detailed information on any potential benefits/barriers to this research and to the treatment options available to people with tinnitus. Participants will also be helping to improve the ways in which hearing research studies are run, both now and in the future.

Where is the study run from?
1. Nottingham University Hospitals NHS Trust (UK)
2. Chesterfield Royal Hospital NHS Foundation Trust (UK)
3. Sheffield Teaching Hospitals NHS Foundation Trust (UK)
4. Sherwood Forest Hospitals NHS Foundation Trust (UK)
5. Cardiff & Vale University Health Board (UK)

When is the study starting and how long is it expected to run for?
October 2018 to January 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Garry Meakin

Contact information

Type(s)
Scientific

Contact name
Mr Garry Meakin

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Additional identifiers

Protocol serial number
38593

Study information

Scientific Title
Feasibility of conducting a multi-centre randomised controlled trial to assess effectiveness and cost-effectiveness of digital hearing aids in patients with tinnitus and hearing loss

Acronym
HUSH

Study objectives
The HUSH trial is a feasibility trial designed to investigate the feasibility and acceptability of conducting a randomised controlled trial (RCT) comparing i) education and advice (Treatment as Usual; TAU) with ii) TAU with digital hearing aids, for management of people with tinnitus and hearing loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands – The Black Country, 06/07/2018, ref: 18/WM/0153

Study design
Randomised; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tinnitus with hearing loss

Interventions
Participants will be randomised in a 1:1 ratio to receive either digital hearing aids plus treatment as usual (intervention group) or treatment as usual alone (control group).

Digital hearing aids are fitted in an audiology clinic according to standard clinical procedures.

Treatment as usual may consist of any combination of the following: information and education about tinnitus and hearing, the impact of tinnitus and hearing loss on participant's quality of life and different levels of counselling depending on patient's need. For the purposes of the trial, TAU must not include the prescription of any combination device or at-ear sound generator, and for the control arm must not include the provision of hearing aids.

Trial participation involves 1 to 2 visits with an audiologist, at-home completion of a questionnaire pack at 12 weeks post baseline and the option to participate in a one-off interview which will take place no more than 18 weeks post baseline.

PRE-BASELINE
Participants receive study invitation letter and participant information sheet in the post along with their tinnitus appointment letter.

BASELINE VISIT
During the standard care audiology appointment, the audiologist will provide information about the study, consent will be taken and eligibility assessed. Participants have the option to

consent to taking part in the study, or only to participating in the patient-interviews. Participants are randomised to receive standard care (take place during the same visit) or standard care plus fitting of a hearing aid. Participants will complete some additional questionnaires during the baseline appointment. All research activities, including the consent process, will take between 30 minutes and 1 hour in addition to standard care.
If participants are received to be fitted with a hearing aid, this may be fitted at the same appointment or at a second appointment taking place approximately 2 weeks after the baseline visit. The timepoint of hearing aid fitting will be dependent on local policy. Hearing aid fitting appointments take approximately 30 minutes.

TREATMENT PHASE
Participants will have a 12-week treatment phase during which they will implement the advice provided to them as a part of standard care and use the hearing aid, if they were randomised to receive one.

OUTCOME COLLECTION
12 weeks post-baseline, the participant will receive a questionnaire pack in the mail. The questionnaire pack will be sent from the trial coordinating unit with a pre-paid return envelope. The questionnaire will take approximately 45 minutes to complete.

PATIENT AND PARTICIPANT INTERVIEWS
If they have consented to being contacted for a participant interview, after return of their 12 week questionnaire they will be contacted by a qualitative researcher to schedule an interview. This may take place over the phone or face to face. The interview will last approximately 1 hour. For patients who did not consent to taking part in the randomised study but did consent to be contacted by a qualitative researcher for an interview, this contact will be made by the qualitative researcher after the clinic visit. The interview may take place over the phone or face to face and will last approximately 1 hour.

Intervention Type
Device

Primary outcome(s)
Feasibility outcomes for the trial have been defined to determine the feasibility and acceptability of running a future large main trial:
1. Recruitment: Outcomes to assess whether it would be possible to recruit to a definitive trial. This includes proportion of patients eligible for the trial, barriers to screening and recruitment, number and proportion of patients recruited and randomised, characteristics of recruited patients, hearing aid compliance, completeness of the collected data, components of TAU used across sites, re-referral rates. Interviews with recruiting audiologists towards the end of the recruitment period (12 months)
2. Acceptability: Outcomes to assess whether patients and clinicians would find the interventions and trial acceptable. This will include feedback from patients and clinicians regarding experience with the trial (e.g. conduct, design, barriers) and opinions of the intervention, hearing aid use compliance. Actual usage at 12 weeks compared to advised usage at baseline

Key secondary outcome(s))
1. Assessment: Outcomes to help identify the most appropriate primary outcome for a definitive trial, including patient opinion of relevance of patient reported outcome measures, distribution of patient reported outcome measures at baseline and 12 weeks

2. Safety: Collection of data to capture exacerbation of symptoms at 12 weeks
3. Patient reported outcome measures will inform choice of primary outcome for the main trial:
3.1. Severity of tinnitus, measured using Tinnitus Functional Index (TFI) at baseline and 12 weeks
3.2. Effects of hearing impairment and social adjustment, measured using Hearing Handicap Inventory for the Elderly (HHIE) at baseline and 12 weeks
3.3. General health status, measured using Health Utilities Index Mark 3 (HUI3) at baseline and 12 weeks
3.4. Depression and anxiety, measured using Hospital Anxiety and Depression Scale (HADS) at baseline and 12 weeks
3.5. Symptoms that the participant consider most important, measured using Measures Yourself Medical Outcome Profile (MYMOP) at baseline and 12 weeks
3.6. Health-related quality of life, measured using EQ5D5L at baseline and 12 weeks
3.7. Participant reported improvement in tinnitus and hearing, measured using Global Rating of Change Score at 12 weeks
4. The feasibility of collecting data for a health economic evaluation will be captured through a healthcare resource use questionnaire at 12 weeks

Completion date
01/01/2020

Eligibility

Key inclusion criteria
1. Age 18 or over with a clinical diagnosis of tinnitus with hearing loss, as defined by assessing audiologist
2. Providing written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
83

Key exclusion criteria
1. Tinnitus of a medically treatable origin
2. Previous use of a hearing aid in the last 12 months

3. Use of any combination device or behind the ear sound generator
4. Inability to communicate in English
5. Started or stopped medication for anxiety/depression within the last 3 months

Date of first enrolment
01/10/2018

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Nottingham University Hospitals NHS Trust
Ropewalk House
United Kingdom
NG1 5DU

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
United Kingdom
S44 5BL

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Royal Hallamshire Hospital
United Kingdom
S10 2JF

Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
Kings Mill Hospital
United Kingdom
NG17 4JL

Study participating centre
Cardiff & Vale University Health Board
University Hospital of Wales
United Kingdom
CF14 4XW

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0816-20014

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/11/2022	07/11/2022	Yes	No
Protocol article	protocol	27/03/2020	02/04/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes