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# Manualisation and feasibility study of audiologist-delivered counselling for tinnitus

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 22/03/2016 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 06/05/2016 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 01/11/2021 | Ear, Nose and Throat | |

## Plain English summary of protocol

Background and study aims
Tinnitus is the experience of noises in the ears or head not related to external sound. It is incurable and is often associated with depression, anxiety, insomnia and reduced quality of life. Tinnitus is treated using a number of interventions. Sound therapy and patient education are widely available but counselling is only available in less than half of audiology departments and there is no agreed standard for what constitutes tinnitus counselling. There is substantial evidence for the clinical benefit of counselling for tinnitus delivered by clinical psychologists or psychiatrists, but there is a lack of evidence for the NHS model of tinnitus care where face-to-face counselling is delivered by audiology professionals. This remains an important unanswered question given that specialist tinnitus care is increasingly becoming the domain of the audiologist. The aim of this study is to assess the feasibility of an audiologist-delivered psychological intervention for tinnitus.

Who can participate?
Adult patients with tinnitus

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives specialised care from an audiologist who has received training in the use of a manual to deliver a psychological intervention for tinnitus treatment. The other group receives usual care from an audiologist who has not trained this specialised training. The researchers evaluate the acceptability of the counselling, patient compliance with therapy, clinician compliance with the manual, willingness of patients to be randomly allocated, and whether there is sufficient interest and need for such a study. Patients and audiologists are interviewed about which elements of counselling are most /least beneficial and why.

What are the possible benefits and risks of participating?
As this stage it is not known whether one treatment is more effective than the other. The researchers cannot promise that the study will help the participants , but participation may help improve the way in which tinnitus is treated in audiology clinics. Psychological treatments are

known to result in improvement in psychological wellbeing for some patients, but a small minority of patients' condition declines from beginning to end of treatment. All participants are given information about a free psychological treatment service they can contact if they wish.

Where is the study run from?
1. Nottingham University Hospitals NHS Trust (UK)
2. Derby Hospitals NHS Foundation Trust (UK)
3. Sherwood Forest Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2016 to April 2017

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

Who is the main contact?
1. Dr John Taylor
2. Dr Derek Hoare

# Contact information

### Type(s)
Public

### Contact name
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### Type(s)
Scientific

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
PB-PG-0613-31106

# Study information

### Scientific Title
Manualisation and feasibility study of an audiologist-delivered counselling for tinnitus

### Acronym
The TinMan study

### Study objectives
Chronic tinnitus is a common incurable condition often associated with depression, anxiety, insomnia and reduced quality of life. Within NHS audiology, tinnitus is treated using a number of recommended interventions but there is no standard protocol for deciding on a first line approach. Sound therapy and patient education are widely available but counselling is only available in less than half of audiology departments and there is no agreed standard for what constitutes tinnitus counselling. There is substantial evidence from systematic reviews for the clinical benefit of counselling for tinnitus delivered by clinical psychologists or psychiatrists, but no studies have sufficiently evidenced the NHS model of tinnitus care where face-to-face counselling is delivered by audiology professionals. This remains an important unanswered question given that specialist tinnitus care is increasingly becoming the domain of the audiologist.

This is a multi-centre feasibility trial of an audiologist-delivered manualised psychological intervention for tinnitus, across three audiology departments where patients are randomised to receive either usual care or care from an audiologist who has received training in the use of the manual.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
NHS Health Research Authority: North West - Preston Research Ethics Committee, 04/02/2016, REC ref: 16/NW/0047, IRAS Project ID: 172091

### Study design
Multi-centre randomised feasibility trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied
Tinnitus

## Interventions
Patients with tinnitus will be randomised to receive either:
1. Specialised care from an audiologist who has received training in the use of a manual to deliver a psychological intervention for tinnitus treatment
2. Usual care (control) from an audiologist who has not trained this specialised training

## Intervention Type
Behavioural

## Primary outcome measure
Feasibility of a full-scale randomised controlled trial is the essential outcome of the feasibility trial. Feasibility would be confirmed by:
1. A conservative recruitment rate of 10% of all eligible patients, calculated using the total number of participation invitation letters sent out
2. Recruitment of 65% of target participants in the 5-month time-frame
3. Retention of 80% of participants with an equivalent proportion of primary outcome data collected
4. Continued compliance to the manualised tinnitus counselling

## Secondary outcome measures
Secondary patient-reported outcome measures for the feasibility trial include a set of measures that might be typical in a tinnitus clinical trial:
1. Severity and impact of tinnitus, measured using the Tinnitus Functional Index (TFI)
2. General well-being, measured using Clinical Outcomes in Routine Evaluation — Outcome Measure (CORE-OM)
3. Health-related quality of life, measured using Health Utilities Index Mark 3 (HUI3)
4. Overall state of health, measured using EuroQol (EQ-5D)
5. Health resource usage, measured using Client Service Receipt Inventory (CSRI)
6. Quality of the therapeutic alliance, measured using the Working Alliance Inventory (WAI), including both patient and clinician forms
These will be completed at baseline, post-intervention and 6-month follow-up.

Audiologists who have delivered and patients who have received the manualised care will be interviewed about their experience of the intervention and qualitative analysis will be conducted to identify which components worked well, were not useful and why?

## Overall study start date
01/05/2016

### Completion date
04/01/2018

## Eligibility

### Key inclusion criteria
For inclusion in the feasibility trial patients must reflect the typical population that might be expected to take part in a Phase 2 clinical trial. All patients will:
1. Be enrolled at their first visit to audiology
2. Have a primary complaint of tinnitus
3. A clinically relevant need will be determined as a Tinnitus Functional Index (Meikle 2012) questionnaire score >24/100 which indicates tinnitus is at least a moderate problem for the patient
4. Be willing to partake in individual counselling if allocated to the specialist care arm of the study
5. Be willing to complete questionnaires at three time points
6. Take part in follow-up interviews about their experiences (if randomised to intervention)

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
30 (15 intervention and 15 control participants across three sites)

### Key exclusion criteria
1. Patients whose tinnitus is of a medically treatable origin (i.e. not chronic subjective tinnitus)
2. Patients who are unable to communicate in English

### Date of first enrolment
01/07/2016

### Date of final enrolment
30/11/2016

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Nottingham University Hospitals NHS Trust**
United Kingdom
NG7 2UH

### Study participating centre
**Derby Hospitals NHS Foundation Trust**
United Kingdom
DE22 3NE

### Study participating centre
**Sherwood Forest Hospitals NHS Foundation Trust**
United Kingdom
NG17 4JL

## Sponsor information

### Organisation
Nottingham University Hospitals NHS Trust (UK)

### Sponsor details
Trust Headquarters
QMC Campus
Derby Road
Nottingham
England
United Kingdom
NG7 2UH

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/05y3qh794

## Funder(s)

### Funder type
Government

### Funder Name
National Institute for Health Research

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Publication and dissemination plan
1. Scoping literature review – already submitted
2. Protocol for Delphi survey – already submitted
3. Delphi survey results (June 2016)
4. Protocol for manualisation phase/feasibility trial (June 2016)
5. Feasibility trial results (both quantitative and qualitative elements) (May 2017). Also possible PPI dissemination at INVOLVE conference (November 2016). There will also be the NIHR report to the funder (May 2017)

### Intention to publish date
01/05/2017

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 15/05/2017 | | Yes | No |
| Results article | results | 01/12/2020 | 04/03/2021 | Yes | No |
| Other publications | Delphi study | 01/03/2018 | 01/11/2021 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |