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Assessing memory in older adults in hearing aid appointments

Submission date
09/06/2022

Recruitment status
No longer recruiting

Registration date
06/07/2022

Overall study status
Completed

Last Edited
14/02/2024

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Both hearing loss and dementia are common in older people and recent research has shown that hearing impairment may increase the risk of developing dementia. However, it is currently uncommon in NHS hearing aid clinics to assess for memory problems. We know that getting help early for such problems is important in improving and maintaining the quality of life. A short memory assessment with older people attending these clinics could allow us to discover any relevant concerns. Knowing this may help with both hearing aid appointments and for prompting early appropriate help beyond these.

The proposed study will examine whether introducing a brief memory assessment in older adults attending the Royal National ENT and Eastman Dental Hospital's hearing aid clinics is achievable and acceptable to patients. The assessment will screen for potential memory problems, it is not intended as a full-scale memory assessment. We will observe how it can be organised, how long it takes, what both patient and audiologist experience is, note how the results affect any follow on appointments in the clinic, and, if relevant, monitor what further steps are taken. We are also exploring the views of patients, their carers/family members, and of clinicians involved in the care of patients with hearing loss on the use of memory assessments in audiology appointments.

Who can participate?
Patients aged 65 and over presenting to University College London Hospitals Royal National Ear Nose and Throat Hospitals hearing aid clinics

What does the study involve?
Patients attending their hearing aid clinic appointment will be greeted by both a clinical audiologist and a research audiologist. The research audiologist will take informed consent from the patient to participate in the study, and observe and take notes on how the appointment runs. The clinical audiologist will then proceed with the standard appointment procedures, which include taking a history of the participant's hearing and general health and examining the participant's ears with an otoscope, followed by the additional short memory assessment. The memory assessment will be done through a visual presentation on an iPad, guided by the clinical audiologist. The participant or their accompanying person will then be asked to complete a

questionnaire about the participant's memory. The clinical audiologist will discuss the results of the memory assessment and, with the participant's agreement, inform the GP in the clinic letter. The memory assessment and discussion of results are expected to take 15 minutes. The appointment will then carry on as per usual i.e. the audiologist will test the patient's hearing, discuss the results and make recommendations on hearing care, including the fitting of hearing aids.

The research audiologist will arrange a telephone/video follow-up appointment 3 months later to ask about further steps taken following the memory assessment, e.g. whether the participant has contacted their GP and what was decided by the GP. The participant will also be asked if they would like to take part in a separate interview to discuss their experience of the study. This is optional and will not affect participation in the main study.

What are the possible benefits and risks of participating?
By taking part in this study, the patient and their GP will have some initial information about their memory. This may allow the GP to be informed at an earlier time than the standard pathway and the patient and GP can decide together whether to seek specialist assessment. This research may also improve hearing care for older people.

The brief memory assessment may cause worry and distress for the patient. This will be addressed as best as possible by providing clear information of what is to be expected from the study, that this is not a full memory assessment and sometimes the result indicates a potential problem but a full assessment may show their memory is fine, and the opposite may be true as well. The patient will have the opportunity to stop the memory tests at any time or withdraw from the study. The patient will also have the opportunity to speak with the chief investigator should they have any worries or concerns.

Where is the study run from?
University College London Hospitals (UK)

When is the study starting and how long is it expected to run for?
October 2021 to March 2024

Who is funding the study?
1. University College London Hospitals (UK)
2. Sonova Hearing Care Solutions (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
302975

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52139, IRAS 302975

Study information

Scientific Title
Pilot study on feasibility of cognitive assessment in Royal National ENT and Eastman Dental Hospital UCLH Trust (RNENTH) hearing aid clinics

Study objectives
This study aims to examine the feasibility and impact of cognitive assessments in RNENTH hearing aid clinics. If the study shows that cognitive assessment is acceptable to patients, their accompanying person(s) and hearing clinicians, feasible within the setting of these clinics and adds value to patient care, it may allow wider implementation across NHS/private hearing aid clinics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/05/2022, London - Riverside Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8184; riverside.rec@hra.nhs.uk), ref 22/LO/0180

Study design
Single-centre pilot feasibility study

Primary study design

Observational

Secondary study design
Pilot feasibility study

Study setting(s)
Hospital

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Hearing loss

Interventions
20 participants aged 65 and over will be recruited through the Hearing Aid Clinics at the Royal National ENT Hospital, Finchley Memorial Hospital and/or Edgware Community Hospital. Prior to starting cognitive assessments, the Clinical Audiologists will undergo required training on performing the assessments, discussion and notification of their GP of results. Candidates will be sent a letter and patient information sheet explaining more about the study. These invites will be sent three weeks prior to attending their hearing aid clinic appointment so that they have time to consider participation.

After check-in by the RNENTH administrative team, the research audiologist will take the patient and accompanying person (if present) to a separate room, verify if they have received and read the information, explore their interest in the study and check inclusion and exclusion criteria. To those patients interested in taking part, they will explain the study and procedures, answer questions and take informed consent. To those consenting, the clinical audiologist will conduct a short cognitive screening test adapted for hearing-impaired patients and a dementia screening questionnaire. If scores are low and/or patients express concern about results, the audiologist will advise that they contact their GP and ask permission from the patient to send the results to their GP, who can decide if further assessment is needed such as referral to a memory service. The cognitive assessment and discussion of results should take around 15 minutes.

Practicalities and timings of cognitive assessment including discussion of results will be observed by the research audiologist and recorded on a Case Report Form (CRF), along with completion of the assessment and the results. Three months after the clinic visit the patient and /or accompanying person will be contacted by telephone/video call by a study team member to establish impact of testing i.e. whether they contacted their GP, whether referral to memory service was made, and the outcome of this referral.
Patients, accompanying persons and clinicians (two of each) will also be invited to take part in a qualitative study, sharing their experiences of participating in or running the study through a semi-structured interview. This qualitative study will also include interviews with the referring clinicians of the participants including ENT surgeons, Audiovestibular physicians and GPs (two of each). They will be recruited from the pool of professionals already involved in the care of the

patient participants. These professionals will only be approached after the patient has consented to the study. Informed consent will be obtained from these individuals to have their answers transcribed for the study.

Intervention Type
Other

Primary outcome measure
Proportion of cognitive assessments completed measured as the percentage of patients completing the cognitive assessment out of the total number approached for the study at their initial Royal National Ear Nose and Throat Hospital hearing aid clinic appointment (baseline)

Secondary outcome measures
1. Impact, defined as follow-on actions regarding onward care of cognitive impairment, assessed at a 3-month remote follow-up appointment
2. Practicality, defined as the amount of training required for staff to perform cognitive assessments (assessed by the research team at the training session for clinical audiologists, prior to baseline visit), and staff and space allocation and duration of cognitive assessments (assessed by the research team at the initial Royal National Ear Nose and Throat Hospital hearing aid clinic appointment; baseline visit)
3. Acceptability, defined as the experience of the patient, accompanying person, and hearing clinician, including reasons for agreeing to the assessment, views on the assessment process, outcome and follow-on actions, and impact on the operation of hearing aid clinics, explored through semi-structured qualitative interviews, after completion of the 3-month remote follow-ups

Overall study start date
13/10/2021

Completion date
31/03/2024

Eligibility

Key inclusion criteria
1. Patients aged 65 years and older
2. Patients attending Royal National Ear Nose and Throat Hospital hearing aid clinics

Participant type(s)
Patient

Age group
Senior

Lower age limit
65 Years

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
Patients who lack the capacity to consent

Date of first enrolment
30/06/2022

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal National Ent and Eastman Dental Hospitals
47-49 Huntley Street
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United Kingdom
WC1E 6DG

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust

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UCLH/UCL Joint Research Office, part of Research Directorate
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Sponsor type
Hospital/treatment centre

Website
https://www.ucl.ac.uk/jro

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Industry

Funder Name
Sonova

Funder Name
University College London Hospitals NHS Foundation Trust

Alternative Name(s)
University College London Hospitals, UCLH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We will present the findings of our project at local and inter(national) stakeholders conferences and publish in the scientific literature for the attention of professional and scientific audiences. A lay summary report will also be published for patients and members of the public who will be reached via our PPI representatives, stakeholder organisations' websites, social media channels and email updates.

Intention to publish date
31/03/2024

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?
HRA research summary			28/06/2023	No	No