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Live Voice Auditory Training RCT 1.1

Submission date
08/01/2018

Recruitment status
No longer recruiting

Registration date
23/02/2018

Overall study status
Completed

Last Edited
14/10/2022

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
One of the main challenges faced by people with hearing loss is understanding speech in noisy environments. Hearing aids can be of some benefit in these situations, but in isolation they are unable to fully overcome the problem. If the hearing-impaired listener is unable to understand conversations in everyday listening environments they risk becoming socially withdrawn and isolated. Auditory training involves structured practice listening to a variety of stimuli and is gaining support as an alternative to hearing aids or a supplementary intervention. Many of the auditory training programs currently available are administered using a computer which may not be appropriate for many older hearing-impaired adults who do not have access to computers. There is therefore a need to develop a non-computerised auditory training intervention which can be delivered easily in the person's home. The aim of this study is to find out whether a new auditory training program, which involves having conversations in the presence of a competing speaker, improves speech perception in everyday challenging listening environments.

Who can participate?
Experienced adult hearing aid users

What does the study involve?
Participants complete a speech and cognition assessment and then undertake a four-week training program at home. They are randomly allocated to one of two training programs using a CD containing either silence (Group 1) or a person speaking (Group 2). Participants are required to play this CD while having a conversation with their communication partner. Each session lasts for 30 minutes and participants are asked to complete this five times per week for four weeks. Their speech in noise performance and cognitive abilities are then evaluated again.

What are the possible benefits and risks of participating?
By taking part in the study participants may see an improvement in their understanding of speech in challenging listening environments. There are no significant risks to taking part as noise levels should not exceed maximum daily noise exposure limits.

Where is the study run from?
Betsi Cadwaldr University Health Board (UK)

When is the study starting and how long is it expected to run for?
November 2012 to June 2019 (as of 18/10/2018)

Who is funding the study?
British Society of Audiology (UK)

Who is the main contact?
Stephanie Greer
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
130980

Study information

Scientific Title
Evaluation of live voice auditory training in a randomised controlled trial of existing hearing aid users

Acronym
Live Voice Auditory Training RCT 1.1

Study objectives
The primary aim of this study is to explore whether novel auditory training intervention can improve speech intelligibility in noise for experienced hearing aid users. The primary research question is: Does repeated practice improve speech perception in everyday challenging listening environments for experienced adult hearing aid users?

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Wales REC (Central & East), 27/03/2014, ref: 14/WA/0089

Study design
Single-centre randomised controlled 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 contact details to request a participant information sheet

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

Interventions
Participants are randomised to either experimental or control groups based on a dynamic adaptive allocation algorithm using stratification variables of age (less than 75 years: 75 years or older) and sex (Male:Female).

Allocation to one of two training programs: a CD containing either silence (Group 1) or a person speaking (Group 2). Participants are required to play this CD while having a conversation with their communication partner. Each session lasts for 30 minutes and participants are asked to complete this five times per week for four weeks.

Participants complete a baseline speech and cognition assessment and then after their four week training program their speech in noise performance and cognitive abilities are evaluated again.

Intervention Type
Other

Primary outcome measure
Speech in noise performance, measured using the signal to noise ratio loss on QuickSIN at baseline and after training has been completed

Secondary outcome measures
1. Subjective handicap assessed by Total, Social and Emotional scores from the Hearing Handicap Inventory for the Elderly Questionnaire and Glasgow disability measured at baseline and after training has been completed
2. Signal to noise threshold on the Modified Co-ordinate Response Measure measured at baseline and after training has been completed
3. Scores for words and numbers on the Dual Task of Listening and Memory measures, measured at baseline and after training has been completed

Overall study start date
04/11/2012

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Current hearing aid user
2. Four-frequency average hearing thresholds greater than 20dB HL
3. Need in their personal plan relating to improving speech-in-noise intelligibility
4. Regular communication partner who is willing to complete the training program with them
5. Fluent and comfortable conversing in English
6. No significant self-reported memory or neurological problems
7. Not colour blind

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
50

Total final enrolment
50

Key exclusion criteria
1. Average hearing threshold within normal limits
2. No reported difficulties understanding speech in noise
3. Unable to complete a training program at home
4. Unable to attend Wrexham Audiology Service for required research appointments

5. Diagnosed or self reported memory or neurological problems
6. Unable to comfortably converse in English
7. Colour-blind

Date of first enrolment
01/04/2014

Date of final enrolment
30/11/2018

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Betsi Cadwaldr University Health Board
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham
United Kingdom
LL13 7TD

Sponsor information

Organisation
Betsi Cadwaladr University Health Board

Sponsor details
Research and Development Department
Holywell Community Hospital
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Sponsor type
Hospital/treatment centre

ROR

https://ror.org/03awsb125

Funder(s)

Funder type
Other

Funder Name
British Society of Audiology

Alternative Name(s)
BSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Article in Audacity (British Society of Audiology magazine)

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. Patient identifiable information will be stored for 3-6 months and anonymised data will be stored for 5 years after the trial end date on a password protected departmental server.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/02/2022	30/09/2022	Yes	No
Protocol file	version 1.3	18/03/2014	14/10/2022	No	No
HRA research summary			28/06/2023	No	No