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Usability and benefit of remote microphone (assisted listening device) in adults with mitochondrial disease hearing loss

Submission date
08/02/2024

Recruitment status
No longer recruiting

Registration date
19/02/2024

Overall study status
Completed

Last Edited
08/03/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Mitochondria are the 'batteries' of our cells that provide the energy we need. When they are faulty, it leads to mitochondrial disease. Currently there is no cure for mitochondrial disease. Treatments are limited and address symptoms rather than causes.

Hearing loss is a common feature, affecting around 50 % of people with mitochondrial disease at some point.

With hearing loss, we often think of 'loudness' of sound i.e., needing sound to be louder to hear it. Many people wear hearing aids to make sounds louder (to amplify the noise). In mitochondrial disease hearing loss, loudness of the sound is not typically the only problem. People with mitochondrial disease hearing loss may also have trouble understanding the clarity of speech. This is due to an issue in the processing of sound. Unfortunately, making the sound louder (e.g., with hearing aids), does not correct for this, as the distorted sound is also made louder. Those affected therefore still struggle to hear and understand speech.

Assistive Listening Devices (ALDs) can be used to help communication. Wireless remote microphones (RMs) are one type of ALD. RMs pick-up the voice of a speaker and send it directly to a listener's ears. RMs utilising the latest adaptive digital technology have been shown to provide a benefit in challenging listening environments, such as in conversations that occur in background noise and when the speaker is distant from the listener.

This pilot trial will test the Phonak Roger On™ remote microphone. Twelve adults with mitochondrial disease and hearing loss will take part. They will use the RM over six months. The usability and effectiveness of the ALD will be assessed along with each participant's hearing and quality of life. The aim is to see if the RM is usable and improves hearing and quality of life.

It is hoped that this trial will lead to further, larger-scale research in this area.

Who can participate?
Adults aged between 16 and 70 years with a confirmed genetic diagnosis of mitochondrial disease and associated hearing loss can take part. Screening tests will confirm that participants are suitable to participate in the trial. Twelve participants will be included in the study.

What does the study involve?
Participation will involve using the RM daily and keeping a record of where, when, and how, the device is used.
Participants will attend visits at the trial site in Newcastle upon Tyne for four visits over 6 months (24 weeks). These will take place at Baseline (the start), Week 2, Week 4 and Week 24 (end of trial)

At each trial visit tests of speech perception will be conducted and participants will be asked to complete questionnaires about hearing, hearing aid satisfaction, quality of life and fatigue.

For the first four weeks of the trial, participants will be randomly allocated to one of two groups:
The first group will start using the RM straight away for the first two weeks. They will then stop using the device for the next two weeks.
The second group won't use the RM for the first two weeks but will then use it for the second two weeks.
After this four-week period, all trial participants will use the RM for the next 20 weeks (remaining five months). During this time, participants will be offered monthly (or ad hoc (as required)) remote follow ups to check on progress or report any issues experienced.

What are the possible benefits and risks of participating?
Although participants may not directly benefit, the study provides an opportunity for participants to learn more about their hearing and pursue a potential treatment option that may be beneficial.

Data from the trial will be used to inform mitochondrial disease specialists and the NHS about whether this type of remote microphone is beneficial for people with mitochondrial disease hearing loss. It is also hoped that it will lead to a larger clinical trial of this type of device in the future.

As part of the trial, participants will be required to travel to the trial site in Newcastle upon Tyne up to four times over six months. Where possible, visits will be timed to coincide with at least one routine clinical appointment. Travel to the Newcastle trial site, parking costs and accommodation (if required) will be provided.

Each trial visit will last a few hours. Participants will be provided with regular breaks and will be able to rest at any point.

As part of the trial, participants will be asked to keep a record of where, when and how they use the RM. They will also be asked to record any issues they experience with the device. In order to make it as easy and convenient as possible, participants will choose to record these details either online or via a paper diary.

The trial team will be available to answer questions at any point. Support will also be available from the device manufacturer (Phonak).

As part of the trial, participants will complete questionnaires about their hearing loss and quality of life. There is a possibility that some participants will find answering these types of questions

upsetting or emotionally distressing. Participants will be informed of this during screening and questionnaires will be made available prior to study entry or study visits, as required. Participants will be signposted to additional support from the trial team where required.

Where is the study run from?
The Newcastle upon Tyne Hospitals NHS Foundation Trust and Newcastle University (UK)

When is the study starting and how long is it expected to run for?
February 2023 until June 2025.

Who is funding the study?
This trial is funded by the Lily Foundation (the Lily-Stoneygate Research Awards Programme) with the support of My Mito Mission.
Sonova AG has provided Roger On systems (manufactured by Phonak, a subsidiary of Sonova) for use of this study under an Educational Grant.

Who is the main contact?
Dr Renae Stefanetti, renae.stefanetti@ncl.ac.uk

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316557

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55975, IRAS 316557

Study information

Scientific Title
EMERALD Pilot study: Evaluating the Tolerability and Efficacy of a Remote Microphone (Assisted Listening Device) in Adult Patients with Mitochondrial Disease

Acronym
EMERALD

Study objectives
The Roger On™ remote microphone is feasible and tolerable in adults with mitochondrial disease hearing loss. Roger On™ remote microphone use will have potential far-reaching benefits to participants' communication, social participation, and wellbeing

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/04/2023, South Central - Oxford A Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)207 1048171; oxforda.rec@hra.nhs.uk), ref: 23/SC/0120

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Mitochondrial disease hearing loss

Interventions
Baseline will consist of a number of audiology assessments and completion of a number of questionnaires as measures of quality of life and hearing satisfaction. Clinical data relating to each participant's mitochondrial disease will also be extracted from their medical records.

Participants will then be randomised to the treatment order to begin the four-week cross-over trial. This will involve two arms (Group 1 and Group 2). Randomisation will be on a 1:1 ratio.

Those randomised to Group 1 will start using the ALD immediately (and for the next two weeks); those randomised to Group 2 will not use the ALD over the next two weeks.
Participants will return for further assessments (audiology tests and questionnaires) after two weeks (Week 2 Visit) at which point the groups will cross over. Group 1 will then stop using the ALD and Group 2 will start.

Two weeks later (Week 4 Visit), participants will return the trial site for further audiology assessments and questionnaires- this will mark the end of the four-week cross-over period.

All participants will then continue using the ALD for a further 20 weeks (five months).

During this five-month period, participants will be reviewed if required on a monthly or ad-hoc basis (by phone or email) and asked to report on tolerability, adverse events or any issues with the ALD. They will also be asked to keep a record of ALD use and setting of use. Technical support will be provided to participants as required.

Participants will return to site at the end of the trial (Week 24, End of Trial Visit) to repeat all the assessments completed at Baseline (plus the NMDAS assessment). They will return the ALD and will be asked to provide informal feedback on the trial and their participation.

Following completion of the End of Trial Visit, participation in the trial for each participant will end. Participants will return the ALD and recommence their usual clinical care.

All data for the trial will be captured via the REDCAP electronic case report form system (eCRF). Participants will be able to complete their Week 2, Week 4 and Week 24 questionnaires and record their ALD use data directly on the eCRF.

Once collected, trial data will be analysed by the trial team at the Wellcome Centre for Mitochondrial Research, Newcastle University and by collaborators at Newcastle University and the University of Melbourne, Australia.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Tolerability and usability of a Roger On™ remote microphone device assessed via:
1. Tolerability, acceptability and satisfaction measured via an investigator-designed questionnaire at Week 2, Week 4, Week 24.
2. Usability measured via System Usability Scale at Week 2, Week 4, Week 24.
3. Hearing aid satisfaction measured by the International Outcomes Inventory Hearing Aid (IOI-HA) Questionnaire at Week 2, Week 4, Week 24.
4. Compliance measured by participant diary from Week 2 – through to Week 24.
5. Device-related adverse effects and undesirable effects measured by participant diary measured from Week 2 – through to Week 24.
6. Participant withdrawal number and reason(s) for trial withdrawal (assessed as applicable and /or at Withdrawal visit).

Secondary outcome measures
The efficacy of a Roger On™ remote microphone in adults with mitochondrial disease hearing loss will be assessed via:
1. Spatial processing measured using the Listening in Spatialised Noise-Sentences test (LiSN-S) at Screening and Week 24.
2. Disease severity measured using the Newcastle Mitochondrial Disease Adult Scale at Screening and Week 24.
3. Speech perception measured using the Consonant-Nucleus-Consonant (CNC) test at Baseline, Week 2, Week 4 and Week 24.
4. Hearing and listening ability measured using the Speech, Spatial & Qualities of Hearing Scale (SSQ)-12 at Baseline, Week 2, Week 4 and Week 24.
5. Social participation measured using the Assessment of Life Habits (LIFE-H- Short Form) at Baseline and Week 24.
6. Participation restriction measured using the Social Participation Restrictions Questionnaire (SPaRQ) at Baseline and Week 24.
7. Verbal communication measured using the Communicative Participation Item Bank (CPIB) at Baseline and Week 24.
8. Health-related Quality of Life (QoL) measured using World Health Organisation QoL-BREF at Baseline and Week 24.
9. Perceived fatigue measured using the Modified Fatigue Impact Scale (MFIS) at Baseline and Week 24.
10. Caregiver burden measured using Significant Other Scale for Hearing Disability (SOS-HEAR) at Baseline and Week 24.
11. Speech perception measured using the Consonant-Nucleus-Consonant (CNC) test at Baseline, Week 2, Week 4 and Week 24.
12. Spatial processing measured using the Listening in Spatialised Noise-Sentences test (LiSN-S) at Screening and Week 24.
13. Disease severity measured using the Newcastle Mitochondrial Disease Adult Scale at Screening and Week 24.

Overall study start date
01/02/2023

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Be between 16 years and 70 years (aged ≥16 to ≤ 70 years)
2. Have ability, in the opinion of the trial team, to participate in trial activities
3. Be capable of providing informed consent
4. Have a genetically confirmed diagnosis of mitochondrial disease
5. Have confirmed hearing loss- via NMDAS hearing score of: 2 (mild), 3 (moderate), or 4 (severe)
6. Have an NMDAS speech score of: 0 (normal), 1 (communication unaffected), or 2 (mild communication difficulties).
7. Have evidence of impaired speech perception in background noise due to:
7.1. Significant sound detection defect measured by a 4-frequency average hearing detection threshold level (pure-tone-audiometry, ≥60 dBHL in the poorer ear) and/or
7.2. Impaired auditory processing (≤2 SDs from the normative mean) assessed by the 'Speech Reception Threshold' subtest of the Listening in Specialised Noise-Sentences (LiSN-S) test most reflective of everyday listening
8. If hearing aid users: Use Phonak hearing aids that are compatible with the remote microphone ALD and be willing to continue using hearing aid(s) during the trial.
9. If non-hearing aid users: Be willing and able to use a receiver device e.g., 'Roger Focus' which will be paired to the ALD during the device use periods of the trial. This receiver will be provided by the trial alongside the ALD.

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
Planned Sample Size: 12; UK Sample Size: 12

Key exclusion criteria
1. Have an NMDAS hearing score of 0 or 1 - no communication problems; tinnitus or deterioration from prior 'normal'
2. Have an NMDAS speech score of 3 (moderate difficulties) or above
3. Have profound/end stage hearing loss i.e. NMDAS hearing score of 5
4. Have conductive hearing loss (≥10-dB air-bone gap at 500 - 3000 Hz)
5. Have current local ear intolerances or issues preventing hearing aid/ALD effectiveness or use i.e., ear infection, significant earwax
6. Are currently using, or have previously used, a Roger On remote microphone assistive listening device

7. If hearing aid users:
8. Use of non-compatible hearing aids (non-Phonak)
9. Planning a change to their hearing aid(s) during the course of the trial
10. Any other medical issues, which in the opinion of the investigator would preclude involvement

Date of first enrolment
01/03/2024

Date of final enrolment
27/03/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Freeman Hospital
Newcastle Upon Tyne Hospital Trust
Freeman Road
High Heaton
Newcastle
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Freeman Hospital, Freeman Road, High Heaton
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+44 191 28224516
nuth.nuthsponsorship@nhs.net

Sponsor type
Hospital/treatment centre

Website

https://www.newcastle-hospitals.nhs.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Lily Foundation

Alternative Name(s)
Lily, The Lily Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Sonova AG

Results and Publications

Publication and dissemination plan
The results from the trial will be published via scientific papers in peer reviewed publications and via presentations and posters at conferences. In addition, the data will be made open access via an approved platform (following initial publication). The trial will also be publicised on a number of partner and charity websites and results disseminated in a variety of print and online media. Social media platforms may also be used to communicate research developments and to stimulate interest and communication amongst patient groups, academics, healthcare professionals and the general public. Trial participants will be advised that their individual trial results will not be made available, however, they will be provided with an End of Trial Information Sheet which will explain where and how a summary of the results can be accessed once available.
Dissemination activities and events involving participants, the wider mitochondrial disease population and the general public will also be planned.

Intention to publish date
01/03/2026

Individual participant data (IPD) sharing plan
It is the intention to make the trial data available as Open Data following the end of trial and publication of the results. The repository and specific details regarding this have not yet been confirmed.

IPD sharing plan summary
Stored in publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0	18/10/2023	16/02/2024	No	Yes
Protocol file	version 3.1	04/12/2023	16/02/2024	No	No