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

(EMERALD)

Participant Information Sheet

You are being invited to take part in a clinical trial.

- Before you say 'yes' or 'no', it is important for you to understand why the trial is being done and what it will involve.

- Please read the following information and discuss it with others if you wish.

- Take time to decide whether or not you wish to take part.

- If there is anything that is not clear, or if you have any further questions, please ask us (our contact details are at the end of this information sheet).

What is the purpose of this trial?

In this trial, we want to see whether a Remote Microphone (Assisted Listening Device) is helpful for people with mitochondrial disease hearing loss.

In mitochondrial disease, hearing loss not only affects the loudness (volume) of sound but also the clarity of sound and spoken words. This is due to the way that the brain processes the sound.

This means that using hearing aids to make sound louder does not fully solve the problem. We know that people with mitochondrial disease often report limited benefit from their hearing aids, particularly in the presence of background noise.

We think that using a Remote Microphone Assisted Listening Device (ALD) could help. In this trial, we will investigate whether a particular type of ALD, called the Phonak Roger On™ (pictured in ***Figure 1***) can improve everyday hearing in people with mitochondrial disease.

Figure 1

This type of device works through connecting (wirelessly) to a receiver inside your hearing aids. It can also be used without hearing aids through a small behind-the-ear receiver.

Phonak Roger On™ is designed for listening in situations with background noise or when trying to hear someone speaking from a distance to improve sound clarity. The microphone automatically adjusts itself depending on the listening situation. For example, it can be used on a table (***Figure 2***), clipped onto clothing (***Figure 3***), or held in your hand (***Figure 4***).

Figure 2. **Using the device on a table.** Roger On is placed in the middle of the table to listen to a group of people.

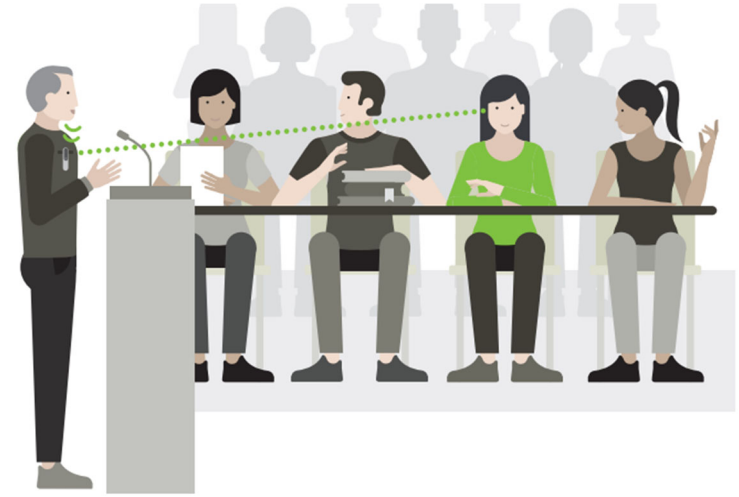


Figure 3. **Clipped the device on clothing or a label.** Roger On is clipped on a distant talker to help you hear them better.

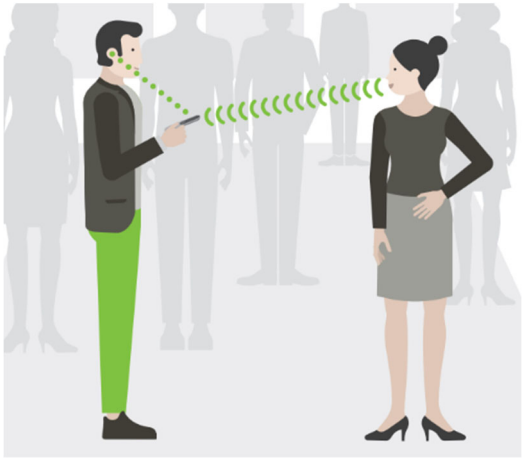


Figure 4. **Held in your hand**. Roger On can be held in your hand and be pointed towards the person you would like to hear.

Why am I being asked to take part?

You are being invited to take part in this trial because you have been diagnosed with mitochondrial disease and have reported hearing loss.

Do I have to take part?

It is up to you to decide whether you want to take part in this trial. If you decide not to take part, it will not affect the care you receive from your usual clinical care team.

If you do decide to take part, you are free to withdraw at any time, without giving any reason and without it affecting your clinical care.

What happens if I am interested in taking part?

If you are interested in taking part in this trial, please get in touch with the trial team (using the details at the end of this information sheet).
We will then arrange a time to talk with you about the trial.

If after this discussion, you are happy to take part we will ask you to come to the trial site to provide consent and attend a Screening and Baseline Visit (on the same day).

What will the trial involve?

The trial will involve visiting the trial site in Newcastle for (up to) four visits over six-month period.

It will also involve using the ALD daily and keeping a record of where, when, and how, you use the device.

You may be suitable to take part in the trial whether you currently use hearing aids or not. If you use compatible hearing aids (Phonak) and are suitable, the device will be linked to your current hearing aids by a qualified member of the research team. If you do not use hearing aids, you may still be eligible. In this case, you will be provided with an additional device– a receiver (with no amplification), to allow you to use the ALD.

At each trial visit we will perform tests of your hearing and will ask you to complete some questionnaires.

If you have a close family member or partner with you at the Baseline and End of Trial (Week 24) Visit, we will ask them to complete a questionnaire about how your hearing loss affects them. This is optional; you can still take part if you do not have a family member or partner who wishes to complete this.

We will also collect information from your medical records (about your medical history, mitochondrial disease and the results from previous clinical tests).

For the first four weeks of the trial, you will be randomly allocated to one of two groups:

- The first group will start using the ALD 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 ALD for the first two weeks but will then use it for the second two weeks.

After this four-week period everyone on the trial will use the ALD for the next 20 weeks (remaining five months).

Before you start the trial, we will ask you to provide written informed consent. We will then perform some screening assessments to check that you are suitable to take part (eligible).

As this is a small trial, we can only include participants who have particular hearing difficulties (assessed at Screening). This is because we need to ensure that those who take part are likely to benefit from an ALD. This means that not everyone who provides consent and undergoes Screening will be suitable to continue participation in the trial.

If after Screening, we find that you are not suitable to take part we will explain this to you.

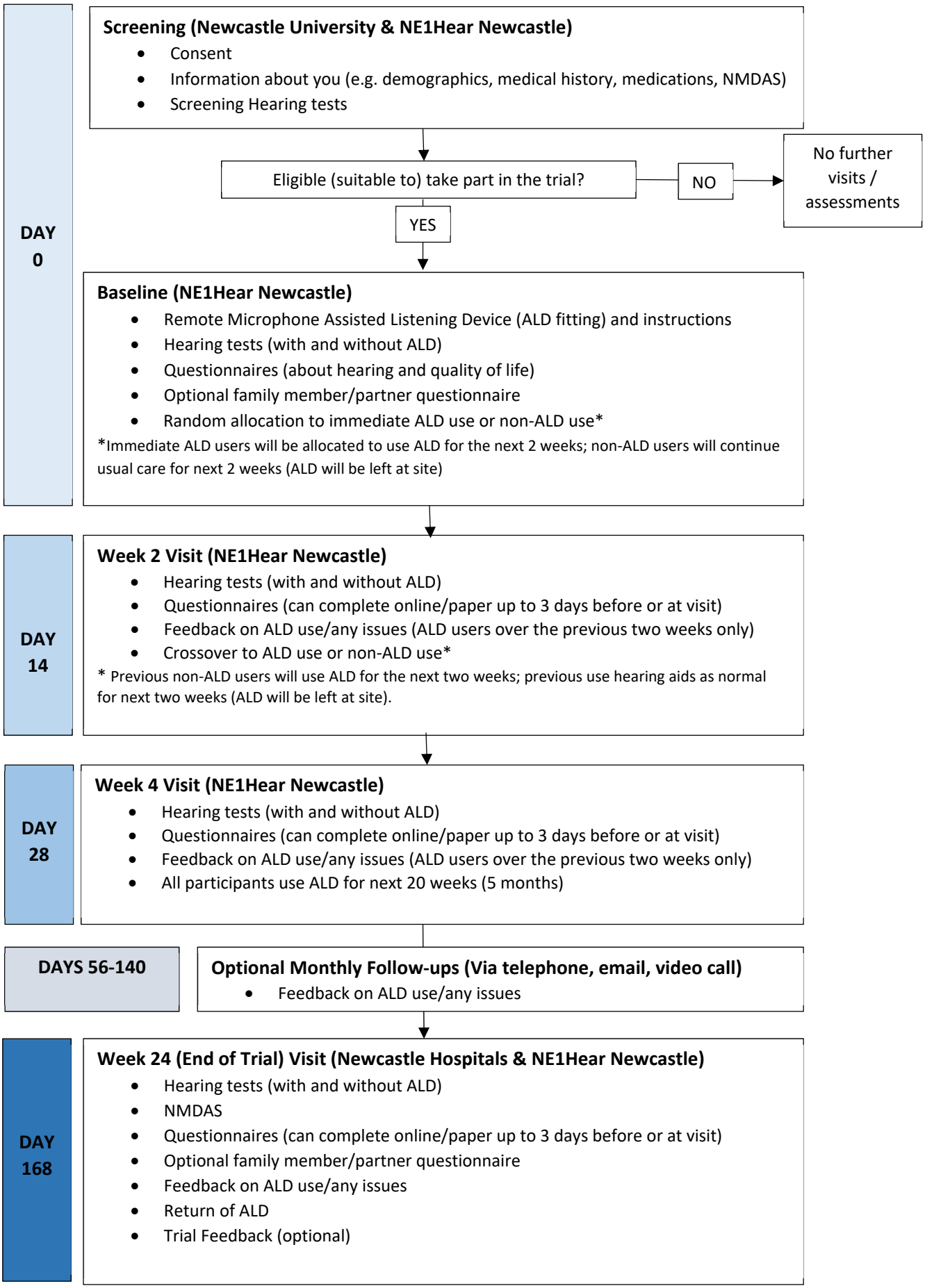
At this point, your involvement in the trial as a participant will end, however we hope that in future we will be able to offer you further research opportunities. We will also ask everyone who agrees to take part if they would be happy to be contacted by the team at the Wellcome Centre for Mitochondrial Research (WCMR) about future research opportunities or activities and events about mitochondrial disease. We will give you a separate information sheet and consent form about this.

It will not be possible to provide you with your individual results from the study. However, once all the study data has been analysed, we will provide you with an End of Trial Information Sheet, which will explain *where* and *how* a summary of the results can be accessed, once available.

We are keen to involve you in activities to communicate your views and perspectives about the trial. Outputs from these activities (such as journal publications, social media posts) may incorporate direct quotations from

you. Any of these quotations will be non-identifiable, unless explicitly agreed with you and consented for separately.

The diagram on the following page provides more detail about what will happen at each of the trial visits.


DAY 0
Screening (Newcastle University & NE1Hear Newcastle)
Consent
Information about you (e.g. demographics, medical history, medications, NMDAS)
Screening Hearing tests
Eligible (suitable to) take part in the trial?
NO
No further visits / assessments
YES
Baseline (NE1Hear Newcastle)
Remote Microphone Assisted Listening Device (ALD fitting) and instructions
Hearing tests (with and without ALD)
Questionnaires (about hearing and quality of life)
Optional family member/partner questionnaire
Random allocation to immediate ALD use or non-ALD use*
*Immediate ALD users will be allocated to use ALD for the next 2 weeks; non-ALD users will continue usual care for next 2 weeks (ALD will be left at site)
DAY 14
Week 2 Visit (NE1Hear Newcastle)
Hearing tests (with and without ALD)
Questionnaires (can complete online/paper up to 3 days before or at visit)
Feedback on ALD use/any issues (ALD users over the previous two weeks only)
Crossover to ALD use or non-ALD use*
* Previous non-ALD users will use ALD for the next two weeks; previous use hearing aids as normal for next two weeks (ALD will be left at site).
DAY 28
Week 4 Visit (NE1Hear Newcastle)
Hearing tests (with and without ALD)
Questionnaires (can complete online/paper up to 3 days before or at visit)
Feedback on ALD use/any issues (ALD users over the previous two weeks only)
All participants use ALD for next 20 weeks (5 months)
DAYS 56-140
Optional Monthly Follow-ups (Via telephone, email, video call)
Feedback on ALD use/any issues
DAY 168
Week 24 (End of Trial) Visit (Newcastle Hospitals & NE1Hear Newcastle)
Hearing tests (with and without ALD)
NMDAS
Questionnaires (can complete online/paper up to 3 days before or at visit)
Optional family member/partner questionnaire
Feedback on ALD use/any issues
Return of ALD
Trial Feedback (optional)

Once you have completed the End of Trial Visit (Week 24) you will have completed the trial and will return to your usual clinical care.

Who is the Sponsor and data controller for this research?

The Newcastle upon Tyne Hospitals NHS Foundation Trust (Newcastle Hospitals) is the Sponsor for this trial.

Newcastle Hospitals will use information from you to undertake this trial and will act as the data controller. This means that Newcastle Hospitals are responsible for looking after your information and using it properly.
The lawful basis for carrying out this clinical trial under the General Data Protection Regulation (GDPR) is Task in the Public Interest, (Article 6,1e) as research is cited as part of the Trust's duties.

Newcastle Hospitals are working closely with the WCMR, Newcastle University on this research therefore staff from Newcastle University will also have access to information from you as part of the trial.

As part of the trial, we will use a local company, NE1Hear, to perform hearing tests and ALD fitting. NE1Hear work with Newcastle Hospitals on a regular basis and work to the same NHS standards as Newcastle Hospitals. NE1Hear will receive and hold identifiable data about you. All data will be held to the same level of security as data held by Newcastle Hospitals. All transfers of data between Newcastle Hospitals and NE1Hear will be secure and will be in line with NHS data protection requirements.

Some hearing assessments during Visit 1 will also take place at Newcastle University Medical School.

As part of the analyses of data from the trial, de-identified information (identifying you be a code rather than your name) will be shared with researchers at Newcastle University and the University of Melbourne, Australia.

Representatives from the Sponsor, Newcastle University, the trial funder, or the regulatory authorities may request access to the trial records to check that the trial is being conducted correctly. This may include accessing identifiable information about you. Any staff accessing this information will work to strict codes of confidentiality.

Identifiable data from this trial will be kept by Newcastle Hospitals and NE1Hear for at least 5 years after the trial has ended. De-identified data (e.g., where you are not directly identifiable) will be held by Newcastle University for longer (indefinitely).

How will you use information about me?

We will need to use information from you for this clinical trial.

This information will include:

- Your full name
- Your date of birth
- Your NHS number (or CHI number if you live in Scotland)
- Your postal address
- Your email address
- Your telephone number
- Details of your medical history, mitochondrial disease genetic diagnosis, demographic information and information about your hearing and quality of life

We will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the trial, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the trial.

The trial data will be de-identified and shared with other researchers in the UK and overseas (Australia).

It may also be made available as “open data” through a research data repository. This means the de-identified trial data will be publicly available and may be used for purposes not related to this trial.

We will make every attempt to ensure that it is not possible to identify you from this open data.

With your permission, we will notify your general practitioner (GP) so they are aware you are taking part in this clinical trial. We will also provide them with a copy of the results from your trial assessments for your GP health records.

We will also audio-record a couple of hearing tests performed during the study. This is so that we can accurately determine the results. These

audio recordings will capture your voice. You will not be identified by your full name in the recordings, although your first name may be used during the assessments. All recordings will be kept securely by Newcastle University and only authorised researchers from the study team will be able to listen to them.

We would also like to use these audio recordings in future research projects, this may involve sharing them with other researchers in the UK and abroad. We will ask you to provide consent for this on the trial consent form.

What are my choices about how my information is used?

You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you lose your capacity to consent at any stage during the trial, you will be withdrawn. At that point onwards, we will stop collecting any new information. However, any information that we have already collected up until that point will be kept and used.

Where can I find out more about how my information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- via a leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to the data protection officer for Newcastle Hospitals nuth.dpo@nhs.net
- by sending an email to nuth.mitoresearch@nhs.net or
- by ringing us on **0191 208 3105**

Are there any benefits to taking part?

We cannot promise that taking part in the trial will help you personally. However, we hope that people who take part will experience some benefit from using the ALD.

Data from the trial will be used to inform mitochondrial disease specialists and the NHS about whether this type of ALD is helpful for people with mitochondrial disease hearing loss. We hope that it will also lead to a bigger clinical trial of this type of device in future.

Are there any disadvantages to taking part?

As part of the trial, you will be required to travel to the trial site in Newcastle up to four times over six months. Where possible, we will try to ensure that one of your trial visits coincides with your routine clinical appointment with the Newcastle Mitochondrial Disease Clinic for Adults and Children.

We will pay for your travel to the Newcastle trial site, parking costs and accommodation (if required). We will also ensure that lunch and refreshments during the visits are provided. Taking part in this trial will not result in any cost to you other than your time.

Each trial visit will last a few hours. We will provide you with plenty of breaks and you can take a rest at any point.

As part of the trial, we will ask you to keep a record of where, when and how you use the ALD. We will also ask you to record any issues you experience with the device, as we are interested in how usable the device is for you. In order to make it as easy and convenient as possible for you to record these details, you will be able to enter these details online.
If you do not have access to a smartphone, computer, or internet, we will arrange for you to record this information on paper (or if this is your preferred method).

The trial team will be available to answer any questions you have at any point. There will also be support from the device manufacturer (Phonak) in case you experience any technical issues.

As part of the trial, we will ask you to complete a number of questionnaires about your lifestyle, hearing loss and quality of life. You may find answering these types of questions upsetting or emotionally distressing. If you have any difficulties with the questionnaire or feel that you need support following completion of the questionnaires, a member of the trial team will be available. If you need further support the research team will arrange this with you and (if applicable) your clinical care team.
Before you decide whether or not to take part, copies of the questionnaires can be shared with you in advance so that you know what questions to expect.

If you have a family member or partner who completes a questionnaire their responses will be kept confidential and will not be shared with you.

They will also be able to discuss any concerns they have about the content of the questionnaire with a member of the trial team should they wish to.

What will happen at the end of the trial?

Once you have taken part in the trial you will return to your usual care. As this is a small trial, it will not be possible for you to keep the ALD.
However, if the trial shows that the ALD is helpful we will work with the NHS to try to get this sort of device introduced into routine clinical practice.

Who has reviewed the trial?

The South Central – Oxford A Research Ethics Committee has reviewed this study to ensure that it meets the required ethical standards.

Who is managing the trial?

Newcastle Hospitals are sponsoring this trial, which means they are responsible for its conduct and management. Newcastle University is providing support with the day-to-day management of the trial.

The Chief Investigator for this trial is Professor Gráinne Gorman. Professor Gorman has responsibility for the overall conduct of the trial.

Who has funded this trial?

This trial is funded by the Lily Foundation (the Lily-Stoneygate Research Awards Programme) with support of My Mito Mission.

Phonak (a Sonova Company) who make the Roger On™ ALD have provided the devices for this trial free of charge.

Who should I contact if I have any concerns?

Chief/Principal Investigator: Professor Gráinne Gorman

Email: nuth.mitoresearch@nhs.net

Trial Contact Name: Isabel Barrow

Tel: **0191 208 3105**

Email: nuth.mitoresearch@nhs.net

If you wish to discuss the trial or have any concerns, you can contact a member of the trial team on the details above.

If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advise and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:

Telephone:	0191 223 1382 or 0191 223 1454
Email:	nuth.patient.relations@nhs.net
Address:	Patient Relations Department The Newcastle upon Tyne Hospitals NHS Foundation Trust The Freeman Hospital Newcastle upon Tyne, NE7 7DN

Thank you for reading this information sheet