Participant Information Sheet

Research Project: Prognostic factors for outcomes of idiopathic Sudden onset Sensorineural Hearing Loss: the SeaSHeL national prospective cohort study

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You have been invited to take part in a research study.

Before you decide whether to take part, it is important you understand why the research is being done and what this will involve. This information sheet explains the research study, what will be expected of you as a participant and what will happen during/after the research has taken place.

If you have any questions or need any clarification after reading this document, please approach a researcher or get in contact with us (details at the end). Please take the time you need to consider whether or not you would like to participate in this study. You may discuss this with other people if you wish.

If you decide to participate, please fill out the accompanying consent form.

Summary of the important things you need to know:

- We are studying patients with sudden onset hearing loss to find out how patients are being treated and how they cope with the condition. This will help develop future treatments for patients.
- The study will involve completing 2 questionnaires, that will take approximately 20 minutes.
- The study will not impact your care in any way.
- You can stop taking part in the study at any time

What is the purpose of the study?

Each year, around 15,000 people in the United Kingdom experience sudden onset hearing loss. When the cause for this is not clear, the condition is called idiopathic 'sudden onset sensorineural hearing loss' (SSHNL). There is increasing research being conducted to develop new treatments for this condition. We are carrying out this study to identify how patients are being treated, and how they cope with the condition afterwards. This will help us understand the

condition better and help the development of new treatments.

Why have I been invited?
You have been invited to participate in this study as you have been diagnosed with SSNHL.

Do I have to take part?
No, you are under no obligation to participate in this study. You may withdraw from this study at any point by contacting a member of the research team, and you do not have to give a reason. Your healthcare will not be affected by your decision to participate or not participate in this study.

What will I have to do?

You will have to fill out a consent form and two questionnaires before and after your treatment that measure how your sudden hearing loss has affected your quality of life.

Each questionnaire will take approximately ten minutes to complete.

What are the possible disadvantages and risks of taking part?
There are no foreseeable physical or mental risks, or disadvantages of taking part in the study.

What are the possible benefits of taking part?
Though there are no direct benefits for participating in the study, your participation will provide very useful information that could potentially improve the care of patients with SSNHL in the future.

What if there is a problem?
If there is a concern regarding any aspect of this study, you may raise it with the researcher on site. Alternatively, you may contact the study supervisor Prof. Anne Schilder (a.schilder@ucl.ac.uk) or a University Research Ethics Co-ordinator on 020 7679 8717 or by email to ethics@ucl.ac.uk.

Will my taking part in the study be kept confidential?
All information collected about you during the course of the study will be fully anonymised (i.e. you cannot be identified) and kept confidential.

The information you provide will be handled and stored in keeping with the Data Protection Act 2018. Once this study is finished, your anonymised data may be used for future studies.

How will we use information about you?
We will need to use information from you and your medical records for this research project.

This information will include your:

- First name and surname
- Hospital ID number

People 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 study, 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 study.

What are your choices about how your information is used?
You can stop being part of the study 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 agree to take part in this study, you will have the option to take part in future research using your data saved from this study (data will be stored in keeping with UCL Data policies).

Where can you find out more about how your information is used?
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team

What will happen if I don't carry on with the study?
You may withdraw at any point of the study by expressing this wish to a member of the research team.

What will happen to the results of the research study?
When we have analysed the results, we would like to share our findings with patients, members of the public and healthcare professionals by written reports and presentations.

Who is organising or sponsoring the research?
The research is being organised by the evident (Evidence-based Ear, Nose and Throat) team, Ear Institute, University College of London (UCL). The sponsor of the study is UCL.

Further information and contact details
Please feel free to contact the following individuals should you wish to seek more information.

Further information regarding the study:

Mr Rishi Mandavia, r.mandavia@ucl.ac.uk

Prof Anne Schilder, a.schilder@ucl.ac.uk

Formal complaints:

University Research Ethics Co-ordinator on 020 7679 8717 or by email to ethics@ucl.ac.uk.