Participant Information Sheet

UCL Research Ethics Committee Approval ID Number: 17413/001

Title of Study:
Impact of hearing disability on overall quality of life in (infratentorial) superficial siderosis versus in age-related hearing loss

(Student Study)

Short Title of Study:
Quality of life in (infratentorial) superficial siderosis and in age-related hearing loss

Department:
Department of Neuro-otology, Faculty of Brain Sciences, Ear Institute, University College London

Name and Contact Details of the Study Co-ordinators:

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Name and Contact Details of the Chief Investigator:

Professor Doris-Eva Bamiou, email: d.bamiou@ucl.ac.uk

1. Invitation

You are being invited to participate in this student research project ("the study"). We thank you for reading this information. Before you decide whether to take part, it is important that you understand the nature of this study, what your participation in it will mean for you and what its results may bring to you and to science. it is important that you read the following information carefully and discuss it with others if you wish. We will be happy to answer your questions or provide you with more information.

2. What is the project's purpose?

This study is designed to assess the impact of hearing problems on the quality of life of individuals with (infratentorial) superficial siderosis (which is a very rare neurological condition) and in those with age related hearing loss.

Infratentorial superficial siderosis (also known as superficial siderosis of the central nervous system) is characterised by a trickle of blood through a defect in the sheath that covers the brain or spinal cord. When blood is broken down, iron gradually becomes deposited on the surface of the brain, brain-related structures and/or spinal cord. Most often, hearing is involved. Because it is very rare and can cause significant hearing loss we would like to gain more information about the impact of this disease on quality of life and how hearing problems impact the quality of life in individuals with this diagnosis. We would like to compare the results from participants with this condition with the results from the participants with age-related hearing loss.

This is an online survey which contains commonly used general quality-of-life and hearing-specific questionnaires. This will be done in anonymised format as a once-off measure. The results of this study will help us understand how hearing problems may impact the quality of life in both groups and how they differ between the two groups. This may in turn may be valuable in the clinical setting in the future when assessing so the values can be compared to those obtained in this study, at the time of diagnosis of either (infratentorial) superficial siderosis or age-related hearing loss. These in

turn may be useful in monitoring progression of symptoms or response to treatment or to rehabilitative measures.

3. **Who are we looking for?**

We would like to invite individuals who are:

- at least 18 years of age

AND

who have a known/CONFIRMED diagnosis of either:

-Superficial siderosis (infratentorial), also known as superficial siderosis of the central nervous system

OR

-Age-related hearing loss

4. Do I have to take part?

Taking part in this study is entirely voluntary. If you volunteer to participate in this study you can withdraw at any time without giving a reason and without it affecting you in any way. Anonymised data collected before you decide to withdraw from the study might still be used for analysis. A decision to withdraw from the study or a decision not to participate in this study will not disadvantage you in any way.

5. What will happen to me if I take part?

If you decide to participate in this study, we will ask to indicate your consent as described below. This will be done in an online format, and you will not be able to proceed to the study questions without your consent and confirming that you understand the purpose and nature of this study, that you are at least 18 years of age, and that you have previously received a formal diagnosis of either (infratentorial) superficial siderosis or age-related hearing loss.

Your participation in this study will be anonymous and will entail completing the online questionnaires that describe your quality of life overall and with regards to your hearing. We would also like to ask your gender, your current age, when (the age at which) you were diagnosed with superficial siderosis or age-related hearing loss (you must indicate which of the two is applicable) and whether you have received or are receiving any treatment (surgery or medication or any hearing device or intervention). We would also like to know your current level of hearing. There are six questionnaires in total which may take between 5 and 10 minutes each to complete (between 30-60 minutes in total). We would like to ask you to set aside some time when completing the questionnaires. You would only need to complete the set of questionnaires once.

We rely on you to provide us with as accurate information as possible and to complete the questionnaires to the best of your ability – this would help us maintain the integrity and high quality of this research.

6. What are the possible disadvantages and risks of taking part?

Your involvement is limited to answering a set of questionnaires which are commonly used in clinical and research settings and are unlikely to cause any upset. If you have a concern about any aspect of this study, you may decide not to complete the questionnaires or any part thereof or omit any question that you find upsetting or disturbing. You can also discuss this by contacting the study research team (the study co-ordinators or the Chief Investigator, as above).

7. What are the possible benefits of taking part?

There are no immediate benefits from participating in this research project. You will not be paid or reimbursed for your participation in this study.

8. What if something goes wrong?

In case you have a concern about any aspect of the study, please do not hesitate to contact the study co-ordinators. In case there is any complaint please contact the Chief Investigator Professor Doris-Eva Bamiou. However, the participants should also be informed that should they feel their complaint has not been handled to their satisfaction (e.g. by the study research team) that they can contact the Chair of the UCL Research Ethics Committee – *ethics@ucl.ac.uk*

9. Will my taking part in this project be kept confidential?

All data will be collected in anonymous format and stored in accordance with the General Data Protection Regulations (GDPR) and Data Protection Act (DPA) 2018. Your participation will not be identified in any ensuing reports or publications.

10. Limits to confidentiality

Please note that confidentiality will be respected subject to legal constraints and professional guidelines, and that despite the data being collected anonymously, confidentiality may not be guaranteed due to the limited size of the participant sample.

11. What will happen to the results of the research project?

The results of this study will retain no personal information so participants cannot be identified in any published articles. The results will be published in scientific journals and public platforms, and as part of students' Masters and PhD Thesises. You can obtain the results and findings of this study by contacting the study co-ordinators.

12. Local Data Protection Privacy Notice

Although no personal data will be collected or stored as part of this study, the controller for this study will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk
This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice: For participants in research studies, click here
The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices. The data collected as part of this project will be in anonymised format. No personal data will be collected. If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

13. Who is organising and funding the research?

This study is sponsored and organised by University College London (UCL). It is supported and part-funded by: (1) the National Institute for Health and Research (NIHR) University College London Hospitals Biomedical Research Centre (BRC) Deafness and Hearing Problems Theme; (2) the Bernice Bibby Research Trust (UK Registered Charity No 1058703). Additional funding for Health Utilities Index (Mark3) license use was sought and granted by (3) Health Utilities Index Inc.

16. Contacts for further information

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Thank you for reading this information sheet and for considering to take part in this research.
