



Information sheet



University of
Nottingham

UK | CHINA | MALAYSIA

THE AURA STUDY

A Biomarker study of stress

We invite you to take part in a research study

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. If you choose not to take part, this will not affect you in any way. Ask us if there is anything that is not clear or if you would like more information contact, sally.thornton@nottingham.ac.uk

1 Why are we doing the AURA Study?

- What we learn in this project will help us find out if the cortisol levels in hair are a good way of assessing stress levels in people with and without a hearing loss.
- We are looking at all the aspects of your life (your health, lifestyle, fitness etc.) which could impact your stress levels. We are also studying your hearing loss (if you have a hearing loss), your tinnitus (if you have tinnitus) your anxiety, depression, sleep and your resilience by recording your answers to a short survey.

2 Why am I being asked to take part?

- You are asked to take part because you are an adult (16+ years of age) and you need at least 2-3cm of hair.
- We are studying people with any type of hearing problems (diagnosed or undiagnosed), treated or untreated, including tinnitus. If you have normal hearing we would like to take this survey too.

3 What will I need to do if I take part?

1. If you choose to take part in the AURA study you will fill in a 20 minute survey now.
2. You do need to donate one hair sample, instructions for this are at the end of the survey. It will be from the middle and back of the head (as best results are from this area) and as close to the root as possible. Please avoid bleached or dyed areas (if you can't please make a note on the envelope).
3. There is an optional online hearing test at the end to complete too.

4 Will my results be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be kept **strictly confidential**. It will be looked after only by authorized persons, stored in a password protected database at the University of Nottingham. The data collected for the study might be looked at by authorized people from regulatory organizations to check that the study is being carried out correctly.

5 Who is funding the study

This project is funded by the National Institute for Health Research (NIHR) Nottingham Biomedical Research Centre, The University of Nottingham School of Medicine. None of these funders have any influence on or involvement with the study design, data collection or analysis.

6 What will happen to the results?

If you take part, after the study has finished the information we have recorded will be written up and submitted to be published in a peer reviewed scientific journal. Your name will not appear anywhere in the paper and you will not be identified.

We will also group your data (anonymously) together with others data to inform a future hearing loss studies.

How long will data be kept for?

All research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality. Only members of the research team will have access to personal data.

7 How will taking part affect me?

What are the advantages of taking part?

There are no direct advantages for you in taking part but it could help others.

Are there disadvantages of taking part?

No.

What will happen if I don't want to finish the AURA study?

You can withdraw at any time, without giving any reason, and without your medical care or legal rights being affected. On withdrawal, no further information will be collected. However, it will not be possible to erase the information already collected, and this information may still be used anonymously in the project analysis.

8 Who has reviewed the study

This study has been reviewed and given favourable opinion by: The Study Sponsor (University of Nottingham).

9 Who do I speak to if problems arise?

Our staff always try to conduct research in a way that is caring and respectful. If you do have any concerns about any aspect of the study, you should contact: Sally Thornton

10 Additional Information

What are the legal requirements?

Under UK Data Protection laws, the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Sally Thornton) is the Data Custodian (manages access to the data). This means we are responsible for looking after the information and using it properly. Rights to; access, change or move your information are limited as we need to manage the information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible. You can find out more about how we use your information and read our privacy notice at:

<https://www.nottingham.ac.uk/utilities/privacy.aspx>.