

FAMOUS Study

Follow-up and monitoring of new users of NHS hearing aids

IRAS Project ID: 313462

Significant Other Information Sheet

Version 2.0 06-APR-2023

1. You are invited to take part in our research study

- The FAMOUS Study is looking at how patients fitted with new hearing aids at <insert clinic name> are getting on with their hearing aids in the first year after fitting. We are also interested to know how the patient's hearing-related quality of life has been impacted, and this involves collecting some information from a 'Significant Other'.
- A 'Significant Other' is a partner or spouse. Your partner or spouse is a new hearing aid user and a participant in the FAMOUS study. They have identified yourself to help with their involvement in this study.
- This information sheet is to help you understand why the research is being carried out and what it will involve for you if you decide to take part.
- Please take time to read this information and ask us if there is anything that is not clear to you, or you would like more information.
- It is entirely your decision whether to take part in this study. If you choose not to take part, your partner's medical care will continue in the normal way. Your partner may still decide to take part in this study even if you do not.

2. A summary of the study

We know that hearing aids can improve communication and quality of life for adults experiencing hearing loss. However, using hearing aids can be difficult at the start and many patients may not use their hearing aids as recommended, or at all.

We want to know if a structured four-step hearing aid follow-up plan is as good as the current NHS follow-up plan for encouraging hearing aid use in adults. This is not yet known.

Around 36 NHS hearing service clinics have taken part in the FAMOUS study, and your partner was enrolled as part of the study. Each clinic taking part was randomly allocated to one of the two follow-up plans for new hearing aid patients.

As part of this research, we have collected information that has been routinely collected by the audiology clinic about your partner's hearing aid assessment, fitting and follow-up appointments, to help us understand if there is a difference in reported hearing aid use between patients receiving the different follow-up plans. To gather more information about your partner's hearing-related quality of life, we have sent them some questionnaires in the post. This includes the documents for you, their 'Significant Other', to complete. If you

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choose to complete these questionnaires, it will help us to understand the patient's and 'Significant Other's' current experience with their hearing loss. Even if your partner is not using their hearing aid(s) as originally intended, we would still like to know about yours and their experience.

3. What is the purpose of the study?

To see whether a structured follow-up and monitoring plan affects hearing aid use in first time hearing aid users, compared to current NHS follow-up.

4. Why have I been asked to help?

You have been invited to help with this study as you are the partner of a participant in the FAMOUS study. We want to understand how your partner's hearing loss and experience with their new hearing aid has impacted their quality of life, which includes asking questions to people who have a close relationship with them.

5. Do I have to help?

It is up to you whether or not you complete the Significant Other questionnaire. If you agree to take part, we will ask you to sign a consent form that is included alongside this information sheet.

6. What would helping out involve?

If you would like to help us after you have read the information in this document, we will need you to sign the enclosed consent form. This will enable us to use the information you provide us with in the study analysis. Also enclosed is a questionnaire for you to complete, entitled the 'Significant Other Scale for Hearing Disability'.

We predict this will take you around 5-10 minutes to complete. Once the consent form and questionnaire has been completed, you can use the enclosed envelope to seal your documents together, and hand them back to your partner.

We have also sent a selection of different questionnaires for your partner to complete, along with a pre-paid stamped addressed envelope for them to return everything to the FAMOUS Study team upon completion, including your Significant Other consent form and questionnaire.

If you would prefer to complete the consent form and questionnaire electronically, we have provided instructions on how to do this within the questionnaire.

7. What are the possible benefits of helping out?

Helping out with the study may not directly benefit you, however this research will help us to understand more about how patients use their hearing aids and improve the care provided to them in the future.

8. What are the possible disadvantages and risks of helping out?

There are no serious risks or disadvantages in helping us with this study. Time taken to complete the

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questionnaires may be a burden to some people.

9. What if there is a problem?

If you have any questions or concerns about the questionnaire that has been given to you, you can contact the study coordinating centre at the Nottingham Clinical Trials Unit (NCTU):

- Email: famous@nottingham.ac.uk
- Telephone: 0115 823 1585

If after this you still have concerns or you wish to complain formally, you can do this through the NHS Complaints Procedure via your local Patient Advisory and Liaison Service (PALS) <insert Local PALS details>.

10. What will happen if I do not want to help out with the study?

You do not have to help with the study if you don't want to. If you choose not to help, then please dispose of the questionnaire.

Information that we have already collected from your partner, including their anonymous routine medical data and the answers they provide in their questionnaires will still be used in the study analysis, even if you decide not to help out.

11. How will information about me be used?

Researchers at the Nottingham Clinical Trials Unit (part of the University of Nottingham) will need to use information from you for this research project. This information will include the answers you provide in the questionnaire. The researchers will use this information to do the research.

Once the study has finished, some of the data will be kept so the results can be checked. Reports will be written in a way so that no-one can work out that you helped us with the study.

12. What are your choices about how your information is used?

By sending your signed consent form and questionnaire answers back to the FAMOUS study team, you are providing your consent for the information to be used as part of the study analysis. You will not be identified personally in any of the study analysis and your personal information will be kept confidential. After 10 years the information collected during the study will be disposed of securely.

13. 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/ and www.hra.nhs.uk/patientdataandresearch
- at <https://mft.nhs.uk/app/uploads/2018/07/Privacy-Notice-May-18-v1.2-Booklet-1.pdf>
- by asking one of the research team by sending an email to famous@nottingham.ac.uk
- by calling the Nottingham Clinical Trials Unit (NCTU) on 0115 823 1585.

14. Who is organising and funding this study? How has it been approved?

The study is being organised by the Manchester University Hospital NHS Foundation Trust (the Sponsor) and
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coordinated by the NCTU. The funding for the study is provided by the National Institute for Health Research. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The London-Chelsea Research Ethics Committee.

Patients who have previously been treated for hearing impairments, including hearing aid users, have helped us plan and design this study. Patients' representatives are also involved in the teams that oversee the running of the study.

15. What happens at the end of the study?

When the FAMOUS study ends, your partner's care will continue to be managed by their hearing clinic. If your partner and/or you decide you do not want to complete the questionnaires we send, we will keep and use the anonymous medical information we have already collected from your partner's hearing aid appointments, but we will not contact them again regarding the FAMOUS Study. At the end of the study the results will be published in scientific medical journals and presented at conferences. Neither you nor your partner will be identified in any publication. We will share study results using newsletter and an animated video available on our study website, at the end of the study.

16. How to contact us

Contact details of your local care team;

- [<insert contact details here>](#)

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