

FAMOUS Study

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

Patient Information Sheet

Version 3.0 06-APR-2023

IRAS Project ID: 313462

1. Taking part in our research study

- The hearing clinic you attended for your hearing aid appointments is taking part in the FAMOUS study. The FAMOUS study is comparing two types of patient follow-up plans in supporting new adult hearing aid users and their families, and to find out what is best value for the NHS. All adults fitted with a hearing aid at <insert site name> over a 12-week period have been included in the study.
- At the time of your hearing aid appointments, you were told about the study, and that your clinic would share some of your anonymous medical information regarding your hearing aid appointments with the FAMOUS study team, for research purposes.
- This information sheet explains why the research is being carried out and what is involved in the next stage of the study. Please take time to read this information and contact us if there is anything that is not clear, or if you would like more information.
- You decide whether you continue to take part in this study. If you choose not to take part, your medical care will continue in the normal way. This information sheet will explain how we will manage the information we collect from you. We will ensure your personal information remains confidential.

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 are taking part in the FAMOUS study. Each clinic taking part has been randomly allocated to one of the two follow-up plans for all new hearing aid patients.

Our research will use information that has been routinely collected by your audiology clinic about your 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, we have sent you some research questionnaires in the post which we would like you to answer, together with this information sheet. Your answers will help us to understand your current experience with your hearing loss.

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

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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 am I being contacted?

You have been contacted because you had a new hearing aid fitted at <insert site name>. We are asking all patients fitted with hearing aids at <insert site name>, to complete questionnaires about how much they are wearing their hearing aid, if at all, and experience with wearing their hearing aids, if at all. As it has been approximately three months since your hearing aid was fitted, we have called this the 'FAMOUS 12-week questionnaire pack'.

5. Do I have to continue to take part?

It is up to you whether or not you complete the questionnaires for the next part of the study. Your audiologist or a member of the FAMOUS team can talk to you about the study and answer any questions you may have. If you choose to take part, there will also be another opportunity to answer some more questionnaires approximately one year after your hearing aid fitting, in around nine months' time. Completing either of these questionnaire packs is optional.

6. What taking part involves?

Your hearing clinic has shared anonymous medical data with us relating to your hearing aid assessment, fitting and follow-up appointments.

Now that it has been a few months since your hearing aid was fitted, we would like to learn about whether you are using your hearing aid or not, and about your hearing aid experience. We would like you to complete some questionnaires that are associated with hearing-related quality of life. The questionnaire pack is accompanied with this information sheet. The questionnaire pack includes:

- A consent form asking for your permission for us to link your anonymous medical information from your audiology clinic to the answers you provide us in the questionnaires. We would also like your permission to contact you again after one year of hearing aid use, with some additional questionnaires
- A selection of hearing questionnaires that assess quality of hearing in patients
- Some quality-of-life questionnaires for you to fill in

We have also sent you a stamped addressed envelope for you to return the completed questionnaires and consent form back to us. All questionnaires should be returned in the same envelope. The postage is prepaid so you will not have to pay for posting. You can complete the consent form and questionnaires electronically if you prefer, please follow the guidance provided in the booklet

We predict it will take no more than 20 minutes to complete these questionnaires. You don't need to complete them all at the same time. You can take your time and return the completed questionnaires to us once you have finished. Please try and fill in as many of the questionnaires as possible.

You will receive one reminder telephone call from your audiology clinic about the questionnaire packs they are

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sending in the post. You will receive the call around the time you receive the questionnaire pack (this may be slightly before, or slightly after). This will give you a chance to ask any questions you might have about what is involved.

If you give consent to being contacted a year after your hearing aid fitting, we will send you another questionnaire pack in around nine months' time. This will include the same questionnaires as in the 12-week questionnaire pack, for you to complete again.

At the same time point, one year after your hearing aid fitting, we would like to understand how your 'Significant Other' might have been impacted by your hearing loss and experience using your new hearing aid/s. Your 'Significant Other' will be your partner, if you have one. We will send you two questionnaire packs, one for yourself to complete, and one for your partner to complete. If at that time you do not have a partner, you can ignore the 'Significant Other' documents. You can still complete your participant questionnaires and return them to us.

If you also agree to be contacted for an informal discussion about your hearing aid use, then someone from the study team will contact you to give you more information.

7. What are the possible benefits of taking part?

Taking part in 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 in the future. As a 'thank you' for completing the questionnaire pack, you will be sent a £10 Love2Shop voucher each time you complete a questionnaire pack. You will receive this either by email or by post, dependent on your preference indicated on the consent form.

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

There are no serious risks or disadvantages in taking part in this study. Time taken to complete the questionnaires may be a burden to some people, and you also might need help from somebody to answer the questions, such as a friend or family member.

9. What if there is a problem?

If you have any questions or concerns about the questionnaires we have sent you, please 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>.

In the unlikely event that something goes wrong and you are harmed during the study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you have grounds for a legal action for compensation but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

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10. What will happen if I don't want to carry on with the study?

You do not have to complete these questionnaires. You can ignore this request without giving any reason, and without your legal rights being affected. If you do not want to carry on with the study, your clinical care will not be affected in any way. If you decline further participation in the study, the information we have already collected from your audiology clinic in relation to your hearing aid appointments will be kept and may be used in the project analysis. This information has been collected anonymously, therefore we will not be able to identify your data to remove it.

11. How will information about me be used?

Researchers at the NCTU (part of the University of Nottingham) will need to use information from you and your medical records for this research project. The researchers will use this information to check your records to make sure that the research is being done properly. If you provide us with your consent, the answers you give in the questionnaire packs will be linked to your anonymous medical data we have collected from your hearing aid appointments. If you provide us with consent to contact you again with the 12-month questionnaire pack and/or an informal telephone call, the FAMOUS Study team will use your contact details (name, address, email and contact telephone numbers) to get in touch with you again. Contact details will be kept confidential and destroyed to maintain your privacy, before any analysis takes place.

If you choose to receive text reminders about your questionnaires, your first name and mobile number will be shared with eSendex, our approved text message provider (<https://www.esendex.co.uk/>). All appropriate security steps are taken to ensure your confidentiality, and protection of your data.

All information about you will be kept safe and secure. 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 took part in the study.

12. 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. Because the data we have collected on you will be anonymous, we will not be able to let you see or change the data we hold about you. If you provide consent to be contacted again, but later change your mind, you can withdraw from future contact by informing the FAMOUS Study team by email or telephone. Our email address and telephone number are in the next section. After 10 years your data collected during the study will be disposed of securely.

13. Where can you find about 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 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 care will continue to be managed by your hearing clinic. If 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 hearing aid appointments. At the end of the study the results will be published in scientific medical journals and presented at conferences. You will not 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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