FAMOUS

Background

In 2018, the National Institute of Health and Care Excellence (NICE) published a national guideline on assessment and management of hearing loss in adults (National Guideline 98; https://www.nice.org.uk/guidance/ng98). The guideline addresses uncertainties and variations in clinical practice.

One topic addressed in the guideline is the effectiveness of follow-up and monitoring for new adult hearing aid users. A review of the literature failed to identify any evidence on the topic. The conclusion from NICE was that current practice varies, is ill-defined and is non-evidence based.

As a result of this finding, the government, via the National Institute for Health Research Health Technology Assessment programme (NIHR131159), commissioned and recently funded, a national project to address this gap-in-knowledge. The project, due to start later this year, is known as the FAMOUS study, short for 'Follow-up And Monitoring Of new USers of NHS hearing aids.

This is an opportunity for NHS audiology services to work collaboratively to provide an evidence-base for clinical practice. The scale and scope of FAMOUS is unparalleled in UK audiology. It will involve the recruitment of a total of around 3,600 new adult hearing aid users across as many as 40 audiology services, and requires no previous experience in clinical research.

Who will conduct the study?

This is a national study and involves a collaboration between the Biomedical Research Centres in Manchester, Nottingham and UCLH. A national study of this size involves a large number of investigators and collaborators, and a full list of those currently involved is provided at the end of this article.

Are you interested in becoming involved?

We are looking for around 40 NHS audiology services to become research sites in the FAMOUS study. The trial will compare the effectiveness of two models of follow-up and monitoring. One model is standard/usual care as currently provided by individual services (we recognise this will vary from service to service). The second model to be delivered at the other half of the sites is based on the best possible evidence and is referred to as 'standard care plus'. The outcome measures that will be used to determine the effectiveness of the two models will be collected by the FAMOUS research team at 12 weeks and 12 months after fitting. Your service will not have to gather these data.

What would you have to do?

FAMOUS is a cluster randomised trial, meaning that sites (i.e. services) and not individual patients will be randomised. As such, each site will be randomised to either continuing your current standard care, or 'standard care plus' to all patients. For your adult hearing aid service to take part in the study, you would need to:

1. Agree to be randomly assigned to either standard care or standard care plus.

2. Identify potential participants for 12 weeks. This doesn't involve taking consent but you will asked to provide all patients seen over this period with a patient information sheet explaining the study.
3. You will provide the same care to ALL first-time adult hearing aid patients who pass through your service during this 12 week period.
4. Send patients a questionnaire with a follow-up telephone call, at 12 weeks and 12 months. The patients will complete and return the questionnaire direct to the FAMOUS research team. You will also need to share some routinely collected data (de-identified) from clinical records with the FAMOUS research team. These tasks do not need to be undertaken by clinical staff.

What is involved in standard care plus?

Standard care plus has four components that are specified in the trial design and may take a little extra time:

a. At the assessment appointment, identify listening situations where hearing loss is causing difficulties;
b. At the fitting appointment, develop an individualised plan to reinforce where and when to use the hearing aids;
c. Provide monitoring, feedback and problem-solving support during the first week of hearing aid use, so that support can be provided before bad habits and poor use sets in; and
d. Augment the 6-week follow-up with a review of the individual plan and, if necessary, provide coping strategies.

What has been done to help busy NHS services become partners in this national study?

To facilitate participation in the study, we have kept the patient identification window to 12 weeks. It is only new adult hearing aid referrals who are being seen for hearing assessment during this one-off 12-week period who will take part. Starting dates will be staggered across NHS services, with the first service commencing in late 2022. Also, to make this as uncomplicated as possible, the same model of care will be provided to every adult in your individual services: either your usual care or 'standard care plus'.

Does your department need prior experience in conducting clinical research?

We understand that NHS departments are busy. We also appreciate that not everyone will have had the opportunity to be involved in research previously. As long as you are motivated and enthusiastic to run the study for 12 weeks, the FAMOUS team will provide all the support you need.

What support will you receive if you agree to take part?

The trial is being coordinated by the Nottingham Clinical Trials Unit (NCTU) at the University of Nottingham. NCTU has experience of conducting trials in adult audiology services, and has a unique understanding of the challenges your service may face, and the support you will need to run the trial. The trial will be supported by dedicated NCTU staff who will help guide you through the site set-up process and will offer general research and trial-specific training before you start recruiting, and a refresher training, as needed, throughout the course of the trial. There will always be an NCTU member of staff available to email or call if you have any questions, at any stage of the trial.

How is the trial Funded, and how will my department be funded?

For sites randomised to the standard care arm, current clinical practice will not change. Research and Service Support activities (which have been costed into the trial) will include: providing written information about the study to all patients seen over your 3 month identification window at their first hearing aid assessment appointment, posting questionnaires at 12 weeks and 12 months post hearing aid fitting, calling above patients at 12 weeks post fitting to let them know a questionnaire has been posted, sharing of routinely collected data with the Nottingham Clinical Trials Unit, and checking of the national data-opt out service records to ensure no data is shared where a patient has opted out of this sharing.

For sites randomised to the standard care plus arm (intervention arm), in addition to the research and service support activities mentioned above, your site will need to adopt the Intervention for a period of 3 months with all patients being assessed for a hearing aid for the first time.

This trial has been funded by the NIHR Health Technology Assessment Programme. That means all trial related costs have been calculated using the ACORD framework, and approved by the national process. We are happy to speak to you, your R&D department and local Clinical Research Network to discuss the financial aspects of the trial.

What next?

Completing the Expression of Interest form does not commit your service to being a site, it is information for us to assess your willingness and readiness to be a site. The trial team will contact potential sites in the first quarter of 2022. We may ask you some follow-up questions before mutually agreeing, in principle, for you to participate as a FAMOUS site. You and your R&D department will then work with the trial coordinating centre to get your site ready to open in late 2022. Formal commitment on your behalf would only take place after your R&D department undertakes HRA Capacity and Capability checks and returns a signed contract (mNCA).