ISRCTN10589817 https://doi.org/10.1186/ISRCTN10589817

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

Submission date	Recruitment status	[X] Prospectively registered
31/08/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
01/09/2022	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/04/2025	Ear, Nose and Throat	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Each year in the UK about 355,000 adults are fitted with hearing aids for the first time. We know that hearing aids improve communication and quality of life for in adults experiencing hearing loss. However, adjusting to hearing aids can be difficult and many patients may not use their hearing aids as recommended, or at all.

Although there are guidelines in place to support first-time hearing aid patients, the way in which the support is provided can vary between hearing clinics, which makes assessing the effectiveness of the current guidelines difficult. We want to find out whether a defined four-step hearing aid follow-up plan is as effective as the current NHS guideline care for hearing aid patients, their families and best value for the NHS.

Who can participate?

FAMOUS will recruit a minimum of 23,400 participants from around 36 NHS hearing service clinics in the UK. These must be adults over 18 years old who are using hearing aids for the first time.

What does the study involve?

Each clinic will be randomly assigned to follow-up hearing aid patients using current NHS guidelines or the FAMOUS four-step support strategy. This means that all patients seen during the time the trial is active at their clinic will all be followed up in the same way. All patients who are fitted with hearing aids will be contacted at 12 weeks and 12 months after fitting, to complete questionnaires to help us understand their usage and experience with the hearing aids. As well as the patient questionnaires, we will use anonymous data from routine clinic records to understand if there is a difference in reported hearing aid use and clinic attendance between the two groups.

What are the possible benefits and risks of participating?

Taking part in the study may not directly benefit the patient, however, the research will help us to understand more about how patients use their hearing aids and improve the care provided in the future. There are no associated risks to patients taking part in this study. There may be some sensitive quality of life questions asked, as part of the 12-week and 12-month questionnaires.

Where is the study run from?
The study is being organised by the Manchester University Hospital NHS Foundation Trust (the Sponsor) and coordinated by the Nottingham Clinical Trials Unit (NCTU) (UK)

When is the study starting and how long is it expected to run for?
January 2022 to December 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
famous@nottingham.ac.uk

Study website
http://www.famousstudy.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Prof Kevin Munro

ORCID ID
http://orcid.org/0000-0001-6543-9098

Contact details
School of Health Sciences
Faculty of Biology, Medicine and Health
A3.11 Ellen Wilkinson Building
University of Manchester
Manchester
United Kingdom
M13 9PL
+44 161 275 3360
kevin.j.munro@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
313462

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

IRAS 313462, NIHR131159

Study information

Scientific Title
Follow-up and structured monitoring for adults offered an NHS hearing aid for the first time (FAMOUS): a cluster randomised controlled trial

Acronym
FAMOUS

Study objectives
To investigate the clinical and cost effectiveness of a 4-step follow-up and monitoring intervention in adults offered hearing aids for the first time, compared to usual care, on self-reported hearing aid use 12 months after initial hearing aid fitting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/12/2022, London - Chelsea Research Ethics Committee (Research Ethics Committee (REC) London Centre, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8029; chelsea.rec@hra.nhs.uk), ref: 22/LO/0836

Study design
Multi-centre two-arm parallel-group cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Adults who present with hearing difficulties and are offered NHS hearing aid/s for the first time.

Interventions
FAMOUS is a multi-centre, two-arm parallel-group Cluster Randomised Controlled Trial (CRCT). During the three-month recruitment phase, the audiology clinic’s trial allocation (usual care or enhanced care) will be adopted as their sole clinical practice for that site. All patients seen in

NHS audiology clinics will be treated in line with the clinic's trial allocation and will be subsequently invited to complete patient-reported outcome measures (PROMs).

During the recruitment phase, all patients seen in NHS audiology clinics will be treated in line with the clinic's trial allocation during a 3-month recruitment period, starting from site green light. The two treatment arms of the trial are as follows:

Usual Care: The control group will receive usual care according to local procedures for the hearing aid assessment, prescription, fitting appointment, and follow-up care. For the purposes of the trial, usual care must not include the prescription of any combination device or at-ear sound generator. Usual care must include some level of follow-up according to NICE guidelines, which is usually a face-to-face appointment offered at six-weeks-post-fitting.
Enhanced care: Patients randomised to the intervention arm will, in addition to receiving usual care, will receive a follow-up and monitoring behaviour change intervention delivered by their NHS audiologist.

At the end of the recruitment phase, sites can revert to the hearing aid follow-up and monitoring that they followed prior to involvement in FAMOUS if they choose to. Sites will continue to provide routine data to the NCTU for 12 months following the completion of the recruitment phase.
Patients randomised to the enhanced care arm will, in addition to receiving usual care as described above, receive a follow-up and monitoring behaviour change intervention delivered by their NHS audiologist or delegate.

This intervention, designed to increase uptake and use of hearing aids, comprises four steps:
1. At the hearing assessment appointment: Patients, in consultation with their audiologist, will compile a list of situations in which they have difficulty hearing and in which they think a hearing aid might help. This activity is consistent with the widely used and accepted Client Oriented Scale of Improvement (COSI) outcomes measurement.
2. At the hearing aid prescription and fitting appointment: A personalised 'Hearing Aid User Checklist and Diary' booklet (based on situations in which the patient has difficulty hearing and in which they think a hearing aid might help) to reinforce where and when hearing aids should be used, and to help integrate them into daily life.
3. Early monitoring of hearing aid use at 7-days after fitting in all patients.
4. Six weeks follow-up after the hearing aid prescription and fitting appointment. In addition to the usual care specified by NICE, audiologists and patients will review the action plans that were made at the fitting appointment and will either reiterate (boost) them or form new plans.

Intervention Type
Behavioural

Primary outcome measure
Self-reported daily hearing aid use, 12 months after initial hearing aid fitting measured using a FAMOUS-specific research question 'In the last week, how many hours per day did you use your hearing aid, on average?'

Secondary outcome measures
1. Self-reported hours of daily hearing aid use measured 12 weeks after initial hearing aid fitting, using a FAMOUS-specific research question 'In the last week, how many hours per day did you use your hearing aid, on average?'
2. Self-reported hours of daily hearing aid non-use measured 12 weeks and 12 months after

initial hearing aid fitting, using a FAMOUS-specific research question ‘In the last week, how many hours per day did you use your hearing aid, on average?’. Non-use is defined as one hour or less per day.
3. Hearing-related quality-of-life (QoL) measured using IOI-HA survey and HHIE survey at 12 weeks and 12 months post hearing aid fitting
4. Relationships with and QoL of significant others (i.e., partner, family members) measured using SOS-HEAR questionnaire at 12 weeks and 12 months post hearing aid fitting
5. Barriers and facilitators to behaviour change within standard practice e.g., capabilities, opportunities and motivations (mechanisms of impact) measured using COM-B questionnaire at 12 weeks post hearing aid fitting
6. Experiences and acceptability of the FAMOUS enhanced care intervention to service users and service providers (process evaluation) measured using semi-structured interviews with patients, service managers and audiologists after the intervention phase has been completed at the site.
7. Estimate the cost to the NHS and value to society measured using HUI-3, HHIE and CSRI questionnaires at 12 months post hearing aid fitting

Overall study start date
01/01/2022

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Adults (≥18 years)
2. Using hearing aids for first time

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10800

Total final enrolment
11733

Key exclusion criteria
1. Adults offered an auditory implant of any kind
2. Adults offered non-conventional hearing aids e.g., that re-route sound between ears.

Date of first enrolment
30/05/2023

Date of final enrolment
07/03/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Manchester University NHS Foundation Trust

Sponsor details
Cobbett House
Oxford Road
Manchester
England
United Kingdom
M13 9WL
+44 1612764125
Research.Sponsor@mft.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://mft.nhs.uk/

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The dissemination of the FAMOUS trial findings (main trial results, SWAT, economic analysis and process evaluation) will be via a publication in the NIHR Journals Library (HTA monograph or threaded publication), publication in peer reviewed journals, presentation at medical conferences and communication of our findings to groups involved in guideline development. The manuscripts will be prepared by the Chief Investigator and Trial Management Group and authorship will be determined by mutual agreement. The Trial Steering Committee and Data Monitoring Committee will be given the opportunity to comment on the manuscripts prior to submission.
Any secondary publications and presentations prepared by Investigators must be reviewed by the Chief Investigator and NCTU. Manuscripts must be submitted to either party in a timely fashion and in advance of being submitted for publication, to allow time for review and resolution of any outstanding issues. Authors must acknowledge that the trial was performed with the support of Manchester University NHS Foundation Trust.
During the trial, press releases may be issued from NCTU or Sponsor. Presentations or other material prepared by local investigators to publicise the trial must be reviewed by the Chief Investigator and NCTU. No party will be entitled to submit any publicity material without prior approval from NCTU.
We will create animated videos that will be translated into 4 key languages explaining the

results in clear terms. These videos will be available on the trial and BRC websites and be promoted by Royal National Institute for Deaf People, our PPI group and the BRC, to ensure the results are disseminated as broadly as possible.

Intention to publish date
01/04/2026

Individual participant data (IPD) sharing plan
Anonymised participant data may be shared with researchers external to the trial research team in accordance with the NCTU's Data Sharing Standard Operating Procedure. All requests for data should be sent to the NCTU to be considered by the NCTU Data Sharing review panel. Participant level data will not be available, as it is not permitted by NHS Digital (and devolved nation equivalents) under the terms and conditions under which NCTU receives the data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	16/12/2022	14/02/2023	No	No
Protocol file	version 3.0	06/04/2023	31/05/2023	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 4.0	17/01/2024	09/05/2024	No	No
Statistical Analysis Plan	version 1.0	22/06/2023	14/05/2024	No	No
Protocol file	version 5.0	20/03/2025	16/04/2025	No	No