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Hearing Aids, Research and Public Involvement: stories behind the FAMOUS study

FAMOUS - a national audiology research study

The FAMOUS trial was designed to discover whether a best practice-based structured package of support for new hearing aid users does or does not improve their experience.

From the start, it was clear that involving hearing aid users in developing and delivering the research programme was key to producing results that would be useful.

The FAMOUS trial began in 2021 and is approaching its final stages (results expected in December 2026). Throughout FAMOUS, Patient and Public Involvement (PPI) has played a key role in trial design and management. But we can trace the importance of PPI to FAMOUS back further than the start of the trial. In this article we'll explore how PPI has shaped one of the largest national audiology trials in the UK.

The challenge

Each year about 355,000 UK adults are fitted with NHS hearing aids for the first time. Hearing aids are transformative in improving the quality of life for people with hearing loss. Nevertheless, 30% of those receiving hearing aids use them only some of the time and a further 20% do not use them at all.

Hearing aids are sophisticated technology, many adults finding them difficult to adjust to and use, and access to aftercare is inconsistent.

Around a quarter of people attending RNID information stands or hearing aid maintenance sessions at one venue in 2012 did not know basics of hearing aid care such as cleaning, changing tubes or even how to change a battery reducing the benefits of their aids. Expectations were often unrealistic that hearing would be restored, not a more measured understanding that it would be improved. These factors led to the aids being left in a drawer or even discarded. Service users, families, carers and audiologists felt frustrated. NHS providers saw it as waste at a time when NHS resources were overstretched.

NHS audiology service user

Having hearing aids fitted for the first time was a big step for me and I did not feel there was time to talk about that. The process felt a little rushed and I was not quite the priority. Info was given quickly and I didn't quite absorb it." NHS audiology service user

From RNID's In Their Own Words (2024)

National guidelines developed with service users as partners

NHS England suggested the need for a guideline on the assessment and management of adult hearing loss. As a result, the National Institute for Health and Care Excellence (NICE) established a Guideline Committee including health professionals, researchers and service users with direct experience of NHS audiology services, to identify variations and uncertainty in current practice, review the evidence, and provide recommendations for diagnosing and managing hearing loss in the UK.

NHS audiology service user

"When my hearing aids were fitted, no one explained how to get used to wearing them. When you don't know what you don't know then it is hard, and I think information could have been more proactively offered." NHS audiology service user

From RNID's In Their Own Words (2024)

The perspectives of the members with hearing loss proved crucial. It meant the committee focused on the real-world problems most important to service users.

Following an extensive review

process, the guideline was published in 2018. As part of any NICE review, gaps in evidence were identified and research recommendations prioritised. Of the five research priorities identified, one was: What is the benefit of monitoring and follow-up for adults with hearing loss post-intervention compared with usual care?

In 2019, a research team led by Prof Kevin Munro designed a clinical trial to address this question. It was funded by the NIHR Health Technology Assessment programme and became known as FAMOUS (Follow up and Structured Monitoring for adults offered Hearing Aids for the first time).

A service users' perspective on NICE guidance committee

NICE has many ways in which people can be involved in developing guidance (Get involved | NICE). Committees are independent and include not only experts but also people who use services and carers. Contributions from people with the relevant condition are welcomed, as we found during the Hearing Loss review.
The committee included two lay members. At least four members had hearing loss themselves.

When it came to the stage of whittling down and setting priorities from a list of 20 potential research questions it was notable how they turned down technical research and pushed for research which might have practical benefit to all patients.

Service users as equal partners in commissioned research

There is good agreement that patients and the public should be involved in the health and care research process. At its best, PPI representatives are active partners in research teams across all aspects of the research cycle. NIHR is at the vanguard of PPI, having integrated PPI into research since its inception in 2006. The benefits of inclusive PPI in research include:

- Improving how research is done by grounding research in lived experience
- Building relationships with community groups, promoting and fostering participation
- Supporting researchers to acquire skills and knowledge of the "lived experience" of health and care conditions
- Enabling people taking part, understand and influence what research should be done and how
- Enabling members of the PPI group to encourage implementation of the results of that research

Commissioning a national audiology research study

The FAMOUS trial randomised Audiology services to deliver a best practice based (structured post-fitting package of support) or to follow usual processes. All service users who were referred to an audiology service during a 3-month trial window received the post-fitting care plan their service was randomised to. All service users seen during the defined window were invited to join the FAMOUS trial, and complete brief questionnaires about their hearing aid use, well-being, and costs. The results of this trial will determine whether:

1. Structured post-fitting support increases the amount of time hearing aids are being used, and
2. This is cost-effective and should be used in all NHS audiology services.

In a national audiology trial of the scale and impact of FAMOUS, it is not unexpected that there have been challenges along the way. We will report on these separately, but they include:

- Impact of the COVID-19 pandemic
- Delays in opening sites
- Delays from assessment to fitting
- Withdrawal of sites
- Variations in electronic audiology patient recording in different audiology clinics
- Return of research questionnaires without the necessary consent
- Low completion of primary outcome measures
- New guidance from NHSE/DHSC on Patient Initiated Follow Ups, suggesting routine follow-up in our population was not required

The insights from our PPI group have been invaluable in managing these challenges. At every step of the project, they ensured the patient voice was central to the design and delivery of the project (see Table 1).

A service users' perspective on the FAMOUS research team

As part of the FAMOUS trial management group, I've had the privilege of ensuring that the needs of people with hearing loss on a national level are considered, which is critical for meaningful participation and outcomes. Throughout the process I've worked with the team to ensure all materials are accessible, such as clear participant information sheets and subtitled videos. It's been rewarding to have been part of such a receptive and collaborative group, who have taken feedback on board. I'm now excited to see how we can

ensure relevant findings are taken forward, resulting in real change for people accessing hearing care.

Thinking ahead, there's a few things I'd like to see embedded in further research, we've learnt a lot since starting FAMOUS. For example, I'd encourage researchers working with people with specific communication needs (such as hearing loss) to fully plan how they communicate progress and findings, embedding accessibility throughout. I'd also encourage engagement with charities and patient groups from the start.

Final comments

Audiology is a relatively research-naïve profession. To our knowledge, FAMOUS is the first national audiology trial of this scale. In addition to answering the specific research question about the benefits of monitoring and follow up, FAMOUS is creating new links between clinical services and research and development in many NHS Trusts. Therefore, not only will FAMOUS potentially provide evidence to change clinical audiology practice but will provide important lessons for future research.

Service users have been partners throughout the project. They actively shaped the NICE guideline e.g., identified follow up and monitoring as an important topic and, when evidence was found to be lacking, prioritised this for research funding. Ten years later service users continue to play an important role as members of the FAMOUS research team e.g., contributing to the research protocol and helping to overcome challenges. We anticipate that they will continue to play an active role in dissemination, implementation, and monitoring and evaluation.

	Description of activity
Grant Application	**Two PPI groups (9 people from Manchester and 5 from Nottingham) provided critical insights into the views, priorities and challenges of hearing aid use in their lived experience of different NHS services.** Specific impact on the project design: 1. The intervention was co-developed and refined to ensure it was meaningful and practicable. 2. The cluster-randomised design, recruitment timing and methods were agreed. The options about the most appropriate manner and time to approach patients was greatly aided by PPI co-applicant TL's experience as a lay member of an NHS REC committee. 3. Both groups felt that the number of hours of use was the most logical primary endpoint 4. The PPI group agreed to form a standing PPI group for the trial if funded.
Delivering Trial	**A Patient Advisory Group (PAG) was formed June 2022, including PPI co-applicants TL and FO and supported by co applicant CR.** This proved key to delivering the trial. The group: 1. Reviewed all patient-facing materials, including suggesting brief information for all patients attending a clinic during the trial delivery to take home as well as posters in the clinics. 2. Refined the intervention, improving the checklist and diary and simplifying the instructions. 3. Supported the process evaluation by advising best methods to contact participants and refining verbal consent scripts and topic guides. 4. With PPI group members from the Centre for Ethnic Minority Health (University of Leicester), created a video of the trial available with voice-overs in English, Polish, Punjabi, and Welsh. 5. Amended instructions and wording on informed consent form, once monitoring showed a high incomplete/incorrect completion rate. 6. Convened focus groups to brainstorm ways to improve 12-month recruitment rates. Following a full review of the 12-month patient pack and associated messaging, the primary outcome return rate increased by ~10%. An independent public contributor provides oversight of the trial as a voting member of the Trial Steering Committee. A PAG newsletter was introduced at the end of 2023 to keep the group informed of study progress during the follow up stages.
Reporting the Trial	**Our PPI group members and co-applicants (TL and FO) will be key to disseminating the trial results:** 1. To trial participants 2. To a wider lay audience 3. To key stakeholders, NHS decision makers and NICE 4. To develop implementation strategies, if the intervention proves effective. Our FAMOUS Trial website is available for patients, public and participating site staff to view here: https://famousstudy.ac.uk/home.aspx.

Table 1

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How patients and patient representatives were involved in the creation of this article

The FAMOUS trial management group includes several members with hearing loss. Two members had a specific role in representing service users and are co-authors of this article: one is a retired GP and the other is employed by RNID, the national charity supporting more than 18 million people in the UK who are deaf, have hearing loss or tinnitus

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