TRIAL PROTOCOL

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

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

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This project will be conducted in accordance with the trial protocol and the ethical principles outlined by Good Clinical Practice (GCP) and the Declaration of Helsinki in its most current version.

Protocol development and sign off

Protocol Contributors
The FAMOUS Trial Management Group and Advisory Committee have contributed to the development of this protocol. A list of contributor names and affiliations can be found in the electronic Trial Master File.

Protocol Amendments				
The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version				
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CI Signature Page	
This protocol has been approved by:	
Trial Name:	FAMOUS
Protocol Version Number:	3.0
Protocol Version Date:	06-APR-2023
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Trial Role:	Chief Investigator
Signature and date:	
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Sponsor approval
Sponsor statement: Where the Manchester University NHS Foundation Trust takes on the Sponsor role for oversight of protocol development, signing of the IRAS form by the Sponsor will serve as confirmation of approval of this protocol. Manchester University NHS Foundation Trust is acting as Sponsor for this trial and is assuming overall responsibility for the initiation and management of the trial. The Trust will provide permission to conduct the research and monitor the progress of that research. The co-investigators institutions have all signed a collaborator agreement with the Trust and therefore the Sponsor has influence over all aspects of the trial design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results which are the responsibility of the research team.

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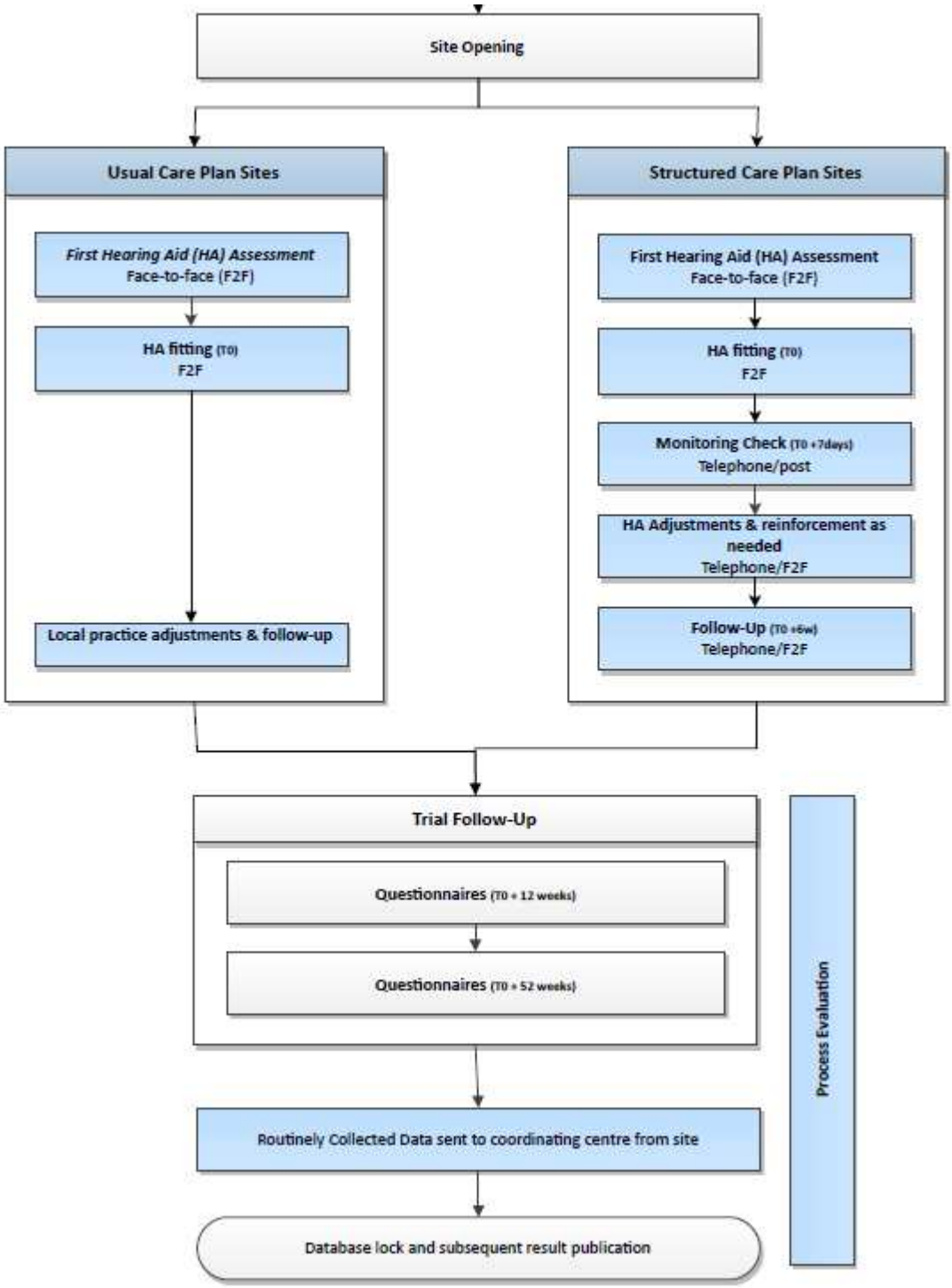
TRIAL SUMMARY

Full Title	Follow-up and structured monitoring for adults offered an NHS hearing aid(s) for the first time (FAMOUS): a cluster randomised controlled trial.
Trial design	Multi-centre, two-arm parallel group cluster randomised controlled trial with integral internal pilot, economic and process evaluations.
Objectives	Primary Objective: To determine the effects of the FAMOUS structured care intervention in adults offered hearing aids for first time compared to usual care, on self-reported daily hearing aid use, 12 months after initial hearing aid fitting. Secondary Objectives: • To determine the effects of the FAMOUS structured care intervention on self-reported hours of daily hearing aid use • To determine the effects of the FAMOUS structured care intervention on self-reported hours of daily hearing aid non-use • To determine the effects of the FAMOUS structured care intervention on hearing-related quality-of-life (QoL) • To determine the impact on relationships with and QoL of significant others (i.e., partner)) • To understand the barriers and facilitators to behaviour change within standard practice e.g., capabilities, opportunities and motivations (mechanisms of impact) • To understand and appreciate experiences and acceptability of the FAMOUS structured care intervention to service users and service providers (process evaluation) • To estimate the cost to the NHS and value to society
Eligibility criteria	Inclusion criteria: • Adults (≥18 years); using hearing aids for first time Exclusion criteria: • Adults offered an auditory implant of any kind • Adults offered non-conventional hearing aids e.g., that re-route sound between ears.
Description of intervention	The intervention is 'structured care' that adds structure to current NHS care, comprising of a four-step follow-up and monitoring intervention that includes: (i) encouraging patients to reflect on situations in which hearing is difficult and where hearing aids may help. (ii) an individualised hearing aid user checklist and diary (action plan) to reinforce where and when to use the hearing aids. (iii) monitoring, feedback, and problem-solving support within seven days of receiving hearing aids; and (iv) a follow-up at six weeks after fitting.
Outcome measures	<u>Objective One: Clinical Outcomes</u> • The primary outcome is self-reported daily hours of hearing aid use 12 months post fitting (also a secondary outcome at 12 weeks). Therefore,

	the question, 'On a typical day over the last week, how many hours did you use your hearing aid?' will be collected via participants' preferred contact method (post, telephone, text). • Secondary outcomes collected at 12 weeks and 12 months include: (i) proportion of non-users, defined as ≤ 1 hour/day. (ii) International Outcome Inventory for Hearing Aids (IOI-HA) survey with questions on usage benefit, satisfaction, QoL, impact on others and residual difficulties. (iii) Hearing Handicap Inventory (HHI) survey with questions on hearing related QoL, and Capabilities, Opportunities, Motivations and Behaviour (COM-B) questionnaire that measures capabilities, opportunities, and motivations. <u>Objective Two: Impact on Families</u> • The Significant Other Scale for Hearing Disability (SOS-HEAR) questionnaire will be completed at 12 months. This questionnaire has been designed to be completed by a partner. <u>Objective Three: Process evaluation</u> • We will conduct semi-structured interviews with participants to explore experience and acceptability of usual care and the intervention. • Early, semi-structured interviews with service managers and audiologists will focus on perceptions and attitudes, training, and reflections on initial implementation experiences. Later interviews will focus on the barriers and enablers to integrating the FAMOUS intervention within existing management care pathways. <u>Objective Four: Health economic evaluation</u> • Effects will be captured at the individual patient level through calculating quality-adjusted life years (QALYs) using Health Utilities Index 3 (HUI-3) at 12 months post-hearing aid fitting.
Sample size	There are approximately 140 NHS services fitting hearing aids to 355,000 new adult users each year, so approximately 211 per service each month. We assume that 25% of participants will provide individual follow-up research data with 80% of these providing primary outcome data and clinics will each recruit for three months, giving an average cluster size for analysis of approximately 130 participants. The intra-class correlation coefficient (ICC) for the primary outcome is unknown, but based on published ICC data for a broad range of outcomes and settings we assume it to be between 0.02 and 0.05. Our target treatment effect is a difference in mean hours of use per day of 1–1.5 hours. With 90% statistical power, 5% two-sided significance level, ICC = 0.02, standard deviation = 5.5 hours and target mean difference of 1 hour, a total of 36 sites and 4,680 participants are required for the analysis. Based on a 25% consent rate (and 80% of these participants providing primary outcome data) a total of 23,400 patients would need to be recruited, with a total of 5,850 participants consenting to follow-up data collection.
Expected recruitment duration	Each participating centre will have a 3-month recruitment period, starting from site green light. 23,400 patients will be enrolled over the period of 16 months.

Randomisation	Sites will be randomised with a 1:1 allocation ratio to either structured care or usual care (stratifying by site size determined by the number of new hearing-aid referrals per month). All eligible patients at that site will receive the intervention as per site randomised allocation.
Study Within A Trial (SWAT)	We will investigate the effects of the timing of telephone contact with potential participants return of 12-week questionnaires.

Figure 1. Patient Care Pathway



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Abbreviations and Definitions

Abbreviations

Abbreviation	Description
AE	Adverse Event
BCT	Behaviour Change Technique
BRC	Biomedical Research Centre
CAG	Confidential Advisory Group
CI	Chief Investigator
COM-B	Capabilities, Opportunities, Motivations and Behaviours Questionnaire
COSI	Client Oriented Scale of Improvement
CRCT	Cluster Randomised Controlled Trial
CRN	Clinical Research Network
CSRI	Client Service Resource Inventory
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
HRA	Health Research Authority
IOH-HA	International Outcome Inventory for Hearing Aids
HHI	Hearing Handicap Inventory
HUI-3	Health Utilities Index-3
NCTU	Nottingham Clinical Trials Unit
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NPT	Normalisation Process Theory
PPI	Patient and Public Involvement
PROMs	Patient Reported Outcome Measures
QoL	Quality of Life
QALYs	Quality Adjusted Life Years
REC	Research Ethics Committee
RCT	Randomised Controlled Trial
SWAT	Study Within a Trial
SOS-HEAR	The Significant Other Scale for Hearing Disability
TMG	Trial Management Group
TSC	Trial Steering Committee

Definitions

Term	Description
Baseline	Initial measurements/assessments made at trial entry
Blinded trial	The study of a drug or treatment where individuals (e.g., clinicians, participants, outcome assessors and/or statisticians) are unaware of the allocation
Cluster-randomised controlled trial	A type of randomised controlled trial in which groups of patients are randomised rather than individuals
Control arm	Each group or subgroup who do not receive the new drug, treatment or intervention that is under study, to provide a comparison to see how the intervention compares against no treatment or an old treatment (e.g., usual care)
Green Light	Final confirmation from Sponsor that all approvals, contracts and supporting documents are in place and verified, allowing trial activities to commence
Good Clinical Practice (GCP)	A set of ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. Some trials are governed by regulatory requirements such as CTIMP, ATIMP, Medical Devices, IRMER etc.
Intervention arm	Each group or subgroup of patients in a clinical trial that receives the change being trialled.
National Institute for Health and Care Excellence (NICE)	Provides national guidance and advice to improve health and social care
Primary Outcome	The measure that is the most relevant to answer the research question
Qualitative research	Data obtained by the researcher from first-hand observation, interviews, questionnaires, focus groups, participant-observation, recordings made in natural settings, documents, and artifacts. The data are nonnumerical.
Secondary Outcome	A measure that is of lesser importance than a primary outcome measure but is part of a pre-specified analysis plan for evaluating the effect of the intervention or interventions under investigation
Source data	All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial
Stop/go criteria	A method to help to determine whether the trial is feasible for the budget set where the criteria are set before the commencement of the trial and are agreed with the funder
Unblinded trial	The study of a drug or treatment in which the recipient or trial team knows if s/he is receiving the actual drug/treatment or a placebo

1. Background and Rationale

1.1. Background

What is the problem being addressed?

Hearing loss is the leading cause of years lived with disability in the UK[1] yet receives <1% of health research funding [2]. Hearing loss leads to communication difficulties between family, colleagues, and friends. It is associated with reduced Quality of Life (QoL), depression and anxiety, poor social interactions and increased risk of dementia [3] at a cost of £30 billion p.a. to the UK [4]. Moreover, the harms to society are worsening: 12.5 million UK adults currently live with hearing loss but this will increase to 14.5 million by 2031 [5].

Hearing aids are effective at improving hearing-related QoL for adults [6], yet we have recently confirmed that about 30% under-use them and a further 20% do not use them at all [7]. Addressing low hearing aid use has been identified as a top five research priority by the James Lind Alliance priority setting partnership[8].

Existing evidence

The National Institute for Health and Care Excellence (NICE) adult hearing loss guideline committee carried out a systematic review on the benefits of monitoring and follow-up in new adult hearing aid users[9]. No relevant studies were identified in this health area, contributing to the wide variation in practice across the UK. Monitoring and follow-up have consistent positive effects in other areas of health[10]. Within hearing aid provision, however, although there is a long history of service providers measuring the extent of common difficulties in outcomes surveys [11-13] detection of problems has rarely, if ever, been routinely used to initiate rapid corrective action.

Recent studies into reasons why people cease using their hearing aids have identified easily resolvable issues[12, 14], including discomfort in ear, own-voice sound quality, and uncomfortable loudness reported by close to half of the patients. Recognising that: a) adults who report issues with their hearing aids make less daily use of them[15, 16]; b) relying on self-referral is not sufficient[17]; and c) evidence regarding the effects of monitoring and follow-up is lacking, the NICE guidance committee recommended a randomised controlled trial (RCT) of monitoring and follow-up as a high priority. The FAMOUS Trial structured 4-step intervention is based on the current evidence and has been refined by input from NHS audiologists and our patient public involvement (PPI) groups to ensure it is fit for purpose in a UK-wide setting.

1.2. Trial Rationale

The direct cost to the NHS of managing hearing loss is £450 million p.a.[18]. The NHS is the largest purchaser of hearing aids in the world, procuring around 1.2 million p.a. with around 355,000 new adult patients p.a. but there is significant low and non-use that affects:

i. Hearing aid wearers and families: non-users get no benefit, with downstream effects arising from social isolation and possible cognitive decline.
ii. Potential hearing aid wearers: negative perceptions may discourage or delay help-seeking.
iii. Society: economic consequences of untreated hearing loss are vast, yet non-use lowers their perceived effectiveness and weakens the case for securing scarce resources.

Follow-up and monitoring appointments for new adult NHS hearing aid users vary greatly between hearing aid clinics. A survey completed by NHS audiologists from across the UK for this trial, showed that follow-up appointments are not always offered. When appointments are offered, they are highly variable, occurring between 4-12 weeks after fitting, if at all. For patients who decline hearing aids, there is no structured monitoring or follow-up, the onus being on the individual to seek re-referral.

FAMOUS, a Cluster Randomised Controlled Trial (CRCT) of monitoring and follow-up of new adult hearing aid users evaluates a 4-step intervention designed to promote hearing aid usage and benefit, thereby reducing low- and non-use. If successful, it can be rolled out nationally using existing facilities with minimal impact on resources. By addressing this urgent unmet need, FAMOUS will evaluate QoL and health outcomes for adults with hearing loss and their families, potentially providing cost savings to the NHS and society.

1.3. Justification for patient population

The target population are adults (≥18 years) who present with hearing difficulties and are offered conventional, acoustic NHS hearing aids for the first time. All eligible patients seen during the audiology clinic's 3-month recruitment phase will be informed of the trial and will be treated in accordance with the allocation to which the site has been randomised.

Routine medical data will be collected from eligible patients who decline a hearing aid fitting, but they will not be followed-up as part of the FAMOUS trial.

Posters and information cards explaining the trial will be displayed in participating audiology clinics. To supplement this information, and to ensure the trial remains as inclusive as possible, an animated video about the trial and what patients should expect, will be translated into 4 key languages. Links to the videos will be provided within the patient information in audiology clinics (posters and information cards) and embedded on the trial and Nottingham and Manchester Biomedical Research Centre (BRC) websites.

1.4 Justification for design

FAMOUS has been designed to assess whether a 4-step follow-up and monitoring intervention will increase self-reported daily hours of hearing aid use in first time hearing aid users, 12 months after initial fitting.

The cluster randomised design, recruitment timing and methods were informed by national input from audiologists and heads of service and the Patient and Public Involvement (PPI) group. These groups felt that the number of hours of use was the most important primary endpoint, and further felt that hours of use was a logical question. Due to the nature of the intervention and the potential for contamination between the two treatment arms, a cluster randomised controlled trial was agreed to be the most appropriate trial design.

1.5 Process Evaluation

Implementation

Understanding how a complex intervention is implemented into standard care is a key issue for wider uptake and spread[19]. We will draw upon Normalisation Process Theory (NPT)[20, 21], which facilitates understanding of the extent to which new work processes become part of routine practice to identify factors impacting on the implementation of FAMOUS at the organisational and clinical level. Using interview topic guides informed by NPT, we will conduct semi-structured interviews at two time points with audiologists and service managers drawn from all clinics providing the intervention.

Early interviews will focus on perceptions and attitudes, training, and reflections on initial implementation experiences. These interviews will take place with audiologists and service managers when the intervention (structured 4-step follow-up) is active within the department. Later interviews will focus on the barriers and enablers to integrating the FAMOUS intervention within

existing management care pathways. These interviews will take place after the intervention phase has passed.

Patient experiences and acceptability
We will use topic guides informed by the theoretical framework of acceptability[22] to understand patient responses to and interactions with their usual care and the intervention. We will interview participants (circa 15 per category below, from both arms) who typically:

a) Use their hearing aid/s for most of the time (8 hours or more) each day
b) Use their hearing aid/s for part of the time (more than 4 hours but less than 8 hours) each day
c) Use their hearing aid/s for a small part of the time (more than 1 hour but less than 4 hours) each day
d) Do not use their hearing aid/s at all on most days (less than 1 hour) each day

We will additionally use the theoretical domains framework[23] to understand the barriers and facilitators to behaviour change not associated with the acceptability of the intervention (i.e., mechanism of impact).

1.6 Health Economics

To provide decision-makers with the best available evidence on whether to recommend a specific form of hearing aid use follow-up and monitoring for routine clinical practice, it is important that evidence around its cost-effectiveness is also provided. This economic evaluation will aim to identify, measure and value the costs and consequences of the intervention method, and to synthesise the evidence using metrics amenable to cost-effectiveness-based decision-making.

The health economics component comprises two complementary cost-effectiveness analyses: (i) a within-trial evaluation where cost and health effects of individual patients are limited to the 12-month follow-up period in the trial and (ii) a decision model approach where cost and health effects are modelled to enable the incorporation of longer benefits and NHS/PSS costs, designed using standard reporting criteria[24].The estimation of incremental cost-effectiveness ratios will be carried out using the payer's perspective (NHS England).

1.7 Choice of intervention

Due to the variability of hearing aid services provided, and to ensure that the trial findings remain generalisable, patients in the control group will receive their local clinic's usual care at all time points in the fitting and follow-up process. Note that while face-to-face follow-up is considered good practice and follows NICE guidelines; this is not always offered in practice. Each clinic will record patient visits (scheduled and unscheduled) and care delivered as part of routine data collection.

In addition to usual care, patients in the structured care group will receive a 4-step follow-up and monitoring behaviour change plan that will be delivered by their NHS audiologist. The four steps include:

i. encouraging patients to reflect on situations in which hearing is difficult and when hearing aids may help.
ii. an individualised hearing aid user checklist and diary (action plan) to reinforce where and when to use the hearing aids;
iii. monitoring, feedback, and problem-solving support within seven days of receiving hearing aids; and

iv. a follow-up at six weeks after fitting (face-to-face is preferred, but remote follow-up is acceptable where required for any reason)

To facilitate steps i – iii, clinics will be given behaviour change management training at Site Initiation and taught how to use the Hearing Aid User Checklist and Diary, to guide the patient through the first six weeks of hearing aid use. This process is described in Section 8.3.2.

2 Aims, Objectives and Outcome Measures

2.1 Aim

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.

2.2 Objectives and outcome measures

2.2.1 Primary

Objective	Outcome Measure	Assessment time point/method
To determine the effects of the intervention compared to usual care on hours of long-term daily hearing aid use.	Participant reported daily hours of hearing aid use 12 months post recruitment.	12-month questionnaire

2.2.2 Secondary

Objective	Outcome Measure	Assessment time point/method
To determine the effects of the intervention compared to usual care on hours of short-term daily hearing aid use.	Participant reported daily hours of hearing aid use 12 weeks post recruitment.	12-week questionnaire.
To determine the effects of the intervention compared to usual care on non-use of hearing aid	Participant-reported hearing aid usage in hours at 12 weeks and 12 months post initial fitting. Non-user defined as ≤1 hour a day.	12-week and 12-month questionnaire
To determine the effects of the intervention compared to usual care on hearing related QoL.	Participant reported hearing related QoL at 12 weeks and 12 months post fitting.	12-week and 12-month questionnaire IOI-HA survey HHI survey COM-B questionnaire
To determine the effects of the intervention compared to usual care on impact of hearing loss/aids on families	Significant other's reports on hearing related QoL at 12 months post fitting.	12-month questionnaire SOS-HEAR
To determine the effects of the intervention compared to	For a sub-set of participants in both arms, interviews will be	Semi-structured interviews with a sub-set of (n=60)

usual care on experiences and acceptability to service users (participants)	conducted after 12-weeks of hearing aid use, with those who have been identified as a range of daily users to discuss the acceptability of the follow-up intervention.	participants selected based on their degree of hearing aid use.
To determine the effects of the intervention compared to usual care on experiences and acceptability of service providers	Service managers and audiologists of structured care sites will be interviewed at two timepoints to discuss the acceptability of implementing the intervention within their care strategy.	Semi-structured interviews with (n= 30-40) service managers and audiologists.
To determine the effects of the intervention compared to usual care on the overall health-related quality of life, on costs, and cost-effectiveness to the NHS and society.	Quality Adjusted Life Years (QALYs) will be calculated by attaching available utility weights to the health states generated from the HUI-3[25]. Comparisons between the two groups will be corrected for clustering and other baseline characteristics. In an additional investigation, we will investigate the extent to which HHIE maps onto HUI-3.	12-month questionnaire HUI-3 HHI Client Service Resource Inventory

3 Trial Design and Setting

3.1 Trial Design

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 structured care) will be adopted as their sole clinical practice for that site. All patients seen in participating 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).

3.2 Trial Setting

The trial will be conducted across approximately 36 NHS-funded adult hearing aid services across the UK.

4 Eligibility

All adults ≥18 years will be considered for inclusion in this trial regardless of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion and belief, sex, and sexual orientation.

4.1 Inclusion Criteria

Adults (≥18 years); offered hearing aids for first time.

4.2 Exclusion Criteria

Adults offered an auditory implant of any kind; offered non-conventional hearing aids e.g., that re-route sound between ears.

5 Consent

The trial is cluster rather than individually randomised, therefore, to avoid contamination (e.g., confusion regarding who gets which level of follow-up) between the intervention and control group, written consent for participation in FAMOUS will not be sought. Individual written consent will be sought from patients for completion of the follow-up research questionnaires at 12 weeks and 12 months. Consent will be sought from the Significant Other at 12 months for completion of the SOS-HEAR questionnaire.

On recommendation from the Research Ethics Committee (REC) after initial submission, information sheets and consent forms for participants and Significant Others are separated from the questionnaire booklets to clearly reflect the requirement to participate.

Assessment, fitting and in-clinic follow up (including SWAT)

With cluster trials, it is crucial that all eligible patients are identified after the site is randomised. As the requirement for a hearing aid can only be identified during an assessment appointment, we need to include all patients attending a hearing aid assessment appointment at each clinic during a 3-month recruitment period. If consent were sought for inclusion in the trial there could be a biased selection by audiologists (overtly or unintentionally due to time pressures), there could be crossover with some practices from the structured care becoming part of usual care within a site, or as a result patients could decline hearing aids, believing that the hearing aid is part of the research. As the follow-up and monitoring of hearing aid use is adopted as standard practice by the clinic and routinely collected data is retrieved, consent to participate in the trial is not necessary.

Specific trial information such as posters and information cards, will be provided to all audiology clinics, to be displayed and available in all clinics and waiting rooms. These will signpost patients to the local FAMOUS team, and the FAMOUS trial website which contains trial information and Frequently Asked Questions (FAQs). Patient information will also be presented via an animated video dubbed into 4 key languages (English, Welsh, Polish and Punjabi), with links to the video provided on trial posters, on patient information sheets, trial and BRC websites and FAMOUS social media pages. We hope this will improve inclusivity for the diverse patient population accessing local hearing aid services.

Additional information on the use of data collected during the trial period will also be available to all enrolled patients.

Follow-up Questionnaires

A consent form will be included with the 12-week questionnaire packs posted to participants by their audiology clinical team. This consent form will request the participants' contact details to enable the Nottingham Clinical Trials Unit (NCTU) to contact them to conduct the 12-month follow-up. Should consent to contact at 12 months not be received by NCTU, the data returned at 12 weeks will be used for analysis but the participant will not be contacted again. The consent form will also request participant confirmation to link their anonymous routine medical data to their research questionnaire data. Contact details will be collected for the purpose of contacting the participant with the 12-month questionnaire (and qualitative interviews where relevant). Contact information

will be stored on the FAMOUS REDCap database as part of the participant record, but the identifiers will not be linked to the pseudo-anonymised data collected. The 12-month questionnaire packs will include a standalone document set for the participant's Significant Other, to be completed by their partner if they have one. This will include a separate information sheet, consent form and questionnaire pack for the Significant Other to complete. If the participant does not have a partner they can dispose of the Significant Other documents.

Process Evaluation: implementation, patient experience and acceptability
Experience and acceptability interviews will take place with audiologists, service managers and patients. Sites participating in the intervention will be asked to volunteer an audiologist and service manager to participate in the interviews after they have been delivering the intervention for four weeks. An information sheet will be shared with the staff members, and an interview time will be agreed. For the patient interviews, participants who confirm within their consent form that they are willing to be contacted by the FAMOUS trial team about an interview will be provided with an information sheet explaining what will be required of them. In both groups, at the time of telephone interview, verbal consent will be taken recorded on a paper form by the FAMOUS Research Associate conducting the interview, before all telephone or video call interviews take place.

6 Enrolment and Randomisation

6.1 Enrolment/Registration

For a cluster randomised trial with a no consent model for obtaining routine medical data, patients will not be approached to join the trial, making the traditional concept of recruitment redundant. Information about the trial will be displayed in the relevant clinical areas and given to patients at their hearing aid assessment and fitting appointment. Detailed written information will be provided on the trial website and 12 weeks following their fitting appointment (e.g., a patient information sheet). Patients will be informed of the clinic's participation in the FAMOUS trial during their hearing assessment and fitting appointments by a member of their clinic's audiology team. They will be informed that they will be contacted by post after 12 weeks of hearing aid use with some research questionnaires, and that completing these is optional. All patients will be given an information card signposting them to the trial website, where they can find more detail about the trial, including the use of their pseudo-anonymised routine medical data pertaining to their hearing aid fitting and subsequent appointments.

6.2 Randomisation

Randomisation will take place at a cluster level (site) with a 1:1 allocation ratio to usual care or structured care using stratified block randomisation (stratifying by tertile of site size determined by obtaining up-to-date figures on the number of new hearing-aid referrals per month directly from sites before randomisation).

Sites will be randomised after confirmation of their participation via a centrally held concealed allocation list hosted by the NCTU. The Trial Manager (or authorised designee) will access the NCTU web-based randomisation system to obtain the allocation for their site.

There will be a second-level randomisation for the SWAT. Further details on the SWAT randomisation can be found in Appendix I.

6.3 Blinding and concealment

Given the nature of the intervention, the trial team, the patients, and site staff will be unblinded to the intervention allocation.

The blinding status of individuals involved in the trial is given below:

	Blinding status	Comments
Patients	Not blinded	Patients will not be blinded since those attending the site randomised to the intervention arm will receive 4-step follow-up and monitoring intervention. The PIS is carefully worded to minimise setting an expectation for patients hearing aid/s use.
Principal Investigator and other site staff	Not blinded	Site staff will not be blinded since they will need to know whether to deliver usual care or 4-step follow-up and monitoring intervention. Site staff will be trained not to set expectation for patients hearing aid use.
Chief Investigators	Not blinded	The CI will not have access to any patient or participant data but will be aware of the site level allocation.
Trial management staff at NCTU	Not blinded	Trial Management staff will not be blinded due to preparation and handling of questionnaires, and issues relating to site compliance with the protocol.
Trial statistician	Not blinded	It is not possible to blind the trial statistician due to the nature of trial design.
Trial Data Management	Not blinded	Trial Data Management staff will not be blinded due to data entry of questionnaires relating to intervention compliance.
IT staff at NCTU	Not blinded	IT staff will have access to this information in order to maintain the database and manage queries.
Health Economist(s)	Not blinded	Health Economist will need to cost usual care and intervention for each patient.
Process evaluator(s)	Not blinded	Process evaluator will approach staff from both intervention and usual care sites so will be aware of their site allocation.

Pre-specified summary data to allow monitoring will be available to the trial management group. Data summaries by treatment group for the Data Monitoring Committee (DMC) closed session will be provided by an independent statistician and none of the trial team or Trial Management Group (TMG) members will have access to this.

7 Trial intervention

7.1 Intervention

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 Plan: 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 6-12 -weeks-post-fitting. Sites that are not already offering a follow-up will not be able to participate in FAMOUS.

Structured Care Plan: Patients randomised to the intervention arm will, in addition to receiving usual care, receive a follow-up and monitoring behaviour change intervention delivered by their NHS audiologist. This intervention comprises of four steps as described in Section 8.3.2.

At the end of the recruitment phase, sites can revert to the hearing aid follow-up and monitoring that they delivered 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.

7.2 Treatment Interaction(s) or Contraindications

The intervention involves follow-up and monitoring behaviour change intervention. There are no known interactions or contraindications to this intervention.

7.3 Accountability Procedures

Site staff will be trained on the trial protocol and behaviour intervention during site initiation. Video recordings of training sessions will be made available for site audiology teams to refer to as needed.

7.4 Treatment Modification

There are no plans to modify or discontinue the intervention (structured care) since this is a low-risk intervention.

8 Trial procedures and assessments

8.1 Summary of assessments

Figure 2: Patient Care Pathway with detail

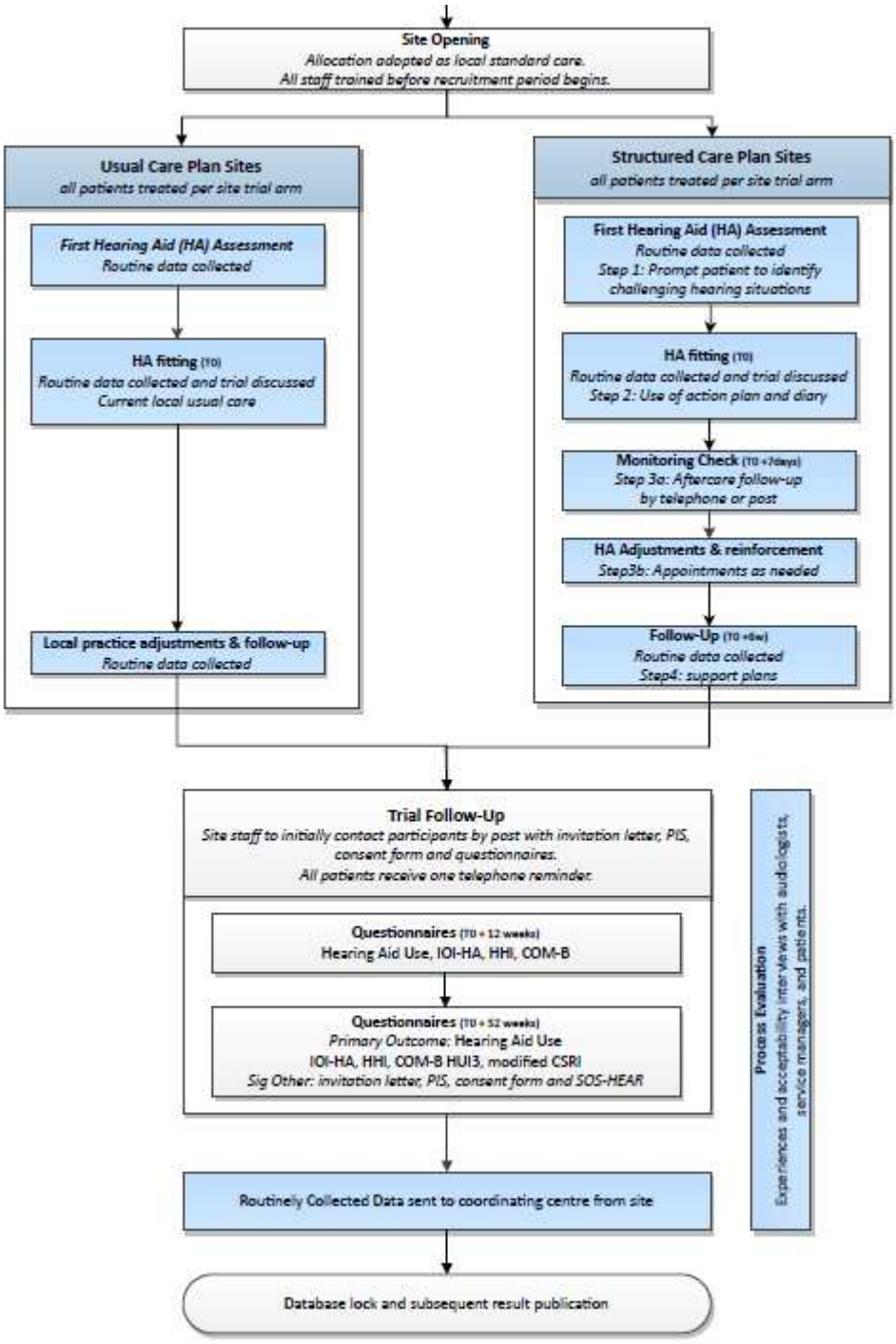


Figure 3: Participant questionnaire follow-up flow diagram

Key:

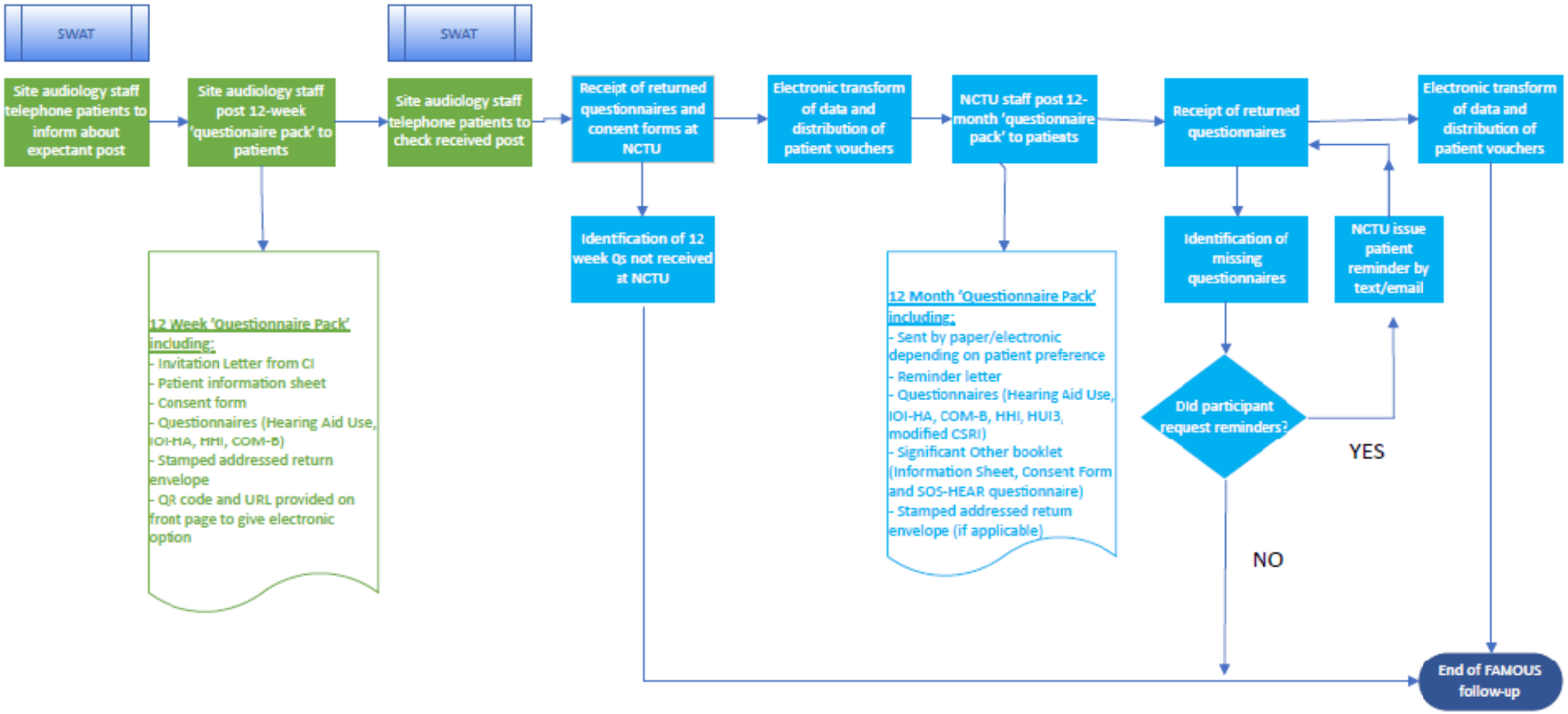
Site Team Responsible

FAMOUS Team Responsible (NCTU)

FAMOUS

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

Patient follow-up flow diagram V1.7



8.2 Schedule of Assessments

8.2.1 Baseline visit and Routine data collection

Trial green light will indicate that the recruitment phase has begun. Routine data from Auditbase will be requested from sites, by the NCTU on a regular basis. Pseudo-anonymised individual-level routine clinical data will be collected on all eligible patients during the recruitment phase, and for 12 months following the last patient's hearing aid fitting appointment. Routine data will include:

i) Baseline (assessment for hearing aids): routine clinical data will include demographics, audiometric data (including pure tone hearing thresholds) and whether the offer of hearing aids was declined.

ii) Hearing aid prescription and fitting: routine clinical data will include number of hearing aids (one or two), real ear measurement verification completion (yes/no).

iii) Aftercare follow-up: routine clinical data will include accelerated 7-day follow-up provided (yes/no) and routine 6-week follow-up (yes/no) and format (face-to-face or telephone) as well as the number of unscheduled hearing aid related visits and their format (face-to-face or telephone) between 12 weeks and 12 months post-fitting.

It is acceptable if sites in both arms combine the hearing aid assessment and prescription fitting appointment if this is usual local practice.

8.2.2 Research outcomes at 12 weeks and 12 months

Research outcomes (see Section 2.2) will be collected at 12 weeks and 12 months directly from participants who provide them.

12-week follow-up:

Site staff will post patients a questionnaire pack that includes:

- Invitation letter from Chief Investigator
- Patient information sheet
- Consent form to request linkage of anonymous medical data to questionnaire data, and collection of identifiable data for the purpose of further contact at 12 months from NCTU trial team. A QR code and web address to an electronic version of the consent form will be included for those who prefer to complete them online.
- Questionnaires (Hearing Aid Use, IOI-HA, HHI, COM-B). A QR code and web address link to the electronic versions of the questionnaires will be included for those who prefer to complete them online.
- Stamped addressed return envelope to NCTU (if postal format used)

12-month follow-up:

For participants who provided their consent at 12-weeks, NCTU will contact participants by post, or electronically (email or text containing link to online questionnaire) with 12-month questionnaire pack that includes:

- Cover letter
- Questionnaires (Hearing Aid Use, IOI-HA, HHI, COM-B, HUI3, modified CSRI). A QR code and web address with a link to the electronic version of the questionnaires will be included for those who prefer to complete them online.

- Documents for the participant's Significant Other to complete, including an invitation letter, consent form and questionnaire (SOS-HEAR). A QR code and web address with a link to the electronic version of the consent form and questionnaire will be included for those who prefer to complete them online. An envelope will be provided for the Significant Other to seal their consent form and questionnaire answers and hand back to the participant for posting together with the participant questionnaires.
- Stamped addressed return envelope to NCTU (if postal format used)

Gift vouchers will be offered to encourage responses from participants, whether the individual uses their hearing aids regularly or not. Participants will have the option on the consent form to request electronic vouchers to their email, or physical vouchers to their home address. If the questionnaires are not returned, participants who choose to will receive up to 3 reminders from NCTU to complete this, by text message or email. If participants do not complete the questionnaires after the 3 reminders, they will be contacted by telephone on one occasion by a member of the FAMOUS trial team to obtain the primary outcome data, which will be to ask, 'On an average day over the past week, how many hours did you use your hearing aid(s)?'

How 12 week and 12-month follow-up will measure research outcomes:

All primary and secondary outcomes will be collected directly from participants via questionnaires at 12 weeks and 12 months post hearing aid fitting, in accordance with Tables 2.2.1 and 2.2.2.

8.2.3 Process evaluation

8.2.3.1 Implementation

We will conduct semi-structured interviews at two time points with audiologists and service managers drawn from all clinics providing the intervention (approximately 30–40 interviews per time point, lower if data saturation occurs with smaller sample). Ideally it will be the same individuals at the two time points, but this is not always possible. Documentary analysis of pre-existing follow-up and monitoring processes will be undertaken prior to interview to understand the organisational context for implementation and to inform the development of the sampling frame.

Early interviews will focus on perceptions and attitudes, training, and reflections on initial implementation experiences. These interviews will take place when the intervention is active within a department. Later interviews will focus on the barriers and enablers to integrating the FAMOUS Intervention within existing management care pathways. These interviews will take place after the intervention time-period has passed at the recruiting site, which will be after the final patient recruited has received their 6-week follow-up appointment.

During the site initiation training, recruiting site staff will be made aware that they may be selected and approached to participate in these interviews, and what will be involved. Likely candidates can be identified by recruiting sites or volunteer by emailing the FAMOUS trial email inbox. Audiologist and service manager interviews will take place at two time-points; the first will be after four weeks of intervention has passed, and the second will be when the intervention has ended at the site. Site staff members will be contacted by the FAMOUS Research Associate by email to arrange a suitable time for interview, and will be sent the participant information sheet by email. The interviews will take place by telephone or video call..

8.2.4 Patient experience and acceptability

After 12-weeks of hearing aid use, patients (n=60) will be invited to take part in semi-structured interviews to explore experiences and acceptability of the trial and trial intervention. One of the consent points listed within the 12-week questionnaire pack will give patients the option to be contacted regarding process evaluation interviews via telephone or video call. Participants who agree to being contacted will be asked to provide their contact telephone number and address on their consent form, which will be received by the FAMOUS trial team at NCTU.

Participants will be categorised according to their self-reported daily hours of use/non-use based on their answer to the 'Hours of Daily Use' question at 12 weeks post fitting. The categories are:

a) Use their hearing aid/s for most of the time (8 hours or more) each day
b) Use their hearing aid/s for part of the time (more than 4 hours but less than 8 hours) each day
c) Use their hearing aid/s for a small part of the time (more than 1 hour but less than 4 hours) each day
d) Do not use their hearing aid/s at all on most days (less than 1 hour) each day

A selection of participants who have agreed to be contacted to discuss their experiences will be contact by the FAMOUS Research Associate at the University of Manchester by telephone. They will be reminded about the telephone interview and sent an information sheet via their preferred method (email or post). A date for the interview will be agreed at a date and time to suit the participant.

In both groups (Audiologist/Service Managers and patients), at the time of the interview, participants will have the chance to ask the FAMOUS Research Associate any questions they might have after reading the information sheet. Verbal consent will be obtained and documented on a verbal consent script by the FAMOUS Research Associate before the interview takes place. The interview will be audio recorded and sent to an external provider for transcription. The participant details will remain confidential and there will be no way of identifying the participant from the audio recording or the answers they provide to the questions. This is clearly stated in the information sheet.

Gift vouchers will be given as a 'thank you' for patients who participate in the patient interviews.

Trial Procedures

8.2.5 Provision of usual care

The control group will receive usual care at the hearing aid assessment, and prescription and fitting appointments. The assessment typically comprises: (i) a case history and examination, (ii) assessment of hearing and communication needs, and (iii) assessment of hearing. The prescription and fitting appointment typically comprise: (i) real-ear sound level verification, (ii) information about the benefits of using hearing aids, (iii) technical information about the hearing aid e.g., location of the microphone, function switches, (iv) practical demonstration as to how to use the hearing aids e.g., change batteries, fit into ear, and (v) guidance on when to use the hearing aids. Most NHS hearing aid services also offer a 'drop in' service for repairs.

Follow-up care is highly variable, ranging from not provided at all, to being delivered face-to-face or remotely via telephone, and occurring anything from 4 to 12 weeks after fitting. The purpose of the

follow-up appointment, if provided as part of usual care, is to: (i) address any concerns and difficulties, (ii) reinforce information provided at the time of fitting e.g., hearing aid maintenance, (iii) provide additional information e.g., about support services and hearing aid features, and (iv) make any necessary adjustments to the hearing aids.

8.2.6 Provision of structured care: Follow-up and monitoring

Patients randomised to the structured 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:

i) **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[26].

ii) **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. The action plan will be developed by the patient in collaboration with their audiologist. Patients will be provided with a booklet with which to self-monitor their hearing aid use and experiences of common problems over the next 12 weeks. This will include a checklist of potential problems that lead to hearing aid non-use. Audiologists should spend some time going through the steps that we would like the patient to complete over the first six weeks, this includes where and how to complete: the daily diary of hours hearing aids are used; a checklist to help identify any problems at the end of week one/before 7-day follow-up; and a shorter checklist to complete at the end of weeks 2, 3, 4, 5 and 6. All patients will be encouraged to bring their self-monitoring checklist to the six-week appointment, allowing the audiologist to personalise and address the specific needs of the individual.

iii) **7-day post-fitting contact:** Early monitoring of hearing aid use at 7-days after fitting in all patients, who will be contacted using their preferred method, to assess hearing aid use and any problems encountered. Patients with low hearing aid use and/or experiencing significant problems will be invited back to the clinic via the standard 'drop in' service at which the diary will be reviewed by the audiologist, who will provide feedback on their behaviour and offer solutions to their problems.

iv) **Six weeks follow-up after the hearing aid prescription and fitting appointment:** As previously noted, provision of follow-up appointments after fitting is variable and so we will encourage services allocated to the intervention group to adhere to the NICE guidelines and introduce (where necessary) a six-week follow-up after fitting. This should be offered as a face-to-face appointment where possible, but can be remote (telephone, video consultation) if preferred by the patient. 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. This process will be facilitated by encouraging patients to continue using their diary and self-monitoring checklist. If needed, 'coping' and/or 'support' plans can be created to help the patient overcome any problems they might encounter in the future. Patients will be advised to continue using their daily diary for the next six weeks.

Behaviour change intervention training for audiologists: Training materials will be provided to ensure that audiologists can implement the intervention. The training sessions will include an explanation of the development and components of the intervention, brief practical sessions where audiologists practise delivering the intervention, live 'Q & A' with members of the trial team, and advice on future online drop-in help sessions. With agreement from site staff, sessions may also be recorded to be replayed for others in the site team.

A checklist will be developed for monitoring delivery of the intervention and usual care. A random selection of assessment, fitting and six-week follow-up consultations will be recorded from clinics in the intervention and control arms. This will be used to check the fidelity of both intervention and usual care at all participating clinics.

8.3 Study Within A Trial (SWAT)

Please see Appendix I.

8.4 Internal pilot

The trial will contain an internal pilot with stop/go criteria set at levels, which if maintained, will enable trial completion as per monitoring plan. This will be reviewed by the trial Data Monitoring Committee (DMC). By the end of month 19, six months after first site green light;

i. Feasibility of recruiting sites: 24 of the 36 sites should have opened.

ii. Sites adherence with delivering intervention: 9 sites should have delivered at least 1 month of the intervention to all eligible patients. Adherence to the structured care intervention will be measured using the routine data collected from sites. Sites will be considered as adhering to the intervention if 80% of new hearing aid patients receive the below steps in the intervention:
   - Step 1: COSI Part 1 completed at hearing aid assessment
   - Step 2: FAMOUS Hearing Aid User Checklist and Diary provided to patient, action plan completed, and patient shown how to utilise the checklist and diary
   - Step 3: Contact from their audiology clinic 7-days post-fitting by telephone

iii. Recruitment into the trial: 300 participants should have completed the 12-week patient-reported outcomes.

Internal Pilot progression criteria	
Green	All 3 indices are at or above 100%, no adjustments necessary
Amber	Any of the 3 indices are at 60-99% of the expected targets, continue with adjustments, unless it is clear that a target is unachievable e.g. there are no further sites willing to join the trial.
Red	Any of the 3 indices falls below 60% of the expected target, discuss barriers with TSC and Funder to determine whether the trial is feasible. If so, agree an action plan with revised milestones and new target timelines.
Black	It is clear at this time that the trial is not feasible, even with significant adjustments. In discussion with the Trial Steering Committee and Funder, the trial will be closed.

8.5 Withdrawal of Consent Procedures

For the cluster trial design, there is no individual consent to participate. However, individual patients may review the trial information (e.g., posters, videos) and decide they do not wish to participate in

completion of the research questionnaires data (12 week and 12-month post hearing aid fitting questionnaires). Patients who do not respond to the FAMOUS 12-week questionnaire pack will not be contacted again for the FAMOUS trial, but their anonymous routine medical data pertaining to their hearing aid assessment, fitting and follow up/s that has already been collected will still be used in the trial analysis.

Participants may withdraw their consent for further contact after they have provided this in their 12-week consent form. Participants will be advised to contact the FAMOUS study team by email or telephone if they change their mind and wish to withdraw from future contact. The FAMOUS study team will then take appropriate action to ensure that the participant's wishes are followed. Any data collected prior to participant withdrawal, including routine medical data and questionnaire data, will be retained and used for study analysis. This process is made clear in the Patient Information Sheet.

For the qualitative element of the trial, participants will be able to decline the opportunity to be interviewed after providing consent to be contacted and can withdraw consent, within 14 days of interview, for the recording and transcribed information from their interview to be used. Once the analysis has been completed, the interview transcript cannot be removed from the dataset. Participants cannot be withdrawn from the trial at the request of the Investigator or clinical care team.

9 Adverse Events

The occurrence of an adverse event as a result of participation within this trial is not expected and no adverse event data will be collected.

9.1 Adverse Event Reporting

The risks of participating in the FAMOUS Trial are comparable to that of usual care. The intervention (structured care) is conceptually similar to what might be done as part of usual practice. For example, patients will attend the usual hearing aid assessment and fitting appointments, plus additional follow-up appointments as required.

Adverse outcomes that might be plausibly related to the trial procedures are distress for the patient as a result of following the 4-step monitoring plan in the structured care arm, or the completion of 12-week and 12-month questionnaires in both groups. Patients will be asked to think about difficult hearing situations and answer sensitive questions about these.

Patients in the structured care arm will be supported in completing their user checklist and diary during their clinic appointments with their audiologist. Audiologists will receive training in how to deliver and facilitate the use of the user checklist and diary in order to best support the patient in how to use the booklet.

10 Data Handling and Record Keeping

10.1 Source Data

To allow for the accurate reconstruction of the trial and clinical management of the participant, source data will be accessible and maintained. For this trial, source data refers to, though is not limited to, the data obtained from sites from Auditbase, an electronic patient management system used in NHS audiology clinics, and follow-up questionnaires.

All data collected directly from participants and Significant Others will be considered as source data. Where paper questionnaires are issued to participants these will be returned to the NCTU for data

entry and will be considered source data. Patient use of the user checklist and diary is encouraged as part of the structured care arm, but these will not be collected by NCTU and will not be considered source data.

The informed consent forms for those completing the questionnaires and qualitative interviews will be stored in the trial database. Original informed consent forms (if written consent provided) will be stored in the NCTU Site Specific File (SSF) and will be scanned onto the trial database and stored securely. Electronic consent forms will be kept securely on the database maintained by the NCTU.

Audio files from the process evaluation interviews with participants, audiologists and service managers will be transcribed by an approved external provider to the University of Manchester. Audio files will be destroyed after the transcription has been checked. Interview transcripts will be classed as source data. Transcripts will be de-identified and issued with a unique trial identification number before qualitative analysis. Transcriptions will be encrypted and stored on a University of Manchester computer for analysis by the FAMOUS trial team.

10.2 CRF Completion

There will be no data collection on Case Report Forms in the FAMOUS Trial.

10.3 Data Management

Routine Medical Data

Recruiting sites will download a pre-specified routine medical dataset from Auditbase for all patients enrolled. Auditbase is an electronic management system used in NHS audiology clinics. The Auditbase data will be downloaded as an Excel file, onto a local NHS computer, and uploaded into the FAMOUS database (REDCap). Delegated members of staff from the recruiting site will be provided with a secure login for the FAMOUS database and will receive email reminders when the data upload is due, preferably monthly. Routine medical data from Auditbase is required from first-patient first visit (hearing aid assessment) up to 12-months post-fitting of the last patient enrolled (last patient first visit + 12 months). Data obtained from these patient routine medical data will not be subject to data queries. Patient data collected from Auditbase will be pseudo-anonymised using Auditbase ID and Site ID so that the patient cannot be identified by anyone outside of their direct care team. At 12 weeks post-hearing aid fitting, the questionnaire pack sent to patients will be labelled with the same Auditbase ID and Site ID number. Upon receipt of the returned consent form and questionnaire pack, the two datasets will be linked using the Auditbase ID and Site ID. Patient identifiable contact information will be collected in the 12-week questionnaire pack with consent, and this will then be used by the FAMOUS trial team to re-contact the participant at 12-months post-hearing aid fitting and for the qualitative interviews where applicable.

Participant personal contact details (full name, address, email address, telephone number) will be stored in the same FAMOUS REDCap database as the pseudo-anonymised linked dataset.

Participant identifiers will be removed from the final dataset after all future contact has ceased, and will not be used in the trial analysis.

Routine medical data will be collected from eligible patients who decline a hearing aid fitting at their assessment appointment, but they will not be followed-up as part of the FAMOUS trial.

PROMs data (12-week and 12-month questionnaires)
Each eligible patient will be sent a paper questionnaire pack at 12 weeks post-fitting by their local audiology clinic. This will include the full patient questionnaire pack and a return envelope for those who opt to complete and return the paper questionnaires. Additionally, to encourage inclusivity and accessibility, each questionnaire pack will include a unique QR code and a Uniform Resource Locator (URL) which provides a secure link to the trial database for participants to complete the questionnaires online using a handheld device or computer. Participants will confirm their 12-month questionnaire format preference (paper or online) at 12 weeks. The same pseudo identifier will be collected as in the routine medical data (Auditbase ID and Site ID) for accurate data linkage.

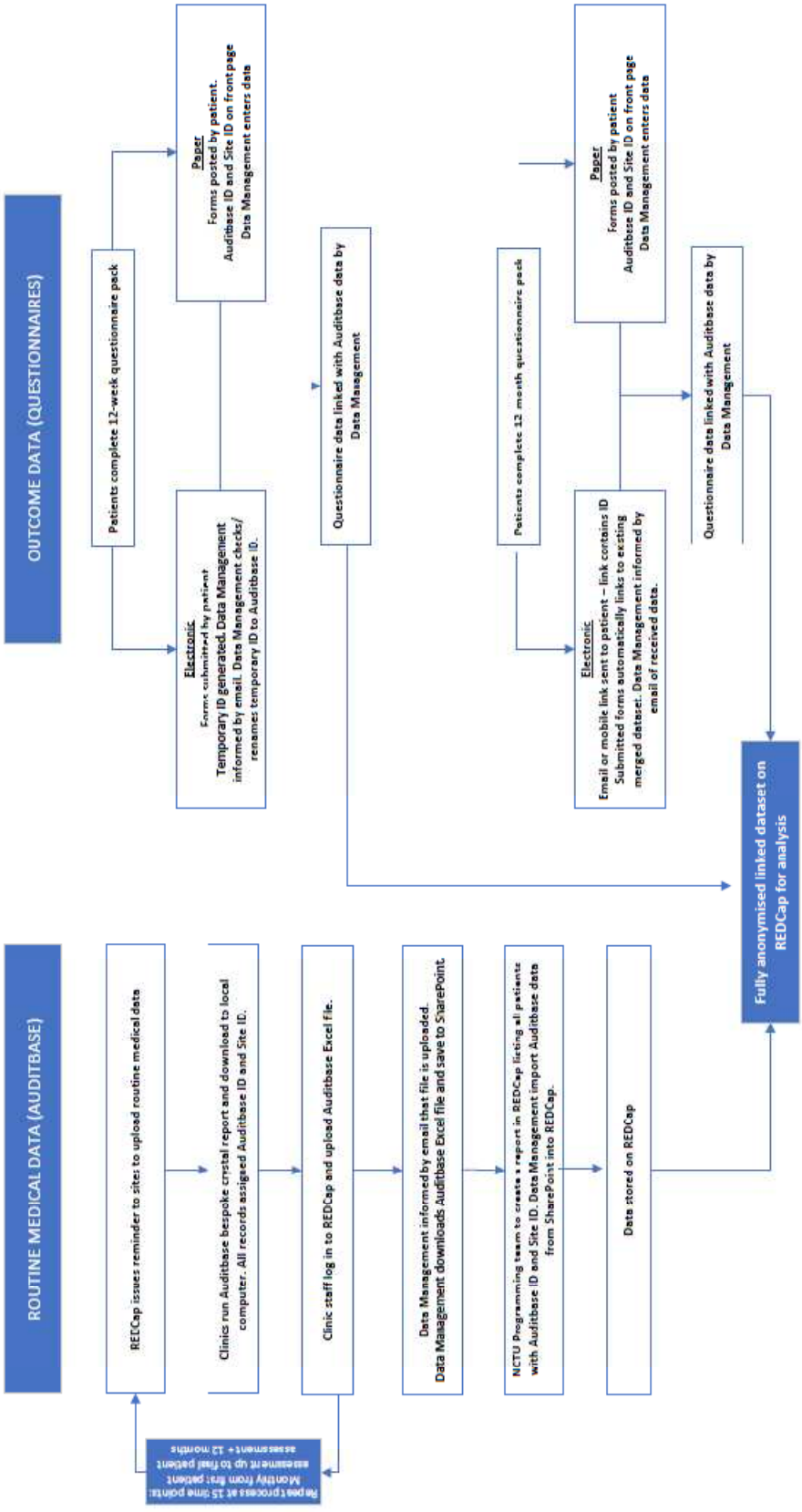
Paper questionnaires returned to the FAMOUS trial team at NCTU will be entered into the FAMOUS REDCap database by a member of NCTU staff and reviewed by a separate member of the data team. Data obtained from these participants reported outcomes will not be subject to data queries. Decisions on how to treat anomalous data will be made by members of the TMG blinded to allocations and documented in the Data Management Plan and/or Statistical Analysis Plan (where required).

The FAMOUS REDCap database is held in a secure server hosted by the University of Nottingham. Routine medical data will be accessed only by the FAMOUS data and programming teams, for purposes of data linkage. The FAMOUS data and programming teams will be responsible for linking routine medical data with questionnaire data. The anonymised dataset will be saved on password protected machines that only trial staff at NCTU have access to. At the end of the trial all datasets with identifiers will be destroyed.

A flow diagram to describe the data management process can be found in Figure 4.

Qualitative trial data
The FAMOUS Research Associate at the University of Manchester undertaking the qualitative research analysis will contact the patients, audiologists and service managers by telephone. Written consent will be obtained from participants at 12 weeks,verbal consent will then be taken on the telephone and recorded on a verbal consent form before the semi-structured interview takes place. Interviews will be audio recorded, and the audio file will be saved using a qualitative trial ID number specific to the interviewee. The audio file will not contain the name of the interviewees, as recording will commence after consent has been obtained. Audio files will be transcribed by an external approved provider to the University of Manchester (UoM) and transferred using a secure encrypted online platform as recommended by the provider. Transcriptions will be returned from the external provider back to the FAMOUS Research Associate and downloaded and stored on a secure server hosted by UoM. This transcription data will be stored for qualitative analysis. Audio files will be destroyed after transcription has been completed and checked.

Figure 4: Data management flow diagram



10.4 Archiving

The trial data will remain the property of Sponsor, Manchester University NHS Foundation Trust (MFT). A complete copy of the trial data will be kept on the MFT secure IT server at the end of the trial. At the end of the trial all documents and data relating to this project will be transferred from NCTU to MFT and stored for 10 years following completion of the project, or in line with MFT policies and in accordance with ICH GCP.

It is the responsibility of the Principal Investigator to ensure all essential trial documentation and source documents (e.g., Investigator Site Files), at their site are securely retained for up to 10 years after the end of the trial. Documents are archived following any regulatory requirements and any local procedures. No documents will be destroyed without prior approval from the Sponsor.

Trial data will remain stored at the NCTU for 10 years, in line with the Sponsor data policy.

10.5 Data sharing after the end of the project

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.

The University of Nottingham's approved provider of SMS texting services, eSendex (https://www.esendex.co.uk/), will be used to send text message participants. This means that if participants consent to being sent text reminders, their mobile numbers will be shared with eSendex via a secure data transfer to run the service, and all appropriate security steps are taken to ensure the confidentiality and protection of the data in their care. Participants have an optional consent to have their information held by eSendex to be contacted via text message in their 12-week questionnaire pack.

11 Quality control and quality assurance

11.1 Site Set-up and Initiation

All participating Principal Investigators will be asked to sign the necessary agreements and supply a current CV and GCP certificate to the NCTU. All members of the site research team will also be required to sign a site delegation log. Prior to commencing recruitment all sites will undergo a process of initiation.. Key members of the site research team will be required to attend either a meeting or a teleconference covering aspects of the trial design, protocol procedures, collection and reporting of data and record keeping. Sites will be provided with an Investigator Site File containing essential documentation, instructions, and other documentation required for the conduct of the trial. The NCTU must be informed immediately of any change in the site research team.

11.2 Monitoring

11.2.1 On-site Monitoring

Monitoring will be carried out as required following a risk assessment and as documented in the monitoring plan. Any monitoring activities will be reported to the Sponsor and any issues noted will be followed up to resolution. Additional on-site monitoring visits may be triggered, for example by poor transfer of electronic routine data or missing data. If a monitoring visit is required, the NCTU

will contact the site to arrange a date for the proposed visit and will provide the site with written confirmation. Investigators will allow the FAMOUS trial staff access to source documents as requested.

11.2.2 Central Monitoring

The NCTU will be in regular contact with site research teams to check on progress and address any queries that they may have. The trial team will check incoming routine clinical data for patient enrolment numbers, compliance with the protocol and treatment arm, data consistency and wide-spread missing data. Sites may be asked for clarification on wide-spread inconsistencies or discrepancies but will not be queried on individual level routine data.

11.3 Audit and Inspection

The Principal Investigator will permit trial-related monitoring, quality checks, audits, ethical reviews, and regulatory inspection(s) at their site, providing direct access to source data/documents. The Principal Investigator will comply with these visits and any required follow up. Sites are also requested to notify the NCTU of any MHRA inspections.

11.4 Notification of Serious Breaches

The Sponsor is responsible for notifying the REC of any serious breach of the conditions and principles of GCP in connection with that trial or the protocol relating to that trial. Sites are therefore requested to notify the NCTU of any suspected trial-related serious breach of GCP and/or the trial protocol. Where the NCTU is investigating whether a serious breach has occurred sites are also requested to cooperate with the NCTU in providing sufficient information to report the breach to the REC where required and in undertaking any corrective and/or preventive action.

Sites may be suspended from further recruitment in the event of serious and persistent non-compliance with the protocol and/or GCP, and/or poor recruitment. Any major problems identified during monitoring may be reported to trial specific committees and/or stakeholders e.g., Trial Management Group, Trial Steering Committee, and the REC. This includes reporting serious breaches of GCP and/or the trial protocol to the REC.

12 End of Trial Definition

The end of trial will be when the database is locked. The NCTU will notify the REC the trial has ended, and a summary of the clinical trial report will be provided within 12 months of the end of trial.

13 Statistical Considerations

13.1.1 Power Calculations / sample size calculation

There are approximately 140 NHS services fitting hearing aids to 355,000 new adult users each year, so approximately 211 per service each month. We assume that 25% of patients will provide individual follow up research data with 80% of these providing primary outcome data and clinics will each recruit for three months, giving an average cluster size for analysis of approximately 130 patients. The intra-class correlation coefficient (ICC) for the primary outcome is unknown but based on published ICC data for a broad range of outcomes and settings[28] we assume it to be between 0.02 and 0.05.

Our target treatment effect is a difference in mean hours of use per day of 1-1.5 hours (60-90 minutes). With 90% statistical power, a 5% two-sided significance level, ICC = 0.02, standard deviation = 5.5 hours[29] and target mean difference of 1 hour, a total of 36 sites and 4,680 participants are required for the analysis. Based on a 25% consent rate (and 80% of these participants providing primary outcome data), a total of 23,400 patients need to be recruited, with a total of 5,850 participants consenting to follow-up data collection.

If the ICC is 0.05, the trial will have 90% power to detect a difference of 1.4 hours (84 minutes), and 80% power for a difference of 1.2 hours (72 minutes). There is an association between daily duration of hearing aid use and reported benefit, such that even a small effect of the intervention in increasing mean hours of hearing aid use could be clinically important. Our PPI contributors indicated that 60-90 minutes is a meaningful increase in usage.

The table below shows the detectable differences in mean minutes of hearing aid usage at 80% and 90% power for ICCs ranging from 0.02 to 0.05:

	Detectable difference	
ICC	**80% Power**	**90% Power**
0.02	54	60
0.03	60	72
0.04	66	78
0.05	72	84

The table below shows the detectable differences in mean minutes of hearing aid usage at 80% and 90% power for ICCs ranging from 0.02 to 0.05 and Coefficient of variation from 0.4 to 0.9.

		Intra-class correlation coefficient (ICC)			
		0.02	0.03	0.04	0.05
Coefficient of variation (CoV)		90% power			
	0.4	60	70	79	86
	0.5	61	70	79	86
	0.6	61	71	80	87
	0.7	62	72	80	88
	0.8	64	73	81	89
	0.9	65	74	82	89
		80% power			
	0.4	52	61	68	74
	0.5	52	61	68	75
	0.6	53	61	69	75
	0.7	54	62	70	76
	0.8	55	63	70	77
	0.9	56	64	71	77

13.1.2 Primary outcome measures

See Section 2.2.

13.1.3 Secondary outcome measures

See Section 2.2.

13.2 Analysis of Outcome Measures

The analysis and reporting of the trial will be in accordance with CONSORT guidelines for cluster trials[30]. A full Statistical Analysis Plan (SAP) will be developed prior to database lock and agreed with the Trial Steering Committee (TSC).

The primary approach to between-group comparative analyses will be by intention-to-treat (i.e., including all patients according to randomised allocation regardless of site adherence to trial allocation). The primary analysis for the primary outcome will include all randomised participants who consent to provide follow-up data at 12 weeks or 12 months. Where appropriate, imputation will be used so that all randomised participants may be included in a sensitivity analysis.

Descriptive statistics will be used to describe balance between the groups at baseline at site- and patient-level[31], including the characteristics of those that do and do not provide consent to follow-up.

The primary comparative analysis will employ a mixed effects linear regression model to compare the hours of use at 12 months in each group, adjusting for factors balanced at randomisation and participant-level characteristics (e.g., age, sex, socio-economic status), where technically possible. The model will include a random effect to adjust for clustering within sites. The comparison will be presented as a difference in means, along with 95% confidence intervals.

Secondary outcomes will be analysed using appropriate multilevel regression models dependent on data type (e.g., binary, continuous, time-to-event), adjusting for factors balanced at randomisation and participant-level characteristics (e.g. age, sex, socio-economic status), where technically possible. The model will include a random effect to adjust for clustering within sites.

13.2.1 Planned Interim Analysis

No formal interim analyses are planned. The trial includes an internal pilot with stop/go criteria described in Section 8.4.

13.2.2 Planned Final Analyses

The planned final analysis will take place when all data relating to all outcomes have been collected, the database has been locked and the allocation codes revealed.

13.2.3 Health economic analysis

Two complementary cost-effectiveness analyses will be performed: (i) a within-trial evaluation where cost and health effects of individual participants are limited to the 12-month follow-up period in the trial and (ii) a decision model approach where cost and health effects are modelled to enable the incorporation of longer term benefits and NHS/PSS costs, designed using standard reporting criteria[24].The estimation of cost effectiveness ratios will be carried out using the payer's perspective (NHS England).

Outcomes: Effects will be captured at the individual patient level as part of the multi-centre-randomised controlled trial. QALYs will be calculated by attaching available utility weights to the health states generated from the HUI-3[25] at 12 months post-intervention. Comparisons between

the two groups will be corrected for clustering and other baseline characteristics. In an additional investigation, we will investigate the extent to which HHIE maps onto HUI-3.

Costs: Costs will comprise intervention, current practice, and downstream audiology costs. Specific parameters include audiology service-level and patient-level resources associated with the intervention (the hearing aid (s), generation of individualised action plan, monitoring hearing aid use, provision of feedback, all follow-up remote or face-to-face consultations).

Comparator arm costs (local usual care) will comprise the hearing aid plus all follow-up remote or face-to-face appointments.

Patient-level costs for 12 months from initial contact will be generated for each patient in the intervention and local usual care arms. Downstream costs will include use of audiology services. The intervention is not expected to impact non-audiology NHS resource use such as hospitalisation rates in the 12 month follow up period, so these data are not being collected. The unit costs of resource use will be taken from publicly available sources of audiology-specific and general NHS reference costs and the Unit Costs of Health & Social Care[32, 33]. Costs will be compared between the two groups using a bootstrapped regression model (as the data are likely to be skewed), and corrected for clustering and other baseline characteristics.

A broader understanding of the effect of hearing loss on wider costs, including the patient, employment status and participation in paid and non-paid activities will be measured using the CSRI[34], adapted by our PPI panel to reflect specific activities.

Economic analysis:

i) Within-trial economic analysis: this analysis will utilise within-trial costs and QALYs to provide an estimate of cost-effectiveness. The uncertainty of the incremental cost-effectiveness ratio (ICER) will be quantified using methods that are based on the distributional characteristics of costs and effects. In the case where the incremental costs and effects follow a bivariate normal distribution, confidence intervals for the ICER will be calculated[35, 36].

ii) Longer-term modelling analysis: As the potential benefits of the intervention are likely to be seen after the observed follow-up endpoint, we will carry out an economic evaluation informed by modelling to estimate longer-term benefits and NHS/PSS costs. This fits within the current NICE decision-making frameworks in England. New hearing aid users are normally around 72 to 75 years of age and would be expected to live for about another 10 years. An economic model with a lifetime time horizon, and appropriate discounting (3.5%), will be constructed to evaluate the cost-effectiveness of the intervention from a health care perspective over the longer term, using standard validation approaches[37]. The model structure will be a cohort-level state-transition model, informed by published clinically validated models already available to estimate the long-term economic impact of interventions to manage hearing loss[38-40].

Deterministic and probabilistic incremental economic analyses will be carried out. The incremental cost-per-QALY generated by the intervention over current practice will be calculated using the following equation:

ICER = (CostINT– CostUC) / (QALYINT– QALYUC), where INT and UC are intervention and usual care, respectively.

Cost-effectiveness acceptability curves (CEACs)[41] will be constructed to express the probability that the intervention is cost-effective as a function of the decision-maker's ceiling cost-effectiveness ratio (λ)[34].

Sensitivity analysis: The implementation work will uncover variation in service (intervention and control) delivery and uptake, and we will examine the economic impact of this variation. The effect of a shorter time horizon and other downstream effects in the modelling analysis will also be examined e.g., a proportion of patients will get a full reassessment, lasting 60 minutes, every three years, and some will need replacement hearing aids within three years of receiving their current devices.

13.2.4 Process evaluation: implementation analysis

Early interviews will focus on perceptions and attitudes, training, and reflections on initial implementation experiences. Later interviews will focus on the barriers and enablers to integrating the FAMOUS Intervention within existing management care pathways. It will specifically focus on understanding:

i) SENSE MAKING: how the FAMOUS Intervention is understood and compared with existing follow-up and monitoring practices

ii) IMPLEMENTATION: how the FAMOUS Intervention is locally developed and translated into practice

iii) EMBEDDING: the extent to which the FAMOUS Intervention does become incorporated into everyday practices

iv) INTEGRATION: the extent to which the FAMOUS Intervention is sustained as part of routine practice

Interviews will be audio-recorded with consent, transcribed, and thematically analysed using a modified Framework approach[42]. By 'modified Framework approach' it is meant that the Framework approach will be initially used to take an inductive approach to theme generation. Subsequent theme refinement will be deductive and guided by NPT. This will produce a matrix of summarised data providing a structure for analysis. This approach will allow us to: (a) answer the specific research questions we have set, whilst (b) allowing important insights to be produced inductively. The wider research team, our PPI group and clinical stakeholders will be involved in the analysis process[22].

The implementation analysis (combining interviews and documents) will then: (i) explore professional perceptions and attitudes towards the FAMOUS Intervention; (ii) consider initial and enduring challenges to adoption and unintended consequences arising from implementation; (iii) survey "core enabling ingredients" that must be replicated at other sites, as well as (iv) any capacity for adaptation in context. A blueprint for implementation for use by those commissioning and delivering services in other settings will then be produced setting out the core barriers and enablers and the costs and/or resources necessary to embed and sustain the intervention in practice.

13.2.5 Process evaluation: Patient experience and acceptability analysis

We will use topic guides informed by the theoretical framework of acceptability[22] to understand participants' responses to and interactions with their usual care and the intervention to interview participants who fall into a range of daily use/non-use categories (circa 15 per category). We will additionally use the behaviour change wheel[43] to understand the barriers and facilitators to

behaviour change not associated with the acceptability of the intervention (i.e., mechanism of impact). Data will be analysed to identify recurrent themes. Inductive thematic analysis will be used followed by deductive thematic analysis using the theoretical framework of acceptability[22] and theoretical domains framework[23]. These analyses will allow us to understand what improvements can be made to the intervention to enhance patient experience and to increase hearing aid use further.

14 Trial Organisational Structure

14.1 Sponsor

The Sponsor for the trial is Manchester University NHS Foundation Trust (MFT).

14.2 Trials Unit

The trial is co-ordinated by the Nottingham Clinical Trials Unit (NCTU).

14.3 Trial Management Group

The TMG will consist of the Chief Investigator, Co-Investigators, Health Economist, PPI representative, Senior Trial Manager, Trial Manager, and Trial Statistician, with other members of the trial team (e.g., Data Manager, IT/Data Coordinator) invited as required. The TMG are responsible for the day-to-day management of the trial and will monitor all aspects of the conduct and progress of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of data collected in the trial. The TMG will report to the independent Trial Steering Committee (TSC).

14.4 Trial Steering Committee

The TSC will provide overall supervision, monitor progress against targets, and advise the Chief Investigator and TMG. The TSC will meet initially to review and agree the protocol, and then approximately every six months. Additional meetings may take place if required.

14.5 Data Monitoring Committee

Reports will be supplied in confidence to an independent DMC, which will be asked to give advice on whether the accumulated data from the trial, together with the results from other relevant research, justifies the continuing recruitment of further patients, using the stop/go criteria detailed in Section 8.5. The DMC will be guided by a trial specific charter[44]. The DMC will meet annually unless there is a specific reason to amend the schedule.

Additional meetings may be called if recruitment is much faster than anticipated and the DMC may, at their discretion, request to meet more frequently or continue to meet following completion of recruitment. An emergency meeting may also be convened if a safety issue is identified. The DMC will report directly to the TSC, who will convey the findings of the DMC to funder, Sponsor, and regulatory authorities as applicable.

14.6 Finance

This trial is funded by the National Institute for Health Research Health Technology Assessment Programme, award ID: NIHR131159.

Participants will not receive a payment to participant in the trial. However, gift vouchers will be offered to encourage responses to the 12-week and 12-month questionnaires, whether the individual uses their hearing aids regularly or not. On receipt of completed 12-week and 12-month questionnaires at NCTU, participants will receive a £10 gift voucher as a thank you for their additional time spent (2 x £10 = £20 total gift vouchers). Participants will have the option on the consent form to request electronic vouchers to their email, or physical vouchers to their home address.

Gift vouchers will also be given to patients participating in the process evaluation patient interviews.

15 Ethical Considerations

The trial will be performed in accordance with the recommendations guiding physicians in biomedical research involving human participants, adopted by the 18th World Medical Association General Assembly, Helsinki, Finland, June 1964, (website: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/).

The trial will be conducted in accordance with the Research Governance Framework for Health and Social Care, the applicable UK Statutory Instruments, (which include the Medicines for Human Use Clinical Trials 2004 and subsequent amendments and the Data Protection Act 2018 and Guidelines for Good Clinical Practice (GCP). The protocol will be submitted to and approved by the REC prior to circulation.

The trial will not be initiated before the protocol and all relevant documents have received approval/ favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other health care provider's Research & Development (R&D) department, the Health Research Authority (HRA) and devolved nation equivalents. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised documents (if appropriate) have been reviewed and received approval / favourable opinion from the REC, HRA, (where required). Non-substantial protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

Amendments to the Protocol

Any amendments to the to the trial shall be reviewed by the sponsorship team prior to submission. Any non-substantial amendments shall be notified to the HRA and any substantial amendments, along with amended documentation, shall be approved by the REC, and HRA, prior to implementation as per nationally agreed guidelines. The Chief Investigator or designee will work with the Sponsor R&D department to put the necessary arrangements in place to implement the amendment and to confirm their support for the trial as amended.

16 Confidentiality and Data Protection

Personal data recorded on all documents will be regarded as strictly confidential and will be handled and stored in accordance with the Data Protection Act 2018. Participants identifiable data will be collected to allow for linkage of the routine medical and research data. First name and surname, address, postcode, email address and telephone number will be collected for each patient, for the purposes of future contact. Identifiable patient contact details will be deleted prior to database lock, and will not be included in the study analysis. Auditbase ID will used for linkage of the routine

medical data and research data. Individual pseudo anonymised patient clinical data obtained for this trial are considered confidential and disclosure to third parties is prohibited.

In the case of specific issues and/or queries from the regulatory authorities, it will be necessary to have access to the complete trial records, provided that participant confidentiality is protected. The NCTU will maintain the confidentiality of all participant's data and will not disclose information by which participants may be identified to any third party than those directly involved in the treatment of the participant and University of Manchester. Representatives of the FAMOUS trial, NCTU and Sponsor may be required to have access to participant's notes for quality assurance purposes, but participants should be reassured that their confidentiality will be respected at all times.

17 Insurance and Indemnity

MFT will act as Sponsor for the trial. Delegated responsibilities will be assigned to the NHS Trusts taking part, NCTU of the University of Nottingham, and the CI Professor Kevin Munro. Insurance and indemnity for trial participants and NHS trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96) 48. There are no special compensation arrangements, but trial participants may have recourse to the NHS complaints procedure. The NHS indemnity scheme will apply to this trial to ensure it meets the potential legal liability of the Sponsor, equipment, employer and investigators/collaborators for harm to participants arising from the management, design and conduct of the research. No arrangements will be made for the payment of compensation in the unlikely event of harm.

The University of Nottingham has appropriate and typical insurance coverage in place (including, but not limited to Clinical Trials, Professional Indemnity, Employer's Liability and Public Liability policies) in relation to the Institution's Legal Liabilities arising from the University's activities and those of its staff, whilst conducting University business and research activity.

The Manchester University NHS Foundation Trust is independent of any pharmaceutical company, and as such it is not covered by the Association of the British Pharmaceutical Industry (ABPI) guidelines for participant compensation.

18 Publication Policy

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. Final dissemination plans will be outlined in the Trial Publication Plan.

The manuscripts will be prepared by the Chief Investigator and Trial Management Group and authorship will be determined by mutual agreement. The TSC and DMC will be given the opportunity to comment on the manuscripts prior to submission. All publications will include PPI using GRIPP2 checklist[45] and the intervention will be reported using the template recommended by Hoffman et al[46].

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.

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Appendix I: Study Within A Trial (SWAT)

Background

A great deal of effort is often expended in recruiting participants to trials. Ensuring that as many of these participants as possible are recruited, retained, and provide outcome data can greatly improve research efficiency and minimise the risk of bias resulting from incomplete data. In FAMOUS, the randomisation of clusters (i.e., sites) means that all eligible patients seen during the trial period will receive care in line with the site's allocation. The strategy of informing patients that the clinic they have attended is participating in research will be delayed until the 12-week time point, at which point the first set of PROMs are due.

Given that patients are being sent information that does not pertain to their hearing aid clinical care, each patient will receive a reminder phone call from their audiology clinic reiterating the details of the FAMOUS trial and the questionnaires. A SWAT will investigate the timing of a single telephone call from the site, during which the questionnaires will be discussed with the patient and find out if they have any further questions or concerns.

Interventions

Group 1: Telephone call at the time of sending to inform them that the questionnaires and consent form are on the way.

Group 2: Telephone call 2–3 days after postage to confirm whether they have received and read the questionnaires and consent form, having given the patient time to read the documents.

Method of allocation

Sites will be randomised in a 1:1 ratio to whether they contact their patients at the time of sending the trial documentation (Group 1) or 2–3 days following postage (Group 2). Timing of contact will be assigned using stratified block randomisation balancing on treatment group (usual or structured care site). The randomisation will be an internal process which is triggered by site allocation to group 1 or 2 and will be communicated to sites as part of their allocation confirmation.

Outcome measures

(i) return rate of 12-week follow-up questionnaire, and

(ii) demographics of populations completing 12-week follow-up questionnaires.

Analysis

A mixed-effects logistic regression model will be used to compare response rates (Group 1 vs Group 2), with a random effect to adjust for clustering within centres. The comparison will be presented as an absolute and relative difference in proportions, along with 95% confidence intervals.

Given the brief site opening period (months 8 to 17) and that recruitment of participants into the SWAT will occur at the 12 weeks post fitting appointment, it will not be feasible to perform an interim analysis on the SWAT and implement a change should one strategy prove more effective. Therefore, the analysis of the SWAT will occur after all patients reach 12 weeks post-fitting.

Dissemination

The SWAT will be registered on the Northern Ireland MRC Trials Hub for Methodology Research SWAT registry. The findings will be made publicly available as soon as possible after the end of the SWAT and will be made available to researchers conducting meta-analysis in this field.