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Co-designing a technology-informed pathway in primary care to improve the kidney health of people living with heart failure

Submission date
19/12/2022

Recruitment status
Recruiting

Registration date
13/02/2023

Overall study status
Ongoing

Last Edited
02/10/2026

Condition category
Circulatory System

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Almost a million people in the UK live with heart failure, most of whom also have kidney problems. This is because the heart and kidneys strongly affect each other. If the heart suddenly works less well, kidney function can worsen. Modern treatments help people with heart failure to live longer, healthier lives but the amount and type of their medication need to be checked regularly. Too low a dose of heart medication makes heart failure symptoms worse. Higher doses of heart medication can make kidney function worse. Either can lead to hospitalisation and increase the risk of death. At present, the frequency of blood tests to measure kidney function varies widely between GPs. Individuals respond differently to changes in medicines, and there is no way to work out how often a kidney blood test is required. If tests are not frequent enough, worsening kidney function might not be detected early, risking hospitalisation. Others might have more tests than needed, causing inconvenience.

The RENAL-HF programme involves a series of linked work packages which aim to improve kidney health in people living with heart failure by developing technology to predict how often each person with heart failure needs a kidney blood test and producing expert and consistent advice for GPs, nurses and pharmacists on how to adjust medicine dose and/or medicine type to keep both the heart and kidneys working together at their best. Work Package 2 (Stages 1-5) involves gathering the views of healthcare professionals, patients, and carers to ensure that the care pathway we develop is acceptable for patients and professionals and complements existing systems in GP practices. This work package aims to design a useful tool for patient benefit. Without this work package, we cannot design a useful tool for patient benefit. To ensure that we achieve this objective, the team plans to conduct surveys and interviews with GPs, nurses and pharmacists who work in GP practices to understand how the kidney health of people with heart failure is currently managed and combine the learning to create a list of components to include in the pathway to help improve guidelines for monitoring kidney health for people with heart failure. Key groups (including patients, GPs, nurses, pharmacists, specialists, and commissioners) will discuss and vote on these components to decide which ones are the most important. The RENAL-HF team, including members of the public, will work out what training would be most helpful to support GPs, nurses and pharmacists in managing the kidney health of people with heart failure and a group of GPs, nurses and pharmacists will be invited to test the new system

for managing kidney health to make sure they are happy with how it works and that the instructions are clear and easy to use. This information will be used to help improve the system, and ready to test the feasibility and acceptability of the new care pathway (Stage 6).

Who can participate?
Stage 1b: GPs, nurses, and pharmacists working in the UK who are part of a YouGov (a public opinion and data company)
Stage 1b: GPs, nurses, and pharmacists working in GP practices in England
Stage 2: GPs, nurses, and pharmacists working in GP practices in England, Cardiology or renal specialists working in NHS settings in England and People living with heart failure and their informal carers registered with a GP practice in England
Stages 3 and 4: No study participants; research team only
Stage 5: GPs, nurses and pharmacists working in GP practices in the North West Coast or Greater Manchester Region in England. People living with heart failure and their informal carers registered with a GP practice in England.

What does the study involve?
Stage 1: Healthcare professionals will take part in a short online survey. GPs, nurses and pharmacists will take part in a focused one-one interview either in -person, via telephone or via video. The survey and the interview topic guide have been designed to understand how the kidney health of people with heart failure is currently managed in GP practices.
Stage 2: We will hold a series of 5 separate workshops for each different group of participants including GPs, nurses, pharmacists and specialists and people with heart failure and their carers. All professional workshops will be held online and people with heart failure and their carers will be given the option of meeting either in person or online. During the workshops, participants will be given the opportunity to discuss and vote on components of the new care pathway so we can decide what is the most important to include.
Stage 3: There will be no participants recruited for Stage 3. Using learning from the early stages of the study, the RENAL-HF team (including PPI advisors, cardiologists, and renal specialists) will work out which components will be the most helpful to include in the care pathway.
Stage 4: There will be no participants recruited for Stage 4. The RENAL-HF team (including PPI advisors, cardiologists, and renal specialists) will work out how the care pathway will look and what training materials will be included to help, nurses and pharmacists deliver the pathway effectively and easily.
Stage 5: GPs, nurses and pharmacists will take part in an interview whilst they are testing the new pathway to check it is easy to use and acceptable before it is used with real patient data.

What are the possible benefits and risks of participating?
The researchers do not perceive any risks in participating. While there are no direct benefits for participants, people often find that taking part in studies of this sort is useful because they have a chance to share their views, reflect on their experiences and contribute to service development.

Where is the study run from?
1. University of Liverpool (UK)
2. University of Manchester (UK)

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

Who is funding the study?
NIHR Programme Grant for Applied Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
316009

Central Portfolio Management System (CPMS)
54090

Study information

Scientific Title
Co-creation of a care pathway for implementing personalised renal function monitoring and interventions for people with heart failure

Acronym
WP2: Pathway co-design

Study objectives
Modern heart failure treatment has reduced morbidity and improved survival, but people with heart failure remain at risk of renal deterioration. This is potentially preventable through regular renal function monitoring and drug dose/choice optimisation. Currently, healthcare professionals treating people with heart failure lack evidence-based guidance on how frequently to monitor renal function and on the best way to adjust drug dose/choice for each individual. We hypothesise that the lack of clear, personalised guidance contributes to renal deterioration and hospitalisation in people with heart failure. Work package 2 (Stages 1-5) forms part of an NIHR Programme Grant for Applied Research - RENAL-HF, which involves various integrated studies to develop an improved care pathway in GP practices to manage kidney health in people with heart failure. Medical records will be used to develop technology to predict how often each person with heart failure needs a kidney blood test and inform the development of expert advice for GPs and nurses on how best to adjust medication. WP2 (stages 1-5) aims to work with patients, primary care practitioners and specialists to find the best way to implement this personalised approach to kidney monitoring and interventions through co-designing an improved care pathway.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 12/10/2022, Yorkshire & The Humber - Sheffield Research Ethics Committee (NHS Blood and Transplant Blood Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear, NE2 4NQ, UK; +44 (0)207 1048388; sheffield.rec@hra.nhs.uk), ref: 22/PR/1172

Primary study design
Observational

Study design
Non-randomized qualitative study

Study type(s)
Other

Health condition(s) or problem(s) studied
Cardiovascular, renal and urogenital

Interventions
Purpose
Primary aim
To co-create with patients, primary care practitioners and specialists a prototype care pathway for implementing personalised renal function monitoring and optimal interventions if renal function is declining in primary, ready for feasibility and acceptability testing in Stage 6.
Objectives
Stage 1: To understand current practice and to identify barriers and facilitators to monitoring renal function in people with heart failure.
Stage 2: to co-develop clinical guidelines associated with our RENAL-HF clinical pathway (including thresholds for intervention).
Stage 3: To consider the elements of the intervention in relation to key intervention criteria
Stage 4: To develop online training materials for the intervention
Stage 5: To beta test and refine the care pathway ready for feasibility testing in stage 6

Design and methodology
This work package (WP2) is part of a programme of research called the RENAL-HF Project, aimed at developing (WP1, WP2, WP5) and evaluating (WP3, WP4, WP5) a complex intervention to improve the kidney health of people living with heart failure. The overarching design and methodology of this programme is informed by the MRC Framework and related guidance for developing and evaluating complex interventions. The complex intervention we are designing is an algorithm-guided care pathway which we anticipate will need to be registered as a Class 1 Medical Device during stage 6 of WP2 which will be covered in a later IRAS application. Stages 1-5 of this work package will focus on the development of a care pathway which will support the implementation of the technology developed in WP1. During these stages we will work with patients, primary care practitioners, specialists, and our colleagues from WP1 to ensure that the care pathway we develop is acceptable for patients and professionals and complements existing systems in GP practices. Without this work package, we cannot design a useful device for patient benefit. Co-production research methods will ensure researchers, clinicians and the public will work together throughout the research process, sharing responsibility from the start to the end of the project. PPIE advisors will be supported to take active roles (according to availability and experience), in all the iterative stages of Work Package 2.

In addition to designing components of the intervention, attention will be given to understanding how and under what circumstance the intervention will bring about change and any potential barriers and enablers when implementing the care pathway. Therefore, we will consider a broader range of questions relating to the context in which the intervention will be developed, implemented, and evaluated. This work will be informed by frameworks relevant to technology-based intervention development and implementation science, including the behaviour change wheel and the non-adoption, abandonment, scale-up, spread, sustainability (NASSS) Framework and Toolkit to support the design and implementation of the pathway in primary care practices. To achieve these objectives WP2 has adopted a mixed methodology involving 6 interlinked stages. The final stage 6 of WP2 involving feasibility and acceptability testing of the care pathway will be discussed in a separate IRAS application and is dependent on the successful completion of stages 1 -5 described in this application.

Sampling and recruitment
Stages 3 and 4 will not involve the recruitment of participants and will only involve members of the RENAL-HF team including our expert panel of specialists and our PPIE group. Only stage 2 (consensus workshops) will involve the recruitment of patients (n=9), who will be recruited from both GP practices and third-sector social media channels and PPIE networks to ensure we capture a diverse range of views. Stages 1, 2 and 5 will involve the recruitment of healthcare professionals working within England with a focus on primary care practitioners (GPs, nurses and pharmacists). We will work closely with the NW Coast and GM CRN to recruit healthcare professionals and will aim to recruit different professionals for each phase (although some overlap is possible) to ensure we capture a diverse range of views, reduce the research burden and mitigate against selection bias.

Stage 1
To enhance intervention effectiveness recent tools in behavioural science such as COM-B model (capability, opportunity, motivation and behaviour) and the Theoretical Domains Framework of the Behaviour Change Wheel have been employed to understand behaviours for intervention development. We have used this behaviour system to inform the design of our survey and topic guide to understand the current standard of care, and to identify barriers and facilitators to monitoring the renal function of patients with heart failure. The survey has been co-developed by our research team and public advisors to ensure relevance and acceptability.

Stage 1a: Nationwide Survey
We plan to conduct a nationwide survey of healthcare professionals, including GPs, pharmacists and nurses (n=115 GPs, n=115 Pharmacists and n=370 Nurses) which will be delivered through YouGov https://yougov.co.uk/ who have access to a representative healthcare workforce sample. YouGov will be responsible for the recruitment of the required sample, secure data collection and sending the data to the research team for data analysis. We will work closely with the University approved Client Engagement Manager for YouGov on the design, implementation and analysis of this practitioner survey and will refine the final version of the survey following piloting.

Stage 1b: Focused qualitative interviews
Research Associates experienced in qualitative research methods, will conduct brief focused qualitative interviews with GPs, nurses and pharmacists recruited from Liverpool and Manchester primary care practices to generate options for intervention functions. We anticipate interviewing 17 participants per group; however, this number will be reduced if saturation is reached earlier. According to individual preference, interviews will take place in person or remotely via video conferencing or telephone. Interviews will be audio-recorded, transcribed,

checked and pseudo-anonymised before analysis. To ensure that the target behaviour is captured during interviews and to minimise the risk of obtaining generalised or idealised accounts, transcripts from interviews will be continually reviewed and used to ground and inform subsequent interviews with guidance from the wider research team and our PPIE advisors. The researcher will ensure that interviews are conversational in tone and that their pace, sequencing, and duration are shaped by the participants. Reflexive notes will be maintained by the interviewer to record systematically the contextual details of the interviews.

Stage 2: Co-designing the care pathway- clinical guidelines
There will be no research participants for Stage 2a. The research team will synthesise the material generated in WP1 and the outputs from WP2 Stage 1 during a series of meetings to generate possible elements of the care pathway. These proposals will be rated during stakeholder workshops (Stage 2b) which will involve the recruitment of both patient and professional participants.

Stage 2a: Evidence synthesis
We will work closely with colleagues from WP 1 (including members from the expert panel) to synthesise learning from WP1 and WP2 Stage 1 to develop the material and set of proposals for our stakeholder consensus workshop. The expert panel will comprise three cardiologists, 3-4 nephrologists, two clinical pharmacologists, three general practitioners and one statistician. All panel members will have the relevant expertise and experience in heart failure or renal failure management and a background in clinical trials.

The proposal and presentations that will be developed for the consensus workshop include:
1. Identifying the best algorithm
We will consider transparency and ease of explanation when choosing between models
2. Defining personalised renal function monitoring frequencies
We aim to achieve agreement on the thresholds required for (a) personalised renal function monitoring schedules; (b) when patients need to move from one renal function schedule to another (more frequent or less frequent); and (c) when an additional renal function test is needed to provide a better estimate of the trajectory in renal function decline.
3. Thresholds for altering heart failure medications
Proposals will be informed by a pharmaco-epidemiological analysis in CPRD Aurum and CPRD Gold conducted by WP1
Stage 2b: Stakeholder consensus workshops

We will use the RAND/UCLA Appropriateness Method (RAM) involving diverse groups (including patients, primary care practitioners and other key informants) to ensure the views of key stakeholders are included in the design of the intervention. Typically, RAM involves only a single group of experts (e.g., nephrologists), but as the complexity of healthcare delivery increases, it is beneficial to adapt the RAM and similar methods of defining standardised quality care to include diverse healthcare professionals. Furthermore, there is a growing need to have patients, involved in healthcare decision-making. Therefore, our workshop design will comprise five stakeholder groups, including (patients, pharmacists, nurses, GPs, and key informants) each containing 9 participants. Each group will engage in three rounds, rating the proposals created from the synthesis of WP1 and Stage 1 of WP2. The rounds will require: (i) independent individual ratings of appropriateness, (ii) moderated group ratings of appropriateness, and (iii) independent individual ratings of necessity. We will set a priori criteria, informed by the RAND /UCLA Appropriateness Method for group consensus, and undertake anonymised electronic voting, recording if and when consensus is reached. Consistent with the RAND/UCLA approach, the criteria for agreement for a 9-member panel will be a median of >7 on a 9-point Likert scale and no more than two members rating outside the 3-point region containing the median (i.e., 7–

9 on a 9-point Likert scale). We anticipate that the workshop will comprise five parallel groups with one round of voting taking place before the event and discussion and two rounds of voting taking place during the workshop. With consent, workshops will be audio-recorded to support the accuracy of anonymised field notes.

Stage 3: Decision-making
There will be no research participants for this stage. Based on data generated by WP2 Stages 1 and 2, the research team will use the behaviour change wheel to identify intervention functions and behaviour change techniques that will be most likely to achieve the change required. We will evaluate the interventions according to intervention design criteria (APEASE) acceptability, practicability, effectiveness/cost-effectiveness, affordability, and safety/side-effects defined in the Behaviour Change Wheel.

Stage 4: Training material
There will be no research participants for this stage. The RENAL-HF research team will develop prototype training material for the primary care teams (GPs, pharmacists, and nurses). We will work with members across work packages, including the PPIE group, primary care staff and specialists, to co-design the proposed behaviour change interventions in a series of up to three workshops in preparation for WP2 stage 5. The NIHR Applied Research Collaboration (ARC) North West Coast (NWC) have extensive experience developing and delivering training programmes. We will draw on their resources to create effective materials. These materials are likely to include: environmental restructuring (e.g., adjustments to the GP dashboard), education, training, and enablement that will be deliverable remotely.

The findings from WP1 and stages 1-3 of WP2 will be important in determining the type of content to be included in the training material. We will cover the rationale for the study, how the algorithm and interventions have been developed (including the input from patients), the evidence bases for undertaking interventions (increased renal function monitoring, changing drugs or doses etc.), and how to use the tool, and how the utility of the device is being assessed. Finally, we will explore the possibility of accrediting the training material for continuing professional development. The format for training materials will be informed by stakeholders but may include videos on platforms such as YouTube, simple animations, and integrated self-guided learning materials.

Stage 5
Only primary care practitioners will be recruited for this stage with the support of NW Coast and GM CRN. Practitioners from participating GP practices in the North West of England will be invited to evaluate the usability of the prototype materials developed during Stages 3 and 4 through a series of beta testing. This evaluation will use 'think aloud' interviews with 36 primary care staff (12 GPs, 12 pharmacists, and 12 nurses). During think-aloud interviews, participants will be instructed to verbalise their thoughts while conducting predefined tasks with the software/dashboard within a 'dummy' environment (i.e., not integrated with live patient data). This approach will enable us to assess whether target users of the system interact with it as intended enabling us to make refinements where appropriate. Data collection for this stage will be completed in person. Participant answers will be audio-recorded, and the data will be analysed using thematic analysis. The prototype training materials will be refined according to the findings of this beta testing in preparation for feasibility/acceptability testing of the device as part of the 'real-world' during stage 6 (not discussed in this registration).

Demographic details
All participants will be invited to answer some background questions (demographic details). For Stage 1a, YouGov will share anonymised demographic data on the professional panel who

participated in the survey. For other stages involving participants, it will be explained in the PIS that this information will be collected to help inform understanding of the data and provide context to individual quotes, e.g., pharmacist. It will be clear to the participants that they are free to decline any questions. A series of background questions have been co-designed with the wider team, including our PPIE group for patients and professional participants. Participants will be invited to complete these questions via an electronic form (via Microsoft word or a University approved secure software) which will require the entry of a participant ID or the data will be collected verbally via the researcher and entered directly into a secure electronic form or excel spreadsheet. The demographic questionnaire will be completed using a non-identifiable study ID and will be archived in aggregate form upon completion of the study. No personally identifiable information will be collected with this demographic data.

Involvement of key interest groups

To ensure practitioner (particularly primary care) and patient acceptability of this new care pathway, we will integrate co-production research methods involving the expertise of key stakeholder groups, including patients, primary care practitioners, specialists, and other key informants who will act as participants. We have also formed an expert panel comprising three cardiologists, 3-4 nephrologists, two clinical pharmacologists, three general practitioners and one statistician with who we will collaborate throughout this Work Package. Our RENAL-HF research team within WP2 and the wider project comprise a multidisciplinary team including clinicians from both primary and secondary care with whom we will also work closely. We have involved our PPIE group with lived experience at all planning stages to refine our study design, including the development of study materials and the quality and acceptability of its procedures. We will continue to enhance the project through the continued involvement of our PPIE advisors in key research activities, including analysis of qualitative data, co-facilitation of patient consensus workshop, synthesis and dissemination.

Project timetable

Stages 1-5 of WP2 will be conducted over 24 months and have commenced with PPIE involvement (WP5) and collaboration with NW Coast CRN, colleagues from WP1 and the wider programme to finalise and optimise the research design. We aim to commence professional interviews and surveys for Stage 1 as soon as possible after approvals are in place (ideally before the end of October 2022) and for data collection and write-up of this stage to be completed by the end of February 2023. In June 2023, we would like to hold the stakeholder consensus workshops, and we would like to begin Beta testing in October 2023. We anticipate that approvals and set-up for Stage 6 will overlap with Stage 5 and will start at the same time as Beta testing. Stage 6 is expected to end in August 2024 and will inform the cluster randomised controlled trial (RCT) of WP3. We must adhere to our timelines as subsequent funding and rollout of the RCT depend on the successful completion of this earlier work. We anticipate stage 5 will close in January 2024. The research team and PPIE advisors will disseminate findings as the study progresses, and each stage's findings will inform the next stage of the study.

Quality issues and managing bias

The Project Management Group will comprise the named co-investigators and researchers included in the NIHR proposal and chaired by the Chief investigator. The programme will be delivered by a study team for each Work Package, collaborating with relevant members of other WPs as needed to ensure a fully integrated project. The Project Management Group will also maintain integration across this large and diverse research group. The Project Management Group will convene once every two months to discuss each WP and review and implement actions recommended by the Programme Steering Committee and the Patient and Public Involvement and Engagement Group, which comprise WP5. We will adhere to the necessary Quality Assurance policies as detailed by our sponsor. An independent Programme Steering

Committee will be appointed to advise the Chief Investigator and co-investigators on the work's quality, scientific and ethical aspects and review progress. The Programme Steering Committee will meet within the first three months of programme commencement and thereafter once yearly. Consideration of health inequalities will underpin our work. The PERMIT study used the Health Inequalities Assessment Tool (HIAT). We will continue to use this tool iteratively to ensure that health inequalities are considered wherever possible and that our care pathway is designed to reduce health inequalities. The WP2 team, PPIE advisors and, where appropriate, the wider renal HF team will contribute to the analysis through periodic discussion and review. Throughout the study, reflexive notes recorded on all aspects of the fieldwork and analysis will be regularly reviewed to identify and account for potential bias.

Intervention Type
Other

Primary outcome(s)
Training material linked to an algorithm-informed care pathway will be developed according to the TIDieR guidelines in preparation for Stage 6 (to be registered as a separate study) measured using data produced in Stages 1 to 5 throughout WP2

Key secondary outcome(s)
1. Current practices, barriers and facilitators to balancing renal and heart failure care measured using surveys and interviews conducted with stakeholders and identified using the Framework approach, with analysis that will produce material to be evaluated during the Stage 2 consensus workshop, during Stage 1
2. Components of the care pathway derived from evidence from WP1 and WP2 Stage 1 measured using consensus workshops with key stakeholder groups and agreed using the RAND /UCLA Appropriateness Method during Stage 2
3. Elements of the intervention measured using the data generated in the earlier Stages and evaluated using the APEASE criteria (acceptability, practicability, effectiveness/cost-effectiveness, affordability, and safety/side-effects) during Stage 3
4. Prototype training material measured using data produced during a series of multidisciplinary co-design workshops and input from a software development team during Stage 4
5. Prototype training material will be Beta tested measured using data produced during ‘think aloud’ interviews and built-in feedback from the prototype system during Stage 5

Completion date
30/11/2026

Eligibility

Key inclusion criteria
Patient sample:
People with a diagnosis of heart failure as identified by their GP practice in England. An individual's self-reported acknowledgement of their formal diagnosis of heart failure is adequate to meet this study's objective, enabling patients to be recruited by other pathways in addition to GP practices, including third sector and PPIE channels.

Professional sample:
1. Professionals working in the NHS or wider care settings in England

2. Stages 1 and 5 samples will include GPs, nurses and pharmacists
3. The stage 2 sample will include specialists and other key informants in addition to GPs, nurses and pharmacists

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
Patient sample:
1. People with heart failure who live outside of the UK. As the study initially focuses on developing a care pathway within England, we feel that our sample should reflect the experiences and views of patients currently living in England.
2. For patients recruited via a GP practice, we will ask practices to exclude patients with heart failure who:
2.1. Lack of mental capacity as identified by the practice
2.2. Are currently receiving inpatient treatment or admitted to the hospital for an exacerbation of their heart failure in the previous six weeks
3. For patients recruited via other routes, we will exclude patients if they are unable to give valid consent, but we will not include capacity assessments in the study design

Professional sample:
Professionals who work outside of England

Date of first enrolment
22/11/2022

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

CRN NWC Primary Care Team
Liverpool Science Park
Innovation Centre 1
131 Mount Pleasant
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England
L3 5TF

Study participating centre
NIHR Clinical Research Network (CRN) Greater Manchester Core Team
Citylabs 1.0 Nelson Street
Manchester
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Study participating centre
NIHR Clinical Research Network (CRN) Support CRN Yorkshire and Humber
-
Leeds, Sheffield, York NO COUNTRY SPECIFIED, assuming England
England
-

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Study participating centre
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Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	24/10/2022	30/01/2023	No	Yes
Protocol file	version 1.4	01/06/2023	08/09/2023	No	No
Protocol file	version 3	28/10/2024	12/09/2025	No	No