ISRCTN76980954 https://doi.org/10.1186/ISRCTN76980954

# Named contact care plan for patients undergoing total knee replacement, an intervention development study

**Submission date**
20/12/2023

**Recruitment status**
No longer recruiting

**Registration date**
28/05/2024

**Overall study status**
Completed

**Last Edited**
18/02/2026

**Condition category**
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
Over 100,000 knee replacements are done every year in the UK. Most people recover by 3 months after surgery. However, one in five people will have ongoing pain and be dissatisfied with their outcome. Patients can feel abandoned after their knee replacement operation. Some people report a lack of continuity of care and having to tell their story repeatedly to different health professionals. In other medical conditions, patients have a named contact, such as a specialist nurse. They can help people to prepare for surgery, answer questions, check on general health and provide information. This approach may be useful for patients before and after knee replacement.
In this study, the researchers will make a new personalised care plan for patients having knee replacement. They are doing this to help people get the best possible results from surgery. The care plan will be delivered by a named, dedicated healthcare professional. They will help patients to receive the care, support and education they need before and after their operation.

Who can participate?
1. People aged 18 years and over who are on the waiting list for or who have received a primary total knee replacement at a participating NHS Trust.
2. Clinicians involved in the care of people on the waiting list for or who have received a primary total knee replacement.

What does the study involve?
The researchers will set up a group of patients, health professionals and researchers. They will work together to design the care plan. This approach is called co-production and members of the group will be equal partners. To help the group in the design of the care plan, we will do three studies:
1. Collect information from hospitals to understand why operations are cancelled
2. Talk to patients and health professionals about what the care plan should include
3. Do a questionnaire study with patients and health professionals to agree on what should be in the care plan
Findings from these studies will be discussed by the co-production group and used to design the

care plan. By the end of the study, the researchers will have a final care plan. They will then apply for funding to do more research to test the care plan and see if it is helpful to patients. This study was developed with patients. Patients involved in this project will be equal partners in the research, providing input at all stages. The researchers will also work with local community groups to understand how to make the study accessible to people from all backgrounds. What they find from this work will come out in a variety of formats for researchers, health professionals, and charities.

What are the possible benefits and risks of participating?
Although this study will not benefit participants directly, it is hoped that the results of the study will help build a care plan to help people having knee replacement surgery in the future. Some people also appreciate having an opportunity to share their experiences. A disadvantage is the time it takes to take part.

Where is the study run from?
University of Bristol (UK)

Who is funding the study?
1. National Institute for Health and Care Research (NIHR) (UK)
2. National Institute for Health and Care Research Bristol Biomedical Research Centre (UK)
3. University Hospitals Bristol and Weston NHS Foundation Trust (UK)
4. University of Bristol (UK)

Who is the main contact?
MyKneePlan@bristol.ac.uk

# Contact information

### Type(s)
Public, Scientific, Principal investigator


### Contact name
Ms Wendy Bertram

### ORCID ID
https://orcid.org/0000-0001-8234-2052

### Contact details
Musculoskeletal Research Unit
University of Bristol
Level 1, Learning & Research Building
Southmead Hospital
Bristol
United Kingdom
BS10 5NB
+44 (0)117 414 7847
Wendy.Bertram@bristol.ac.uk


# Additional identifiers

### Integrated Research Application System (IRAS)
318565

### Central Portfolio Management System (CPMS)
53541

# Study information

### Scientific Title
Named contact care plan for patients undergoing total knee replacement: intervention development

### Study objectives
What does a named contact care plan before and after total knee replacement (TKR) include when co-produced by researchers, clinicians and patients?

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 05/04/2023, Health and Social Care Research Ethics Committee A (HSC REC A) (Office for Research Ethics Committees Northern Ireland (ORECNI) Lissue Industrial Estate West, 5 Rathdown Walk, Lisburn, BT28 2RF, United Kingdom; +44 (0)28 95 361400; info.orecni@hscni.net), ref: 23/NI/0053

### Study design
Co-production of a care plan delivered by a named contact, providing support and treatment before and after total knee replacement, using data collected from three studies: 1) reasons for cancellation from UK hospitals, 2) qualitative interviews with patients and health professionals, and 3) a modified Delphi study with key stakeholders.

### Primary study design
Observational

### Study type(s)
Other

### Health condition(s) or problem(s) studied
People waiting for or undergoing total knee replacement

### Interventions
The researchers will set up a group of patients, health professionals and researchers. They will work together to design the care plan. This approach is called co-production and members of the group will be equal partners. To help the group in the design of the care plan, the researchers will do three studies:
1. Collect information from hospitals to understand why operations are cancelled
2. Talk to patients and health professionals about what the care plan should include
3. Do a questionnaire study with patients and health professionals to agree on what should be in the care plan

Findings from these studies will be discussed by the co-production group and used to design the care plan. By the end of the study, the researchers will have a final care plan. They will then apply for funding to do more research to test the care plan and see if it is helpful to patients.

This study was developed with patients. Patients involved in this project will be equal partners in the research, providing input at all stages. The researchers will also work with local community groups to understand how to make the study accessible to people from all backgrounds. What they find from this work will come out in a variety of formats for researchers, health professionals, and charities.

### Intervention Type
Other

### Primary outcome(s)
Care plan components determined using qualitative interviews and questionnaires with patients and health professionals between April 2023 and November 2024

### Key secondary outcome(s))
Reasons for cancellation from UK hospitals collected from routinely collected data on planned total knee replacement operations which were cancelled between 01/04/2018 and 31/03/2023

### Completion date
31/12/2024

## Eligibility

### Key inclusion criteria
Patients:
1. Patients aged 18 years and over
2. Patients on the waiting list for or who have received a primary total knee replacement at a participating NHS Trust

Clinicians:
NHS staff involved in the care of patients waiting for or undergoing primary total knee replacement

### Participant type(s)
Health professional, Patient, Service user

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
120 years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
Interview study:
1. Lack of capacity to provide informed consent to participate
2. Unable to complete question sheet or interview in the English language
3. Unable to complete interview over the telephone or video call

### Date of first enrolment
09/06/2023

### Date of final enrolment
01/09/2023

## Locations

### Countries of recruitment
United Kingdom

England

Wales

### Study participating centre
**North Bristol NHS Trust**
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

### Study participating centre
**Cardiff and Vale NHS Trust**
Cardigan House
University Hospital of Wales
Heath Park
Cardiff
Wales
CF14 4XW

**Study participating centre**
**Nottingham University Hospitals NHS Trust**
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
England
NG7 2UH

# Sponsor information

**Organisation**
North Bristol NHS Trust

**ROR**
https://ror.org/036x6gt55

# 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

**Funder Name**
National Institute for Health and Care Research Bristol Biomedical Research Centre

**Funder Name**
University Hospitals Bristol and Weston NHS Foundation Trust

**Funder Name**
University of Bristol

# Results and Publications

### Individual participant data (IPD) sharing plan
In line with NIHR guidance which encourages the sharing of anonymised datasets (for further information, please see: http://www.journalslibrary.nihr.ac.uk/replace/report-preparation/publication-ethics/3), the researchers will be seeking consent from participants for their data to be shared anonymously with other researchers. Participants who do not wish to consent to this can still participate in the study and their data would be removed before the dataset is archived for potential sharing. The shared dataset will include anonymised transcripts of study two interviews, and the modified Delphi study data.
After the study is complete, anonymised data will be shared via the University of Bristol Research Data Repository (https://data.bris.ac.uk/data/). Access to the data will be restricted to ensure that data is only made available to bona fide researchers after a Data Access Agreement has been signed by an institutional signatory.

### IPD sharing plan summary
Available on request, Stored in publicly available repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 01/12/2025 | 18/02/2026 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |