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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
28/05/2024

Condition category
Musculoskeletal Diseases

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

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

Study website
https://www.bristolbrc.nihr.ac.uk/research/research-projects/my-knee-plan/

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
318565

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 318565, 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

Secondary study design
Intervention development

Study setting(s)
GP practice, Hospital, Medical and other records

Study type(s)
Other

Participant information sheet
The project website has downloadable pdf copies of the information leaflets and an information video: https://www.bristolbrc.nihr.ac.uk/research/research-projects/my-knee-plan/

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 measure
Care plan components determined using qualitative interviews and questionnaires with patients and health professionals between April 2023 and November 2024

Secondary outcome measures
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

Overall study start date
01/02/2023

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)
Patient, Health professional, Service user

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
140

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
England

United Kingdom

Wales

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol

United Kingdom
BS10 5NB

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

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

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Level 3, Learning & Research Building
Southmead Hospital
Bristol
England
United Kingdom
BS10 5NB
+44 (0)117 414 9330
ResearchSponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/

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

Publication and dissemination plan
The main output from this research will be a robustly developed care plan for patients undergoing TKR, ready for evaluation within a randomised controlled trial.

This research will be published as open-access peer-reviewed articles, a project final report, and summaries of findings for stakeholders and patient participants. Materials will be developed by the co-production group to ensure the results reach a wide audience of stakeholders using accessible methods. Traditional academic publications will include a manuscript describing the qualitative study in detail and a second manuscript describing the Delphi study and intervention development process. A third manuscript describing PPI within the project will be co-written with one or more members of the patient panel, if they are interested in being involved.

Patient and public dissemination materials will be co-produced with patient members of the co-production group and through community involvement activities to ensure that materials are appropriate and relevant and published in places where patients want to access them.
Patient members of the co-production panel will be invited to be involved in writing up the main study findings, e.g. the PPI sections.

The research will be drawn together into a grant application to NIHR with the aim of evaluating the effectiveness and cost-effectiveness of the finalised care plan in a randomised controlled trial.

Intention to publish date
31/12/2025

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
Stored in publicly available repository, Available on request