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Occupational support for patients undergoing hip or knee replacement

Submission date
30/01/2023

Recruitment status
Recruiting

Registration date
09/02/2023

Overall study status
Ongoing

Last Edited
09/09/2025

Condition category
Musculoskeletal Diseases

[X] 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
Hip and knee joint replacements relieve pain and improve function in patients with arthritis. One in four patients are in work at the time of their hip or knee replacement surgery, equivalent to 50,000 people in the UK each year. Many patients get back to work after surgery, however, the time this takes varies considerably. A lengthy recovery time can affect patients' physical and mental wellbeing. Patients receive little or no return-to-work support from their hospital or GP specific to their individual needs and work situation. As part of an earlier research study we developed an 'occupational' (back-to- work) programme (known as OPAL) that supports return-to-work after surgery. We now need to assess whether this is effective in supporting a timely, safe and sustained return-to-work.

The OPAL occupational support programme provides personalised, targeted support for people in a range of jobs. As part of the programme, patients receive a variety of resources to help them plan their return-to-work. This includes access to a trained co-ordinator who helps and supports them before and after surgery. We will compare the OPAL occupational support programme against standard care.

Who can participate?
All adults listed for elective primary hip or knee replacement from a minimum of 14 UK hospitals, who are in paid or unpaid work, will be invited to take part.

What does the study involve?
Consenting participants will be randomly assigned (using a computer) to receive either the OPAL programme or standard care. We aim to recruit 742 participants over 15 months. We will ask participants to complete questionnaires for 12 months following surgery in relation to when and how they return to work, and their normal activities. From these, we will understand if the OPAL programme helps to reduce the length of time until full, sustained return-to-work. We will find out if the cost of care differs between the two groups, to determine whether one is better value for money for the NHS.

What are the possible benefits and risks of participating?
Individual participants may not benefit directly from this research. Those in the intervention

group have access to a) a website which support key aspects of returning to work, and b) a return-to-work coordinator (RTWC) who provides 1:1 support and helps the participant understand and interact with the information and guidance provided.This approach provides greater support than a typical standard care approach of sign-posting.

For participants in the standard care group, although there is no direct benefit, they are participating in research that could help to update the current approach to benefit future patients.

Where is the study run from?
South Tees Hospitals NHS Foundation Trust (UK)

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

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Lucy Sheehan, lucy.sheehan@york.ac.uk

Study website
https://www.opalreturntowork.nhs.uk/

Contact information

Type(s)
Principal Investigator

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
320809

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55035, NIHR133880, IRAS 320809

Study information

Scientific Title
Occupational support for Patients undergoing Arthroplasty of the Lower limb trial (OPAL trial)

Acronym
OPAL

Study objectives
We aim to evaluate the OPAL occupational support programme to find out whether it assists patients to make a timely, safe and sustained return-to-work and normal activities after hip or knee joint replacement surgery.

The OPAL feasibility study is registered on ISRCTN at https://www.isrctn.com/ISRCTN27426982

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval 08/02/2023, West Midlands - Edgbaston Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 2071048070; edgbaston.rec@hra.nhs.uk), ref: 23/WM/0013

Study design
Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital, Internet/virtual, Telephone

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Occupational support for patients undergoing arthroplasty of the lower limb

Interventions
The OPAL trial is a two-arm multi-centre, randomised, superiority trial with parallel groups. Patients will be allocated to a) the OPAL support intervention or b) standard care. There will be a 6-month internal pilot, and embedded economic and process evaluations. The trial will assess the effect on time to full, sustained RTW of the OPAL occupational support intervention versus standard care in 742 people undergoing elective primary hip and knee replacement in the UK. The risk of group contamination is low due to the experimental intervention being tailored to participants and being delivered when patients are physically separated.

Allocation will be on a 1:1 ratio (intervention : control). Randomisation will be carried out using a secure web-based randomisation system (REDCap) ensuring allocation concealment and stratified by site with randomly permuted blocks of randomly varying size. Stratification by surgical site (hip or knee joint) will be included within the randomisation process.
The randomisation service will require the recording of information and a check of patient eligibility to avoid inappropriate entry of patients into the trial. This will be conducted by local site teams including clinicians and research nurses. The randomisation system will provide an immediate allocation and a confirmation email. The email confirming randomised allocation will be sent to the PI and all authorised users of the randomisation system at the recruiting site. The local site team/treating clinician will inform the participant of their group allocation.

For the Process evaluation and to address important issues of fidelity and acceptability of the intervention, we will undertake the following:
- Qualitative observations of the RTWC during an initial appointment with a sample of participants pre-surgery (n=15-20) to understand how the intervention is implemented in practice.
- Qualitative interviews with trial participants from the intervention arm (n=15-20). Participants will be purposively sampled to ensure maximum variation (on the basis of age, gender, job role and site) to ascertain the acceptability of the interventions, ease of use and perceived impact of the intervention.
- Interviews with a sample of trial participants' employers (n=5) will be conducted to understand key stakeholder perspectives.
- Interviews with RTWCs (n=14) will be conducted on two occasions. At the start of the study brief interviews will be conducted regarding reasons for applying for the position, expectations

for the post/intervention, anticipated barriers and facilitators to using the intervention. At the end of the intervention period, RTWCs will be asked about their experience of delivering the service, interfacing with other service providers and to highlight challenges/facilitators associated with service delivery.
- Interviews with service leaders/key stakeholders (n=15-20) including clinicians, and commissioners will be conducted at two time points: during project set up to discuss current provision, how the new intervention will fit within existing services and how this will be funded; and at end of trial to discuss incorporating trial findings into service development.

Intervention Type
Behavioural

Primary outcome measure
Time until 'full' sustained return to any work, defined as work resumption to the same hours as prior to joint replacement, in any role, without any day of sick leave for a consecutive 4-week period. This is measured monthly via questionnaire.

Secondary outcome measures
1. Time to any return to work, measured monthly via questionnaire.
2. Measures of functional recovery to daily activities and social participation using the following:
2.1. Oxford hip/knee score (OKS/OHS) - at baseline, 3, 6, 9, and 12 months.
2.2. Lower extremity functional scale (LEFS) - at baseline, 3, 6, 9, and 12 months.
2.3. PROMIS social participation short form questionnaires (social roles and activities questionnaire, satisfaction with participation in social roles questionnaires) - at baseline, 3, 6, 9, and 12 months.
3. Number of 'sick days' between surgery and 'full' sustained return to work - measured monthly via questionnaire.
4. Participant adherence to the intervention and the intervention's physical rehabilitation programme - self-reported Likert scales upon achieving the primary outcome.
5. Proportion of participants using workplace interventions, adaptions and modifications to facilitate their RTW measured by questionnaire upon achieving the primary outcome.
6. Health-related quality of life measured via EQ-5D-5L at baseline, 3, 6, 9, and 12 months.
7. Work Productivity measured via Work Limitations Questionnaire at baseline, 3, 6, 9, and 12 months.

Overall study start date
01/06/2022

Completion date
30/09/2026

Eligibility

Key inclusion criteria
Adults (>=16 years) listed for elective primary hip or knee replacement in paid or unpaid work who intend to RTW after surgery.

Participant type(s)
Patient

Age group

Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 742; UK Sample Size: 742

Key exclusion criteria
1. Patients undergoing emergency arthroplasty (e.g. for trauma).
2. Adults listed for elective ankle replacement.
3. Adults planned to undergo further surgery within the 6 months after their joint replacement.

Added 07/06/2024:
4. Patients listed for bilateral knee replacements.

Date of first enrolment
19/04/2023

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland

United Kingdom
SR4 7TP

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Freeman Road Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Norwich
Norfolk & Norwich University Hosp'
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
James Paget University Hospital
Lowestoft Road
Gorleston
Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough

United Kingdom
TS4 3BW

Study participating centre
North Tyneside General Hospital
Rake lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
University Hospital of Hartlepool
Holdforth Road
Hartlepool
United Kingdom
TS24 9AH

Study participating centre
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore
United Kingdom
HA7 4LP

Study participating centre
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre

John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
NHS Lanarkshire
14 Beckford Street
Hamilton
United Kingdom
ML3 0TA

Study participating centre
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
Guys Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Dewi Sant Hospital
Albert Road

Pontypridd
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CF37 1LB

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

Sponsor details
James Cook University Hospital
Marton Road
Middlesbrough
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TS4 3BW
+44 7972086421
jane.greenaway@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://southtees.nhs.uk/

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/01/2026

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

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?
HRA research summary			28/06/2023	No	No
Protocol file	version 3.0	15/04/2024	10/06/2024	No	No
Protocol article		16/09/2024	26/09/2024	Yes	No