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# Occupational support for patients undergoing hip or knee replacement

**Submission date**
30/01/2023

**Recruitment status**
No longer recruiting

**Registration date**
09/02/2023

**Overall study status**
Ongoing

**Last Edited**
23/01/2026

**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 a 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 supports 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 January 2027

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

Who is the main contact?
Mrs Lesley Sinclair-Smith, lesley.sinclair@york.ac.uk

# Contact information

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Principal investigator

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# Additional identifiers

### Integrated Research Application System (IRAS)
320809

### Central Portfolio Management System (CPMS)
55035

### National Institute for Health and Care Research (NIHR)
133880

# 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 (0)2071048070; edgbaston.rec@hra.nhs.uk), ref: 23/WM/0013

### Primary study design
Interventional

### Study design
Interventional randomized controlled trial

### Study type(s)
Treatment

### 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(s)

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.

### Key secondary outcome(s)
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.

### Completion date
31/01/2027

## 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

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
16 Years

### Upper age limit
99 Years

### Sex
All

### Total final enrolment
0

### 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
United Kingdom

England

Scotland

Wales

### Study participating centre
**Royal Derby Hospital**
Uttoxeter Road
Derby
England
DE22 3NE

### Study participating centre
**Sunderland Royal Hospital**
Kayll Road
Sunderland
England
SR4 7TP

### Study participating centre
**Northern General Hospital**
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road

Sheffield
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S5 7AU

**Study participating centre**
**Freeman Road Hospital**
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

**Study participating centre**
**Norwich**
Norfolk & Norwich University Hosp'
Colney Lane
Colney
Norwich
England
NR4 7UY

**Study participating centre**
**James Paget University Hospital**
Lowestoft Road
Gorleston
Great Yarmouth
England
NR31 6LA

**Study participating centre**
**James Cook University Hospital**
Marton Road
Middlesbrough
England
TS4 3BW

**Study participating centre**
**North Tyneside General Hospital**
Rake lane

North Shields
England
NE29 8NH

**Study participating centre**
**University Hospital of Hartlepool**
Holdforth Road
Hartlepool
England
TS24 9AH

**Study participating centre**
**Royal National Orthopaedic Hospital**
Brockley Hill
Stanmore
England
HA7 4LP

**Study participating centre**
**St Helier Hospital**
Wrythe Lane
Carshalton
England
SM5 1AA

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

**Study participating centre**
**John Radcliffe Hospital**
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OX3 9DU

**Study participating centre**
**NHS Lothian**
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2-4 Waterloo Place
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EH1 3EG

**Study participating centre**
**NHS Lanarkshire**
14 Beckford Street
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ML3 0TA

**Study participating centre**
**Darlington Memorial Hospital**
Hollyhurst Road
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DL3 6HX

**Study participating centre**
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**Study participating centre**
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Albert Road
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# Sponsor information

**Organisation**

South Tees Hospitals NHS Foundation Trust

**ROR**
https://ror.org/02js17r36

# Funder(s)

**Funder type**
Government

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

# 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? |
|---|---|---|---|---|---|
| Protocol article | | 16/09/2024 | 26/09/2024 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Protocol file | version 3.0 | 15/04/2024 | 10/06/2024 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |