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Occupational advice for patients undergoing arthroplasty of the lower limb

Submission date
28/11/2016

Recruitment status
No longer recruiting

Registration date
20/12/2016

Overall study status
Completed

Last Edited
16/09/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Hip and knee arthritis causes pain which limits physical function and can affect ability to work. Hip and knee replacements are proven to relieve pain and improve function, and help many patients of working age to continue working or get back to work. Currently there is variation in the advice and support given about sickness absence, recovery to usual activities and return to work after these procedures. Earlier, sustainable, return to work improves the health of patients and benefits their employers and society. It is therefore important to better understand what is currently being done and how current care can be improved. In this study, information will be collected about the issues they face when returning to work after hip and knee replacement in order to develop an 'occupational advice intervention' which is tailored to their requirements, in the form of a manual that will provide support and advice to enhance their early recovery to usual activities, including work. The aim of this study is to investigate the feasibility of conducting a full scale trial evaluating whether an occupational advice programme delivered to working adults, starting before hip or knee joint replacement surgery, improves speed of recovery to usual activities including work.

Who can participate?
In the first part of the study, patients undergoing a hip or knee replacement who are aged 16 and over can take part. In the second part of the study, patients undergoing a hip or knee replacement who are aged 16 and over and are intending to return to work following surgery can take part.

What does the study involve?
This research has two separate parts and lasts for a total of 27 months. In the first part, information about work roles and return to work is collected from a variety of sources including surgeons, allied health professionals (AHPs), general practitioners (GPs), employers and patients using questionnaires and interviews. This runs during the first 13 months of the study. These interviews provide detailed information about the shortcomings and difficulties in current care and support available, and identify possible solutions and improvements to overcome them. Patients in the first part of the study are also asked to complete the initial questionnaire while in hospital and then follow up questionnaires 8 and 16 weeks after their operation. Some patients also receive a follow up questionnaire at 24 weeks. If patients also agree to take part in the

interview part of the study, their contact details are sent to researchers from the University of Nottingham. They then contact the patients to arrange an interview to discuss in greater detail about the work patients do, and what advice and support they received to help them return to work and their usual activities following their surgery. The interview lasts for around 30 minutes. In the second part of the study, information from the first part is used to develop the 'occupational advice intervention' manual to help patients return to usual activities including work and aim to test the acceptability, practicality and feasibility of this intervention. Patients in this part of the study are asked to complete the initial questionnaire while in hospital and then follow up questionnaires 8 and 16 weeks after their operation. These patients are also interviewed about the implementation of the 'occupational advice intervention' manual.

What are the possible benefits and risks of participating?
There may be no direct benefit to participants. However, the information we collect from the study will help us understand patients' experiences of the support and advice they receive and will identify improvements that might be made in the future. Participants will be helping to shape and improve advice for those patients hoping to return to work after hip or knee replacement in the future. There are no notable risks involved with participating.

Where is the study run from?
1. The James Cook University Hospital (UK)
2. Queen's Medical Centre (UK)
3. Nottingham City Hospital (UK)
4. Norfolk and Norwich University Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2016 to September 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Lucksy Kottam
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32609

Study information

Scientific Title
Occupational advice for Patients undergoing Arthroplasty of the Lower limb (OPAL). HTA Call: Occupational advice initiated prior to planned surgery for lower limb joint replacement.

Acronym
OPAL

Study objectives
The aim of this study is to investigate the feasibility of conducting a full scale trial evaluating whether an occupational advice intervention delivered to working adults, commencing prior to primary hip or knee joint replacement surgery, improves speed of recovery to usual activities including work.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Derby Research Ethics Committee, 18/08/2016, ref: 16/EM/0341

Study design
Non-randomised; Both; Design type: Education or Self-Management, Rehabilitation, Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

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
Specialty: Musculoskeletal disorders, Primary sub-specialty: Other; UKCRC code/ Disease: Musculoskeletal/ Other disorders of the musculoskeletal system and connective tissue

Interventions
Phase 1
Cohort study 1: A minimum of 150 patients undergoing hip or knee replacement who are currently working will be recruited overall from the study centres. Patients will be asked to complete questionnaires at baseline (peri-operatively), at 8 and 16 weeks post operatively which will collect information about their pre-surgical activity, work roles, absenteeism and work place disability. The first 45 patients recruited will also have an additional questionnaire follow-up at 24 weeks after surgery. Individual qualitative interviews will be undertaken in up to 45 patients who intend to 'return to work' and 9 patients who 'do not intend to return to work' performed at 16 weeks post-surgery.
Additionally, interviews with surgeons, allied health professionals (AHPs), general practitioners (GPs) and employers will be undertaken.

Phase 2
A modified 3-round Delphi consensus process will include representatives from all stake holders (patients, surgeons, allied health professionals (AHPs), general practitioners (GPs) and employers) to agree the content of the final intervention.

Cohort study 2: A minimum of 30 patients undergoing hip or knee replacement who are currently working will be recruited to test the occupational advice intervention developed. Patients will be asked to complete questionnaires at baseline (peri-operatively), at 8 and 16 weeks post operatively which will collect information about their pre-surgical activity, work roles, absenteeism and work place disability, this will be supplemented by the selected 'return to work' outcome measure/s defined during the consensus process (If not already collected). Individual qualitative interviews will be undertaken in up to 5 patients at 16 weeks post-surgery. This information will be supplemented by 4 stakeholder interviews (sampling from employers, health professionals, GPs, orthopaedic surgeons etc.). These interviews will collect information about the acceptability and utility of the final intervention.

Intervention Type
Other

Primary outcome measure
Return to work rate is assessed at 16 weeks

Secondary outcome measures
Following outcomes are measured at baseline, 8 and 16 weeks. Also measured at 24 weeks for first 45 patients.
1. Functional status:
1.1. Joint function, measured using the Oxford hip / knee score
1.2. Health utility, measured using the EQ5D-5L
1.3. Workplace disability and participation, measured using the Workplace limitations

Questionnaire (WLQ), Elements of the Workplace design questionnaire (WDQ), PHQ - 9 (Patient health questionnaire), Brief resilience scale (BRS) and GAD-2 (Generalised anxiety disorder scale - 2)
2. Occupational information
3. Use of fit notes
4. Healthcare utilisation and adherence with rehabilitation programmes
5. Details of interactions with occupational health practitioners / departments
6. Details of occupational advice received
7. Return to driving following surgery

Overall study start date
01/07/2016

Completion date
30/09/2018

Eligibility

Key inclusion criteria
Phase 1:
1. Age 16 years and above
2. Patients undergoing primary hip or knee replacement
3. In work within 6 months prior to joint replacement (including Full time, Part time, Paid & unpaid job roles)

Phase 2
1. Inclusion criteria as listed for Phase 1
2. Patients intending to return to work following surgery

Stakeholder interviews/focus groups (phase 1 & 2) or Delphi consensus process (phase 2) will include some patients (as above), AHP, GPs, Orthopaedic surgeons and Employer representatives. Orthopaedic surgeons, AHPs , GPs and employers would have to be involved directly in the care of patients undergoing hip and knee replacement procedures in the preceding 12 months. Orthopaedic consultants undertaking a minimum of 20 Total Hip or Knee Replacement operations per year will be eligible as this threshold will encompass surgeons with a specific interest in hip and knee replacements that are more likely to have experience of patients that return to work following surgery. AHPs involved in the current care pathways at each centre will be recruited. GPs with experience of treating patients undergoing either hip and knee replacements in the previous twelve months will be eligible.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 310; UK Sample Size: 310

Key exclusion criteria
Phase 1 & 2:
1. Lack of mental capacity to understand and participate in the cohort study
2. Patients who do not understand written and spoken English
3. Emergency surgical procedure e.g. Surgery for an indication of trauma
4. Surgery for cancer
5. Surgery for infection

Date of first enrolment
01/11/2016

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The James Cook University Hospital
South Tees Hospitals NHS Foundation Trust
Marton Road
Middlesbrough
Cleveland
United Kingdom
TS4 3BW

Study participating centre
Queen's Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
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NR4 7UY

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

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TS4 3BW
+44 (0)1642 854089
researchdevelopment@stees.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

Publication and dissemination plan
1. Planned submission of the main report of findings to the British Medical Journal. There will be other articles to publish such as the rapid review which will be submitted to relevant academic journals to ensure maximum exposure to relevant groups.
2. Planned presentation at relevant conferences of (e.g. British Orthopaedic Association (BOA) Annual Congress, Physiotherapy UK conference, College of Occupational Therapists' Annual Conference; Society for Research in Rehabilitation) and provision of a summary report to be circulated through networks such as that provided by BOA, the National Physiotherapy Research Network and the College of Occupational Therapists. Wider dissemination to other health professionals such as general practitioners as well as employers through organisations such as EEF and CBI will also be facilitated.
3. The study team will work with the patient representatives to produce a short lay report which will be fed back directly to the study participants and wider patient community via the National Joint Registry and BOA patient groups
4. Publication of the findings will be press released through the collaborating NHS organisations, employers, occupational health service organisations and universities and the potential for short articles in the relevant lay media will be explored

Intention to publish date
30/09/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made 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?
Protocol article	protocol	28/06/2018		Yes	No
Results article	delphi study results	06/07/2020	09/07/2020	Yes	No
Results article	results	01/09/2020	16/09/2020	Yes	No
HRA research summary			28/06/2023	No	No