ISRCTN38381590 https://doi.org/10.1186/ISRCTN38381590

A pilot randomised controlled trial of occupational therapy to optimise recovery for patients undergoing primary total hip replacement for osteoarthritis

Submission date
06/02/2012

Recruitment status
No longer recruiting

Registration date
06/02/2012

Overall study status
Completed

Last Edited
28/07/2015

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11294

Study information

Scientific Title
A pilot randomised controlled trial of occupational therapy to optimise recovery for patients undergoing primary total hip replacement for osteoarthritis

Acronym
PROOF THR

Study objectives
Occupational therapy will optimise recovery for patients undergoing primary total hip replacement for osteoarthritis

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 22/06/2011, ref: 77739

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Musculoskeletal, All Diseases

Interventions
A multi centre pilot RCT of a pre-surgery home based occupational intervention versus hospital based usual care. Sixty participants awaiting primary elective unilateral total hip replacement (THR) due to osteoarthritis, with no history of previous joint replacement, will be randomised centrally following baseline assessment by a computer generated block randomisation

algorithm. The intervention group will receive a pre-surgery home visit by an occupational therapist (n=30) who will discuss expectations and anxieties, assess home safety, provide adaptive devices and education depending on identified needs. The control group will receive treatment as usual (TAU) (n=30). Randomisation will be stratified by surgery site and age (above or below 65 years). The outcome assessor will be blinded to group allocation.

Pre-surgery Occupational Therapy (OT)
Patients randomised to this arm of the study will be visited by an OT prior to surgery who will assess the individual needs of each participant and their home circumstances. The OT will deliver all the adaptive devices required by the participant and educate them in how they should be used. In addition, the OT will discuss the patients expectations, discuss any anxieties the person (or carer) may have, give explanations about the surgery, hospital stay and post operative rehabilitation as an I

Followed up at 6 months

As of 07/02/2012, this ISRCTN record has been updated to include description: 30 participants will be in the control group receiving routine NHS care (treatment as usual group). 30 participants will receive the bespoke OT intervention in their own homes prior to admission for THR surgery

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Assess the feasibility of a full scale RCT measured at the end of study with respect to:
1. Recruitment procedures measured by identification and response rates, recruitment rates and establishment of site specific procedures
2. Appropriateness, responsiveness and acceptability of outcome measures measured by analysis of any missing data and completion rates
3. Fidelity of the intervention assessed by dropout rates, content of the intervention using an intervention log and acceptability of randomisation into the intervention/control.

Secondary outcome measures
1. Pain
2. Functional activity
3. Societal participation
Measured at 4, 12 and 26 weeks and physical activity levels at 12 weeks (using accelerometry).

4. Record resource use
5. Adverse events
6. Clinical effect size
7. Directionality of the outcome measure questionnaires
Measured at the end of study

8. Health resource usage measured at 26 weeks
9. Pain
10. Functional activity

11. Societal participation
The above outcomes will be measured using patient administered questionaires at 4, 12 and 26 weeks

12. Physical activity using accelerometery will be measured at 12 weeks

Overall study start date
01/02/2012

Completion date
31/01/2013

Eligibility

Key inclusion criteria
1. Patients accepted for surgery for primary THR following review in orthopaedic clinic
2. No previous lower limb joint replacement surgery
3. Osteoarthritis as the primary indication for surgery
4. No planned additional lower limb joint replacement surgery within 12 months
5. Unilateral surgery
6. Male & female participants
7. Lower Age Limit 55 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 60. UK Sample Size: 60.

Key exclusion criteria
1. Patients with inflammatory arthritis
2. Patients whose existing comorbidities prevent them from participating in the proposed treatment intervention (such as stroke or amputation)
3. Patients who are unable to provide informed consent

Date of first enrolment
01/02/2012

Date of final enrolment
31/01/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Department of Primary Care & General Practice
Primary Care Clinical Sciences Building
School of Health and Population Sciences
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
Hospital/treatment centre

Website
http://www.birmingham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Programme Grants for Applied Research (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2016		Yes	No