

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	<input type="checkbox"/> Prospectively registered
Registration date 06/02/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/07/2015	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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 questionnaires at 4, 12 and 26 weeks

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

University of Birmingham

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University of Birmingham (UK)

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Government

Funder Name

NIHR Programme Grants for Applied Research (UK)

Results and Publications

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