

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

<b>Submission date</b> 06/02/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/02/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/07/2015	<b>Condition category</b> 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

### Contact name

Prof Catherine Sackley

### Contact details

Primary Care Clinical Sciences  
School of Health and Population Sciences  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TT

-

c.m.sackley@bham.ac.uk

## 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 questionnaires at 4, 12 and 26 weeks

12. Physical activity using accelerometry 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?
<a href="#">Results article</a>	results	01/02/2016		Yes	No