# Optimising patient function following elective Total Hip Replacement (THR) surgery

Submission date Recruitment status [ ] Prospectively registered 21/02/2011 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 13/05/2011 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 04/05/2016 Musculoskeletal Diseases

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** 09/WNo01/52

# Study information

#### Scientific Title

The effect of resisted muscle strengthening exercises on patient function following elective Total Hip Replacement (THR) surgery: a prospective, single blind, randomised, controlled trial

### Acronym

THR Exercise Study

### **Study objectives**

A home based, largely unsupervised resistance training programme after total hip replacement surgery improves patient function relative to standard physiotherapy

### Ethics approval required

Old ethics approval format

# Ethics approval(s)

North West Wales Research Ethics committee, 14/01/2010

### Study design

Prospective single-blind randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

# 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

Rehabilitation after total hip replacement

#### **Interventions**

- 1. Patients will be randomised to either be in the control group (standard rehabilitation regime) or the intervention group
- 2. All patients in either group will have assessments pre-operatively and post operatively at 6 weeks, 3 months, 6 months and 1 year
- 3. The control group will receive routine inpatient and outpatient physiotherapy with the appropriate standard information leaflets provided
- 4. The intervention group will be shown the training exercises in the pre-assessment clinic and given information sheets
- 5. On post-operative day 2 (allowing for complications), these exercises will again be shown to them by an experienced physiotherapist

- 6. On discharge home, they will be seen by a qualified physiotherapist and the program will be adapted to their home environment
- 7. They will then be reviewed on a weekly basis for 6 weeks where the exercises shall be reviewed and resistance increased

### Intervention Type

Behavioural

### Primary outcome measure

- 1. Objective measures of physical function (related to activities of daily living):
- 1.1. Timed up and go test
- 1.2. Six minute walk test
- 1.3. Gait speed, stair climbing performance, and sit to stand score
- 1.4. Maximal voluntary contraction of quadriceps muscle and hip abductors

The outcomes will be measured pre-operatively and post-operatively at 6 weeks, 6 months and 1 year

### Secondary outcome measures

- 1. Subjective measures of physical function (Oxford Hip Score (OHS) and Western Ontario and McMasters University Osteoarthitis Personal Function (WOMAC PF) subscale
- 2. Short questionnaire to assess health enhancing physical activity (SQUASH)
- 3. EuroQoL Quality of life index
- 4. Objective assessment of physical activity (pedometers for 3 days to assess activity preoperatively and during the intervention) as well as clinical assessment
- 5. Recovery locus of control questionnaire, theory of planned behaviour questionnaire, modified zung depression index and modified somatic perception questionnaire will be used to assess motivation to exercise, mood, and perceptions in the recruited population

  The outcomes will be measured pre-operatively and post-operatively at 6 weeks, 6 months and 1

year

### Overall study start date

01/03/2010

### Completion date

31/03/2012

# Eligibility

# Key inclusion criteria

- 1. Patients undergoing primary total hip arthroplasty via a posterior approach which can either be cemented or uncemented
- 2. The joint affected should be the only severely arthritic joint, with no evidence of inflammatory arthropathy
- 3. Patient agreement to inclusion is also necessary

# Participant type(s)

Patient

### Age group

Adult

#### Sex

Both

# Target number of participants

50

# Key exclusion criteria

- 1. Dementia, or neurological impairment
- 2. Presence of cancer or muscle wasting illness, severe musculoskeletal impairment, unstable chronic or terminal illness, major depression, and co-morbid disease that contraindicates resistance training

### Date of first enrolment

01/03/2010

#### Date of final enrolment

31/03/2012

# Locations

#### Countries of recruitment

United Kingdom

Wales

Study participating centre Bangor University

Bangor United Kingdom LL57 2AS

# Sponsor information

### Organisation

Bangor University (UK)

### Sponsor details

c/o Professor Michael Rees School of Medical Sciences Brigantia Building Penrallt Road Bangor Bangor Wales United Kingdom LL57 2AS

### Sponsor type

University/education

#### **ROR**

https://ror.org/006jb1a24

# Funder(s)

# Funder type

Research organisation

### **Funder Name**

North Wales Research Committee (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	21/04/2016		Yes	No