

# SPiRAL study: Self-managing Pain In aRthritis and ArthroPlasty

<b>Submission date</b> 28/06/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/06/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/06/2014	<b>Condition category</b> Musculoskeletal Diseases	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
11270

# Study information

## Scientific Title

A feasibility randomised controlled trial of a pain self-management group for patients undergoing total hip replacement

## Acronym

SPIRAL

## Study objectives

This pilot randomised controlled trial will involve delivering a pain self-management course to patients undergoing total hip replacement (THR). The course will be delivered by Arthritis Care and will consist of two workshops while patients are on the waiting list for a THR and one workshop at 6-9 weeks post-operative. Eighty patients will be recruited into the study and randomised to the control or intervention arm and then followed-up by postal questionnaire for 6-months after surgery. The study will assess the feasibility of a full-scale randomised controlled trial in terms of recruitment rates, reasons for non-participation, attendance at the course, the suitability of outcome measures and assessment timings.

More details can be found at: <http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=11270>

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

South West 4 NRES Committee, ref: 11/SW/0056; First MREC approval date 03/06/2011

## Study design

Feasibility randomised controlled trial; Interventional; Design type: Treatment

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Osteoarthritis, hip replacement

## Interventions

Pain self-management course, The Challenging Pain course is a pain self-management course run by Arthritis Care. The course will be delivered to participants by lay trainers who have experience of living with chronic pain. The emphasis of the course is on pain management and introduces participants to a variety of cognitive pain management techniques, with the aim of providing coping skills to enable patients to manage their pain and its impact more effectively.

Follow Up Length: 6 months

Study Entry : Single Randomisation only

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Feasibility of a full scale randomised controlled trial; Timepoint(s): From recruitment to 6-months after surgery

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

20/06/2011

### **Completion date**

27/06/2012

## **Eligibility**

### **Key inclusion criteria**

1. Listed for a primary total hip replacement because of osteoarthritis
2. Target Gender: Male & Female ; Lower Age Limit 18 years

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

Planned Sample Size: 80; UK Sample Size: 80

### **Key exclusion criteria**

Listed for revision surgery  
Inability or unwillingness to provide informed consent

**Date of first enrolment**

20/06/2011

**Date of final enrolment**

27/06/2012

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Bristol Implant Research Centre**

Bristol

United Kingdom

BS10 5NB

## **Sponsor information**

**Organisation**

North Bristol NHS Trust (UK)

**Sponsor details**

Trust Headquarters

Beckspool Road

Frenchay

Bristol

England

United Kingdom

B16 1JE

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.nbt.nhs.uk/>

**ROR**

<https://ror.org/036x6gt55>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR (UK) - Programme Grants for Applied Research

# 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	20/05/2014		Yes	No