

SPiRAL study: Self-managing Pain In aRthritis and ArthropLasty

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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Bristol Implant Research Centre
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation

North Bristol NHS Trust (UK)

ROR

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

Funder(s)

Funder type

Government

Funder Name

NIHR (UK) - Programme Grants for Applied Research

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	20/05/2014		Yes	No