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SPIRAL study: Self-managing Pain In aRthritis and ArthropLasty

Submission date	Recruitment status	[ ] Prospectively registered
28/06/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/06/2013	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/06/2014	Musculoskeletal Diseases	

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

Primary study design
Interventional

Study design
Feasibility randomised controlled trial; Interventional; Design type: Treatment

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