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Inpatient versus outpatient treatment for the management of early osteoarthritis of the hip

Submission date
09/11/2015

Recruitment status
No longer recruiting

Registration date
10/11/2015

Overall study status
Completed

Last Edited
12/07/2018

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hip pain in adults has traditionally been attributed to osteoarthritis. However, developments in imaging and surgery have improved our understanding of hip problems that occur before the onset of arthritis. These pre-arthritic hip disorders can lead to changes that cause significant hip pain in young adults. The physical demands of military training expose the hip to extreme forces and stresses, and pre-arthritic hip pain is common amongst this young active population. This research aims to improve our understanding of the treatment and prevention of pre-arthritic hip pain in a young active population. This study will compare the effects of multidisciplinary team versus individual physiotherapist led treatment for the management of pre-arthritic hip pain with UK military patients.

Who can participate?
Male military personnel aged 18 to 50 with symptoms of hip pain.

What does the study involve?
Participants are randomly allocated to one of two groups: the inpatient or the outpatient group. Participants allocated to the inpatient group receive multidisciplinary inpatient rehabilitation over 7 days, with seven 30-60-minute therapy sessions including group exercise classes, group education sessions, individually tailored exercise programmes, and one-to-one physiotherapy. Participants allocated to the outpatient group attend seven one-to-one physiotherapy sessions spanning a period of 6 weeks.

What are the possible benefits and risks of participating?
There are no direct benefits to the participants. Furthermore, there are no potential hazards, risks or adverse effects of participating. Any potential risks arising from participation in rehabilitation will be experienced by patients regardless of their decisions to volunteer in the study.

Where is the study run from?
Defence Medical Rehabilitation Centre (UK)

When is the study starting and how long is it expected to run for?
October 2014 to October 2018

Who is funding the study?
Arthritis Research UK

Who is the main contact?
Dr James Bilzon

Contact information

Type(s)
Scientific

Contact name
Dr James Bilzon

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effects of a 7-day inpatient multidisciplinary intervention, versus outpatient physiotherapy, with 3-months follow-up on the physical and functional outcomes of UK military personnel with pre-arthritic hip pain: a parallel-group randomised controlled trial

Acronym
MILO

Study objectives
1. Null hypothesis: a 7-day multi-modal residential intervention will not result in significantly greater improvements in pain and physical function compared to individualised outpatient treatment in young adults with pre-arthritic hip pain

2. Research hypothesis: a 7-day multi-modal residential intervention will result in significantly greater improvements in pain and physical function compared to individualised outpatient treatment in young adults with pre-arthritic hip pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
UK Ministry of Defence (MOD) Research Ethics Committee, 01/08/2015, ref: 576/MODREC/14

Study design
Interventional parallel-group randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Pre-arthritic, intra-articular hip pain and femoroacetabular impingement (FAI)

Interventions
1. Residential group. Participants randomised to the MDT inpatient group will receive comprehensive multidisciplinary inpatient rehabilitation. The intervention duration is 7 days anchored by admission and discharge procedures at day 1 and day 7, respectively. Participants will typically complete seven therapy sessions each day of 30-60 mins duration over the remaining 5 days. Treatment sessions will include group exercise classes, group education sessions, individually tailored exercise programmes, and one-to-one physiotherapy.

2. Outpatient group. Participants randomised to the outpatient group will attend seven physiotherapy sessions spanning a period of 6 weeks. Each treatment will be administered on a one-to-one basis. The timing of the sessions will be twice in the first week and then weekly until week 6. The duration of session one will be 45-60 minutes to allow for a comprehensive objective assessment. All subsequent treatment sessions will be 30 minutes in duration. The treatment session duration reflects a realistic treatment dosage in clinical practice and has been shown sufficient to allow all components of treatment to be carried out. Delivering the intervention in this realistic setting is important to determine the likelihood of effectiveness of the intervention in everyday practice.

Intervention Type

Mixed

Primary outcome measure
1. The Copenhagen Hip and Groin Outcome Score (HAGOS)
2. The Non-arthritic Hip Scores (NAHS)
3. The Visual Analogue Pain Scale

All measures will be taken at baseline (pre-treatment), post treatment (1 week for MDT Group; 6 weeks for Outpatient Group), and 3 months.

Secondary outcome measures
1. The EuroQuol-5D (EQ-5D-3L)
2. The Hospital Anxiety and Depression Scale (HADS)
3. The 6-Minute Walk Test
4. The Modified Star-Excursion Balance (Y-Balance) Test
5. Hip Range of Motion (ROM)
6. The Sports Injury Rehabilitation Beliefs Survey (SIRBS)

All measures will be taken at baseline (pre-treatment), post treatment (1 week for MDT Group; 6 weeks for Outpatient Group), and 3 months.

Overall study start date
10/10/2014

Completion date
23/12/2019

Eligibility

Key inclusion criteria
100 male military participants aged 18 to 50 will be recruited from patients attending the centre for lower-limb rehabilitation outpatient injury assessment clinic (DMRC Headley Court), with symptoms of intra-articular hip pain.

The specific inclusion criteria are:
1. Anterior or lateral hip pain for at least 3 months
2. Clinical signs and symptoms of pre-arthritic intra-articular hip pathology/FAI diagnosed by a specialist Rehabilitation/Rheumatology/Sports and Exercise Medicine Consultant Physician
3. Physical examination findings or reproduction of pain in the groin or lateral hip with the log roll, anterior hip impingement test, or resisted straight leg-raise test (see figures 2, 3 and 4 below)
4. Sufficient time to keep therapeutic appointments
5. Aged ≥ 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Male

Target number of participants
100

Key exclusion criteria
1. Ipsilateral hip surgery
2. Inflammatory arthropathy
3. Hip infection or tumour
4. Hip fracture
5. Existing extra-articular hip disorders and/or any other pre-existing hip pathology
6. Major structural deformity of the hip
7. Advanced degenerative disease of the hip (Tönnis classification 2-3)
8. Any physical impairment or co-morbidities (including cardiovascular disease) precluding the safe participation in the rehabilitation programme and/or assessment procedures
9. History of congenital/adolescent hip disease
10. Corticosteroid or analgesic injection intervention for hip within the previous 30 days
11. Clinical signs of lumbar spine disease including radiculopathy
12. Aged ≥ 50 years
13. Insufficient capacity to provide informed consent

Date of first enrolment
10/01/2016

Date of final enrolment
01/06/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Defence Medical Rehabilitation Centre
Headley Court
Epsom
United Kingdom
KT18 6JW

Sponsor information

Organisation
Arthritis Research UK Centre for Sport, Exercise and Osteoarthritis (UK)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.sportsarthritisresearchuk.org/seoa/

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
01/05/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/11/2016		Yes	No