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A cycling and education programme in the treatment of hip osteoarthritis

Submission date
29/08/2019

Recruitment status
No longer recruiting

Registration date
21/10/2019

Overall study status
Completed

Last Edited
04/08/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Over 2 million people have hip osteoarthritis in the UK. Hip osteoarthritis can cause pain and interfere with many usual daily activities. The latest NICE guidance on the treatment of osteoarthritis recommends exercise, education and weight loss, if indicated. Cycling strengthens muscles around the hip and is an excellent form of low impact exercise. This study will compare the effectiveness of an eight-week static-cycling and educational programme with usual physiotherapy care for the treatment of hip osteoarthritis. Patients' ability to complete activities of daily living, pain levels, and quality of life will be compared and cost-effectiveness will be assessed.

Who can participate?
Patients aged and over with hip pain and/or with osteoarthritis of the hip who have been referred for physiotherapy

What does the study involve?
Participants undergo an assessment to ensure that they are suitable to take part. This assessment includes a review of participant medical history to make sure that they meet the standard GP exercise referral criteria, undertaken by a trained physiotherapist. The participants are also asked to complete an 18-minute fitness test as part of their assessment to ensure they are suitable to take part in the study. If suitable, participants are randomly allocated to either take part in a cycling/educational programme or receive usual physiotherapy care. Participants on the cycling/educational programme attend a one-hour session once a week for eight weeks at a local leisure centre. Participants in the usual care group receive usual physiotherapy care. As well as an assessment before the treatment, participants are also assessed once they have completed treatment. These assessments include measures of function, hip pain, quality of life, attitudes to managing hip osteoarthritis, relevant medications use and costs of care. After 6 months participants are asked to complete some of the same questionnaires from their previous assessments relating to their symptoms, pain, ability to perform daily tasks, quality of life and resource use. Both the standard physiotherapy treatment and the education and cycling programme follow National Institute for Health and Care Excellence (NICE) guidelines for the treatment of osteoarthritis of the hip, benefiting the participants in either group. The study uses the facilities of a local leisure centre for the cycling and education programme and participants

who have been allocated to take part in this programme are made aware that classes are held in a public environment. It is anticipated that cycling is no more likely to cause harm compared to usual physiotherapy care, but the cycling may increase tiredness so every opportunity is taken to make sure participants are comfortable and have the opportunity for rest breaks. The education session is run by a trained physiotherapist and the cycling sessions are run by qualified gym instructors. The content of cycling and education sessions has evolved through feedback from past users as well as being based on results from the feasibility study to ensure suitability for the participants.

What are the possible benefits and risks of participating?
Based on results from the feasibility study, participants may benefit from reduced pain, improved mobility and function and increased motivation to exercise after the education and cycling intervention. Whilst some participants may not benefit themselves from taking part in the study, it is hoped that the information obtained will contribute to advances in the treatment of these patients.

Where is the study run from?
University Hospitals Dorset NHS Foundation Trust (UHD) (UK)
(updated 18/10/2021, previously: Royal Bournemouth and Christchurch Hospitals Foundation Trust (RBCH) (UK))

When is the study starting and how long is it expected to run for?
April 2019 to March 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
1. Prof Thomas Wainwright (Chief Investigator)
twainwright@bournemouth.ac.uk
2. Tikki Immins (Trial Manager)
t.immins@nhs.net

Study website
https://www.uhd.nhs.uk/directory/name/28-services/bournemouth/1480-cycling-and-education-cleat

Contact information

Type(s)
Public

Contact name
Ms Tikki Immins

Contact details
University Hospitals Dorset NHS Foundation Trust
Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

+44 (0)1202 961941
t.immins@nhs.net

Type(s)
Scientific

Contact name
Prof Thomas Wainwright

ORCID ID
https://orcid.org/0000-0001-7860-2990

Contact details
Floor 6 Orthopaedic Research Institute
Executive Business Centre
Holdenhurst Road
Bournemouth
United Kingdom
BH8 8EB
+44 (0)1202 961656
twainwright@bournemouth.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ORTH1802; CPMS: 43333

Study information

Scientific Title
A pragmatic randomised controlled trial with economic evaluation to compare a cycling and education programme with usual physiotherapy care in the treatment of hip osteoarthritis: CycLing and EducATion (CLEAT)

Acronym
CLEAT

Study objectives
The aim of the study is to investigate the effectiveness and cost-effectiveness of a cycling and education intervention compared to usual physiotherapy care to manage symptoms of hip osteoarthritis in people 45 years and over.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/10/2019, South Central - Oxford C Research Ethics Committee, Level 3, Block B, Whitefriars Building, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8241; nrescommittee.southcentral-oxfordc@nhs.net), ref: 19/SC/0502

Study design
Single-centre pragmatic parallel-arm randomized 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 to request a patient information sheet.

Health condition(s) or problem(s) studied
Hip osteoarthritis

Interventions
The study will use block randomisation. Each programme in the study will have up to 30 participants randomised to the intervention: the education and cycling programme, or routine physiotherapy care, with a 1:1 allocation ratio. Randomisation will be performed for each programme using a web-based system. The randomisation process will be performed using an algorithm on the web-based system once up to 30 participants have agreed to take part and will be blinded to the assessors and trial manager. The randomisation allocation for each participant will not be revealed until participants have signed the consent forms and completed their baseline assessments. Screening ID, gender and date of birth data will be attached to each randomisation, to ensure the there is an audit trail to show that the correct participants have been randomised accordingly. Assessors undertaking assessments at 10 weeks will also be blinded to the randomisation, and participants will be educated to ensure that they do not inform the assessors of which treatment arm they participated in. The nature of the intervention means that participants and treatment providers will not be blinded. Ideally each programme will have 30 patients, 15 randomised to the education and cycling programme, and 15 to routine care. However, if there is a shortfall in recruitment to a programme, the programme can proceed with fewer patients so that patients do not have to wait longer. The number of participants must be even so that randomisation to each arm is equal.

Intervention:
For eight weeks following randomisation, participants will attend a one-hour education and

exercise session on a weekly basis at a local leisure centre. For the first thirty minutes, participants will take part in an education class, facilitated by a qualified physiotherapist. The education sessions will be standardised through video recordings and are based upon NICE guidelines, aiming to promote the effective on-going self-management of hip pain. The education classes also aim to motivate participants to exercise, reassure them that it is safe to do so, and facilitate positive lifestyle/activity change. At the end of the class, the physiotherapist will encourage group discussion so that participants can share their questions and experiences with the group.
The education session will be followed by a 30-minute indoor static cycling class (35 and 40 minutes for the last two sessions), facilitated by a gym instructor trained in leading indoor cycling classes at Littledown Leisure Centre. On the first week, participants will be shown how to set up their bike. The intensity of the exercise class will increase on a weekly basis, and will be clearly defined to ensure each cohort will be given the same programme. Each session will finish with a cool-down period which will include relevant stretches. Participants will be encouraged to work at a level that they are comfortable with and will be encouraged to increase their intensity progressively over the eight weeks.
After completion of the class, the participants will receive a video of the education class and of the static cycling session, via text or email, to encourage exercise and compliance to behaviour change advice at home. A home exercise programme comprising of various ankle, knee and hip stretches will also be provided to the participants and they will be encouraged to stretch regularly in their own time. Cycling between sessions will also be encouraged but will not be mandatory. To encourage participants to increase their exercise activities, an activity diary will be provided so that progress at home can be recorded and monitored for the duration of the intervention. Plans for lifestyle changes and ongoing participation in community-based activities will also be discussed.

Control:
Over eight weeks, participants in the control group will attend up to four sessions of physiotherapy (as per standard care) for a total of two hours. Treatment will be multimodal and include exercise, education, manual therapy and other physiotherapy techniques. Participants will receive a series of home exercises. The exact treatment received, and the duration and number of sessions delivered will be recorded from patient notes and the patients' home activity diary.
Physiotherapists giving routine care will be trained on the recording and appropriate capture of the intervention by trial investigators.

The duration of the intervention will be 8 weeks (weeks 2 – 9) and participants will be invited to a follow-up appointment at week 11 where repeats of the functional assessments, range of motion of hip, weight, heart rate and blood pressure will be performed and completion of trial-related questionnaires.
Final follow-up of participants will be 24 weeks after baseline assessment where participants will be asked to complete trial questionnaires remotely, i.e. via email, link in text message or post. Participants will not be seen by the research team during this final follow up appointment.

Intervention Type
Behavioural

Primary outcome measure
Self-reported function measured using the function, daily living component from the Hip Disability and Osteoarthritis Outcome Scale (HOOS) at baseline and at 10 weeks

Secondary outcome measures
1. Hip Disability and Osteoarthritis Outcome Score (HOOS) function measured as a score out of 100 after completion of the HOOS Questionnaire at baseline and 24 weeks (score at 10 weeks is primary outcome)
2. HOOS pain score after completion of the HOOS Questionnaire at baseline, 10 weeks and 24 weeks
3. HOOS symptoms score after completion of the HOOS Questionnaire at baseline, 10 weeks and 24 weeks
4. HOOS stiffness score after completion of the HOOS Questionnaire at baseline, 10 weeks and 24 weeks
5. HOOS sports and recreational activities score after completion of the HOOS Questionnaire at baseline, 10 weeks and 24 weeks
6. HOOS Quality of Life score after completion of the HOOS Questionnaire at baseline, 10 weeks and 24 weeks
7. Function assessed by 30-second chair stand test at baseline and 10 weeks
8. Function assessed by stair climb test at baseline and 10 weeks
9. Function assessed by 40-metre walk test at baseline and 10 weeks
10. Patient activation measured by responses to PAM Questionnaire at baseline, 10 weeks and 24 weeks
11. BMI, body composition, blood pressure and resting heart rate measured at baseline and 10 weeks
12. Analgesia use measured by Resource Use Questionnaire at baseline, 10 weeks and 24 weeks
13. Patient-perceived general health measured using EQ-5D Visual Analogue Score (VAS) at baseline, 10 weeks and 24 weeks
14. Patient-perceived quality of life measured by EQ-5D-5L Questionnaire at baseline, 10 weeks and 24 weeks, used to derive Quality Adjusted Life Years (QALYs)
15. Self-reported resource use measured by responses to the Resource Use Questionnaire at baseline, 10 weeks and 24 weeks

Overall study start date
01/04/2019

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 08/11/2022:

1. Diagnosed with osteoarthritis of the hip as per OARSI criteria
2. Male and female, aged 18 years and over. If under 45, an x-ray confirming diagnosis of osteoarthritis is required.
3. Meeting the GP criteria for exercise referral (British Heart Foundation 2010)
4. Capable of giving informed consent
5. Willing to commit to the exercise intervention if randomised to the treatment arm.
6. Able to commit to the exercise intervention if randomised to the treatment arm as assessed by the physiotherapist after reviewing participant medical records at the baseline assessment
7. Be able to understand English as necessary to benefit from the intervention, in the investigators' opinion

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Previous inclusion criteria:

1. Diagnosed with osteoarthritis of the hip as per OARSI criteria
2. Male and female, aged 45 years and over
3. Meeting the GP criteria for exercise referral (British Heart Foundation 2010)
4. Capable of giving informed consent
5. Willing to commit to the exercise intervention if randomised to the treatment arm.
6. Able to commit to the exercise intervention if randomised to the treatment arm as assessed by the physiotherapist after reviewing participant medical records at the baseline assessment
7. Be able to understand English as necessary to benefit from the intervention, in the investigators' opinion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
256

Total final enrolment
221

Key exclusion criteria
Current exclusion criteria as of 08/11/2022:

1. Hip surgery within the last 6 months
2. On the waiting list for a hip replacement or planning back or lower limb surgery in the next 9 months
3. Current or past (within 3 months) intra-articular corticosteroid injection (or any other therapeutic injection) of the hip.
4. Due to the safety limitations of the static bikes used, participants need to be >=150cm tall and weight <=135kg.
5. Women who are pregnant and have not previously or are not currently exercising regularly to the equivalent of 30 minutes of static cycling per week
6. Judged by the investigator to have high levels of functional limitations which will prevent the participant from getting on and off the exercise bike

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Previous exclusion criteria:

1. Hip surgery within the last 6 months
2. On the waiting list for a hip replacement or planning back or lower limb surgery in the next 9 months
3. Current or past (within 3 months) oral or intra-articular corticosteroid use
4. Women who are pregnant and have not previously or are not currently exercising regularly to the equivalent of 30 minutes of static cycling per week
5. Judged by the investigator to have high levels of functional limitations which will prevent the participant from getting on and off the exercise bike

Date of first enrolment
29/01/2020

Date of final enrolment
28/04/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Bournemouth General Hospital
Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

Sponsor information

Organisation
University Hospitals Dorset NHS Foundation Trust

Sponsor details
Research & Development Department
Cornelia House
Poole Hospital
Churchfield Road
Poole
England
United Kingdom
BH15 2QP
+44 (0)300 019 8500
Researchsponsorship@uhd.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.uhd.nhs.uk/services/research-and-development

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The researchers plan on publishing the study protocol and the results of the study in peer-reviewed journals. They also plan on preparing abstracts for conference papers, press releases and will make a lay summary of the results available on the study website, when available.

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
The data recorded for each participant will be stored on a secured electronic data capturing system (database) via an online portal during the trial. Sharing of data within a repository once the trial has completed is yet to be finalised.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/05/2023	04/05/2023	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 1.0	08/09/2023	12/02/2024	No	No
Statistical Analysis Plan	Health Economics Analysis Plan version 1.0	02/10/2023	12/02/2024	No	No
Results article		31/07/2025	04/08/2025	Yes	No