

# A cycling and education programme in the treatment of hip osteoarthritis

<b>Submission date</b> 29/08/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/10/2019	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/08/2025	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> 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)

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### **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**

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**Type(s)**  
Scientific

**Contact name**  
Prof Thomas Wainwright

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## 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 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  $\geq 150$ cm tall and weight  $\leq 135$ kg.
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

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**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?
<a href="#">Protocol article</a>	version 1.0	03/05/2023	04/05/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Statistical Analysis Plan</a>		08/09/2023	12/02/2024	No	No
<a href="#">Statistical Analysis Plan</a>	Health Economics Analysis Plan version 1.0	02/10/2023	12/02/2024	No	No
<a href="#">Results article</a>		31/07/2025	04/08/2025	Yes	No