Clinical and cost-effectiveness of a cycling and education intervention versus usual physiotherapy care for the treatment of hip osteoarthritis in the UK (CLEAT): a pragmatic, randomised, controlled trial

Thomas W Wainwright, Tikki Immins, Sharon Docherty, Geoff Saunders, Annie Hawton, Elizabeth Goodwin, Tim Rees, Matthew Low, Jo Samways, Fran Webley, Nikki Howard, Paul H Lee, Robert G Middleton

Summary

Background Osteoarthritis of the hip is a leading cause of chronic disability. The cycling and education intervention (CLEAT) trial aimed to compare the clinical and cost-effectiveness of the cycling against hip pain (CHAIN) intervention, a group-based cycling and education programme, with usual physiotherapy care for patients with hip osteoarthritis referred for physiotherapy at a UK hospital.

Methods CLEAT was a pragmatic, single-centre, randomised controlled trial done in Bournemouth, UK. Patients older than 18 years with activity-related joint pain, either no morning stiffness or morning stiffness lasting no longer than 30 min, and who met the primary-care criteria for exercise referral were eligible to participate. Patients aged 18–45 years were only eligible to participate if an x-ray confirmed the presence of hip osteoarthritis. Participants were randomly assigned (1:1) to either the CHAIN intervention or usual physiotherapy care using random permuted blocks of sizes 2, 4, and 6. Participants in the CHAIN intervention group attended an 8-week group programme at a local leisure centre comprised of education and static cycling. Participants in the physiotherapy group had usual one-to-one care with a physiotherapist at the local hospital or by telephone, depending on usual care at the time of treatment. The primary outcome was the difference in Hip Disability and Osteoarthritis Outcome Score (HOOS) activities of daily living subscale at 10 weeks post-treatment (visit 4) between groups. The trial included a parallel economic evaluation from the primary perspective of the UK NHS and personal social services. All participants who provided data at visit 4 were included in the efficacy analysis, and data on safety and adverse events were collected between baseline and visit 4. People with lived experience of hip osteoarthritis were involved in the design and management of the study. This trial is registered with ISRCTN (ISRCTN19778222).

Findings Between Feb 24, 2020, and April 28, 2023, 221 participants were recruited to the study and randomly assigned to the CHAIN intervention (110 [50%]) or usual physiotherapy care (111 [50%]). 126 (57%) participants were female, 95 (43%) were male, 217 (98%) were White, and the mean age was 64·4 years (SD 9·5). Participants in the CHAIN group had greater improvements in mean HOOS activities of daily living subscale scores (from 60·8 [SD 19·2] at baseline to 73·5 [20·0] at 10 weeks) compared with participants in the usual physiotherapy care group (from 59·3 [19·6] to 65·4 [19·9]; adjusted mean difference 6·9 [95% CI 2·5–11·2]; p=0·0023). Although the primary outcome showed a statistically significant improvement for CHAIN over usual physiotherapy, the between-group difference of 6·9 HOOS points did not meet the pre-defined minimum clinically important difference of 7·4. CHAIN cost £4092 per quality-adjusted life year gained compared with usual physiotherapy care, below the £20 000 to £30 000 National Institute of Health and Care Excellence threshold for cost-effectiveness. There were no treatment-related serious adverse events.

Interpretation The CHAIN intervention showed superior outcomes compared with usual physiotherapy care, and the feasibility of delivering a low-cost, community-based intervention within the NHS was shown. However, longer-term benefits and broader generalisability warrant further investigation.

Funding The National Institute for Health and Care Research for Patient Benefit Programme.

Lancet Rheumatol 2025

Published Online
July 31, 2025
https://doi.org/10.1016/S2665-9913(25)00102-X

See Online/Comment
https://doi.org/10.1016/S2665-9913(25)00154-7

Physiotherapy Department, University Hospitals Dorset NHS Foundation Trust, Bournemouth, UK (Prof T W Wainwright PhD, T Immins MSc, M Low MSc, J Samways MA, Prof R G Middleton FRCS [Orth]); **Orthopaedic Research Institute, Bournemouth University, Bournemouth, UK** (Prof T W Wainwright, T Immins, Prof R G Middleton); **Bournemouth University, Bournemouth, UK** (S Docherty PhD, Prof T Rees PhD); **Southampton Clinical Trials Unit, University of Southampton & University Hospital Southampton NHS Foundation Trust, Southampton, UK** (G Saunders MSc, F Webley, P H Lee PhD); **University of Exeter, Exeter, UK** (A Hawton PhD, E Goodwin PhD); **Bournemouth, UK** (N Howard)

Correspondence to:
Prof Thomas W Wainwright, University Hospitals Dorset NHS Foundation Trust, Bournemouth BH7 7DW, UK
twainwright@bournemouth.ac.uk

Introduction

Osteoarthritis is a leading cause of disability in people over the age of 55 years worldwide. In the UK, 10 million people have osteoarthritis, with 3·2 million having hip osteoarthritis. Clinical guidelines for the management of hip osteoarthritis consistently recommend education, weight loss if applicable, and exercise as core treatments. However, current evidence does not allow for the recommendation of one type of exercise programme over another.[1]

Research in context

Evidence before this study

Although exercise and education are recommended in international guidelines for the management of hip osteoarthritis, the most effective modes of delivery remain unclear. When planning this trial in 2017, we searched PubMed and the Cochrane Central Register of Controlled Trials from database inception to Oct 1, 2017, using the terms "hip osteoarthritis" and "exercise" to identify randomised controlled trials and systematic reviews evaluating relevant interventions published in English. Combining the evidence up to 2017 with two key subsequent systematic reviews and meta-analyses in 2019 and 2023, it can be concluded that further research is needed to determine the most effective type of exercise for this population and to avoid the problematic generalisation of findings from trials on knee osteoarthritis. The 2025 PHOENIX trial, examining whether the addition of aerobic exercise to resistance exercise would help patients with hip osteoarthritis, showed no advantage of the combination over resistance exercise alone. Further to this, few trials have evaluated structured group interventions for hip osteoarthritis, and those that have evaluated group interventions in this population have relied on feasibility trials or observational cohort data. Similarly, the cycling against hip pain (CHAIN) intervention, a group-based education and static cycling programme for hip osteoarthritis, had shown promise in cohort studies. However, its effectiveness compared to usual physiotherapy care had not been tested in a randomised controlled trial and its cost-effectiveness had not been evaluated.

Added value of this study

This study adds to the limited number of trials evaluating exercise interventions for hip osteoarthritis and is among the few to directly compare a group-based intervention with one-to-one physiotherapy care in this population. A key strength is its pragmatic design that evaluated the intervention under conditions closely aligned with routine clinical practice. The trial assessed both clinical and economic outcomes. The CHAIN intervention resulted in a statistically significant improvement in patient-reported function after treatment compared to usual physiotherapy care. However, the clinical meaningfulness of this between-group difference remains uncertain. CHAIN was also cost-effective, with a cost per quality-adjusted life year far below the National Institute for Health and Care Excellence threshold, even under sensitivity analyses.

Implications of all the available evidence

CHAIN's cost-effectiveness within an NHS context positions it as a valuable alternative to usual physiotherapy care. These findings make an important contribution to the limited pool of high-quality randomised controlled trials in this area, where collectively, there remains insufficient evidence to recommend one type of exercise and education programme over another for hip osteoarthritis. Future research of the CHAIN intervention should explore strategies to sustain long-term adherence and assess the applicability of interventions in diverse settings and populations.

Individuals with hip osteoarthritis often have reduced cardiovascular fitness and chronic low-grade inflammation.[2] These factors have been linked to osteoarthritis symptoms in the knee[3] and have been found to be more effectively addressed through aerobic exercise than resistance training.[4] In hip osteoarthritis, exercise has small-to-moderate benefits for pain and function, and thus optimal clinical management remains uncertain.[5,6] To date, research on land-based interventions (as opposed to water-based interventions) have mainly focused on resistance or neuromuscular training, with a 2023 systematic review[6] reporting only three studies incorporating an aerobic component. Furthermore, a 2025 trial that added aerobic exercise to resistance exercise did not find improvements to pain or function when compared with resistance exercise alone.[7]

Further studies are needed on aerobic exercise in hip osteoarthritis. Cycling is an aerobic exercise that can improve cardiovascular fitness, balance, and proprioception, and can strengthen muscles in the upper leg.[8] In static cycling, people with mixed abilities can exercise together successfully.

The cycling against hip pain (CHAIN) intervention was developed as a group static cycling programme for patients with hip osteoarthritis, incorporating aerobic exercise and education. Preliminary research suggests that CHAIN reduces pain, improves function, and motivates people to manage their hip pain.[8] The present study investigates whether CHAIN is more clinically effective and cost effective than usual physiotherapy care for patients with hip osteoarthritis.

Methods

Study design

The cycling and education intervention versus usual physiotherapy care for the treatment of hip osteoarthritis study (CLEAT) was a single-centre, pragmatic, parallel-group, randomised controlled trial conducted and sponsored by University Hospitals Dorset NHS Foundation Trust in England. Study assessments were done at Bournemouth University, Poole, UK. The protocol for the study has been published.[8] The South Central—Oxford C Research Ethics Committee confirmed a favourable opinion for the trial on Oct 14, 2019 (19/SC/0502), and approval from the Health Research Authority was given on Nov 5, 2019. The trial is registered with the ISRCTN registry (ISRCTN19778222).

The design of the CLEAT trial was informed by previous quality improvement studies (that can be found

in the protocol[8]) of the CHAIN intervention, which were done to assess clinical outcomes and the feasibility of delivering the intervention. People with lived experience of hip osteoarthritis contributed to the study design and the choice of outcome measures,[9] and were part of an advisory group to advise on patient-facing documentation, study delivery, interpretation, and the write up and dissemination of findings to optimise the trial's accessibility and performance. The Clinical Trials Unit at the University of Southampton, Southampton, UK, provided oversight on the management of the study.

Participants

Participants were patients referred to a UK National Health Service (NHS) hospital outpatient physiotherapy department with osteoarthritis of the hip, as defined by National Institute for Health and Care Excellence (NICE) criteria.[1] These criteria state that osteoarthritis is diagnosed in patients aged 45 years and over with activity-related joint pain, and either no morning stiffness or morning stiffness lasting no longer than 30 mins. Initially, only patients aged 45 years and over were eligible for the study; however, in October, 2022 (16 months into recruitment), this criterion was amended to increase recruitment. The study was subsequently opened to patients aged 18 years and over; an x-ray confirming osteoarthritis was required to take part in the study if they were aged under 45 years in line with NICE guidance.[1] Sex (male, female, or other) and ethnicity data were self-reported by participants. Participants were also required to meet the primary care criteria for exercise referral.[10] They must also have been willing and able to commit to the exercise intervention if randomly assigned to the intervention group, as assessed by the physiotherapist after reviewing the participant's medical records, and have height and weight measurements that comply with the safety limitations of the static bike. Women who were pregnant and had not or were not currently exercising regularly to the equivalent of 30 min of static cycling per week were excluded from participation. Patients who had undergone hip surgery within the last 6 months or were on the waiting list for a hip replacement or planning back or lower limb surgery in the next 9 months were also excluded. Participants were also required to understand English to benefit from the intervention. Full details on eligibility criteria can be found in the protocol.[8] All participants provided written informed consent.

Randomisation and masking

At the end of baseline data collection, participants were randomly assigned to either the CHAIN intervention or usual physiotherapy care using an automated web-based system. Randomisation used random permuted blocks of sizes 2, 4, and 6 with a 1:1 allocation ratio, conducted by the trial manager, as the assessors were masked to group assignment. The automated web-based system enabled the allocation to be concealed from trial staff until this point. The nature of the treatment meant that participants and treatment providers could not be masked, and participants were advised to not reveal their allocation to the assessors during their post-treatment visit. Ideally, randomisation occurred when there was a group of 30 participants; however, the programme proceeded if fewer participants were available. The trial statisticians conducted data checks and preliminary analyses while masked to allocation, but due to the nature of the intervention and a need to know the cohort sizes, they were unmasked before undertaking the primary analysis. The health economists conducted the outcome and health-care resource use analyses masked to allocation. Estimates of total cost required the addition of intervention and control group costs, requiring the health economist to be unmasked at this point of the analysis.

Procedures

Once the physiotherapy department identified enough potential participants to create a cohort of up to 30 participants, trial cohorts took place approximately every 2–3 months. The chief investigator, a senior physiotherapist within the department, telephoned those identified to invite them to participate in the study, checked their eligibility with a brief questionnaire, and discussed the study details. If interested, participants were emailed (or posted) an invitation letter, information sheet, and consent form. 3–5-days later, they were followed up by the trial manager to see if they had any further questions, and an appointment to attend a baseline clinic was made. Further details on recruitment can be found in the trial protocol.[8]

At the baseline visit (visits 1 and 2), physiotherapists assessed participants' vital signs, and data was collected on their health-care resource use by other delegated members of the research team (visit 1). To confirm if participants met the primary care criteria for exercise referral, they undertook an exercise tolerance test (visit 2). Participants rode a static cycle for up to 18 min, with heart rate, blood pressure, and exertion rates tested at intervals. Those who met the contraindication criteria for exercise were excluded from the study.[8]

At the end of the baseline visit, participants were given a leaflet confirming their treatment group and the date, time, and location of their first treatment (visit 3). Treatment in either group took place within 2 weeks of randomisation. Participants were also booked to attend their post-treatment study visit (visit 4). Only physiotherapy sessions within the 8 weeks of visit 3 were classified as study visits. All data entered into the data collection system were monitored by the sponsor for accuracy, as per their standard operating procedures.

Outcome assessment was repeated post-treatment (visit 4) by masked physiotherapists, and research team members collected data on participants' vital signs and

health-care resource use. If participants could not return to the clinic, the visit was done remotely. 3 months after the post-treatment assessment, at visit 5, participants were sent questionnaires by post to complete and return. If the questionnaires were not returned within 2 weeks, the research team contacted the participants and either completed the questionnaires with the participants by telephone or encouraged them to complete and return the forms. Participants were contacted for a final time 2 weeks later if nothing had been received. Data on adverse events were collected between consent (visit 1) and visit 4. Only events that required a visit to a health-care professional were recorded.

Details of the treatment groups are outlined in the published protocol,[8] and further details on the CHAIN intervention are in the appendix (pp 37–38). Participants randomised to the CHAIN intervention group attended an 8-week group programme at a local leisure centre. Each week comprised a 30 min education session facilitated by an experienced physiotherapist, supported by a research team member who was available to take a register, check for any adverse events, and answer any administrative questions. The sessions were standardised through pre-recorded videos (appendix p 37) based on NICE guidelines for effective self-management of hip pain.[1] Participants were encouraged to ask questions and share their experiences with the group. The education session was followed by 30 min of static cycling (increased to 35 min and 40 min for the last 2 weeks), facilitated by a gym instructor qualified to lead static cycling classes for people with health conditions. Cycling intensity increased each week and participants rated their effort intensity, and each session finished with a cool-down period and stretching. The content and intensity for each week were defined to ensure standardisation over each cohort and allow for individualisation, helping to ensure that although participants were encouraged to increase their intensity levels over the 8 weeks, they worked to a level they found comfortable. After each session, participants were sent a message with pre-recorded videos of the education and static cycling classes at the intensity level for that week, and they were given a leaflet with ankle, knee, and hip stretches to do at home if they wished. The number of CHAIN sessions each participant attended was recorded to measure compliance with the intervention. If a participant missed a session, they were followed up by telephone and encouraged to return the following week. As part of the intervention, after the post-treatment study visit, participants and their general practitioner were sent a report showing their outcome measure scores.

See Online for appendix

Participants assigned to the usual physiotherapy group had usual one-to-one care delivered at the physiotherapy department at the local hospital or by telephone, depending on usual care at the time of treatment. As per routine NHS practice, participants had up to four physiotherapy sessions. Treatment was per usual care, pragmatic, and multimodal, and therefore included exercise, education, manual therapy, and other physiotherapy techniques. The physiotherapist recorded the time for each treatment given at a session and the intensity, if relevant. Participants were also given home exercises to complete as per usual physiotherapy care.

Outcomes

The primary outcome for the study was the difference in self-reported function of performing everyday activities at the post-treatment assessment (visit 4) between the CHAIN group and the usual physiotherapy care group, as measured by the Hip Disability and Osteoarthritis Outcome Score (HOOS) activities of daily living (ADL) subscale.[11] The ADL score is measured on a scale of 0 to 100 with a higher score indicating reduced symptoms.

Secondary outcomes were assessed pre-treatment at baseline (visits 1 and 2) and post-treatment (visit 4). They comprised BMI, body composition (% body fat), blood pressure, and resting heart rate; the remaining HOOS subscales (scored from 0 to 100 with higher score indicating reduced symptoms) measuring self-reported pain, symptoms and stiffness, function in sports and recreational activities, and quality of life; EuroQol 5-Level Descriptive System (EQ-5D-5L; assesses five dimensions of health-related quality of life, with higher scores indicating more severe problems); Patient Activation Measure (PAM; assesses participants' knowledge, skill, and confidence to manage their own health on a scale of 0–100, with higher scores showing higher patient activation); performance based functional measures as recommended by the Osteoarthritis Research Society International (OARSI; 40 m fast-paced walk test, 30 s chair stand test, and the stair climb test, where higher speed, more repetitions, and quicker time indicate better function, respectively); and a health-care resource use questionnaire, described under the health economic analysis section, which included a question on analgesic use.[8] Outcome measures are further described in the study protocol.[8]

To measure the longer-term effects of the intervention, 3 months after treatment completion, all participants completed the HOOS, EQ-5D-5L, and PAM measures again, along with the resource use questionnaire. Adverse events recorded from consent to post-treatment are also reported.

Health economic analysis

The economic endpoint was the cost per quality-adjusted life year (QALY) at 3 months post-treatment. The trial included a parallel economic evaluation from the primary perspective of the UK NHS and personal social services. The resources needed for the CHAIN intervention and usual physiotherapy care were identified and measured. This process involved the intervention developers, physiotherapists, participant

case report forms, and estimates from the therapists and research team.

Participants self-completed a resource use questionnaire at baseline (visits 1 and 2), 10-week follow-up (visit 4), and 3 months post-treatment (visit 5) on their use of NHS primary and secondary care resources, social care, analgesic medication, aids and adaptations, support from friends and family, time away from paid employment, and self-funded costs for care. The resource use questionnaire drew on measures used in similar populations in the Database of Instruments for Resource Use Management repository[12] and was refined through discussion with the patient advisory group.

Resource use was costed using nationally recognised sources, such as Unit Costs for Health and Social Care[13] and the National Schedule of NHS Costs.[14] In cases where national costs were not available, finance records and provider estimates were used. All costs were valued based on the value of UK pounds sterling in 2021–22 and the sources of all unit costs are reported in the appendix (pp 2–3).

QALYs were derived from health state values obtained using the EQ-5D-5L. Participant-level EQ-5D-5L data were collected at baseline (visits 1 and 2), 10-week follow-up (visit 4), and 3 months post-treatment (visit 5). Health state values were derived using the approach recommended by NICE at the time of analysis[15] (ie, mapping between EQ-5D-5L responses and the published UK health state value set for EQ-5D-3L, using an approved algorithm).[16]

Statistical analysis

The sample size was based on the primary outcome measure, the ADL subscale of the HOOS measured post-treatment (range 0–100) at visit 4. This score was compared between the two study groups using baseline primary outcome score as a covariate. A correlation of 0·6 between pre-exercise and post-exercise outcomes was derived from existing literature,[17–19] and reduced the sample size required by a factor of 0·64. The variance of the CHAIN intervention group was increased by a factor of 1·22, assuming a cluster size of 12 and intracluster correlation coefficient of 0·02·[20] To provide 90% power with a 5% two-sided significance test, an effect size of 7·4 (based on the average of minimum clinically important differences found previously in the literature)[21] and SD of 19·1[21–23] for the primary outcome, a sample size of 102 participants per group was required. Initially, an adjustment of 20% was made to allow for withdrawals and incomplete primary outcome data, increasing the sample size to 256 participants, 128 in each group. However, after the trial had been running for 18 months, the sample size was recalculated due to smaller cluster sizes, and reduced withdrawal and loss of primary outcome data. Assuming an average cluster size of 11 and a 10% adjustment for incomplete primary outcome data, a total sample size of 221 participants was required, with 199 requiring complete primary outcome data at visit 4.

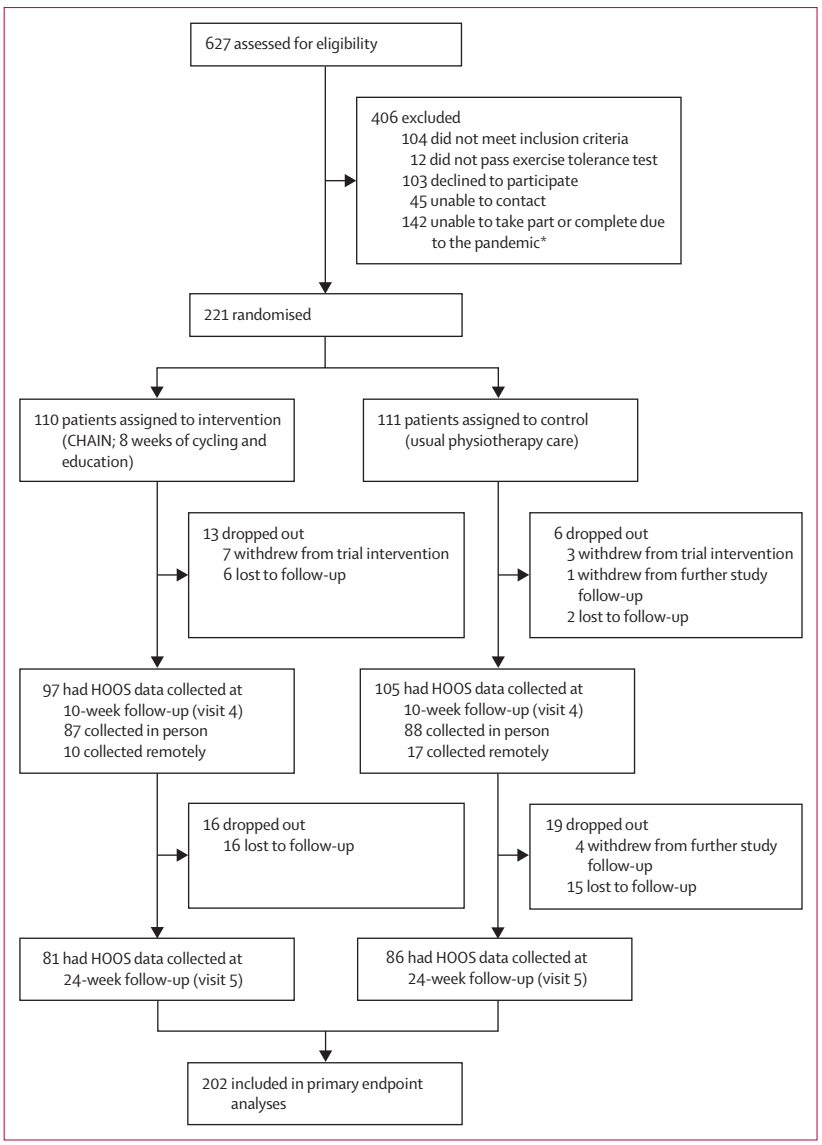

Figure 1: **Trial profile**
*Cohort 1 (n=23) were excluded from the main study population as they were unable to continue with treatment in March, 2020, due to the COVID-19 pandemic.

A statistical analysis plan was agreed upon and finalised prior to the final analysis and before cleaning and inspection of the data for outliers. Statistical analyses were conducted in Stata 17.0.

The primary analysis compared the ADL subscale for visit 4 only between trial groups using a multilevel linear mixed model with baseline ADL subscale as a covariate and cycling group (cluster) as a random intercept (using an independent residual variance-covariance structure). For the usual care group, each participant was assumed to be in their own group (or cluster) of one. The distribution of the residuals was assessed for normality. The model

	CHAIN (n=110)	Physiotherapy (n=111)
Age at inclusion, years	64·1 (9·5)	64·7 (9·6)
Sex		
Male	50 (45%)	45 (41%)
Female	60 (55%)	66 (59%)
Ethnicity		
White (British, Irish, other)	107 (97%)	110 (99%)
African	0	0
Caribbean	0	0
Arab	0	0
Indian	0	0
Pakistani	0	0
Bangladeshi	0	0
Chinese	0	0
Mixed or multiple ethnic groups	1 (1%)	0
Other ethnic group*	2 (2%)	1 (1%)
Education level		
Doctorate or higher degree	10 (9%)	7 (6%)
Degree or equivalent	36 (33%)	34 (31%)
A level or equivalent	20 (18%)	25 (23%)
O level, CSE, GCSE	36 (33%)	34 (31%)
Other qualifications	0	1 (1%)
None	8 (7%)	9 (8%)
Unknown	0	1 (1%)
Employment status		
Unable to work because of osteoarthritis	1 (1%)	0
Unable to work for reason other than osteoarthritis	2 (2%)	3 (3%)
Paid or unpaid work (part-time)	22 (20%)	13 (12%)
Paid or unpaid work (full-time)	29 (26%)	30 (27%)
Unemployed (currently not looking for work)	2 (2%)	4 (4%)
Unemployed (currently looking for work)	2 (2%)	0
Retired	52 (47%)	61 (55%)
Physiology		
BMI, kg/m²	28·8 (5·1)	28·2 (4·6)
Body fat composition, %†	32·2 (7·6)	32·8 (7·2)
Resting heart rate, bpm	71·5 (10·5)	73·9 (13·0)
Systolic blood pressure, mm Hg	145·6 (18·3)	146·7 (19·1)
Diastolic blood pressure, mm Hg	82·8 (7·9)	83·2 (8·2)
(Continued from previous page)		
Analgesia taken		
Yes	89 (81%)	83 (75%)
No	21 (19%)	28 (25%)
Comorbidities		
Musculoskeletal disease	103 (94%)	100 (90%)
Neurological disease	5 (5%)	11 (10%)
Cardiovascular disease†	46 (42%)	59 (53%)
Respiratory disease	21 (19%)	23 (21%)
Dermatological disease	16 (15%)	16 (14%)
Haematological disease	8 (7%)	6 (5%)
Endocrine disease	26 (24%)	26 (23%)
Hepatic disease	8 (7%)	2 (2%)
Gastrointestinal disease	22 (20%)	20 (18%)
Urogenital disease	14 (13%)	11 (10%)
Number of comorbidities		
0	1 (1%)	3 (3%)
1	28 (25%)	19 (17%)
2	35 (32%)	38 (34%)
3+	46 (42%)	51 (46%)
Baseline HOOS		
ADL	60·8 (19·2)	59·3 (19·6)
Pain	58·5 (17·1)	57·8 (16·8)
Symptom and stiffness	62·3 (18·5)	60·5 (18·8)
Sports and recreational activities	44·7 (21·5)	41·2 (23·6)
Quality of life	43·6 (21·5)	39·1 (19·7)
Baseline performance		
30 s chair stand, repetitions	10·6 (4·5)	9·8 (3·9)
Stair climb, s	13·3 (7·7)	14·1 (7·7)
40 min walk test, m/s	1·2 (0·3)	1·2 (0·3)

(Table 1 continues on next page)

Data are n (%), or mean (SD). ADL=activities of daily living. HOOS=Hip Disability and Osteoarthritis Outcome. *The three participants who identified as "other ethnic group" were South American, Persian, and Asian, and did not feel that they identified with the given categories. †Data missing for one person.

Table 1: **Baseline characteristics of the intention-to-treat population**

used all the observed data. A sensitivity analysis to assess the effect of the missing data was undertaken using multiple imputation (using the predictive mean matching method with 100 imputations, incorporating the outcome, treatment, and relevant auxiliary variables such as age, sex, BMI, comorbidities, and baseline mechanistic variables), as well as a per-protocol analysis where participants were excluded from the analysis if treatment adherence was poor (eg, attendance of less than seven cycling sessions or less than four physiotherapy sessions). The analysis of the secondary outcomes used the same approach as the primary outcome, adjusting each outcome for its baseline and adding a random intercept for cycling group, using multilevel linear mixed models for continuous outcomes and multilevel logistic mixed models for dichotomous outcomes. Where visits 4 and 5 were included in the model, a repeated measures model was used with random intercept effects for the patient and cycling group. The fixed effects of treatment group, time, and group-by-time interaction were also included. The primary and all secondary analyses were analysed on a modified intention-to-treat basis (ie, analysed as randomised, excluding participants missing the relevant outcome [complete case

	Visit 4				Visit 5		Treatment by visit interaction (95% CI)	p value
	CHAIN (n=97)	Physiotherapy (n=105)	Effect size (95% CI)*	p value	CHAIN (n=81)	Physiotherapy (n=86)		
Primary outcome (visit 4 only)								
HOOS ADL score	73·5 (20·0)	65·4 (19·9)	6·9 (2·5 to 11·2)	0·0023	..	..	..	..
Secondary HOOS outcomes (including visit 5 and treatment by visit interaction)								
HOOS ADL score	73·5 (20·0)	65·4 (19·9)	6·8 (2·3 to 11·3)	0·0032	67·8 (20·2)	63·5 (21·7), n=85	−3·6 (−8·6 to 1·5)	0·17
HOOS pain score	68·8 (18·4)	63·4 (18·1)	5·2 (0·0 to 10·5)	0·051	63·5 (18·2)	60·4 (20·5)	−2·9 (−8·0 to 2·1)	0·25
HOOS symptoms and stiffness score	71·1 (18·2)	64·5 (19·4), n=104	6·3 (1·7 to 10·8)	0·0072	61·5 (19·1)	59·8 (19·5)	−4·3 (−9·2 to 0·6)	0·088
HOOS sports score	57·5 (26·2)	48·3 (23·5), n=104	6·6 (1·0 to 12·2)	0·022	52·1 (25·2)	49·8 (25·4), n=84	−5·9 (−12·2 to 0·4)	0·065
HOOS quality of life score	56·0 (21·9)	47·9 (22·4), n=104	5·8 (0·2 to 11·4)	0·042	50·5 (21·5)	44·7 (22·8)	−2·9 (−8·6 to 2·9)	0·32
Other secondary outcomes								
Performance outcomes (visit 4 only)								
30 s chair stand	13·0 (5·3), n=87	11·9 (4·0), n=88	0·3 (−0·7 to 1·3)	0·55	..	..	..	..
Stair climb test	11·5 (7·5), n=86	11·6 (4·8), n=88	0·4 (−1·3 to 2·2)	0·61	..	..	..	..
40 min walk speed, m/s	1·3 (0·3), n=87	1·3 (0·3), n=88	0·02 (0 to 0·1)	0·36	..	..	..	..
PAM (including visit 5 and treatment by visit interaction)								
PAM	71·8 (15·7), n=95	65·4 (14·4), n=102	5·2 (0·9 to 9·6)	0·018	67·0 (15·8), n=79	65·3 (16·8)	−4·8 (−10·4 to 0·9)	0·097
Physiology outcomes (visit 4 only)								
Body mass index	28·4 (5·1), n=87	28·0 (4·5), n=88	−0·2 (−0·3 to 0)	0·062	..	..	..	..
Body fat composition	31·5 (7·5), n=87	32·3 (7·2), n=87	−0·1 (−0·6 to 0·3)	0·53	..	..	..	..
Systolic blood pressure, mm Hg	135·7 (18·0), n=87	137·5 (19·2), n=88	−0·7 (−5·0 to 3·6)	0·76	..	..	..	..
Diastolic blood pressure, mm Hg	80·1 (8·9), n=87	79·5 (7·9), n=88	−0·5 (−2·6 to 1·5)	0·59	..	..	..	..
Resting heart rate, bpm	71·1 (9·6), n=86	73·0 (11·0), n=88	−0·3 (−3·0 to 2·5)	0·84	..	..	..	..
Analgesia use (including visit 5 and treatment by visit interaction)								
Analgesia taken	n=93	n=102	OR 0·6 (0·1 to 3·0)	0·52	n=80	n=81	1·8 (0·38 to 8·49)	0·46
Yes	60 (65%)	68 (67%)	..	..	59 (74%)	59 (73%)	..	..
No	33 (36%)	34 (33%)	..	..	21 (26%)	22 (27%)	..	..

Data are mean (SD) or n (%) unless otherwise stated. ADL=activities of daily living. HOOS=Hip Disability and Osteoarthritis Outcome. PAM=Patient Activation Measure. *Adjusted for baseline. All effect sizes are mean difference, except analgesia taken which is odds ratio (OR). Low scores on stair climb test and physiological measures indicate favourable outcomes. High scores on HOOS, 30 s chair stands, 40 min walk test and Patient Activation Measure indicate favourable outcomes.

Table 2: **Analysis of primary and secondary clinical outcomes (complete case analysis)**

analysis]). A p value of less than 0·05 was considered statistically significant.

For the health economic evaluation, a cost-utility analysis estimated the incremental cost-per-QALY of the CHAIN intervention compared with usual physiotherapy care. Generalised linear models with bootstrapping (1000 replications) were used to estimate mean incremental costs (intervention and other resource use) and mean incremental effects, presenting between-group differences as total costs and QALYs at 24-week follow-up. All analyses included baseline scores on the trial primary outcome (HOOS ADL score) and cycling group (cluster) as covariates. Analysis of the difference in costs included total costs of care at baseline as a covariate, and analysis of the difference in QALYs included baseline EQ-5D-5L as a covariate.

A cost-effectiveness acceptability curve was derived using the net benefit approach, to indicate the probability that CHAIN is cost-effective compared with usual physiotherapy care against the NICE threshold of £20 000 to £30 000 per QALY.[24] An additional cost-effectiveness analysis used the trial primary outcome (HOOS ADL score) at baseline and 10-week follow-up.

Additionally, a series of cost-effectiveness sensitivity analyses were undertaken. The economic evaluation followed the Consolidated Health Economic Evaluation Reporting Standards guidelines.[25] Analyses were specified in a health economics analysis plan and conducted in Stata 18·0.

Role of the funding source

The funder of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Feb 24, 2020, and April 28, 2023, 627 patients were assessed for eligibility with 221 subsequently

	Mean difference (bootstrap 95% CI)*	Incremental cost-effectiveness ratio, £ per QALY	Probability CHAIN intervention is cost effective compared with usual physiotherapy at willingness to pay values per additional QALY	
			£20 000 per QALY	£30 000 per QALY
Base case	£0 (reference)	£4092	0·80†	0·88‡
Cost to NHS and Social Care (including CHAIN and physiotherapy intervention)	£77·75 (–1197·22 to 1172·37)	..	..	..
EQ–5D: QALYs (24 weeks)	0·019 (–0·010 to 0·051)	..	..	..

QALY=quality-adjusted life year. *Adjusted for the following baseline and participant covariates: value at baseline; cycling group using a unique identifier for each cycling group in the intervention group, and a unique group for each participant in the usual physiotherapy intervention arm . †£20 000 per QALY. ‡£30 000 per QALY.

Table 3: **Incremental cost-effectiveness analysis**

randomly assigned to the CHAIN intervention (n=110) or usual physiotherapy care (n=111; figure 1). The first cohort (n=12 CHAIN, n=11 usual physiotherapy care) was recruited to the study in February, 2020, and was subsequently withdrawn as the study was paused in March, 2020, due to the COVID-19 pandemic. These participants were not included in the analysis. The study recommenced on June 8, 2021, and 11 further cohorts were recruited. Cohort sizes ranged from 14 to 24 participants. Eight of the 11 cohorts had a median attendance of seven or more sessions, although variability increased in later cohorts (appendix p 39).

126 (57%) participants were female, 95 (43%) were male, 217 (98%) were White and the mean age was 64·4 (SD 9·5) years (table 1). At baseline, participants had a mean HOOS ADL score of 60·0 (SD 19·3). The mean score was 60·8 (SD 19·2) in the CHAIN group and was 59·3 (19·6) in the physiotherapy group (higher scores suggest better function). Participants in the CHAIN group attended a mean of 6·2 (SD 2·19) cycling sessions (out of eight; appendix p 39) whereas physiotherapy group participants attended a mean of 2·1 (0·93) physiotherapy sessions.

The primary outcome of the HOOS ADL score at visit 4 (10 weeks post-treatment), based on 202 participants with complete baseline and visit 4 data, showed a significant increase in the CHAIN group compared with the physiotherapy group (adjusted mean difference 6·9 [95% CI 2·5–11·2]; p=0·0023; table 2). The primary outcome was not collected for 19 (9%) of 221 participants; 13 (12%) of 110 participants in the CHAIN group and six (5%) of 111 participants in the physiotherapy group (figure 1).

The sensitivity analysis to assess the effect of missing data using multiple imputation also showed a significant increase in the HOOS ADL score in the CHAIN group (6·2 [1·6–10·9]; p=0·0082). The per-protocol analysis is not reported as only ten participants had the full four sessions of physiotherapy.

Using a repeated measures model and including visit 5 (24 weeks post-treatment) and treatment-by-visit interaction (secondary outcome), the mean significant difference of the HOOS ADL score at visit 4 remained largely unchanged (adjusted mean difference 6·8 [95% CI 2·3 to 11·3]; p=0·0032). The treatment-by-visit interaction estimate was –3·6 ([–8·6 to 1·5]; p=0·17), leading to a difference in means at visit 5 of 3·3 ([–1·6 to 8·1]; p=0·19; table 2).

Other secondary outcomes of the HOOS subscales at visit 4 showed significant increases in the CHAIN group in the symptoms and stiffness score (adjusted mean difference 6·3 [95% CI 1·7 to 10·8]; p=0·0072), the sports score (6·6 [1·0 to 12·2]; p=0·022), and the quality of life score (5·8 [0·2 to 11·4]; p=0·042), but not the pain score (5·2 [0·00 to 10·5, p=0·051]; table 2). For all HOOS subscores, the treatment-by-visit interactions estimated there were reduced differences at visit 5 compared with visit 4, but none of the interactions were statistically significant.

There were no significant differences observed between groups for any performance tests, including the 30 s chair stand test, the stair climb test, and the 40 m fast-paced walk test (table 2).

There was a significant increase in the PAM in the CHAIN group at visit 4 compared with the physiotherapy group (adjusted mean difference 5·2 [95% CI 0·9 to 9·6]; p=0·018; table 2). The treatment-by-visit interaction estimate was –4·8 (–10·4 to 0·9]; p=0·097), leading to a difference in means at visit 5 of 0·5 [–4·3 to 5·2]; p=0·85. For this model, the assumptions of the residuals following a normal distribution were not conclusive. A log transformation was used to mitigate this and verified there were no differences in the overall conclusions (treatment coefficient at visit 4 on the log scale 0·1 [0·0–0·1]; p=0·015). For BMI, body composition, systolic and diastolic blood pressure, resting heart rate, and analgesia use there were no significant differences between groups (table 2). The correlation between pre-intervention and post-intervention outcomes was estimated as 0·61, which matched the correlation assumed for the sample size calculation.

Results from the health economic analysis showed that the estimated mean cost per participant of the CHAIN intervention was £84, with the main cost drivers being physiotherapists' time for delivery and training, gym instructors' time, and leisure centre room hire (table 3). The estimated mean cost per participant for usual physiotherapy care was £110 (appendix pp 4–5). The estimated mean total NHS and social care costs per participant (adjusted for baseline covariates) were £103·31 (95% CI –£1092·08 to £1183·40) more for the CHAIN group than the physiotherapy group over the 24-week follow-up. This was reduced to £77·75 (–£1197·22 to £1172·37) when the costs of the CHAIN intervention and physiotherapy usual care were included (appendix pp 5–33). Over the 24-week follow-up, those in

the CHAIN group had a higher (but not significant) mean number of QALYs (0·019 [95% CI –0·010 to 0·051], adjusted for baseline covariates) than did those in the physiotherapy group (appendix p 34). The base case analysis cost-per-QALY was £4092. The cost-effectiveness acceptability curve (figure 2) shows a probability of 0·80 that the CHAIN intervention was cost-effective compared with usual physiotherapy at a willingness to pay threshold of £20 000 per QALY and 0·88 at a willingness to pay threshold of £30 000 per QALY. These thresholds are used by NICE in their health technology assessments.

Additional cost-effectiveness analysis estimated that those in the CHAIN group cost £32·97 (–£70·82 to £183·42) more per person than those in the usual physiotherapy group to the NHS and social care over the 10-week follow-up and had 6·7 points (–0·2 to 14·1) more on the HOOS ADL score (adjusted for baseline covariates). This result represents a cost of approximately £5 per one-point improvement in the HOOS ADL score (appendix p 35). It was intended that physiotherapy group participants would have four physiotherapy sessions, which was in line with usual NHS practice. In the trial, participants had a mean of two sessions. The effect of this on cost-effectiveness was explored in a sensitivity analysis by altering the number of physiotherapy sessions from four to two. This alteration resulted in a cost-per-QALY of the CHAIN intervention compared with physiotherapy care of £7375 (appendix p35).

Interrogation of cost drivers led to identifying four individuals who had hip replacements during the 24-week follow-up. These individuals had notably higher costs to the NHS and social care than any other participant in the study (£10 934–24 520; the mean cost per participant was £738). It is unlikely that treatment in either group would have affected the possibility of hip replacement over the study period. Removing these costs in a sensitivity analysis resulted in the CHAIN group costing £198·69 (–£557·83 to £61·83) less per person than the physiotherapy group, with 0·018 (–0·011 to 0·050) more QALYs, suggesting the CHAIN intervention was the preferred treatment strategy (appendix p 35). Adding broader societal costs to the cost-effectiveness analysis resulted in an increased cost for the CHAIN group compared with the physiotherapy group, equating to a cost-per-QALY of £65 450 (appendix p 35).

No serious adverse events were reported in the study. Three of the 48 adverse events reported were judged to be related to the CHAIN intervention: one participant bruised their coccyx from riding on the static bike at the baseline visit, one was dizzy and had hypotension after completing a CHAIN session, and one had bilateral shoulder pain following a CHAIN session. The first two of the participants with CHAIN-related adverse events withdrew from the study; the remaining withdrawals from the CHAIN treatment were due to non-study-related health or pain issues (n=4) and a social issue (n=1).

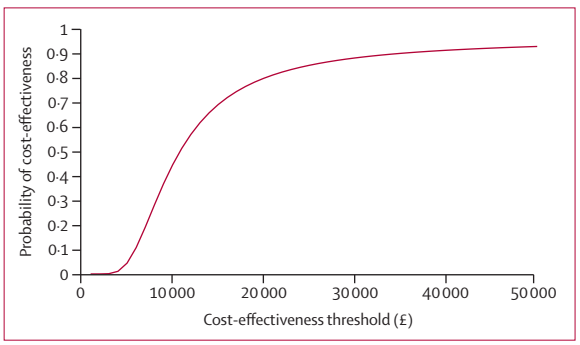

Figure 2: **Cost-effectiveness acceptability curve**
Curve shows the probability that the CHAIN intervention is cost-effective, compared with usual physiotherapy care, at a range of willingness-to-pay cost-effectiveness thresholds.

Discussion

This pragmatic randomised controlled trial compared the effectiveness of a group-based cycling and education programme (CHAIN) with usual physiotherapy care for people with hip osteoarthritis. Both groups showed improvements in the primary outcome measure (HOOS ADL at 10 weeks post-treatment [visit 4]), but the CHAIN group had a statistically significant improvement over the physiotherapy group. However, the observed adjusted mean difference (6·9) was lower than that used in the sample size calculation (7·4). Therefore, there was no clinically meaningful between-group difference in the primary outcome.

These findings extend the small number of randomised control trials examining exercise programmes for hip osteoarthritis and corroborate the findings of previous cohort studies of the CHAIN intervention.[8] The observed adjusted mean between group difference of 6·9 in HOOS ADL compares well with the minimal important change of 6·7 reported in 2025 for patients with hip osteoarthritis following 12 weeks of exercise, and falls within the previously reported range of minimal important changes.[26,27] This finding suggests that, for many participants, the CHAIN intervention provided a meaningful improvement. However, given that the lower bound of the confidence interval falls below this range, some individuals had less benefit, highlighting a variability in response to the intervention.[26]

Other group exercise programmes, such as the Enabling Self-Management and Coping with Arthritic Pain using Exercise and Good Life with Osteoarthritis in Denmark trials,[28,29] have shown positive outcomes. This study addresses the gap in high-quality trials examining group-based exercise interventions for hip osteoarthritis, where many studies have been cohort or feasibility trials.

Although CHAIN included moderate-intensity aerobic exercise, no significant changes were observed in cardiovascular-related outcomes (eg, blood pressure,

resting heart rate). This finding might be due to the relatively short 8-week duration and the average attendance of 6·2 sessions. Nonetheless, moderate-intensity exercise is known to improve cardiovascular health in other populations,[30] suggesting that CHAIN's intensity was likely appropriate but insufficient in duration or dosage to yield measurable effects. The PHOENIX trial found no added benefit from aerobic exercise over resistance training for hip osteoarthritis,[7] consistent with the findings of this study. Similarly, the study by Kjeldsen and colleagues,[31] comparing neuromuscular and resistance exercise, found no significant between-group differences in outcomes. Taken together, these findings add to a growing body of evidence suggesting that, although exercise is beneficial, between-group differences in function and pain are often small when comparing active interventions.

Although CHAIN participants reported greater improvements in self-reported function (HOOS ADL), corresponding findings were not observed in objective performance-based measures, where both groups improved similarly. This discrepancy might reflect the ability of self-reported measures to capture perceived function and confidence—factors not directly assessed by physical performance tests. In this context, the significantly higher PAM scores in the CHAIN group at visit 4 could be noteworthy. The PAM measures individuals' knowledge, skills, and confidence to manage their health, and the observed mean difference of 5·2 in favour of CHAIN suggests participants might have felt more capable and in control of their condition. This elevated sense of self-efficacy could have contributed to improved self-perceptions of functional ability, helping to explain why subjective outcomes improved more than objective ones.

These findings suggest that contextual factors—such as delivery setting, group dynamics, and perceived support—could have contributed to the observed improvements in patient-reported outcomes and activation. The CHAIN programme's structured format, consistent delivery, and group-based environment likely enhanced engagement and self-efficacy, even in the absence of large between-group differences in objective function. This finding is consistent with previous studies in hip osteoarthritis showing that group-based interventions incorporating education and exercise can foster adherence and perceived improvement, in part due to non-specific effects.[28,29]

In addition to positive clinical benefits, CHAIN appeared cost-effective within the context of the UK NHS. The cost per additional QALY of CHAIN compared with usual physiotherapy care was £4092, well below the NICE threshold of £20 000 to £30 000 per QALY. This result was obtained when the assumption was made that those in the physiotherapy group would have had up to four physiotherapy sessions, as per usual NHS practice. When only two physiotherapy sessions were costed into the analysis (given the mean attendance of two sessions in this study), the cost-per-QALY of the CHAIN intervention compared with physiotherapy care increased to £7375, still well below the NICE threshold. However, if hip replacement costs are excluded from the analysis, given that it is unlikely that treatment in either group would have affected the likelihood of needing surgery during the study, the CHAIN intervention seemed more effective and less costly.

The potential clinical implications of this study are substantial within the UK, given the highlighted need for scaling up group-mediated exercise solutions to meet current NHS capacity and economic challenges. A 2024 survey of general practitioners, physiotherapists, and people with osteoarthritis reported that the main barriers to people undertaking exercise interventions for osteoarthritis were cost and accessibility of treatment for patients, insufficient space and equipment resources, and pain or other joint symptoms.[32] The CLEAT trial shows that interventions can be low cost (cost per participant to deliver the CHAIN intervention was £84) and accessible at places such as local leisure centres. However, barriers such as staffing capacity, patient accessibility, and session scheduling could affect uptake. Offering flexible delivery options, including home-based digital adaptations or hybrid models, could enhance accessibility for those unable to attend sessions in-person. Additionally, future work should explore how CHAIN can be adapted for more diverse populations, particularly those with varying levels of health literacy, physical function, or cultural preferences.

Although the CLEAT trial met its primary objectives, there are several considerations to note. The reduction in treatment effect at the 3-month follow-up suggests that ongoing support might be necessary to sustain the benefits of exercise interventions such as CHAIN. This reduction in effect over time has been found by other studies of exercise interventions and exercise promotion more widely.[33] Strategies such as booster sessions, community-based maintenance programmes, or self-directed digital resources could help sustain engagement, and future work should evaluate such approaches.

Although a multicentre trial might have improved confidence in the generalisability of the study findings, the funding for this trial was only sufficient for data collection at one site. However, the single site afforded us several advantages: we had a high volume NHS physiotherapy department; people with hip pain could self-refer to the physiotherapy department without first consulting a general practitioner; we had more flexibility in cohort size, facilitated by using random permuted blocks ranging from 2 to 6 for allocation; we could manage postponement of study visits due to illness, enabling completion of the primary outcome remotely when participants could not attend clinics, and

thereby closely monitoring compliance to CHAIN; we could be agile and flexible in delivery when the COVID-19 pandemic began; and it was easier to follow-up patients, resulting in a high level of completion of the primary outcome (202 [91%] of 221 participants). We therefore could reduce the sample size to 221, because there was less than 10% attrition.

Participants in the study were predominantly White (217 [98%] of 221 participants), with 132 (60%) of 221 participants educated to A-Levels or higher, reflecting the demographics of the local population rather than any specific selection criteria. Although no specific measures were implemented to ensure balanced representation, women comprised 126 (57%) of 221 participants. Eligibility criteria required participants to have sufficient English proficiency to engage with the CHAIN education sessions, limiting the applicability of findings to non-English speakers. Additionally, individuals who could not complete the exercise tolerance test were excluded, meaning results might not extend to those with lower baseline fitness levels. Furthermore, as CHAIN was delivered in scheduled weekly sessions, we observed that in later cohorts, some individuals were unable to commit to a fixed timetable, highlighting the changing culture of so-called on demand rather than scheduled events, and a potential barrier to accessibility. Such factors guide broader generalisability considerations, namely that differences in ethnic diversity, educational background, health-care access, and exercise preferences across regions in the UK and globally could influence the feasibility and effectiveness of CHAIN in other populations.

A limitation of this study is that most participants did not have their osteoarthritis radiographically confirmed, and so baseline grading of osteoarthritis severity was not available. A further key limitation is the moderate-to-high risk of performance bias due to the inability to mask participants and treatment providers. Although outcome assessors were masked, it is possible that expectations or perceptions influenced self-reported outcomes. Additionally, statisticians were unmasked before the primary analysis due to the need for group-level information, which could have introduced interpretation bias despite adherence to a predefined statistical analysis plan.[34]

In conclusion, in people with hip osteoarthritis referred for physiotherapy, CHAIN showed a statistically significant increase in the mean HOOS ADL score compared with physiotherapy after treatment. Although the study did not identify a clinically meaningful between-group difference, CHAIN's cost-effectiveness within the NHS positions it as a viable alternative to usual physiotherapy care. These findings make an important contribution to the limited pool of high-quality randomised controlled trials in this area, and future research should explore strategies to sustain long-term adherence and assess its applicability in more diverse populations.

Contributors

TWW and RGM conceived the trial. TWW, RGM, SD, TR, AH, ML, FW, JS, and TI secured funding for the trial. TWW and RGM led the development of the CHAIN intervention with input from ML and TR. TWW, TI, and JS managed and coordinated all aspects of the trial and data management, with oversight from FW. SD wrote the statistical analysis plan with oversight from GS and PHL. EG wrote the health economics analysis plan with input from AH. SD and TI accessed and verified the underlying data reported in the manuscript. SD, GS, and PHL conducted the statistical analysis, and drafted statistical analysis aspects of the paper. AH conducted the health economics analysis and drafted these aspects in the paper. NH is a representative of the patient advisory group, who have made a valuable contribution to the design and conduct of the trial. TI drafted the manuscript with revision and input from TWW, RGM, SD, GS, AH, EG, ML, TR, JS, PHL, and NH. All authors had full access to all the data in the study and all authors had final responsibility for the decision to submit the manuscript for publication.

Declaration of interests

TWW reports institutional research funding from the National Institute of Health and Care Research (NIHR), Stryker, and Zimmer Biomet; and personal fees from Pharmacosmos, Firstkind, Enhanced Medical Nutrition and Molnlycke Health Care. RM reports royalties from Zimmer Biomet and Lima Corporate for hip replacement surgery; and consulting fees from Zimmer Biomet. All other authors declare no completing interests.

Data sharing statement

Anonymised data will be available for up to 10 years after the publication of this Article to researchers who complete a Data Sharing Agreement that describes a methodologically sound proposal for the purpose of the approved proposal. Proposals should be directed to: twainwright@bournemouth.ac.uk. Data will be shared once all relevant parties approve and sign the Data Sharing Agreement.

Acknowledgments

NH is a member of a patient advisory group. We would like to thank the NIHR Research for Patient Benefit (RfPB) Programme for funding this study (PB-PG-0816–20033). We would also like to thank the trial steering committee for their oversight of this study, the University of Southampton Clinical Trials Unit for their support on the management, and the patient advisory group for their input and support in the design and delivery of the study. We would like to thank the physiotherapists who did the study assessments, and those that delivered the CHAIN intervention and usual physiotherapy care. We would also like to thank all past co-investigators for their valuable input into the study, and all the staff at the R&D Department at University Hospitals Dorset for their tireless work in setting up and supporting the study. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

References

1 National Institute for Health and Care Excellence (NICE). Osteoarthritis in over 16s: diagnosis and management. Oct 19, 2022. https://www.nice.org.uk/guidance/ng226 (accessed July 19, 2024).
2 Ries MD, Philbin EF, Groff GD. Relationship between severity of gonarthrosis and cardiovascular fitness. *Clin Orthop Relat Res* 1995; **313:** 169–76.
3 Lima YL, Lee H, Klyne DM, et al. How do nonsurgical interventions improve pain and physical function in people with osteoarthritis? A scoping review of mediation analysis studies. *Arthritis Care Res* 2023; **75:** 467–81.
4 Zhao H, He Z, Yun H, Wang R, Liu C. A meta-analysis of the effects of different exercise modes on inflammatory response in the elderly. *Int J Environ Res Public Health* 2022; **19:** 10451.
5 Goh SL, Persson MSM, Stocks J, et al. Relative efficacy of different exercises for pain, function, performance and quality of life in knee and hip osteoarthritis: systematic review and network meta-analysis. *Sports Med* 2019; **49:** 743–61.
6 Teirlinck CH, Verhagen AP, van Ravesteyn LM, et al. Effect of exercise therapy in patients with hip osteoarthritis: a systematic review and cumulative meta-analysis. *Osteoarthr Cartil Open* 2023; **5:** 100338.

7 Hall M, Allison K, Knox G, et al. Addition of aerobic physical activity to resistance exercise for hip osteoarthritis (PHOENIX): a randomised comparative effectiveness trial. *Lancet Rheumatol* 2025; **7:** e343–54.

8 Wainwright TW, Parkinson EP, Immins T, et al. CycLing and EducATion (CLEAT): protocol for a single centre randomised controlled trial of a cycling and education intervention versus standard physiotherapy care for the treatment of hip osteoarthritis. *BMC Musculoskelet Disord* 2023; **24:** 344.

9 Andrews LM, Allen H, Sheppard ZA, Baylis G, Wainwright TW. More than just ticking a box... how patient and public involvement improved the research design and funding application for a project to evaluate a cycling intervention for hip osteoarthritis. *Res Involv Engagem* 2015; **1:** 13.

10 NCSEM. Exercise referral toolkit. https://www.ncsem-em.org.uk/get-active/exercise-referral-toolkit/ (accessed Jan 10, 2025).

11 Klässbo M, Larsson E, Mannevik E. Hip disability and osteoarthritis outcome score. An extension of the Western Ontario and McMaster Universities Osteoarthritis Index. *Scand J Rheumatol* 2003; **32:** 46–51.

12 Ridyard CH, Hughes DA. Development of a database of instruments for resource-use measurement: purpose, feasibility, and design. *Value Health* 2012; **15:** 650–55.

13 Jones K, Weatherly H, Birch S, et al. Unit costs of social care 2022 manual. https://www.pssru.ac.uk/pub/uc/uc2022/Unit_Costs_of_Health_and_Social_Care_2022.pdf (accessed Jan 10, 2025).

14 NHS England. 2021/22 national cost collection data publication. July 9, 2024. https://www.england.nhs.uk/publication/2021–22-national-cost-collection-data-publication/ (accessed Jan 10, 2025).

15 NICE. NICE health technology evaluations, the manual. Jan 31, 2022. https://www.nice.org.uk/process/pmg36/chapter/economic-evaluation-2 (accessed July 19, 2024).

16 Hernandez Alava M, Pudney S, Wailoo A. The EQ-5D-5L value set for England: findings of a quality assurance program. *Value Health* 2020; **23:** 642–48.

17 Borm GF, Fransen J, Lemmens WAJG. A simple sample size formula for analysis of covariance in randomized clinical trials. *J Clin Epidemiol* 2007; **60:** 1234–38.

18 Wallis JA, Webster KE, Levinger P, Fong C, Taylor NF. A pre-operative group rehabilitation programme provided limited benefit for people with severe hip and knee osteoarthritis. *Disabil Rehabil* 2014; **36:** 2085–90.

19 Bennell KL, Egerton T, Pua Y-H, et al. Efficacy of a multimodal physiotherapy treatment program for hip osteoarthritis: a randomised placebo-controlled trial protocol. *BMC Musculoskelet Disord* 2010; **11:** 238.

20 Allen KD, Oddone EZ, Coffman CJ, et al. Patient, provider, and combined interventions for managing osteoarthritis in primary care. *Ann Intern Med* 2017; **166:** 401–11.

21 Tubach F, Ravaud P, Baron G, et al. Evaluation of clinically relevant changes in patient reported outcomes in knee and hip osteoarthritis: the minimal clinically important improvement. *Ann Rheum Dis* 2005; **64:** 29–33.

22 Angst F, Aeschlimann A, Stucki G. Smallest detectable and minimal clinically important differences of rehabilitation intervention with their implications for required sample sizes using WOMAC and SF-36 quality of life measurement instruments in patients with osteoarthritis of the lower extremities. *Arthritis Rheum* 2001; **45:** 384–91.

23 Bennell KL, Egerton T, Martin J, et al. Effect of physical therapy on pain and function in patients with hip osteoarthritis: a randomized clinical trial. *JAMA* 2014; **311:** 1987–97.

24 National Institute for Health and Care Excellence. NICE health technology evaluations: the manual. Jan 31, 2022. https://www.nice.org.uk/process/pmg36 (accessed July 19, 2025).

25 Husereau D, Drummond M, Augustovski F, et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) statement: updated reporting guidance for health economic evaluations. *Value Health* 2022; **25:** 3–9.

26 Chéret EPBM, Mechlenburg I, Skou ST, Dalgas U, Stisen MG, Kjeldsen T. Minimal important change in the Hip Disability and Osteoarthritis Outcome Score and the European Quality of Life 5 Dimensions in adults with hip osteoarthritis after 12 weeks of exercise. *Musculoskelet Sci Pract* 2025; **76:** 103274.

27 Fernandes L, Roos EM, Overgaard S, Villadsen A, Søgaard R. Supervised neuromuscular exercise prior to hip and knee replacement: 12-month clinical effect and cost-utility analysis alongside a randomised controlled trial. *BMC Musculoskelet Disord* 2017; **18:** 5.

28 Roos EM, Grønne DT, Skou ST, et al. Immediate outcomes following the GLA:D® program in Denmark, Canada and Australia. A longitudinal analysis including 28,370 patients with symptomatic knee or hip osteoarthritis. *Osteoarthritis Cartilage* 2021; **29:** 502–06.

29 Bearne LM, Walsh NE, Jessep S, Hurley MV. Feasibility of an exercise-based rehabilitation programme for chronic hip pain. *Musculoskeletal Care* 2011; **9:** 160–68.

30 Pinckard K, Baskin KK, Stanford KI. Effects of exercise to improve cardiovascular health. *Front Cardiovasc Med* 2019; **6:** 69.

31 Kjeldsen T, Skou ST, Dalgas U, et al. Progressive resistance training or neuromuscular exercise for hip osteoarthritis. *Ann Intern Med* 2024; **177:** 573–82.

32 Bhardwaj A, Hayes P, Browne J, et al. Barriers, facilitators and referral patterns of general practitioners, physiotherapists, and people with osteoarthritis to exercise. *Physiotherapy* 2024; **125:** 101416.

33 McEwan D, Rhodes RE, Beauchamp MR. What happens when the party is over?: Sustaining physical activity behaviors after intervention cessation. *Behav Med* 2022; **48:** 1–9.

34 Järvinen TLN, Sihvonen R, Bhandari M, et al. Blinded interpretation of study results can feasibly and effectively diminish interpretation bias. *J Clin Epidemiol* 2014; **67:** 769–72.