

Health Economics Analysis Plan

A pragmatic multi-centred randomised controlled trial with economic evaluation, to compare a cycling and educational programme with usual physiotherapy care in the treatment of hip osteoarthritis:

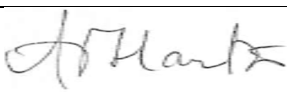
CycLing and EducATion (CLEAT)

ISRCTN: 19778222

IRAS Project ID: 232991

SECTION 1: ADMINISTRATIVE INFORMATION

Title of Trial	A pragmatic multi-centred randomised controlled trial with economic evaluation, to compare a cycling and educational programme with usual physiotherapy care in the treatment of hip osteoarthritis: CycLing and EducATion (CLEAT)
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This HEAP was prepared by Dr Annie Hawton and Dr Liz Goodwin, and approved by Prof Tom Wainwright. Drs Hawton and Goodwin are responsible for conducting and reporting the economic evaluation in accordance with the HEAP.

The purpose of this HEAP is to describe the analysis and reporting procedure intended for the economic analyses to be undertaken. The HEAP is designed to ensure compatibility with the protocol and associated statistical analysis plan and it should be read in conjunction with them.

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ABBREVIATIONS

CEA	Cost-Effectiveness Analysis
CEAC	Cost-Effectiveness Acceptability Curve
CHEERS	Consolidated Health Economic Evaluation Reporting Standards
CRF	Case Report Form
GLM	Generalised Linear Models
HEAP	Health Economics Analysis Plan
HOOS	Hip Disability and Osteoarthritis Outcome Score
HOOS function score	The “Function, daily living” component score from the HOOS
ICER	Incremental Cost-Effectiveness Ratio
ITT	Intention to Treat
MAR	Missing At Random
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OLS	Ordinary Least Squares
PSS	Personal Social Services
QALY	Quality-adjusted life-year
RCT	Randomised Controlled Trial

SECTION 2: TRIAL INTRODUCTION AND BACKGROUND

2.1 Trial background and rationale

In the UK, 8.75 million people aged over 45 years (33%) have sought treatment for osteoarthritis, and with increasing levels of obesity and an ageing population, projections show that by 2035 this number could nearly double (Arthritis Research UK 2013).

Osteoarthritis is a chronic degenerative joint disorder usually associated with ageing, and it is estimated that a quarter of people affected by osteoarthritis have osteoarthritis of the hip (2.12 million people, 8% of the UK population) (Versus Arthritis 2018). Hip osteoarthritis is associated with hip pain, stiffness and limitations to activities of daily living, and is the most common reason for a total hip replacement.

There is no known cure for osteoarthritis, and so non-surgical management for people with symptoms not yet severe enough for surgery mainly focuses on alleviating pain, and maximising function by addressing aspects which can be modified. The National Institute for Health and Care Excellence (NICE) guidelines (2014) state that three core treatments should be the first line treatment for patients with osteoarthritis. These are education and advice, exercise (aerobic and local muscle strengthening), and weight loss where appropriate, however there is no specific guidance on type of exercise, dose or intensity.

To date, studies have used exercises of low to moderate intensity with low to moderate success, but as yet there is little research on whether increasing the intensity of exercise in a safe way can increase the benefit of the exercise. It is important that appropriate models of prevention and treatment are developed to support and treat osteoarthritis sufferers.

Cycling may be of benefit in comparison to other forms of exercise because it is a health enhancing form of physical activity (Bauman and Rissel 2009) and a non-weight bearing activity that is considered less stressful on the body than impact or other running sports (Rissel et al. 2013). Furthermore, positive relationships between cycling and increased cardiorespiratory fitness, increased functional ability, and disease risk factor profiles have been found (Oja et al. 2011). There is also evidence in longitudinal epidemiological studies that cycling can lead to significant risk reduction for all-cause and cancer mortality, cardiovascular disease, colon and breast cancer, and obesity morbidity in the middle-aged and elderly (Oja et al. 2011).

In addition to the specifics of the cycling activity, the programme has been designed to influence behaviour change and includes components to motivate, increase adherence and prevent drop out of participants. There will be (1) a programme of education, (2) plans for lifestyle changes, (3) involvement of participants in the development of the programme, (4) a

group-based cycling class, with (5) a dedicated exercise leader, (6) encouragement to maintain an exercise diary, (7) resources to remove barriers to the uptake of the programme and continued involvement after the programme, and (8) on-going encouragement and support. These components have been designed to increase the likely efficacy of the intervention, by drawing on the evidence and models regarding behaviour change (Michie et al. 2013) addressing participants' needs at individual (personal), group (social), and environmental levels; (King and Sallis 2009; Michie 2008) and focusing on developing participants' capability, motivation, and opportunity (Michie and West 2013).

This study will compare outcome data collected from hip osteoarthritis patients undertaking an eight-week education and cycling programme (CHAIN) with patients who undertake routine physiotherapy care.

2.2 Aim of the trial

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 aged 18 years and over.

2.3 Objectives of the trial

Primary objective: To determine whether there is a difference in self-reported function of performing everyday activities (i.e. walking, using the stairs, driving and shopping) between those receiving the cycling and education intervention compared to those with usual physiotherapy care.

Secondary objectives:

- To determine whether there is a difference in self-reported hip pain between those receiving the cycling and educational intervention compared to those with usual physiotherapy care.
- To determine whether there is a difference in objectively observed function between those receiving the cycling and education intervention compared to those with usual physiotherapy care.
- To determine whether there is a difference in quality of life between those receiving the cycling and educational intervention compared to those with usual physiotherapy care.
- To determine whether there is a difference in resources used and associated costs between those receiving the cycling and educational intervention compared to those with usual physiotherapy care.

- To estimate the resources used and costs of providing the cycling and education intervention and its cost-effectiveness compared with usual physiotherapy care.
- To determine whether there is a difference in activation levels (defined as the individual's knowledge, skill and confidence to manage their own health) between those receiving the cycling and educational intervention compared to those with usual physiotherapy care.

2.4 Trial population

The trial population will be patients who have been diagnosed, using the NICE criteria, with osteoarthritis of the hip. The osteoarthritis will be diagnosed by a clinician reviewing medical history and current symptoms.

Inclusion criteria

- Diagnosed with osteoarthritis of the hip as per NICE criteria.
- Male and female, aged 18 years and over. If under 45, an x-ray confirming diagnosis of osteoarthritis is required.
- Meeting the GP criteria for exercise referral (British Heart Foundation 2010)
- Capable of giving informed consent
- Willing to commit to the exercise intervention if randomised to the treatment arm.
- 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.
- Be able to understand English as necessary to benefit from the intervention, in the investigators opinion.

Exclusion criteria

- Hip surgery within the last 6 months
- On the waiting list for a hip replacement or planning back or lower limb surgery in the next 9 months.
- Current or past (within 3 months) HaAn intra-articular corticosteroid injection (or any other therapeutic injection) of the hip in the last 3 months.
- Due to the safety limitations of static bikes used, participants need to be $\geq 150\text{cm}$ tall and weigh $\leq 135\text{kg}$.
- 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

- Judged by investigator to have high levels of functional limitations which will prevent the participant from getting on and off the exercise bike

2.5 Intervention(s) and comparator(s)

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. This will consist of a 30 minute education class, facilitated by a qualified physiotherapist, 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 a suitable facility.

Comparator: Over an eight week treatment period, participants in the control group will attend up to four sessions of physiotherapy, as per standard care. 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.

2.6 Trial design

CLEAT is a pragmatic parallel-arm randomised controlled trial comparing a 8-week cycling and education complex intervention, that is underpinned by physiological and behaviour change theory, with routine physiotherapy care reflecting standard practice in the NHS in the UK. This trial is based at the University Hospitals Dorset NHS Foundation Trust. Patients referred to the Physiotherapy Department at the hospital will be considered for the trial. The trial intervention will be conducted at a local centre, led by instructors with previous experience of delivering spin classes, for all patients in the intervention arm; whilst the control arm, physiotherapy care, will be delivered by the Physiotherapy Department at the University Hospitals Dorset. Participants will be followed up at 10 weeks and at 24 weeks from baseline assessment.

2.7 Trial start and end dates

First participant recruited: June 2021

End of recruitment: May 2023

SECTION 3: ECONOMIC APPROACH

3.1 Aim(s) of economic evaluation

The aim of the economic evaluation is to address the question: “What is the cost-effectiveness of an 8-week Education and Cycling programme (CHAIN) compared with usual physiotherapy care in the treatment of hip osteoarthritis?”

3.2 Objective(s) of economic evaluation

The objectives of the health economic evaluation are to establish the resources required to provide the CHAIN intervention, estimate the cost of the intervention, and conduct a full cost-effectiveness analysis (CEA).

3.3 Overview of economic analysis

The within-trial economic analysis will be performed using individual patient level data from the CLEAT trial. The analytical approaches will take the form of cost-utility analysis and cost-effectiveness analysis. Based on trial evidence, incremental cost-utility and cost-effectiveness ratios will be calculated by taking a ratio of the difference in the mean costs and difference in mean effects.

3.4 Jurisdiction

The trial is conducted in the UK which has a national health service (NHS), providing publicly funded healthcare, primarily free of charge at the point of use.

3.5 Perspective

The primary economic analysis will be from the NHS and personal social services (PSS) perspective. Participant and broader societal perspectives will be considered in sensitivity analyses.

3.6 Time horizon(s)

The economic analysis will compare the costs and consequences of each arm over the first 24 weeks after baseline.

SECTION 4: ECONOMIC DATA COLLECTION AND MANAGEMENT

4.1 Statistical software

Stata version 17.0 or higher will be used for exploratory analysis and for the main statistical analysis involving multivariable regression.

4.2 Resource use and costs

4.2.1 CHAIN intervention (intervention group) and usual care (control group) resource use and costs

The economic evaluation will estimate the full resource consequences and additional (incremental) costs required for delivery of the CHAIN intervention as compared to usual care.

Identification of relevant intervention resource use (e.g. gym instructor time, physiotherapist time, hire of leisure facilities, educational materials, travel, telephone calls, consumables) will be based on information from the research team and the therapists delivering the intervention. The main cost drivers are expected to be staff time and costs (and related consumable items).

Measurement of intervention resource use will be undertaken within-trial using participant-level case report forms (CRFs), completed by the intervention therapists, and via estimates derived from the therapists and research team.

Valuation of resource use will be via nationally recognised sources, including Unit Costs for Health and Social Care (Jones et al., 2022) and the National Schedule of NHS Costs (NHS, 2021/2022). Where national costs are not available costs will be obtained from finance records and therapist estimates.

4.2.2 NHS and PSS resource use and costs

To provide a basis for comparing usage and costs of NHS and PSS resource use by participants in the intervention and control groups over the period of follow-up, the research team will develop a bespoke resource use questionnaire for completion by participants.

Identification of relevant categories and items of NHS and PSS resource use will be undertaken by the research team, and informed by measures used with similar populations in the Database of Instruments for Resource Use Management (DIRUM) repository (Ridyard et al. 2015; Ridyard et al. 2012), current practice and recent methodological developments in the field of resource use assessment (Thorn et al. 2018), and input from the study Patient

Advisory Group. This information will be used to develop a resource use questionnaire, which will include primary, secondary and social care resource use.

Measurement of NHS and PSS resource use will be by participant-level self-reported resource use questionnaires (as described above). Data will be collected at baseline, and at the 10 week and 24 week follow-up assessments.

Valuation of resource use will be via nationally recognised sources, including Unit Costs for Health and Social Care (Jones et al., 2022) and the National Schedule of NHS Costs (NHS, 2021/2022). Sources for all unit costs will be clearly reported.

4.2.3 Patient and broader societal resource use and costs

Broader areas of societal resource use and costs will also be collected, in order to inform a sensitivity analysis from a societal perspective.

Identification of key categories and items of resource use areas to be collected for this broader analytical perspective will be undertaken in the same way as the identification of NHS and PSS resource use (as described in Section 4.2.2). These items will be incorporated into the bespoke resource use questionnaire, and will include informal care, travel costs, time off work, and additional participant purchases and costs.

Measurement via participant self-report resource use questionnaires.

Valuation of non-NHS or PSS services will be undertaken using estimated unit costs, where these are available. Time spent on informal care and time off work will be valued using the most relevant average salary figures from the Office of National Statistics.

4.3 Outcomes

4.3.1 Identification of outcomes

The primary economic outcome measure will be Quality-Adjusted Life Years (QALYs), derived from health state values obtained using the EQ-5D-5L health-related quality of life instrument (Herdman et al, 2011).

In addition, cost-effectiveness will be assessed based on the trial primary endpoint, the score (0-100) from the self-reported “Function, daily living” component from the Hip Disability and Osteoarthritis Outcome Scale (HOOS) at 10 weeks from the baseline assessment. The cost per minimum clinically important change (7.4%) on HOOS will be estimated.

4.3.2 Measurement of outcomes

Participant-level EQ-5D-5L data will be collected within the trial at baseline (pre-intervention), at 10-week follow-up and at 24-week follow-up.

Participant-level HOOS data collected at baseline and 10-week follow-up will also be used in the health economics analysis.

4.3.3 Valuation of outcomes

Health state values will be derived from responses to the EQ-5D-5L, using the approach recommended by the National Institute for Health and Care Excellence (NICE) at the time of data analysis (NICE, 2022). As of April 2023, the NICE position statement recommends mapping between EQ-5D-5L responses and the published UK health state value set for EQ-5D-3L, using an approved algorithm (Hernández Alava et al, 2020; Dolan, 1997).

SECTION 5: ECONOMIC DATA ANALYSIS

5.1 Analysis population

The primary analysis will be based on the intention-to-treat (ITT) principle; participants will be analysed as randomised, regardless of their compliance with the trial protocol or lack of participation with or completion of their allocated treatment.

5.2 Timing of analyses

The economic analysis will be undertaken after the final data at the 24 week follow-up has been collected and the database is locked.

5.3 Data cleaning for analysis

Face validity tests will be conducted on data and discrepancies checked against the source documents. Corrections made will be documented in the Stata code.

5.4 Missing data

Trial data will be examined for missing data. The appropriate method for dealing with missing data will depend on the combination of the proportion of missing data and the likely mechanism of missingness. For example, multiple imputation methods may be used if the data appears to be missing at random (MAR).

5.5 Discount rates for costs and benefits

As the time horizon for the analysis is less than one year, discount rates are not applicable.

5.6 CHAIN intervention and standard care costing

Each component of intervention resource use will be presented in a tabular format (mean and standard deviation) at an aggregate trial level together with the associated unit cost data (national estimates, e.g. by staff grade/level) for each item of resource use (with standardised currency year, £ 2021). A mean cost per participant for the CHAIN intervention and a mean cost for usual care will be presented, and any uncertainties will be explored through scenario and/or sensitivity analyses.

5.7 Analysis of costs and outcomes

Mean (standard deviation) resource use, by item, will be presented for baseline assessment, and for resource use over the 24-week follow-up period (adding resource use reported at 10 and 24 week assessments). Unit costs will be applied to items of resource use and mean (standard deviation) cost data will be presented, by treatment arm, for the baseline assessment, and for the 10 week and 24 week follow-up assessments. Cost data for resource use will be presented using appropriate sub-categories e.g. primary care, hospital care, social care, societal.

Mean (standard deviation) EQ-5D-5L values will be presented for baseline assessment, 10 week follow-up and 24 week follow-up. Derived health state values will be used to estimate QALYs through application of standard area-under-the-curve methods (Brazier et al, 2007), using baseline, 10 week and 24 week assessments. The primary economic analysis of outcomes will be between baseline and 24-week follow-up, compared across treatment and control arms of the trial.

5.8 Analysis of cost-effectiveness

Generalised linear regressions (with appropriate family and link functions e.g. gamma/identity) and bootstrapping methods will be used to estimate mean costs per group, mean QALYs per group, and to compare mean costs and mean QALYs between treatment and control groups. As per the CLEAT SAP, baseline scores on the primary outcome (HOOS function component score) and cycling group (cluster) will be included as covariates in all regression analyses. Grouping will be treated as a random effect in the analyses, with each participant in the control arm assumed to be in their own group (or cluster) of one.

Analysis of difference in costs will include total cost of baseline NHS and PSS resource use as a covariate, and analysis of difference in QALYs will include baseline EQ-5D-5L as a covariate. The baseline cost and outcomes covariates will be transformed appropriately for the generalised linear model family and link functions used in the analysis. Results of adjusted and un-adjusted analyses will be presented.

Analysis will estimate mean incremental costs (intervention cost and other resource use costs) and mean incremental effects, presenting between-group differences in total costs and QALYs at 24-week follow up. A cost-utility analysis will be conducted to present the incremental cost-per-QALY (based on the EQ-5D-5L) of the intervention.

Like analysis will also be undertaken to estimate the incremental cost-per-minimum clinically important change on the HOOS at 10-week follow up.

Cost-effectiveness planes and cost-effectiveness acceptability curves (CEACs) will be presented using the net benefit approach (Fenwick and Byford, 2005). The CEAC will show the probability that the CHAIN intervention is cost-effective compared with usual care, against a range of willingness-to-pay values that a health/social care commissioner may be prepared to accept for improvements in outcome. We will follow the thresholds used by NICE, which regards interventions as a cost-effective use of NHS/PSS resources when the cost-per-QALY is £20,000 or less, and potentially cost-effective when the cost-per-QALY is £20,000 to £30,000.

The key findings of the economic evaluation (ie. mean differences in costs, mean differences in QALYs, incremental cost-effectiveness ratios [ICERs] and net benefits between the treatment groups) will be presented with associated 95% confidence intervals.

5.9 Sensitivity analyses

Uncertainty in data estimates and/or assumptions will be subject to detailed sensitivity analysis, using plausible data ranges (e.g. variations in staff grades and staff costs, variations in the estimates for NHS resource use and the relevant unit costs). In addition, sensitivity analyses will consider total societal resource use cost. As appropriate, sensitivity analyses will comprise one-way analysis, multi-way analysis, and scenario analysis.

5.10 Cost-consequences analysis

A cost-consequences analysis will also present key costs and outcomes in a disaggregated, tabular format (Centre for Reviews and Dissemination 2008; Drummond 2005). This will enable assessment of the component parts of the CHAIN intervention, usual physiotherapy

care, health and social care and patient resource use and costs of care, and multiple outcomes, for those receiving/not receiving the intervention.

SECTION 6: REPORTING AND PUBLISHING

6.1 Reporting standards

The health economic evaluation will be reported in a format appropriate to stakeholders and policy makers, following the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guidelines (Husereau et al, 2022).

6.2 Deviations from the HEAP

Any deviation from HEAP will be described and justified in the final published report.

SECTION 7: REFERENCES

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SECTION 8: APPENDIX: RESOURCE USE QUESTIONNAIRE