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# Osteoarthritis preoperative package for care of orthotics, rehabilitation, topical and oral agent usage and nutrition to improve outcomes at a year

**Submission date**
04/04/2018

**Recruitment status**
No longer recruiting

**Registration date**
18/04/2018

**Overall study status**
Completed

**Last Edited**
01/03/2024

**Condition category**
Musculoskeletal Diseases

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

## Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is a joint disease that results from the breakdown of cartilage and bone. It is the fastest-growing cause of disability worldwide. Patients with severe OA can be treated with joint replacement surgery. Patients' health and physical function before surgery is known to influence their outcomes after surgery, and non-operative treatments such as exercise, shoe insoles, painkillers and weight loss are known to benefit patients with OA. However, these options are often not optimised before joint replacement. The aim of this study is to assess the feasibility and acceptability of a package of non-operative care versus standard care before joint replacement. The study aims to take advantage of the incentive for behavioural change in these patients to obtain a durable alteration in the patients' weight and exercise level, which coupled with appropriate analgesia (pain relief) and insoles could relieve their OA symptoms and improve outcomes after surgery.

Who can participate?
Patients aged 18-85 years who have been recently placed on the waiting list for a total knee replacement due to osteoarthritis

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the intervention group are provided with the relevant elements of the package they 'qualify' for: a weight loss plan, exercises to do at home, advice on analgesia for knee pain, and insoles and advice on footwear. Participants are asked to undertake the intervention for 8-12 weeks, depending on when they are scheduled for surgery. Participants in the control group receive usual local standard care before total knee replacement at their local treatment centre. All participants attend for study visits at the start of the study, the end of the intervention (pre-surgery), and 3 months after the planned surgery date. Participants are also invited to take part in an interview with a researcher to discuss the intervention. Healthcare practitioners involved in the delivery of the intervention are invited for interview as well as staff at the sites where the intervention is being delivered.

What are the possible benefits and risks of participating?
As non-operative treatments such as exercise, shoe insoles, painkillers and weight loss are known to benefit patients with OA and health and physical function before surgery is known to influence outcomes after surgery, it is hope that participants will benefit from the components of the intervention they receive as part of the study. Participants may experience some side effects from the weight loss programme and the home exercises. The research team will closely assess participants at the weekly reviews and ask about any side effects so that they can advise on what action to take. Taking part in the study may involve the discussion of sensitive issues but the research team will be fully trained and will support participants fully during these discussions.

Where is the study run from?
1. Royal Infirmary Edinburgh (UK)
2. Chapel Allerton Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2017 to July 2020

Who is funding the study?
Arthritis Research UK

Who is the main contact?
Prof Hamish Simpson, hsimpson@ed.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Prof Hamish Simpson

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
CPMS 38215

# Study information

### Scientific Title
Osteoarthritis Preoperative Package for care of Orthotics, Rehabilitation, Topical and oral agent Usage and Nutrition to Improve ouTcomes at a Year (OPPORTUNITY)

### Acronym
OPPORTUNITY

### Study objectives
Osteoarthritis (OA) is the fastest growing cause of disability worldwide. Patients with severe OA are referred to secondary care for consideration of joint replacement surgery. Patients' pre-operative health and physical function is known to influence their postoperative outcomes and non-operative treatments such as exercise, shoe insoles, painkillers and weight loss are known to benefit patients with OA however these options are often not optimised prior to joint replacement. The OPPORTUNITY study is a multicentre randomised controlled feasibility trial which aims to assess the feasibility and acceptability of a pre-operative package of non-operative care versus standard care prior to joint replacement. The patient group will be patients that have been recently placed on the waiting list for a total knee replacement due to osteoarthritis. The study aims to take advantage of the incentive for behavioural change in these patients to obtain a durable alteration in the patient's' weight and exercise level, which coupled with appropriate analgesia and insoles could relieve the morbidity of their OA and improve outcomes following surgery.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
South East Scotland Research Ethics Committee 2, 18/01/2018, ref: 17/SS/0156

### Study design
Randomized; Interventional; Design type: Not Specified, Education or Self-Management

### 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
Osteoarthritis

## Interventions
This study aims to take advantage of the incentive for behavioural change in patients with osteoarthritis (OA) who have been placed on the waiting list for orthopaedic surgery, to obtain a durable alteration in the patient's' weight and exercise level. Non-operative treatments such as exercise, orthoses, analgesics and weight loss are known to benefit patients with OA but are often not optimised prior to joint replacement. The trialists postulate that the reduction in weight and increased activity coupled with an appropriate analgesia review and attention to footwear in the preoperative window will result in a sustained improvement in the patient's health-related quality of life following knee replacement. A stratified list will be used to randomise the participants to a treatment group.

Patients randomised to the intervention arm will be provided with the relevant elements of the package they 'qualify' for: a weight loss plan, exercises to do at home, advice on analgesia for knee pain, and insoles and advice on footwear. The intervention will be started as soon as possible after patients have been added to the waiting list for joint replacement surgery to take advantage of the incentive for behavioural change that this will create. Participants will be asked to undertake the intervention for 8-12 weeks, depending on when they are scheduled for surgery.

Participants in the control arm will receive usual local standard care prior to total knee replacement at their local treatment centre.

Data will be collected at baseline (before the start of the intervention), at the end of the intervention (pre-surgery) and around 3 months after the planned date of surgery. Care received and any change in the trial parameters (weight loss, analgesia usage etc) in the control arm will be documented and evaluated to determine any behaviour change in this arm brought about through the informed consent process or completion of study questionnaires. For participants in the intervention arm, adherence will be reviewed each week during the intervention period (by telephone or in person). Participants will also be invited to take part in an interview with a researcher to discuss the intervention. Health care practitioners involved in the delivery of the intervention will be invited for interview as well as staff at the sites where the intervention is being delivered.

## Intervention Type
Other

## Primary outcome measure
The primary endpoint of the study is whether the intervention and study protocol is feasible and acceptable and whether a full-scale effectiveness trial is warranted. The following will be measured and used to inform study feasibility:
1. Rate of recruitment
2. Rate of retention at follow up review after planned surgery date
3. Adherence to the intervention estimated through review questionnaires and weight change (for those receiving weight loss aspect of intervention)

In addition the following information will be assessed qualitatively:
1. Qualitative interviews (with participants, researchers and clinical staff) exploring acceptability, feasibility, adherence and possible barriers to implementing the intervention
2. Acceptability of the different outcome measures

### Secondary outcome measures
Change will be monitored a minimum of 90 days after the planned surgery date in the outcomes the trialists are interested in evaluating in the effectiveness trial. These are:
1. Pain, function, and stiffness, measured using WOMAC sub scores
2. Change, measured using OKS (function and pain), EQ5D score (health status), timed get-up-and-go test (time a person takes to rise from a chair, walk three meters, turn around, walk back to the chair, and sit down) and self-efficacy (proficiency to do various tasks) questionnaire scores
3. Clinical outcomes following surgery, measured using a review questionnaire completed 90 days after surgery
4. Management of patient comorbidities, measured using a review questionnaire completed 90 days after surgery
5. Patient satisfaction with knee pain and function, measured using a satisfaction questionnaire
6. Identification of key cost drivers, measured using through consultations with local experts to discuss the types of NHS services expected to be major and minor drivers differences in costs in patients undertaking the intervention or standard care

### Overall study start date
01/07/2017

### Completion date
20/03/2020

## Eligibility

### Key inclusion criteria
For participants:
1. Undergoing total knee arthroplasty for OA
2. Participant meets at least 1 of the following threshold criteria:
2.1. BMI ≥30 kg/m2
2.2. Inability to perform straight leg raise (no extensor lag) or patient-reported 'giving way'
2.3. Not taking appropriate analgesics unless analgesics are not tolerated/contra-indicated
2.4. Not using shock-absorbing footwear
3. Participants are able to consent and willing to comply with the study protocol
4. Sufficient time for the intervention to be delivered before planned date of surgery and for the follow up appointment to be conducted 3 months after planned date of surgery

For staff:
Staff members to be interviewed should be members of the research team involved in delivering the intervention to participants or members of the clinical care team/associated personnel at the site where the intervention is being delivered.

The age range was omitted in V1 of the protocol but has been included in V2 (amendment currently being processed). The age range for the study is 18-85 years (inclusive).

### Participant type(s)

Patient

## Age group
Adult

## Lower age limit
18 Years

## Upper age limit
85 Years

## Sex
Both

## Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

## Total final enrolment
60

## Key exclusion criteria
For participants:
1. Patients undergoing revision knee arthroplasty or fully constrained knee arthroplasty
2. Knee replacement for a diagnosis other than OA
3. Patients with a second contralateral procedure planned within the study timeframe
4. Procedures done purely for pain relief (such as for patients with no walking capacity)
5. Patients involved in another research study containing elements of behaviour change related to diet, physical activity and other study elements
6. Participants that cannot understand verbal explanations or written information given in English
7. Pregnant until >4 months postpartum; breastfeeding

Additional exclusion criteria applicable to participants eligible for weight loss aspect of the intervention:
1. Patients who have recently lost a significant amount of weight (>5kg in the preceding 3 months) or who are already on a specialised diet
2. Patients with:
2.1. Insulin dependent diabetes
2.2. Brittle type 2 diabetes which is managed in secondary care (confirmed by recent HbA1c measurement if available)
2.3. Patients with moderate or severe retinopathy
3. Patients taking 4 or more antihypertensive agents
4. Patients with active mental illness: severe depression, bipolar disorders, schizophrenia or other psychotic disorders
5. Myocardial infarctions or stroke within the previous 3 months
6. Heart failure of grade III New York Heart Association or more severe
7. Porphyria
8. Substance abuse e.g., drugs, alcohol
9. Eating disorder accompanied by purging (through laxative abuse or induced vomiting)
10. Previous bariatric surgery or scheduled bariatric surgery
11. Angina, arrhythmia, including atrial fibrillation or prolonged QT syndrome

12. Taking monoamine- oxidase inhibitor (MAOI) medication
13. Taking anticoagulant medication (e.g., warfarin)
14. Taking varenicline (smoking cessation medication)
15. Chronic renal failure of stage 4 or 5 (as indicated by a recent eGFR reading of <30mls/min/1.73)
16. Patients:
16.1. With active liver disease (except non-alcoholic fatty liver disease (NAFLD)
16.2. With a history of hepatoma
16.3. Within 6 months of onset of acute hepatitis
17. People having active treatment for cancer other than skin cancer treated with curative intent by local treatment only, or people taking hormonal or other long-term secondary prevention treatment after initial cancer treatment
18. Active treatment or investigation for possible or confirmed gastric or duodenal ulcer; maintenance treatment with acid suppression is not a contraindication
19. Displaying symptoms associated with gallstones in the last 3 months
20. Not taking a proton-pump inhibitor if taking oral ibuprofen

### Date of first enrolment
01/05/2018

### Date of final enrolment
30/08/2019

## Locations

### Countries of recruitment
England

Scotland

United Kingdom

### Study participating centre
**Royal Infirmary Edinburgh**
Orthopaedics Department
Chancellor's Building
Little France Crescent
Edinburgh
United Kingdom
EH16 4SU

### Study participating centre
**Chapel Allerton Hospital**
Leeds Institute of Rheumatic and Musculoskeletal Medicine
Chapeltown Road

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United Kingdom
LS7 4SA

# Sponsor information

### Organisation
NHS Lothian

### Sponsor details
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### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/03q82t418

# Funder(s)

### Funder type
Charity

### Funder Name
Arthritis Research UK; Grant Codes: 2018/0059

### Alternative Name(s)

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Other non-profit organizations

### Location
United Kingdom

# Results and Publications

## Publication and dissemination plan

The trialists plan to publish the study protocol. On completion of the study, the study data will be analysed and tabulated and a clinical study report prepared in accordance with ICH guidelines. The clinical study report will be used for publication in peer reviewed scientific journals and presentation at scientific meetings. A separate publication policy will be prepared for the study.

## Intention to publish date

31/07/2022

## Individual participant data (IPD) sharing plan

Access to the de-identified dataset will be under a controlled access model in line with Edinburgh University/ECTU policies at that time. Currently this requires a request to be made by the interested party. Requests should be discussed with the Chief Investigator if not made directly to them. A brief application should be completed describing why access is being requested and how the data will be stored. Requests are processed by senior statisticians within ECTU. Participants will asked for consent for their data to be anonymised and stored by the research team at the University of Edinburgh and NHS Lothian for possible use in future research.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 19/02/2020 | 24/02/2020 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | | 26/02/2024 | 01/03/2024 | Yes | No |