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# PROvision of braces for Patients with knee OsteoArthritis (PROP OA): a randomised controlled trial

**Submission date**
19/07/2018

**Recruitment status**
No longer recruiting

**Registration date**
26/07/2018

**Overall study status**
Completed

**Last Edited**
20/05/2025

**Condition category**
Musculoskeletal Diseases

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

## Plain English summary of protocol

Background and study aims
Osteoarthritis of the knee is very common. It causes pain, problems with walking and movement, and can make daily life very difficult. There is no cure for osteoarthritis, but with treatment, symptoms can be improved allowing people to stay active. Wearing a brace could help patients with osteoarthritis of the knee by reducing the load going through the joint and improving its stability. However, there are mixed reports about whether wearing a knee brace does actually help. This study will help to show whether wearing a knee brace provides more relief for people with painful osteoarthritis of the knee than just having best primary care (education, advice and exercise), and whether this is good value for money for the NHS.

Who can participate?
Patients aged 45 years or older with osteoarthritis of the knee. Patients will be identified after they have consulted their GP with knee pain, by screening physiotherapy referrals in NHS services in Staffordshire, Cheshire, Greater Manchester, and Northumbria, and by asking people to volunteer following local radio and other advertising.

What does the study involve?
All participants receive 'best primary care'. This includes an appointment with a physiotherapist who gives them education about knee osteoarthritis and the benefits of exercise, physical activity and weight loss, advice about how to relieve knee pain, and a knee exercise program. They are also given an information booklet. Half of the participants are randomly chosen to also get a knee brace that is checked by the physiotherapist 2 weeks later. The type of brace they get is based on the physiotherapist’s assessment and X-ray findings. They are supported to keep wearing the brace for at least 6 months. This includes text message support to help them with use of the brace. Participants are asked about their pain and symptoms after 3, 6, and 12 months to see whether the knee brace was a useful addition to best primary care. Participants are asked for access to their medical records to see if wearing the knee brace has reduced the need for surgery. Some patients are interviewed to find out more about using the knee brace and whether they followed the advice they had from physiotherapists.

What are the possible benefits and risks of participating?
All participants will receive at least best primary care and some participants also receive a knee brace. These treatments are already used in the NHS for the treatment of knee osteoarthritis and are deemed safe. Some participants may experience skin irritation from knee braces and muscle soreness from exercise. Physiotherapists delivering the treatments advise participants about how to manage such symptoms and participants are able to seek healthcare in addition to the care they receive within the study. Some individuals may need a knee X-ray which involves exposure to ionising radiation. The study procedures for taking X-rays follow routine safety procedures used in the NHS.

Where is the study run from?
The study is being run by Keele University working with the University of Manchester and Newcastle University. Treatments are delivered in clinics held within NHS settings in Staffordshire, Cheshire, Manchester and Northumbria.

When is the study starting and how long is it expected to run for?
September 2018 to May 2024

Who is funding the study?
National Institute for Health Research Health Technology Assessment programme (UK)

Who is the main contact?
Prof. George Peat
g.m.peat@keele.ac.uk

### Study website
https://www.keele.ac.uk/propoa/

## Contact information

### Type(s)
Public

### Contact name
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### Type(s)
Scientific

### Contact name

Prof George Peat

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
HTA 16/160/03

# Study information

### Scientific Title
A multi-centre, primary care, randomised, parallel-group, superiority trial (with internal pilot) to evaluate the effectiveness of bracing in the management of symptomatic knee osteoarthritis: the PROP OA trial

### Acronym
PROP OA

### Study objectives
To determine the clinical and cost-effectiveness of adding knee brace (matched to patients' clinical and radiographic presentation and with adherence support) to Best Primary Care compared to Best Primary Care (education, advice and exercise) alone, in adults with symptomatic knee osteoarthritis.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 03/06/2019, North West - Preston Research Ethics Committee (no address; +44 (0)207 104 8206; preston.rec@hra.nhs.uk), ref: 19/NW/0183

### Study design
Multi-centre, primary care, randomised, parallel-group, superiority interventional trial (with internal pilot). Masking: trial administrator, data entry administrator, trial statistician.

## Primary study design
Interventional

## Secondary study design
Randomised parallel trial

## Study setting(s)
Community

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Knee osteoarthritis (symptomatic)

## Interventions
Participants will be randomised (1:1 allocation, random permuted blocks) to receive either Best Primary Care (comparator) or Best Primary Care plus Bracing with Adherence Enhancing Component (intervention) using a web-based randomisation service. Randomisation will be stratified by clinic site, predominant compartmental distribution of knee osteoarthritis and by presence/absence of self-reported knee buckling.

Comparator: Best Primary Care
Participants randomised to receive Best Primary Care will receive a single, face-to-face consultation with a physiotherapist that will include education, self-help advice on pain management and a lower limb exercise program to be completed at home. Participants will also be provided with high quality written material, and a print out of their exercise program to facilitate their exercise practice at home.

Intervention: Best Primary Care plus Bracing with Adherence Enhancing Component
Participants randomised to receive the intervention will receive an initial face-to-face treatment session with a physiotherapist that will include best primary care (as described above) and prescribing of either a patellofemoral, tibiofemoral unloading, or neutral stabilising knee brace according to their pattern of knee osteoarthritis (based on clinical assessment and plain X-ray findings). Braces will be fitted to ensure maximum comfort and dose of brace use will be individually tailored. Participants will be advised to wear the brace on painful weight-bearing activity, with a starting minimum usage of 1 hour on two or more days per week, gradually increased based on tolerance to wearing the brace on all painful weight-bearing activity up to a maximum of 8 hours per day. Individuals will be advised to wear the brace for 6 months, and continue to wear it beyond this time if they find it beneficial.

Two weeks after the initial treatment session participants will return for a follow-up consultation. During this time the physiotherapist will check response to, and fit of the brace.

Treatment sessions will also be used to elicit self-motivational statements -individualised, motivational prompts to encourage adherence to brace use will be sent to participants via SMS text message (weekly for the first 4 weeks, every fortnight for 8 weeks, and then monthly until the end of the intervention period at 6 months).

## Intervention Type
Device

## Pharmaceutical study type(s)
Not Applicable

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Knee braces

## Primary outcome measure
Knee Injury and Osteoarthritis Outcome Score (KOOS-5) - composite score of patient-reported pain, other symptoms, activities of daily living, function in sport and recreation and knee-related quality of life at 6 months

## Secondary outcome measures
Current secondary outcome measures as of 05/10/2023:
Secondary outcomes are captured using participant self-report questionnaires at 3, 6 and 12 months post-randomisation:
1. Pain is measured using the Knee injury and Osteoarthritis Outcome Score (KOOS) pain subscale, Numeric Rating Scale of knee pain on activity, measure of Intermittent and Constant Osteoarthritis Pain (ICOAP); Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [items for which are included within the KOOS]
2. Arthritis self-efficacy is measured using the Arthritis Self-Efficacy Scale (ASES)
3. Function is measured using the Knee injury and Osteoarthritis Outcome Score Activities of Daily Living (KOOS ADL), Function in Sport and Recreation (KOOS Sport/Rec) subscales and WOMAC
4. Physical activity is measured using the International Physical Activity Questionnaire - Elderly (IPAQ-E)
5. Symptoms are captured using the Knee injury and Osteoarthritis Outcome Score (KOOS)
6. Social participation is measured using the Patient-Reported Outcomes Measurement Information System (PROMIS)
8. Patient global rating of change is measured using a Numeric Rating Scale
9. Treatment response is measured using the OMERACT-OARSI responder criteria (this combines data on pain and function from the WOMAC with patient's global assessment of change)
10. Instability (buckling) is measured by self-report questions
11. Treatment acceptability is measured by self-report questions
12. Adverse events are captured through case report forms (CRF), and direct contact between the CTU and the participant, their PROP OA physiotherapist, GP or the Site PI
13. Adherence to brace use is captured in part through SMS text messages (tapering schedule over the first 6 months of follow-up, with a text message also at 12 months)
14. Cost effectiveness is evaluated using EuroQol EQ-5D-5L, Healthcare resource use (NHS /private), out-of-pocket expenses, Time Off Work. Unit costs from standard UK sources will be sought for all health care resource use items. The average wage for each respondent will be identified using UK Standard Occupational Classification coding and annual earnings data for each job type

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Previous secondary outcome measures as of 14/05/2021:
Secondary outcomes are captured using participant self-report questionnaires at 3, 6 and 12 months post-randomisation:
1. Pain is measured using the Knee injury and Osteoarthritis Outcome Score (KOOS) pain subscale, Numeric Rating Scale of knee pain on activity, measure of Intermittent and Constant Osteoarthritis Pain (ICOAP); Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [items for which are included within the KOOS]
2. Anxiety and Depression is measured using the Hospital Anxiety and Depression Scale (HADS)
3. Arthritis self-efficacy is measured using the Arthritis Self-Efficacy Scale (ASES)
4. Function is measured using the Knee injury and Osteoarthritis Outcome Score Activities of Daily Living (KOOS ADL), Function in Sport and Recreation (KOOS Sport/Rec) subscales and WOMAC
5. Physical activity is measured using the International Physical Activity Questionnaire - Elderly (IPAQ-E)
6. Symptoms are captured using the Knee injury and Osteoarthritis Outcome Score (KOOS)
7. Social participation is measured using the Patient-Reported Outcomes Measurement Information System (PROMIS)
8. Quality of life is measured using Knee injury and Osteoarthritis Outcome Score Quality of Life (KOOS QOL) subscale
9. Patient global rating of change is measured using a Numeric Rating Scale
10. Treatment response is measured using the OMERACT-OARSI responder criteria (this combines data on pain and function from the WOMAC with patient's global assessment of change)
11. Instability (buckling) is measured by self-report questions
12. Treatment credibility is measured by self-report questions
13. Knee pain-related perceptions and expectations are measured by questions from the Brief Illness Perceptions Questionnaire
14. Adverse events are captured through case report forms (CRF), and direct contact between the CTU and the participant, their PROP OA physiotherapist, GP or the Site PI
15. Adherence to brace use is captured in part through SMS text messages (tapering schedule over the first 6 months of follow-up, with a text message also at 12 months)
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3. Arthritis self-efficacy is measured using the Arthritis Self-Efficacy Scale (ASES)
4. Function is measured using the Knee injury and Osteoarthritis Outcome Score Activities of Daily Living (KOOS ADL), Function in Sport and Recreation (KOOS Sport/Rec) subscales and WOMAC
5. Physical activity is measured using the Physical Activity Scale for the Elderly (PASE)
6. Symptoms are captured using the Knee injury and Osteoarthritis Outcome Score (KOOS)

7. Social participation is measured using the Patient-Reported Outcomes Measurement Information System (PROMIS)
8. Quality of life is measured using Knee injury and Osteoarthritis Outcome Score Quality of Life (KOOS QOL) subscale
9. Patient global rating of change is measured using a Numeric Rating Scale
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13. Knee pain-related perceptions and expectations are measured by questions from the Brief Illness Perceptions Questionnaire
14. Adverse events are captured in part through SMS text messages (monthly over the first 6 months of follow-up, with a text message also at 12 months) and through case report forms (CRF), and direct contact between the CTU and the participant, their PROP OA physiotherapist, GP or the Site PI
15. Adherence to brace use is captured in part through SMS text messages (monthly over the first 6 months of follow-up, with a text message also at 12 months)
16. Cost effectiveness is evaluated using EuroQol EQ-5D-5L, Healthcare resource use (NHS /private), out-of-pocket expenses, Time Off Work. Unit costs from standard UK sources will be sought for all health care resource use items. The average wage for each respondent will be identified using UK Standard Occupational Classification coding and annual earnings data for each job type

### Overall study start date
01/09/2018

### Completion date
31/05/2024

## Eligibility

### Key inclusion criteria
Current inclusion criteria as of 14/05/2021:
1. Aged 45 years and over
2. Residing in England
3. Clinically significant knee pain on weight bearing (NRS >=4)
4. With or without knee instability or buckling
5. Able to have knee x-ray
6. Able to read and write English
7. Access to a mobile phone that can receive SMS text messages
8. Able to give full informed consent
9. Willing to participate

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Previous inclusion criteria:
1. Aged 45 years and over
2. Residing in England
3. Clinically significant knee pain on weight bearing (NRS >=4)
4. With or without knee instability or buckling
5. No morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes

6. Able to have knee x-ray
7. Able to read and write English
8. Access to a mobile phone that can receive SMS text messages
9. Able to give full informed consent
10. Willing to participate

## Participant type(s)
Patient

## Age group
Adult

## Lower age limit
45 Years

## Sex
Both

## Target number of participants
434

## Total final enrolment
466

## Key exclusion criteria
Current inclusion criteria as of 14/05/2021:
1. Red flags in the history or clinical examination that may indicate further investigation or referral for possible serious underlying pathology
2. Vulnerable individuals (e.g. in palliative phase of care for cancer, unstable mental health disorders)
3. Inflammatory arthritis (e.g. rheumatoid arthritis, psoriatic arthritis)
4. Symptoms not attributable to knee osteoarthritis
5. Previous total knee replacement, high tibial osteotomy, or autologous cartilage implantation
6. On the waiting list for TKR/THR within the next 6 months
7. Unwilling to wear a knee brace
8. Brace size unavailable for leg circumference
9. Knee brace contraindicated (superficial wounds where the knee brace would reside, psoriasis, eczema or poor circulation, arterial insufficiency, or severe varicosities that could result in skin at risk with regular brace wear, a history of thrombophlebitis in either leg)
10. Recent/routine knee brace wear within the last 3 months
11. Nursing home resident
12. Unable to attend clinic
13. Close family member already a trial participant
14. Knee injection in the last 3 months
15. Course of physiotherapy in the last 3 months
16. Significant neurological disorder (e.g. stroke, Parkinson’s disease, multiple sclerosis, dementia)
17. Fibromyalgia
18. Autologous cartilage implantation in last 12 months in the knee to be treated
19. Significant fixed flexion deformity that prevents fitting of brace

Previous exclusion criteria:
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### Date of first enrolment
25/11/2019

### Date of final enrolment
16/09/2022

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Keele CTU**
David Weatherall Building
Keele University
Stoke on Trent
United Kingdom
ST5 5BG

## Sponsor information

### Organisation
Keele University

### Sponsor details
Innovation Centre 2
Keele University
Keele
Staffordshire
Stoke on Trent
England
United Kingdom
ST5 5NH

### Sponsor type
University/education

### Website
https://www.keele.ac.uk/admin/directorateofresearchinnovationengagement/

### ROR
https://ror.org/00340yn33

## Funder(s)

### Funder type
Government

### Funder Name
Health Technology Assessment Programme

### Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Publication and dissemination plan

1. Planned publication in high-impact peer reviewed medical journals
2. Present findings at national and international meetings
3. Dissemination through University and osteoarthritis websites, in GP practices, via press releases and articles in local magazines and newspapers, and for radio stations

## Intention to publish date
30/11/2024

## Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from James Bailey (medicine.datasharing@keele.ac.uk). The datasets have to be requested on a case-by-case basis although multiple objectives from one dataset can be stated. To access data reasoning has to be provided in the application form along with a study protocol and a short CV for the study CI/PI. Only team members listed in the application form should have access to the data. Consent from the participants would have been obtained, if necessary for the study and any data provided would be anonymised accordingly. Information on how Keele uses information can be found here: https://www.keele.ac.uk/legalgovernancecompliance/legalandinformationcompliance/informationgovernance/

## IPD sharing plan summary
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol file | version v2.1 | 10/07/2019 | 15/05/2020 | No | No |
| Protocol article | | 26/03/2021 | 13/08/2021 | Yes | No |
| Statistical Analysis Plan | version 1.0 | 13/09/2023 | 15/09/2023 | No | No |
| HRA research summary | | | 20/09/2023 | No | No |
| Protocol file | version 2.4 | 08/12/2021 | 16/01/2024 | No | No |
| Statistical Analysis Plan | Data Analysis Plan version 1.1 | 03/03/2025 | 25/03/2025 | No | No |
| Basic results | | 12/05/2025 | 20/05/2025 | No | No |