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Is knee-cap taping feasible and acceptable as part of a treatment package for painful knee-cap arthritis?

Submission date
14/11/2024

Recruitment status
No longer recruiting

Registration date
20/11/2024

Overall study status
Completed

Last Edited
05/11/2026

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
Knee-cap arthritis (wear and tear) causes pain and disability for millions of adults in the UK. There are few effective treatments. Knee braces can help but they can be expensive and two-thirds of patients stop wearing them because either their leg is the wrong shape or it slips down. Therefore, this study will test the feasibility of a long-term simpler, cheaper intervention - knee-cap taping. If this study shows that taping is feasible and acceptable to patients, the ultimate goal is to carry out a large Health Technology Assessment-funded trial to test the extended effectiveness of self-managed knee-cap taping in painful knee-cap arthritis. This study aims to see if knee-cap taping is feasible and acceptable as part of a treatment package for painful knee-cap arthritis.

Who can participate?
People with painful knee-cap arthritis

What does the study involve?
Participants will receive the treatment package of best practice care and taping for 3 months. The number of participants willing to enrol will be recorded, their adherence to the intervention, how precisely they applied the tape, if taping had any side effects, and how many people did not complete the trial. Then, 15 participants will participate in one-to-one semi-structured interviews about their experiences of using the tape. Participants will provide advice regarding the treatment package and give insights to inform the development of a large, long-term trial of the effectiveness of taping.

What are the possible benefits and risks of participating?
Participants will benefit from improvement in their knee pain over the 12-week trial period, the aesthetics of using the tape over wearing a bulky knee brace, the comfort of wearing tape over the knee brace, and taping method training (for future use). The clinical follow-up appointments at 2, 6 and 12 weeks, mean being seen more frequently than routine clinic visits.

There are no foreseen ethical, legal or management issues arising from this study.
There may be minimal risk to the participants in Work Package 2 (WP2) and Work Package 3 (WP3), these have been fully disclosed in the Patient Information Sheet.

WP2 risks:
1. Reaction to tape - will have an exclusion criterion that removes people with known allergies to tape, psoriasis, broken skin or lesions in the area. If they have an unknown allergy and react to the tape they will be withdrawn and referred to their GP for treatment.
2. No improvement/worsening of pain - participants will be referred back to their GP or referring clinician at the end of the study for the next step of treatment.
3. Incorrect self-application of tape - this would just lead to inefficacy. The week two visit is in place to check the participants are using the correct method.

WP3 risks:
Participants may find discussing their experiences of taping or knee pain upsetting, and they are asked to let the team know if they wish to take a break or end the interview. If during the interview the participant reveals that their safety or the safety of others may be at risk, this information will be discussed with individuals outside the study team. Lastly, there may be a risk of a breach of confidentiality. Extensive systems are in place to try to prevent this and are detailed this in the PIS. Two PPIE workshops were held in Work Package 1. The purpose of these workshops was to co-design and refine the treatment package using patellar taping for kneecap arthritis, for use in a subsequent clinical trial feasibility study (WP2). It is believed that risks have been minimised from these workshops.

Where is the study run from?
The University of Manchester, Manchester Metropolitan University and the Sponsor is Manchester University NHS Foundation Trust (MFT).

When is the study starting and how long is it expected to run for?
December 2023 to February 2026

Who is funding the study?
NIHR Research for Patient Benefit (RfPB) programme

Who is the main contact?
Prof Michael Callaghan (Chief Investigator), Michael.callaghan@mmu.ac.uk

Contact information

Type(s)
Scientific, Principal investigator, Public

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Integrated Research Application System (IRAS)
322953

Central Portfolio Management System (CPMS)
54632

National Institute for Health and Care Research (NIHR)
204993

Study information

Scientific Title
The feasibility of knee taping in painful patellofemoral joint osteoarthritis (PFJOA): TAPE-it

Acronym
TAPE-it

Study objectives
The hypothesis is that medical sports taping of the knee will be both feasible and acceptable to participants as part of a treatment package for painful patellofemoral osteoarthritis.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/11/2024, Cambridge South (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)207 1048 154; cambridgesouth.rec@hra.nhs.uk), ref: 24/EE/0248

Primary study design
Interventional

Study design
Non-randomised study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Medical sports taping of the knee for painful patellofemoral osteoarthritis

Interventions
Before the original application: Five patients were invited to be introduced to the project concept and design. Their feedback helped inform the Work Package 1 (WP1) part of the study.

WP1: Before this protocol, two workshops were held in January and February 2024. This involved 11 participants being taken through the study concept, and then shown the taping methods and planned training materials for the actual intervention study. This was a PPIE exercise to ensure the right questions were being asked and, the best methods used and were meaningful. The findings from WP1 fully informed the WP2 methods described below.

WP2
1. Screening: Manchester Local Care Organisation (MLCO) and Salford Royal Hospital: Clinicians refer potentially eligible patients with PFJOA to the study team either directly to CI or Study Team via secure NHS or NHS.net email address or online Trust system. Participants are given a Participant Information Sheet (PIS) for at least 24 hours to digest the information and ask questions. A member of the research team calls the participant to book a baseline visit.
2. Baseline Visit (30 - 60 minutes): face-to-face in a private room in the NIHR Manchester Clinical Research Facility.
2.1. Aims explained and any questions from PIS answered.
2.2. Provide written informed consent for trial.
2.3. Clinical examination and eligibility questions asked to diagnose PFJOA and confirm eligibility (ineligible patients will be screened fail and referred back to GP or referring clinician).
2.4. Determine aggravating activity, assess the best taping method, show the participant how to apply tape, and provide a Patient Treatment Package.
2.5. Supply two weeks pre-cut tape.
2.6. Baseline Assessments: electronic or paper copy knee pain (VASNA) and knee function (KOOS-PF) questionnaires
2.7. Two-week assessment (20 minutes): Check taping treatment accuracy and correct if required. Supply 10 weeks pre cut tape. Knee pain (VASNA) and knee function (KOOS-PF) questionnaires and adverse events recording
2.8. Six-week assessment (15 minutes): Telephone assessment - knee pain (VASNA), function (KOOS-PF) questionnaires and adverse event recording.
2.9. Twelve-week assessment (15 minutes): Telephone assessment - knee pain (VASNA), function (KOOS-PF) questionnaires and adverse event recording

End of WP2: all completing participants will be given a PIS for WP3 and asked if they might want to take part. Then a sample of fifteen consenting participants will be purposefully selected (to show a range of age, sex, and ethnicity) to participate in the one-to-one interviews in WP3 below:

WP3:
1. Participants were given a PIS and 24 hours to consider the study and whether they would like to take part.
2. Full Informed Consent was taken and demographic information was collected. A semi-structured interview (approx 60 minutes) will be conducted to gain an in-depth understanding of the participant's experience of WP2.
3. Interviews will be conducted by a trained Research Associate (RA) either in person, online via Teams or over the phone depending on participants' preference. In-person interviews will be held in a private room at the Brooks Building, Birley Campus, Manchester Metropolitan University.
4. Discussions will be from an interview question list but also guided by each patient's response to allow exploration of unanticipated issues/feedback. Emerging findings from each interview will iteratively feed into subsequent interviews.
5. Interviews will be digitally recorded, professionally transcribed and then analysed by the Research Associate.

Intervention Type
Other

Primary outcome(s)
Current primary outcome(s)

Participant uptake is assessed as follows:
1. Recruitment numbers measured using study data at baseline
2. % dropout/withdrawal numbers measured using study data at 2, 6 and 12 weeks

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Previous primary outcomes as of 20/01/2026:

1. Recruitment rate: number of participants recruited over the recruitment period.
2. Intervention adherence: determined by self-report at 2, 6 and 12 weeks
3. Self-report number of tape strips used at weeks 2, 6, 12.
4. Retention: proportion of participants who were contactable by telephone at 12 weeks.
5. Understanding participants' experience of taping, the acceptability of the intervention and follow-up methods through semi-structured interviews conducted over the post intervention follow-up period.
6. Willingness to be randomised: proportion of eligible patients approached who would be willing to be randomised to a 'no-tape' group in a future RCT.

Previous primary outcomes:

Participant uptake is assessed as follows:
1. Recruitment numbers measured using study data at baseline
2. % dropout/withdrawal numbers measured using study data at 2, 6 and 12 weeks

Key secondary outcome(s)
Current key secondary outcome(s) as of 04/02/2026:

. Correct tape application measured using study observation by the CI at the 2-week visit. Advice and adjustments to the taping method if required by the CI.
2. Adherence measured using a count of the remaining tape strips at weeks 2,6,12: Approximate amount of time of tape wearing measured using patient self-reported hours per day and days per week of tape wearing at weeks 2, 6 and 12.
3. Reduction in knee pain measured using the 11-point (0-10) Visual Analogue Scale during a Nominated Activity (VASNA) and knee pain and function measured using the Knee Injury and Osteoarthritis Outcome Score for patellofemoral pain and osteoarthritis (KOOS-PF) at baseline, 2, 6 and 12 weeks

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Previous secondary outcomes as of 20/01/2026:

Reduction in knee pain measured using the 11-point (0-10) Visual Analogue Scale during a Nominated Activity (VASNA) and knee pain and function measured using the Knee Injury and Osteoarthritis Outcome Score for patellofemoral pain and osteoarthritis (KOOS-PF) at baseline, 2, 6 and 12 weeks.

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Previous secondary outcomes:

1. Correct tape application measured using study observation by the CI at the 2-week visit. Advice and adjustments to the taping method if required by the CI.
2. Adherence measured using a count of the remaining tape strips at weeks 2,6,12: Approximate amount of time of tape wearing measured using patient self-reported hours per day and days per week of tape wearing at weeks 2, 6 and 12.
3. Reduction in knee pain measured using the 11-point (0-10) Visual Analogue Scale during a Nominated Activity (VASNA) and knee pain and function measured using the Knee Injury and Osteoarthritis Outcome Score for patellofemoral pain and osteoarthritis (KOOS-PF) at baseline, 2, 6 and 12 weeks

Completion date
28/02/2026

Eligibility

Key inclusion criteria
1. Adults over 40 years of age
2. Pain predominantly over the patella (anterior knee pain) and greater than medial or lateral knee pain
3. Clinically significant patellofemoral pain/anterior knee pain on weight-bearing activity such as stair ascent/descent, sit-stand scored at 4 or above on an 11-point (0-10) visual analogue scale (VAS)
4. Already on a stable/regular dose of analgesia
5. Able to understand English (or English speaking) and give full informed consent
6. Willing to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
100 Years

Sex

All

Total final enrolment
0

Key exclusion criteria
1. Symptoms not attributable to predominant patellofemoral OA or attributable only to medial or lateral knee compartment OA
2. Previous major surgery in the knee to be treated (partial/total knee replacement, knee fracture or knee realignment surgery, high tibial osteotomy)
3. Diagnosis of rheumatoid arthritis, gout or other forms of inflammatory arthritis
4. Cancer within the last 5 years (except non-melanoma skin cancers)
4. Planned knee replacement surgery or other knee surgery in the next 6 months
5. Responded to a steroid or viscosupplementation injection to the painful knee in the last 3 months
6. Those with a known allergy to elasticated tape, with fragile or very sensitive skin, psoriasis, or with lesions/rash/open wound in the are where the tape will be applied
7. Significant neurological disorder (e.g. stroke, dementia, MS, Parkinson's) affecting cognitive ability

Date of first enrolment
16/12/2024

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester Metropolitan University
All Saints
Grosvenor Square
Manchester
England
M15 6BH

Study participating centre
University of Manchester
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Sponsor information

Organisation
Manchester University NHS Foundation Trust

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			05/11/2026	No	No
Participant information sheet	version 1.1	31/10/2024	20/01/2026	No	Yes
Plain English results	version 2	20/05/2026	05/11/2026	No	Yes
Protocol file	version 1.0	02/10/2024	19/12/2024	No	No