Protocol

Full/Long Title Of The Study: The feasibility of knee taping in painful patellofemoral joint osteoarthritis (PFJOA): TAPE-it

Short Study Title/Acronym: Patellar taping for painful patellofemoral osteoarthritis (TAPE-it).

Protocol Version Number And Date: FINAL Version 1.0 02_Oct_2024

Amendment History

Amendment No.	Protocol Version and date	Details of Changes Made

Research Reference Numbers

IRAS Number	**322953**
Sponsor Reference	B02227
Funder Reference	NIHR204993

This protocol has regard for the HRA guidance.

This project will be conducted in accordance with the study protocol and the ethical principles outlined by Good Clinical Practice (GCP) and the Declaration of Helsinki in its most current version.

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Signature Page

The sponsor signature on the IRAS form, acts as documented acceptance that the sponsor approves the protocol.

The Chief Investigator should sign below to confirm the following:

The Chief Investigator confirms the protocol has been agreed and accepted and agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: Date:

....//...../.....

Name: (please print):

Professor Michael Callaghan .....

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Study Summary

Study Design	Feasibility study and qualitative assessment of an intervention
Study Participants	Adults aged ≥ 40 years with patellofemoral knee osteoarthritis
Planned Size of Sample	WP2: N=30 WP3: N≈15
Recruitment Period	6 months
Follow Up Period	3 months
Overall Study Duration	16 months
Research Question/Aim(s)	To determine whether patellar taping is feasible and acceptable as part of a treatment package for painful patellofemoral joint osteoarthritis (PFJOA) If feasible and acceptable, to plan a full, definitive randomised controlled trial (RCT) to determine long-term clinical effectiveness.
Study objectives	i) To assess recruitment to the study and participant retention ii) To determine whether the tape can be applied by participants correctly at home. iii) To determine adherence to the taping intervention. iv) To assess how to optimise adherence to taping over an extended period. v) To determine participants views about the acceptability of taping. vi) To determine whether participants experience a reduction in pain in response to tape. vii) To determine a primary outcome for a large scale RCT and to inform the sample size calculation.

Primary Outcome Measures	**Primary Endpoints**
(i) WP2: To assess recruitment to the study and participant retention: Uptake - number recruited and % drop out rate.	WP2: Participant uptake - number recruited per month and % drop out rate.
WP3: Report on participant experiences of taping and the trial process.	WP3: Qualitative Report.

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Explore facilitators and barriers to adherence. Evaluate the performance of the participant treatment package.	
Secondary Outcome Measure(s)	**Secondary Endpoint(s)**
(ii) To determine whether the tape can be applied by participants correctly at home - Clinical checks at 2 weeks recorded on the Clinical Report Form. iii) Adherence to wearing the tape: Number of returned/counted tapes, number of days per week worn and the average hourly use.	1. Intervention adherence – number of tapes returned or counted at week 2, 6 and 12. 2. Number of days that participant reports wearing the tape at weeks 2, 6 and 12. 3. Number of hours the participant reports wearing the tape daily at weeks 2, 6 and 12.
(iv & v) To assess how to optimise adherence top taping over an extended period and to determine participant views about the acceptability of prolonged taping: Participant interviews in WP3	1. Qualitative analysis of interviews.
(vi) Effect of intervention, reduction in pain (a) Knee pain measured by VAS_{NA} at baseline, 2, 6 & 12 weeks (b) Knee pain and knee function measured by KOOS-PF at baseline, 2, 6 & 12 weeks.	1. Pain relief during nominated activity (VAS_{NA}) – the difference between baseline and 12 week measures. 2. KOOS-PF – the difference between baseline and 12 week measures.
(vii) To determine a primary outcome for a large scale RCT and to inform sample size: Analyses of quantitative data in (vi. a & b)	

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Funding and Support in Kind

Funder(s)	**Financial And Non-Financial Support Given** Detail financial and non-financial support given by each organisation listed
National Institute for Health Research (NIHR)	The total amount awarded under this Project to all the Parties from the Funder shall be £249,419.00

Role of Study Sponsor and Funder

Manchester University NHS Foundation Trust (MFT) is acting as sponsor for this study and is assuming overall responsibility for the initiation and management of the study. The Trust will provide permission to conduct the research and monitor the progress of that research. The research team all hold substantive or honorary contracts with the Trust and therefore the sponsor has influence over all aspects of the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results which are the responsibility of the research team.

Roles and Responsibilities of Study Management Committees/Groups & Individuals

1. Trial Management Group (TMG): Monthly team meetings held online or in person. These meetings are to update the study team, highlight any risks or issues and include mitigation plans, raise any amendments to the study and ensure timelines and task deadlines are met.
2. PPIE - Ann McGovern is our PPIE Co-Applicant. She attends the TMG meetings and provides feedback on all aspects of the project.

Key Words: Patellofemoral Joint Osteoarthritis (PFJOA)

Feasibility and acceptability

Taping

Intervention

AbbreviationsAbbreviation	**Definition**
MFT	Manchester University NHS Foundation Trust
REC	Research Ethics Committee
TMF	Trial Master File
PPIE	Patient and Public Involvement and Engagement
CI	Chief Investigator
PFJOA	PatelloFemoral Joint OsteoArthritis
OA	Osteoarthritis
RCT	Randomised Controlled Trail
FDA	Food and Drug Administration
NSAIDS	Non-Steroidal Anti-Inflammatory Drugs
HTA	Health Technology Assessment
WP	Work Packages
VAS	Visual Analogue Scale
KOOS-PF	Knee Injury and Osteoarthritis Outcome Score - PatelloFemoral

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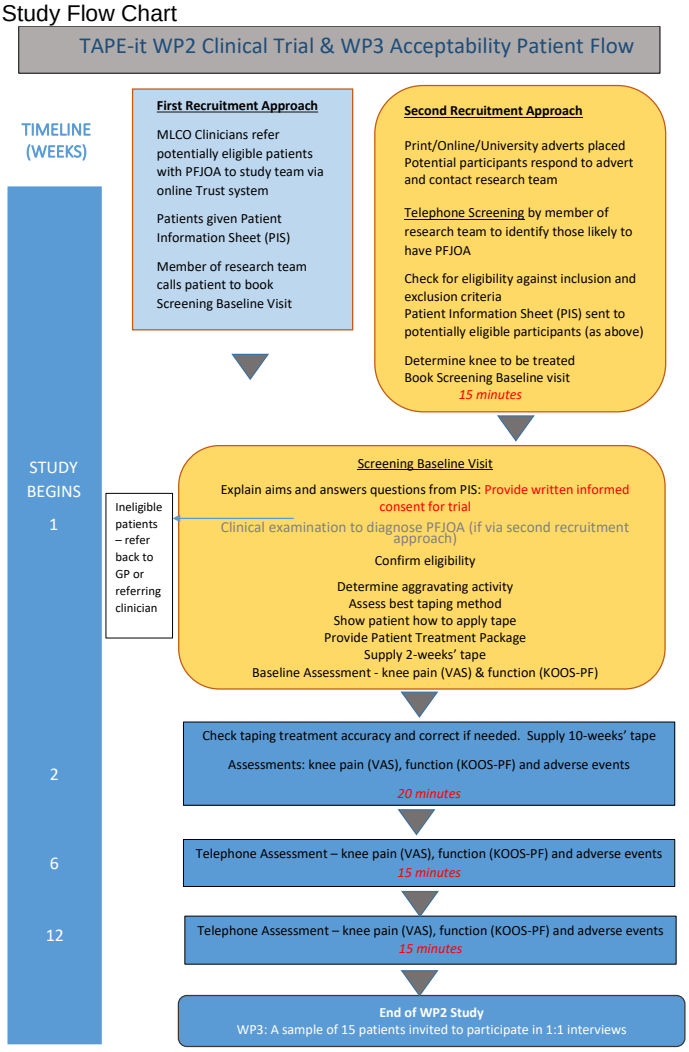
Study Flow Chart



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1. Background

Osteoarthritis (OA) is a leading cause of knee pain and disability affecting one in eight men and women aged over 50 years (1) and is associated with large healthcare and personal costs (2). There is no cure, little effective treatment and none proven that delays the disease progressing. Patellofemoral joint osteoarthritis (PFJOA) is a significant source of knee pain, yet it receives relatively little attention (3), despite being associated with high levels of pain, stiffness and functional limitation (4, 5). PFJOA has only recently been recognised as a distinct subgroup of knee OA. The prevalence for PFJOA is about 25% (95% CI: 15–37%) in population-based cohorts and 39% (95% CI: 25–54%) in symptom-based cohorts. Approximately half those with radiographic knee OA have some degree of PFJOA. In particular, females aged ≥50 years appear to have a higher prevalence of PFJOA (41%) than their male counterparts (23%) (6). Also, PFJOA tends to affect younger adults more than generalised knee OA so it is plausible that burden of disease measures, such as years lived with disability, would be higher in PFJOA than generalised knee OA (6).

Targeted interventions for PFJOA are required because it differs from tibiofemoral OA (3). Our previous work on PFJOA (7) showed significant benefits of a knee brace for this condition. However, two thirds of patients had difficulty wearing the brace, in part due to fitting issues causing discomfort and due to its appearance, both of which affected treatment adherence and treatment efficacy. Patellar taping is a low-cost treatment commonly used by physiotherapists and other clinicians in the short-term to ease joint pain. We want to test the feasibility of a taping intervention as part of a long-term treatment package for PFJOA which acts similarly to a brace but addresses the fitting and appearance problems posed by brace therapy and can be individualised to address patients' specific symptoms, unlike knee braces. The medical tape used is widely used in UK clinical practice and is FDA approved and CE-marked. Dependent upon the results, this feasibility study will inform the development of a Health Technology Assessment (HTA) application for a large randomised controlled trial looking at the cost effectiveness of a taping intervention in PFJOA.

Non-pharmacological, self-managed treatments (e.g. weight control and structured exercise) are important and valued by patients (8). Current management of knee OA focuses on reducing pain. However, patients are often reluctant to take analgesia or NSAIDs (9) due to lack of efficacy or significant toxicities. Our taping intervention could provide a safe, effective, and low-cost non-pharmacologic treatment in primary care to ameliorate clinical symptoms of pain and dysfunction. Five patients in a group convened for this application told us that a study on taping would be important for those with painful PFJOA and agreed with the benefits listed above.

Patellar taping is a well-established and successful intervention in physiotherapy practice for non-arthritic patellofemoral pain (10) or anterior knee pain (11-14), a condition affecting mostly young women. Data from our recent systematic review suggest that patellar taping may also be beneficial for older people with symptomatic PFJOA (15). The two trials to date (16, 17) on taping efficacy, however, have been short term (only up to 3 months) whilst this is a chronic condition. Additionally, these previous trials required physiotherapists applying taping treatment to patients

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in a formal clinic setting and did not test the feasibility of having the patient administer the tape themselves in their own home settings.

Our study will be novel in terms of the condition treated and the method of participant self-application. The effectiveness of tape as part of a treatment package for PFJOA remains uncertain and a definitive randomised controlled trial is needed. Such a trial needs to be informed by evidence that patients with PFJOA can apply the tape, and that they will wear it over an extended period. We also need to know how symptoms, including pain, change in participants who use the tape. Such data are lacking for which further research is required.

2. Rationale

Patellofemoral joint osteoarthritis (PFJOA) has only recently been recognised as a distinct subgroup of knee OA. It is a significant source of knee pain, yet it is often overlooked despite being associated with high levels of pain, stiffness and functional limitation. In our previous trial on PFJOA using sleeve knee braces the majority of patients found adherence difficult due to the braces being uncomfortable, bulky and awkward to wear. A different device, sports tape, may have several advantages over knee braces such as being individualised to each person's knee shape, slim to wear under tight clothing and comfortable for long-term use.

Patellar taping is commonly used by physiotherapists and others in the short-term to ease non-arthritic patellar pain; it is low-cost compared to braces. We want to test the feasibility of a taping intervention as part of a long-term treatment package for PFJOA. Our PPIE group in WP1 of the grant have tried the tape in 2 workshops and been involved in the design of the intervention. They have described the taping as easy to apply at home, comfortable and easy to wear. All these observations may help taping treatment adherence but there are still uncertainties we need to address before progressing to a full clinical trial.

Our aim is for this feasibility trial to answer these uncertainties. This will determine whether patellar taping is a feasible and acceptable part of a treatment package for painful PFJOA.

3. Research Question/Aim(s)

To determine whether patellar taping is feasible and acceptable as part of a best practice care treatment package for painful patellofemoral joint osteoarthritis (PFJOA).

If feasible and acceptable, to plan a full, definitive randomised controlled trial (RCT) to determine long-term clinical effectiveness.

3.1 Objectives

Primary Objective:

i) To assess recruitment (uptake) to the study and retention.

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Secondary Objectives:

ii) To determine whether the tape can be applied by participants correctly at home.

iii) To assess adherence to the taping intervention.

iv) To assess how to optimise adherence to taping over an extended period.

v) To determine participants views about the acceptability of taping.

vi) To determine whether participants experience a reduction in pain in response to tape.

vii) To determine a primary outcome for a large scale RCT and to inform the sample size calculation.

3.2 Outcome Measures

Primary outcome

i) WP2: To assess recruitment to the study and retention: Participant uptake – number of participants recruited and number of participants who complete the study.

WP3: Report on participant experiences of taping and the trial process. Explore facilitators and barriers to adherence. Evaluate the performance of the participant treatment package.

Secondary outcomes (ii – vii)

ii) To determine whether the tape can be applied by participants correctly at home: Clinical checks at 2 weeks recorded on the Clinical Report Form.

iii) Adherence:
   a. Number of returned or counted unused tapes

   b. Number of days since the previous timepoint that participants report wearing the tape collected at weeks 2, 6 and 12.

   c. Average number of hours the participants report wearing the tape daily since the previous timepoint at weeks 2, 6 and 12.

(iv & v) To assess how to optimise adherence of taping over an extended period and to determine participants views about the acceptability of prolonged taping: Participants interviews in WP3.

(vi) Effect of intervention: Reduction in pain

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(a) Knee pain measured by VAS_{NA} at baseline, 2, 6 & 12 weeks.

(b) Knee pain and function measured by KOOS-PF at baseline, 2, 6 & 12 weeks.

(vii) To determine a primary outcome for a large scale RCT and to inform sample size calculation: Analysis of quantitative data in vi a & b

4. Study Design and Methods of Data Collection

4.1 Study Design

A feasibility prospective intervention trial (WP2) with qualitative assessment of participants' opinions of the acceptability of the intervention (WP3).

This protocol includes two work packages (WP2 & 3) which are part of a wider research programme focused on patellofemoral taping in OA. The wider programme comprises seven WPs which are summarised below. This protocol relates specifically to WP2 and WP3.

Prior to this protocol, WP1 was undertaken in January and February 2024. This involved 11 participants who were taken through the study concept, 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, best methods used and that the planned study was meaningful. The findings from WP1 fully informed WP2 as described below.

WP2 is a feasibility open label trial of the taping intervention developed in WP1.

WP3 is a qualitative assessment of the acceptability of the taping intervention package (WP2) using semi-structured interviews and qualitative analysis.

WP1: Workshops: intervention development

WP2: Clinical trial: intervention delivery

WP3: Interviews: intervention acceptability

WP4: Generating impact: RCT

WP5: Dissemination

WP6: Follow on Clinical Trial

WP7: Project Management

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4.2 Methods of Data Collection

Work Package 2 (WP2):

Once the eligible participants have been consented and recruited into the study, each participant will have an individualised taping technique determined by the immediate pain relief the tape provides (11). Taping will be demonstrated and applied to the participant. The length of tape will be calculated at 50% of the circumference of each subject's knee. We will provide two weeks' supply of pre-cut tape. Two strips of tape are applied across the front of the knee and patella dependent on each participant's preference and symptom change. Participants will then perform an activity that normally triggers their pain. They will decide if taping gives them immediate decrease in pain using a VAS pain score applied before and during the task with the tape. The tape technique with the best pain relief during the activity will be used for that subject for the taping intervention during the feasibility trial. Instructions in ***written, illustrative and video formats*** indicating the correct application of the patellar taping intervention have been developed by our PPIE group and two intervention development workshops (WP1). Participants will be asked to use the tape daily for 12 weeks. They will be advised on the amount of time daily they should wear the tape, what to do if the tape comes off and skin care. All subjects will receive advice, written information, and exercise instruction that aligns with best practice care for patients with knee OA and recommendations from NICE (18) and those available in the Osteoarthritis Guidebook https://www.keele.ac.uk/media/keeleuniversity/ri/primarycare/pdfs/OA_Guidebook.pdf)

Participants will be assessed face-to-face at baseline and again face-to-face after 2 weeks and then by telephone or online (e.g. Zoom, Teams) at 6 and 12 weeks. At baseline and weeks 2, 6 and 12 subjects will complete the following assessments: Knee pain during a nominated aggravating activity (VAS_{NA} 0-10), the Knee Osteoarthritis & Injury Outcome Score for the patellofemoral joint (KOOS-PF) (20). Subjects will have a face-to-face assessment 2 weeks after treatment commences to check for correct application of the tape. At this 2 week visit a further 10 weeks of tape will be supplied. At each contact, participants will be asked about treatment adherence. They will be asked since the last timepoint (Baseline, or weeks 2, 6 or 12) approximately how many days per week and how many hours per day on average the tape was worn.

As there is no gold standard for measuring adherence to taping, we will estimate adherence by counting the number of unused strips of tape at the end of the trial and by asking how many days per week and how many hours per day on average the tape was worn. We will collect this information at the 2 weeks tape check and at the two telephone or online consultations at 6 and 12 weeks. Participants will be encouraged to adhere to the tape during the 6-week telephone call. Information on any adverse events will also be collected at each contact.

Work Package 3 (WP3):

Participants completing WP2 will all be given a PIS for WP3 and asked if they are interested in taking part in WP3. It will be explained that they may not be picked, depending on how many say yes as we will only require fifteen. Fifteen participants from the feasibility trial (WP2) will be invited to participate in one-to-one semi-structured interviews for WP3. Participants will be purposively recruited from those who consented to be contacted in WP2, to reflect a range of sex, age and ethnicity. It is anticipated that this sample size will be sufficient to generate rich data. However, recruitment will continue until data saturation has been achieved. Moreover, if data saturation is achieved before recruiting the fifteenth participant, recruitment will be stopped at that point. Purposive recruitment will allow us to include the voices of participants not commonly heard in this type of research, including those from underserved communities. As such, we are confident that purposively recruiting 15 participants is appropriate for this study. Semi-structured interviews of approximately 60 minutes will be conducted to gain in-depth understanding of participants' experience of the intervention. Interviews will be informed by an interview guide developed from the findings of WP1, the research team including PPIE representative, underpinned by the Theoretical Framework of Acceptability (21) (see appendix 1). Participants will be interviewed by the research associate (RA) who is trained in undertaking qualitative interviews either in-person, online via Teams, or over the phone depending on the participants' preference. In-person interviews will take place in a private room at the Brooks Building, Birley Campus, Manchester Metropolitan University. Two participants who will have taken part in the clinical trial will pilot the guide to ensure its appropriateness. Consent and demographic information will be collected at the start of the interview. Further discussion will be guided by each participant's response to the questions to allow exploration of unanticipated issues. Emerging findings from each interview will iteratively feed into subsequent interviews. Interviews will be digitally recorded, and interviews will be professionally transcribed.

Interviews will explore what went well and any barriers to adherence. This will help evaluate the performance of the participant treatment package. Currently, it is unclear how long taping can be used for effective treatment, so we will explore whether the number of hours of use is associated with a perceived reduction in knee pain and if there is a minimum threshold whereby a how long the tape must be used before any long-term pain reduction. Additionally, as there is no currently available evidence that tape is effective in the long-term specifically for PFJOA, we will explore participant views and willingness to be randomised in a future RCT.

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Feasibility and adherence outcomes			
Measure	Stop	Edit	Go
Number recruited	1 per month	2-3 per month	4 per month
Percentage recruited (uptake)	< 25%	≥25% and < 75%	≥ 75%
% of recruited participants with complete data	< 20%	≥20% and < 70%	≥ 70%
% of recruited participants lost to follow-up at 12 weeks	> 20%	≤20% and ≥10%	< 10%
% of recruited participants whose pain had clinically improved at 12 weeks	<20%	≥20 and <65%	≥65%
% of recruited participants who would use the tape again	<20%	≤20 and ≥65%	≥65%

4.3 End of Study

End of study is defined as the date of the final interview of participants in work package 3.

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4.4 Schedule of Procedures

Work Package 2 (WP2):

Procedures	Visits			
	Baseline	Week 2*	Week 6*	Week 12*
Informed consent	x			
Demographics	x			
Intervention training	x	x if required		
VAS / KOOS-PF	x	x	x	x
Adverse Events		x	x	x
Observation of treatment		x		
Feedback on treatment		x	x	x
Telephone/online assessment			x	x
WP3 Interview discussion				x

*+/- 5 days

Work Package 3:

Procedures	Single visit
Informed consent	x
Face to face, telephone or online interview	x

4.6 Device in Use

The sports medical tape for this trial is widely used in UK clinical practice and is FDA approved and CE-marked. The tape is approved for use for the treatment of knee pain. It is budgeted for purchase within the study funding stream. Purchase orders will be raised by MFT, product will be shipped, once invoices are paid, to the Stopford Building/or Manchester CRF building and received by the Goods-In Department and delivered to the study team. Sufficient tape will be cut and distributed to the participants at the baseline and 2 weeks visits by the CI along with in person training plus the training materials submitted alongside this protocol. Any excess tape will be disposed of in general waste by the participants at home, information is in the PIS. The advice given will be that participants

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should try and wear the tape for as long as is comfortable and taken off at night to be applied fresh the following day. There are no known complications with other treatments being used at the same time.

Manufacturer: We Tape

Brand: Rocktape UK: https://www.rocktape.co.uk

Distributer: c/o Fit Brands Ltd, Unit 33A Number One Industrial Estate, Consett, Co.Durham, DH8 6SZ

This product is a class I medical device and is CE Marked. The CE mark is clearly visible on the outside of the packaging.

The product is made from 97% cotton and 3% nylon, it is hypoallergenic and it does not contain latex.

5. Study Sample and Recruitment

5.1 Eligibility Criteria

All individuals will be considered for inclusion in this study regardless of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion and belief, sex, and sexual orientation except where the study inclusion and exclusion criteria EXPLICITLY state otherwise.

5.1.1 Inclusion Criteria

- Adults of any gender aged 40 years of age or over.
- Pain predominantly over the patella (anterior knee pain) and greater than medial or lateral compartment knee pain.
- Clinically significant patellofemoral pain / anterior knee pain on weight bearing activity such as stair ascent/descent, sit-stand-sit scored at 4 or above on an 11 point (0 no pain–10 worst pain) visual analogue scale (VAS).
- Already on a stable/regular dose of analgesia.
- Able to understand English (or English speaking) and give full informed consent.
- Willing to participate.

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5.1.2 Exclusion Criteria

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

5.2 Study Setting and Sample Identification

Participants will be identified by Dr Janet Suckley and clinical team at the Manchester Local Care Organisation (MLCO) or by Dr Nasimah Maricar in clinics at Salford Royal Hospital. Participants will be given a PIS to read and consider.
Those who are interested in taking part will be invited to attend a face-to-face baseline visit at the NIHR Manchester Clinical Research Facility. At the baseline visit potential participants will be asked to confirm that they have received and read this PIS. The researcher will further discuss the study with the potential participant and give an opportunity for them to ask questions.

If recruitment is not met by the above clinics an advert will be posted on the University of Manchester intranet and in the Manchester Evening News. This will invite potential participants to scan a QR code which leads them to some basic questions about their knee health and skin condition. If they are suitable, they will be given details to contact the research team.

The assessment and delivery of WP2 will take place in the NIHR Manchester Clinical Research facility. Participants will self-apply the taping intervention in their homes. The delivery of WP3 will take place in the Department of Health Professions at Brooks Building, Birley Campus, Manchester Metropolitan University. Participants will be purposefully selected from those in the WP2 arm who have completed the 12 weeks programme by the CI and Professor Gillian Yeowell from the Manchester Metropolitan University.

5.3 Sampling

5.3.1 Size of Sample

This is a pragmatic sample size calculation for a feasibility study. A sample size of 30 is sufficient to allow estimation of feasibility parameters with 95% confidence intervals, including a drop out of 20% (19). A target of 50% for the primary outcome, participant uptake, can be estimated with 95% confidence intervals 36.8-63.2%.

5.4 Recruitment

Central Manchester has a diverse ethnic and socio-economic population. Based on previous trials we would expect the diversity of the population to be reflected in our recruitment. Two recruitment methods will be used for WP2.

1. Musculoskeletal physiotherapy practitioners from the Manchester Local Care Organisation (MLCO) will refer participants with PFJOA from clinics using, preferably the online NHS Trust research referral pathway (HIVE). If this is not available, then participants will be directly referred using the Study Team's secure NHS or NHS.net email address. Potential participants will be given a participant information sheet (PIS) with study details and an invitation to contact the trial team by email or telephone visit. If, after talking with the trial team, they are still interested they will be invited to attend for a face-to-face screening baseline visit.
2. Participant Identification Centre: Salford Royal Hospital – Dr Nasimah Maricar will act as a collaborator to identify potential participants from musculoskeletal clinics. The referral method would then be as method 1 above with the MLCO with potential participants being offered a participant information sheet (PIS) with study details and an invitation to contact the trial team by email or telephone.
3. Subjects will be recruited through advertisements on the university websites / online and print news media. Potential participants will be invited in these advertisements to scan a QR code that leads them to some questions about their knee health and skin conditions. The questions have been informed by our previous work to identify those likely to have PFJOA; this is estimated to take about 15 minutes. Participants who are interested in taking part and where there are no obvious exclusions (e.g. age, recent knee surgery, poor skin condition around the test site) will be given details to contact

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the research team and be sent a PIS. If, after reading the PIS, they are still interested they will be invited to attend for a face-to-face baseline visit.

5.5 Consent

Subjects will be asked to sign an informed consent form in the presence of the CI prior to taking part in any study procedures. As part of the informed consent process, participants will have been given a PIS to read for at least 24 hours. At the baseline visit, participants will have the opportunity to ask any questions, discuss the research and their involvement before they decide.

At the last visit of WP2, participants will be asked if they would like information to take part in follow-up interviews to explore their experiences of the trial and intervention acceptability in WP3. Further PIS for WP3 will be provided at this stage.

WP3 may take place purely online (via Teams) or by telephone, therefore copies of the consent form will be sent and returned with scanned or e-signatures via email or through the post in pre-paid envelopes.

Data protection and confidentiality measures taken by the CI and the host institution will be explained to the participant.

It will also be explained that participants are free to withdraw consent at any time without giving any reason, and without their legal rights being affected. All data collated up to the point of withdrawal will be retained for use with the analysis.

5.6 Participant Compensation

We will offer £70 per participant as a thank you for peoples' time and effort at the end of Work Package 2. This is for 2 face-to-face visits and 2 online/telephone calls.

We will offer £25 per participant as a thank you for time and effort for Work Package 3.

6. Statistics and Analysis

6.1 Data Analysis

<u>Intervention arm WP2:</u>

All variables will be examined using appropriate descriptive statistics (mean [standard deviation], median [interquartile range], n [%]) and graphics for completeness and form. No imputation will be made for missing data, however quantities and location will be used to inform the design of a future RCT.

The primary outcome, recruitment rate, will be presented as a proportion with 95% binomial confidence intervals. This will also be presented on a monthly basis. Other feasibility parameters, dropout rates and those with complete data, will be presented similarly.

Adherence, i.e. number of returned tapes and the number of days and average hours of daily usage, will be reported for each timepoint as continuous measures with mean/median and SD/IQR as appropriate. Overall measures of usage will be presented and comparative statistics or line graphs will illustrate any changes in usage over the study duration. It is possible there may be reasons other than non-adherence which result in unused tapes (e.g. major increases or decreases in symptoms). We will collect this information at the 2 weeks clinical check, at the two telephone consultations at 6 and 12 weeks, and during the qualitative study WP3. Further prompts to encourage tape adherence will be done during the telephone consultations using the questionnaires at 6 and 12 weeks.

Adverse events (such as skin irritation, the development of new pain in other body regions thought to be related to the interventions) will be presented as the total number and proportion.

The measures of treatment efficacy, pain scale (VAS_{NA} 0-10) and the Knee Osteoarthritis & Injury Outcome Score for the patellofemoral joint (KOOS-PF) (20) will be reported with descriptive statistics and graphics at baseline, 2, 6 and 12 weeks. Preliminary analysis of all timepoints alongside the change from baseline to 12 weeks will be presented to inform the design of the future full RCT. The KOOS-PF will be scored as per validated instructions (20). This includes a "rule" that a subscale score can be calculated if 50% or more of the items in specific subscale have been completed by the participant.

The recruitment strategy will be assessed by examining the summary statistics and distribution of participants using the ethnic and socio-economic data, including the Index of Multiple Deprivation Decile. Using Census data, we will assess how participants recruited to the study reflect both the ethnic diversity of the UK population as a whole and that of Manchester and Trafford. This will inform the equality, diversity, and inclusion (EDI) recruitment strategy for the future RCT.

<u>Qualitative assessment – WP3</u>

An inductive thematic analysis framework will be used to analyse the data (22). This involves initial open coding of the data, applying categories to the data that identifies salient points. Patterns are then identified across the dataset to form sub-themes. Conceptually similar sub-themes are then grouped to form overarching themes. Data analysis will be undertaken by the research team. Critical discussions amongst the team, including the PPIE representative, will verify, modify and refine the themes. Reflexive field notes will feed into the analysis using NVivo software.

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7. Ethical and Regulatory Considerations

7.1 Risks and Burdens to Participants

Work Package 2 - Due to the nature of the intervention, we do not anticipate any unwanted incidents, adverse events or effects on our participants. Nevertheless, we will have procedures in place for reporting of adverse events or serious adverse events, as detailed in the safety reporting section.

There is a risk of reaction to the tape used in the intervention. Participants will be asked in the PIS and again prior to consent if they have a known allergy to any form of adhesive taping. They will be excluded if they declare any known allergies to the tape.

We will also ensure that participants with fragile skin or with thin, easily bruised skin will not take part. Despite these precautions, if a participant develops skin irritation, however minor, we will withdraw them from the trial and will advise them to see their GP.

There is a risk that participants may see no improvement or worsening of symptoms following taping intervention, if this happens, we will refer them back to their GP or referring clinician at the end of the study when it is clear the intervention has not had an effect or has made any pain worse.

There is a time burden to this study, recruitment (including consent), taping demonstration, questionnaire completion. The feedback from our PPIE workshops was that the burden of time for visits and practically applying the tape was minimal, this was also outweighed by the benefits felt from wearing the tape.

Work Package 3: It is not anticipated that there are any risks to taking part in this study. However, there is a possibility that the participant may find discussing their experiences of the taping or knee pain upsetting. If this happens, we will ask them to please let the researcher know; they can take a break at any time or stop the interview if they wish to do so. If during the interview they reveal that their safety or the safety of others may be at risk, this information will be discussed with individuals outside the study team. This will be in the PIS and consent form to ensure full understanding.

7.2 Research Ethics Committee (REC) and Other Regulatory Review & Reports

Before the start of the study, a favourable opinion will be sought from a REC and/ or HRA depending on the type of study for the study protocol, informed consent forms and other relevant participant facing documents e.g., advertisements.

7.2.1 NHS REC Reviewed Research

Before the start of the study, a favourable opinion will be sought from an NHS Research Ethics Committee (REC) for the study and all the supporting documents including the protocol, information sheets, informed consent forms and other relevant documents. The

study team will be responsible for the maintenance of a trial master file or TMF, in which all current and superseded study documents will be retained. Also contained in the site file/TMF will be the approval documentation including correspondence with relevant authorities such as the HRA and REC.

The Chief Investigator will notify the REC of the end of the study, and will submit a final report with the results, including any publications/abstracts, to the REC within 12 months of the end of the study. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

No participants will be enrolled into this research study prior to the study being reviewed by the relevant regulatory authorities and receiving HRA and REC approvals, as well as approval from the R&D office at Manchester University NHS Foundation Trust.

7.3 Amendments

7.3.1 Studies Involving the NHS

Any amendments to the study shall be reviewed by the Sponsorship Team prior to submission. Any non-substantial amendments shall be notified to the HRA and any substantial amendments, along with amended documentation, shall be approved by the REC, and HRA, prior to implementation as per nationally agreed guidelines. The Chief Investigator or designee will work with the R&I department to put the necessary arrangements in place to implement the amendment and to confirm their support for the study as amended.

7.4 Peer Review

This study has been peer reviewed by the NIHR as part of the grant process.

7.5 Patient & Public Involvement

To inform the original successful application for this grant, a group of five patients were gathered and the concept of the taping method and the project as a whole were discussed. The patients were very positive and enthusiastic about sports taping being used for painful PFJOA. Findings from this discussion assisted the design of the intervention phase. The relevance of the questions asked, and the acceptability of the reasoning were also confirmed.

To help us plan the first workshop, three people with a lived experience of kneecap arthritis took part in a Patient and Public Involvement and Engagement (PPIE) consultation meeting. The participants' age range was 40-59, two were female, two identified as White British, one as Asian/Kashmir. They helped us with participant recruitment, and the planning, content and running of WP1.

Prior to this current protocol, WP1 (mentioned in 4.1 of this protocol) was undertaken in January and February 2024. This involved two workshops. The purpose of these workshops was to co-design and refine a treatment package using patellar taping for kneecap arthritis, for use in a subsequent clinical trial feasibility study (WP2). In workshop 1, 11 participants with a lived experience of kneecap arthritis co-designed the intervention with regards to the resources (video and participant instructions) to be used in WP2. Participants age range was 50-81, 10 were female, six identified as white British, six Asian/British Asian, one Black/Black British; UK indices of deprivation deciles ranged from 2-9. The preliminary findings and prototype resources developed from workshop 1 were shared with the same participants in a follow-up workshop (workshop 2). The final resources and any amendments were discussed and agreed on. This work package (WP1) then fully informed WP2 methodology described below.

We also have a PPIE Co Applicant who has been involved from the start (Mrs Ann McGovern, - AMc). She attends the TMG meetings and had full input in the design of the intervention methodology during the workshops in WP1. She helped prepare our forward-facing documents for WP1 and will support the development of participant facing documents in WP2 and WP3, support the data generation and analysis in WP3 and advise on dissemination plans at the later stages.

7.6 Protocol Compliance

- The research team will be vigilant in protocol deviations and will record them on a study specific deviation log which will be regularly assessed by the CI
- Deviations that may affect the safety, physical or mental integrity of participants or scientific value of the study will be reported to the study sponsor via research.sponsor@mft.nhs.uk by the research team.
- Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach and should also be reported to the sponsor without delay.

7.7 Data Protection and Participant Confidentiality

All investigators and study site staff will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing, and disclosure of personal information and will uphold the Act's core principles.

For Work Package 2, Pseudo-anonymised data will be stored on secure databases within the University of Manchester and Manchester University NHS Foundation Trust and paper CRFs in locked filing cabinets (which will, in turn, be in locked offices) in the Centre for Musculoskeletal Research at the University of Manchester. Only the research team will have access to this area.

For Work Package 3, consents and transcriptions of interviews will be stored on secure databases within the Manchester Metropolitan University. If consents are paper copies, they will be stored in locked filing cabinets (again in locked offices).

Recorded data will be pseudo-anonymised by the person taking informed consent and, therefore, confidentiality will be maintained. Professor Michael Callaghan will act as custodian of the data. Participants in work Package 2 will be given a study ID. The link between Participant and ID number will be kept secured and encrypted by Professor Michael Callaghan. Access to any identifiable data will only be permitted for the Research Team to contact the participants for follow up appointments.

Access to this pseudo-anonymised data will be restricted, only the people entering the data or contacting the participants for follow ups will have access to the information and this will only be the pseudo-anonymised data. Bone fide researchers will have access to the pseudo-anonymised data. The identifiable information will be kept for 10 years after the study has finished. The data will be archived onsite at the University of Manchester.

The Manchester University NHS Foundation Trust, University of Manchester and Manchester Metropolitan University IT systems are backed up to the server daily.

The results of this research will be published and/or used by other bone fide researchers in the research field. However, all identifiable information will be removed. Information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

The participants' rights to access, change or move your information are limited, as we need to manage their information in specific ways in order for the research to be reliable and accurate. If participants withdraw from the study, we will keep the information about that has already been obtained. This is fully explained in the Participant Information Sheet.

We will always act in accordance with the General Data Protection Regulations.

7.7.1 Data Management

Please refer to the Manchester University NHS Foundation Trust study specific Data Management Plan for further details.

Paper forms of consent forms and questionnaires from WP2 will be stored in a locked office in the University of Manchester. Access to the building is by swipe cards and door codes are required. The questionnaires will only contain the study ID and non-personal data for data entry purposes. Only the research team will have access to this data. The questionnaires will be entered on to the REDCap database for analysis. The University of Manchester and MFT systems are backed up to the server daily.

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The digitally recorded interviews from WP3 will be downloaded, password protected and stored securely on Manchester Metropolitan University computers before being sent for professional transcription. Anything obvious (e.g. name) is pseudo anonymised by the professional transcription company (TypeitWrite: TypeitWrite Home Page - Fast & Efficient Audio Transcription Services (typeitwritetranscription.co.uk) when they are transforming the audio data to a word document. The professional transcription company will then send us the transcript as a password protected Word doc. This transcript is then reviewed by the RA. Any additional or missed identifiable data is then pseudo anonymised by the RA.

Only the CI and members of the research team who are involved in analysis will have access to the transcripts.

The paper questionnaires are source data as are the original recordings. These will be kept securely and archived with the study site file for the required retention period.

7.7.2 Redcap

REDCap is a secure web application for building and managing online surveys and databases. In this study, it is being used to host online CRF/questionnaires, and/or transcribe paper CRFs/questionnaires.

The system is specifically designed for research and data is stored on an MFT server (not shared with any third party). MFT servers are backed up at the end of each day and are maintained by MFT Informatics Team. If data is lost, it can be recovered via the Trust IT back up service for the REDCap server.

7.8 Indemnity

The NHS indemnity scheme will apply to this study to ensure it meets the potential legal liability of the sponsor, equipment, employer, and investigators/collaborators for harm to participants arising from the management, design and conduct of the research. No arrangements will be made for the payment of compensation in the unlikely event of harm.

The University of Manchester and Manchester Metropolitan University both have insurance for research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students, subject to policy terms and conditions.

7.9 Monitoring

The study will be subject to the audit and monitoring regime of Manchester University NHS Foundation Trust in line with applicable MFT SOPs and policies. The study will have, as a minimum, an annual survey sent out for completion by a member of the research team.

7.10 Access to the Final Study Dataset

The final dataset will be held in the Open Access repository, permissions for access to pseudo-anonymised data only granted on a request basis. The Research study team will have access to the final study dataset.

Our PIS states that the pseudo-anonymised dataset may be used in relevant future research.

The study statistician will only have access to pseudo-anonymised dataset. The analysis dataset will be stored on the study statistician's specific area on secure servers at University of Manchester.

8 Safety Reporting

Reports of Serious Adverse Events (SAEs) that are:

- related to the study (i.e., they resulted from administration of any of the research procedures) and
- unexpected (i.e., not listed in the protocol as an expected occurrence)

will be emailed to the REC using the Non-CTIMP safety report to REC form within 15 days of the Chief Investigator becoming aware of the event.

A Serious Adverse Event (SAE) is defined by the Health Research Authority (HRA) as an untoward occurrence that:

(a) results in death;

(b) is life-threatening;

(c) requires hospitalisation or prolongation of existing hospitalisation;

(d) results in persistent or significant disability or incapacity;

(e) consists of a congenital anomaly or birth defect;

(f) is otherwise considered medically significant by the investigator.

A SAE occurring to a research participant must be reported to the REC where, in the opinion of the CI, the event was: "Related" that is, it resulted from administration of any of the research procedures, including the use of the device and "Unexpected" that is, the type of event that is not an expected occurrence as a result of the intervention provided.

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The potential harms of the intervention arm (WP2) and the qualitative assessment (WP3) are considered to be minimal.

Safety Reporting Process

All SAEs occurring from the point at which participants consent to participate will be notified to the sponsor via telephone within 1 working day of the study clinicians becoming aware of the event. They will also be notified via email within 24 hours to adverse.events@mft.nhs.uk

Field Code Changed

The Study CI will be asked to assess SAE causality.

Any follow-up information should be sent to the Sponsor via the Study Team as it is available, and where appropriate. Events will be followed up until the event has been resolved or a final decision made.

The reporting clinician will give their assessment and the CI will assess whether the event is related to or resulted from any of the study procedures or interventions and expectedness.

9. Dissemination

9.1 Dissemination Policy

Dissemination will focus on key stakeholders for this research and those needed for a future RCT: a) patients with PFJOA, patient groups and charities; b) primary care practitioners and physiotherapists and other clinicians; c) academia.
Work Package 5 objectives are:

a. To prepare a plain English summary

b. To use this and social media postings to disseminate to targeted groups

c. A presentation at the 2025 UK physiotherapy congress

d. An in-service training presentation to local physiotherapists in primary care

e. An academic paper

Participants that wish to receive study results will be sent a plain English summary via their preferred method (email/post) at the end of the study.

As a future RCT would be centred on Greater Manchester, we will focus particularly on community (MLCO) physiotherapists and local groups likely to include PFJOA patients. VOCAL has provided a list of local groups already raising awareness of musculoskeletal studies to their members, for example Healthwatch Salford, Age UK Salford and local women's groups and ethnic groups.

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We will liaise with charities which have a focus on the condition (PFJOA) such as Versus Arthritis and Arthritis Care to contribute to and capitalise on their networks. Our patient group will help us prepare a plain English summary of our findings for sharing with stakeholders, e.g. in local NHS and research newsletters.

During the project, we will present early results at one physiotherapy conference (2025 UK physiotherapy congress). We will also prepare and submit one academic paper to a high impact rheumatology or physiotherapy journal.

Digital and social media platforms have become critical media for distributing academic works (21). We will post on social media, e.g. Twitter, Instagram, TikTok, Facebook, and LinkedIn and on the interactive network for UK physiotherapists (iCSP).

After the end of the project, we aim to present to community physiotherapy (MLCO) in-service training within six months, and present at further academic conferences, e.g. CSP, OARSI and EULAR.

9.1.1 Publication and Dissemination (REDCap) (if applicable)

Any study manuscripts will follow the REDCap publication requirements (https://projectredcap.org/resources/citations/).

9.2 Authorship Eligibility Guidelines and Any Intended Use of Professional Writers

Authorship will be granted following the NIHR guidelines: Authorship (nihr.ac.uk)

10. Archiving

Study documentation and data will not be destroyed without the approval of the research team at the Centre for Musculoskeletal Research at The University of Manchester and the Sponsor, Manchester University NHS Foundation Trust.

The study data will remain the property of MFT. A complete copy of the study data will be kept on the MFT secure IT server at the end of the study. At the end of the study all documents and data relating to this project will be stored securely at the University of Manchester onsite archive facilities for 10 years following completion of the project, or in line with MFT policies and in accordance with ICH GCP.

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APPENDIX 1

Interview guide

Demographics: Age, Sex, Ethnicity, Postcode (for deprivation data), duration of kneecap arthritis.

Explore

Taking part

- motivations to taking part in the study and using the tape.
- How they felt about taking part in study
    - prior to taking part
    - after taking part.
- How they understood the intervention and how it works

Treatment intervention

- How they perceived burden of the intervention
- How they perceived amount of effort that was required to participate in the intervention
- Experiences of wearing using the tape
    - Application - The participants confidence that they could apply the tape to participate in the treatment package – what worked well and what worked less well.
    - wearing the tape – including comfort relating to the tape and explore any issues.
    - adherence to using the tape - what helped adherence, were there any barriers to adherence.
    - How long did they wear tape for – whether the number of hours of use is associated with perceived reduction in knee pain.

Following the treatment

- The extent to which the intervention is perceived to have achieved its intended purpose.
- Overall, what went well and what could be improved?
- Views and willingness to be allocated to the control or intervention arm in a future RCT.

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