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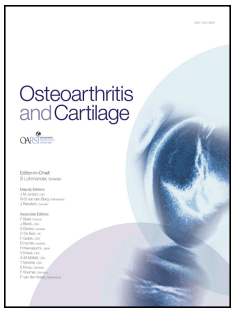

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Exercise, education, manual-therapy and taping compared to education for patellofemoral osteoarthritis: A blinded, randomised clinical trial

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Abstract (249words)

Objective Patellofemoral joint osteoarthritis (PFJ OA) contributes considerably to knee OA symptoms. This study aimed to determine the efficacy of a PFJ-targeted exercise, education manual-therapy and taping program compared to OA education alone, in participants with PFJ OA.

Methods: A randomised, participant-blinded and assessor-blinded clinical trial was conducted in primary-care physiotherapy. 92 people aged ≥40 years with symptomatic and radiographic PFJ OA participated. Physiotherapists delivered the PFJ-targeted exercise, education, manual-therapy and taping program, or the OA-education (control condition) in 8 sessions over 12 weeks.

Primary outcomes at 3-month (primary) and 9-month follow-up: (i) patient-perceived global rating of change (ii) pain visual analogue scale (100mm); and (iii) activities of daily living (ADL) subscale of the Knee injury and Osteoarthritis Outcome Score.

Results: 81 people (88%) completed the 3-month follow-up and data analysed on an intention-to-treat basis. Between-group baseline similarity for participant characteristics was observed. The exercise, education, manual-therapy and taping program resulted in more people reporting much improvement (20/44) than the OA-education group (5/48) (number needed to treat 3 (95% confidence interval (CI) 2 to 5)) and greater pain reduction (mean difference: -15.2mm, 95%CI -27.0 to -3.4). No significant effects on ADL were observed (5.8; 95%CI -0.6 to 12.1). At 9 months there were no significant effects for self-report of improvement, pain (-10.5mm, 95%CI -22.7 to 1.8) or ADL (3.0, 95%CI -3.7 to 9.7).

Conclusion: Exercise, education, manual-therapy and taping can be recommended to improve short-term patient rating of change and pain severity. However over 9-months, both options were equivalent.

Trial Registration: Australian New Zealand Clinical Trials Registry (ACTRN12608000288325): https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=82878'

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Introduction

Patellofemoral joint osteoarthritis (PFJ OA) remains an under-recognized category of arthritis. Evident in almost 70% of adults with knee pain[1-5], it is more prevalent than tibiofemoral (TFJ) OA[1-3, 5, 6]. Patellofemoral OA is observed early in the trajectory of knee OA disease process[7], and is observed in 55% of people aged under 50 years[3]. Since the PFJ contributes more to the symptoms of knee OA than the TFJ [4, 8, 9], PFJ OA can adversely affect quality of life, economic productivity and daily function in younger adults with critical career and childcare responsibilities.

Clinical guidelines prioritise conservative (non-pharmacological) treatments as a first line knee OA management and recommend tailoring treatments to the location of joint damage[10-12] (i.e., to the PFJ compartment for individuals with PFJ OA). Many trials have evaluated physical therapies for patients with predominantly TFJ OA[13]. It is notably that PFJ OA severity limited the effectiveness of exercise and manual-therapy applied to those with predominant TFJ OA[14, 15], supporting the recommendation for targeted interventions. Only two clinical trials specifically assessed treatments for PFJ OA, with no positive effects reported for either combined exercise therapy with patellar taping[16] or patellofemoral bracing[17]. The lack of benefit may reflect the lack of tailoring of exercise and patellar taping to the individual[16, 17] or the use of a single treatment component (bracing)[17].

The Consensus Statement from the 3rd International Patellofemoral Research Retreat[18] suggested a disease continuum that manifests as PFJ pain in younger adults and PFJ OA at later stages [19, 20]. Common impairments include patellar malalignment[21-23], quadriceps and hip muscle weakness[24-29]. This provides a rationale to consider treatments designed for PFJ pain in younger adults for older people with PFJ OA. Our previous clinical trials proved the effectiveness of quadriceps and hip muscle retraining exercises, patellar taping, and patellar mobilisation for PFJ pain in younger adults[30, 31].

We aimed to evaluate whether a PFJ-targeted program that combined (i) exercise, (ii) education, (iii) manual therapy and (iv) taping, results in greater improvements in patient rated change, pain and physical function than physiotherapist-delivered OA education in participants with symptomatic and radiographic PFJ OA. We hypothesised that the PFJ-targeted program of exercise, education, manual-therapy and taping would be superior to the OA-education at 3 months, and that beneficial effects would not be present at 9-months.

Methods

Design Overview

We conducted a randomised, assessor- and participant-blinded controlled clinical trial, as described previously[32]. The trial was prospectively registered in the Australian New Zealand Clinical Trials Registry (ACTRN12608000288325). The study had ethical approval (HREC number: 0721163) and all participants provided written informed consent prior to commencement, and all human testing procedures undertaken conformed to the standards of the *Declaration of Helsinki*.

Setting and Participants

The clinical trial was conducted in primary care physiotherapy practices. Volunteers from the greater Melbourne (Australia) area responded to advertisements in print and radio media, posters in sporting clubs, health and medical practices and referrals from practitioners. Potential participants underwent telephone screening, followed by a physical screening by an experienced physiotherapist and standardised weight-bearing semi-flexed, standing, posteroanterior and skyline radiographs to assess the severity of TFJ and PFJ OA.

To be included, volunteers were required to be aged at least 40 years; have anterior or retro-patellar pain that was aggravated by two or more PFJ-loaded activities (e.g. stair ambulation, rising from sitting or squatting); have an average pain score of at least 3 on an 11-point scale (0=no pain;

10=worst pain possible) during aggravating activities and on most days during the past month; and have evidence of lateral PFJ osteophytes[33] on weight-bearing skyline radiographs[34]. Participants were excluded if they had pain from other lower-limb sites; predominantly TFJ joint symptoms on clinical examination (e.g. location of pain, tenderness on palpation); current or previous (prior 12 months) physiotherapy for knee pain; recent knee injections (prior 3 months); previous or planned (following 6 months) knee surgery; physical inability to undertake testing; other medical conditions; inability to understand written and spoken English; and a body mass index (BMI) greater than 34 $kg.m^{-2}$. Additionally, individuals with medial > lateral PFJ osteophytes or moderate-to-severe concomitant TFJ OA (Kellgren and Lawrence[35] grade >2) were excluded.

Randomisation and Interventions

The randomisation sequence (computer-generated permuted blocks of 8 to 12) was generated *a priori* and kept external (University of Queensland) to the administration site (University of Melbourne) by an independent investigator. Participants were randomly allocated to either exercise, education, manual-therapy and taping or OA-education and were informed that two types of physiotherapist-delivered treatments were being compared, but the types of intervention and study hypotheses were concealed. A research assistant, not involved in outcome assessment, revealed the allocation to the physiotherapist delivering the intervention following baseline assessment and prior to the first appointment.

Each participant attended the private practice of one of eight trained project physiotherapists, at various Melbourne metropolitan sites. Physiotherapists were experienced in treating patients with knee and PFJ conditions and underwent 6 hours of training (with KMC) to standardise the treatment elements and their prescription, as described in the published protocol[32]. Physiotherapists provided both the active and control interventions and thus were not blinded to group allocation. Eight treatments (approximately 60 minutes duration) were provided once a week for 4 weeks and then

once every two weeks for 8 weeks for each group. The interventions have been described in detail previously[32].

The PFJ-targeted exercise, education, manual-therapy and taping program was standardised to consist of (i) functional retraining exercises for the quadriceps and hip muscles; (ii) quadriceps and hip muscle strengthening; (iii) patellar taping; (iv) manual-therapy (PFJ, TFJ and soft tissue mobilisation); and (v) OA-education (Supplementary Table). The standard elements of the treatment were then tailored, such that each participant's clinical presentation (e.g. strength, pain severity, swelling) as well as the presence of co-morbidities (e.g. back and hip pain or pathology) were taken into consideration, and exercises were chosen and progressed by the physiotherapist based on each participant's response to exercise load. This approach ensured that the highest level of load could be applied, whilst keeping the participant's pain to a minimal level (≤2 on a 0-11 numerical rating scale). Exercises were taught and supervised by the physiotherapist during each visit with a home exercise program prescribed, to be performed independently at home 4 times per week. An exercise manual was provided for participants with clear instructions and diagrams to ensure correct and safe performance of all exercises. At the completion of the 3-month intervention period and outcome assessment, participants were encouraged to continue with their home exercise program.

The OA-education intervention (control group) was a physiotherapist-delivered series of single-patient sessions, designed to control for the patient-therapist interaction and psychosocial contact inherent with the PFJ-specific physiotherapy intervention. The information was obtained from the Arthritis Victoria patient information sheets (http://www.arthritisvic.org.au), and at each session different topics were discussed (1: introduction to OA; 2: maintaining physical activity; 3: medicines; 4: complementary therapies; 5: healthy eating; 6 dealing with chronic pain; 7: emotions and depression and 8: summary, revision of key concepts).

Participants in both groups were encouraged to continue regular physical activity that did not provoke their pain. The use of adjunctive treatments (including prescription and over-the-counter medicines) were permitted and recorded in weekly log books.

Outcome measurements

A blinded examiner administered all outcome measures. In those with bilateral symptoms, the most symptomatic eligible knee was assessed. Participant characteristics were recorded at baseline. The principal time-point for efficacy analyses was at treatment completion (3 months), with a secondary follow-up time-point included after 6 months of no treatment to assess maintenance of effects (9 months).

Primary outcomes were patient-perceived global rating of change (from baseline) on a 5 point Likert scale (5=much worse; 4=worse; 3=same; 2=improved; 1=much improved)[30], knee pain severity during an aggravating activity on a 0-100mm visual analogue scale (VAS)[32] and the activities of daily living (ADL) subscale of the Knee injury and Osteoarthritis Outcome Score (KOOS)[36]. The KOOS-ADL subscale is identical to the physical function subscale of the Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC)[37], and a normalised score was calculated (100 represents no symptoms and 0 represents maximum symptoms). Secondary outcome measures included the pain, symptoms, sport and recreation and quality-of-life subscales of the KOOS. Adherence was measured from attendance at physiotherapy and completion of home exercise log books. Adverse events and medication use were recorded in log books. Participants were considered to be adherent with the home exercises if they completed 3 of the required 4 times per week (i.e. 75%).

Sample size

Based on our previous RCT of PFJ-targeted physiotherapy for PFJ pain [31], we required 38 people per group to detect 49% of people in the physiotherapy group reporting much improvement on the global rating of change, compared with 19% of people in the education group, with 80% power (α=0.05). A sample size of 90 also enabled detection of the minimal clinically important improvements of 19.9 (21.5) mm on a 100mm pain VAS and 9.1 (13.9) normalised units on the WOMAC physical function subscale [38], with 90% power (α=0.05) and accounting for approximately 10% dropouts.

Statistical analysis

All analyses were performed with SPSS for Windows 21.0 software (SPSS, Chicago, IL, USA), conducted on an intention-to-treat basis. Global rating of change was dichotomised as no success (much worse, worse, same, moderate improvement) and success (marked improved), and expressed as relative risk reduction and Numbers Needed to Treat (NNT). Worst-case scenario imputation of missing values was performed, with targeted physiotherapy assigned much worse and OA-education assigned much improved. We analysed continuous outcome measures using linear mixed regression models, including their respective baseline scores as a covariate, participants as a random effect, treatment condition as a fixed factor and the covariate by treatment interaction. Analyses were repeated with participant characteristics (age, gender, BMI and radiographic disease severity) included as covariates to evaluate their impact. Regression diagnostics were used to check for normality of the measures and homogeneity of variance, where appropriate. Statistical significance was set at $p = 0.05$.

Results

Between August 2008 and December 2010, 365 people volunteered to participate in the study. In total, 92 people (Figure 1) fulfilled the eligibility criteria and were randomised to the PFJ OA-targeted exercise, education, manual-therapy and taping protocol (n=44) and OA-education control (n=48)

groups; 81 people completed the 3-month follow-up (39 physiotherapy and 42 OA-education; 88%) and 73 people completed the 9-month follow-up (35 physiotherapy and 38 OA-education; 79%). The two groups were similar at baseline for all participant characteristics (Table 1). The characteristics of the 11 participants lost to follow-up were not different to those who completed the study.

Primary outcomes

The exercise, education, manual-therapy and taping resulted in more people being much improved (20/44) than the OA-education group (5/48) at 3-months (relative risk 4.31; 95% confidence interval (CI): 1.79 to 10.36; NNT 3 (95% CI: 2 to 5) (Figure 2). The worse-case scenario imputation of missing values, with the exercise, education, manual-therapy and taping intervention assigned much worse and the OA-education assigned much improved, did not change the outcome substantially or statistically beyond 0.05. People in the combined exercise, education, manual-therapy and taping group reported significantly greater reductions in pain than those in the OA-education group (mean difference: -15.2 mm, 95% CI: -27.0 to -3.4). However, there were no significant effects on physical function as measured using the KOOS-ADL (5.8; -0.6 to 12.1). Including age, gender, BMI and radiographic disease severity as covariates did not affect the outcomes and hence, the unadjusted data are presented (Table 2).

Secondary timepoint (9 months)

At 9-months, more people in the exercise, education, manual-therapy and taping group than in the OA-education group reported being much improved (relative risk 3.26 (95% CI 1.46 to 7.26); NNT 3 (95%CI 2 to 7)) (Fig 2). However, imputing missing data (21%) on a worse-case scenario, the results were no longer statistically significant. No significant between-group differences were observed for participant-reported knee pain (10.5 mm; 95% CI -1.8 to 22.7), KOOS-ADL (3.0; 95% CI -3.7 to 9.7).

Secondary outcomes

At 3-months, the exercise, education, manual-therapy and taping intervention and the OA-education control resulted in similar outcomes for all secondary outcome measures (Table 3) except for KOOS-pain, where those in the exercise, education, manual-therapy and taping group reported significantly greater reductions in KOOS-pain than those in the OA-education group (6.0; 95% CI 0.1 to 12.6). After 6-months of no treatment, there were no significant between-group differences (Table 3).

Adherence, adverse events, and co-interventions

No significant differences were observed between groups for attendance (mean (SD) number of sessions: Physiotherapy: 8 (2); OA-education 8 (1)). Log-books for exercise adherence were obtained from 31 (71%) of the participants in the physiotherapy group. Adherence with home exercises was recorded by 24 (77%) participants. Adverse events were noted in seven of the participants receiving the exercise, education, manual-therapy and taping intervention (skin reaction to tape wearing (n = 2)); swelling after treatment (n = 2); and pain in other areas after exercises (back n=1; ankle n= 1; other knee n=1). All adverse events were mild, did not require medical treatment, nor cause cessation of treatment (some adjustments to taping and/or exercises were made by the treating physiotherapist). Use of co-interventions, including medications, was similar between groups. In the group undertaking exercise, education, manual-therapy and taping, medication use was recorded in 10 people: analgesics (n= 7), non-steroidal anti-inflammatory drugs (n= 4) and glucosamine (n=2). Similar medication use was recorded in the OA-education group: analgesics (n= 7), non-steroidal anti-inflammatory drugs (n= 4), glucosamine (n=2) and fish oil (n=1).

Discussion

Exercises, education, manual-therapy and taping, targeted to the PFJ resulted in superior outcomes for patient-perceived change in condition and pain, compared to physiotherapist-delivered OA-

education. However physical function was not different between groups. There were no differences at 9-months.

Our study fills a gap in the literature, where most evidence exists for medial TFJ OA. The importance of our targeted intervention is underpinned by recent recommendations to tailor non-pharmacological management for knee OA [10]. Considering that approximately 70% of people aged above 50 with knee pain with or without radiographic OA have PFJ involvement, and the differences between the PFJ and TFJ compartment in joint biomechanics[39], risk factors for disease progression [40, 41] and symptomatic presentations[27, 29, 42], a PFJ OA-focussed intervention is appropriate. Furthermore, people with PFJ OA derive lesser benefits than those with TFJ OA from a non-specific exercise therapy[14] that does not consider the unique functional and biomechanical impairments associated with PFJ OA. Our study shows that three patients with PFJ OA would need to be treated with our targeted physiotherapy intervention compared to OA-education, for one person to report a marked improvement in their condition.

Implications for management of PFJ osteoarthritis

Current management of PFJ OA remains problematic for most health and medical practitioners due to the lack of trials evaluating treatments tailored to this condition. Our treatment protocol addressed shortfalls of previous trials. We included information and education that addressed pacing of activity and discussion of weight management. Most importantly, the exercise program addressed the impairments commonly observed in PFJ OA (quadriceps and hip muscle weakness), tailoring the prescription and progression of exercises to individual abilities and co-morbidities. Patellar malalignment, a prominent feature of PFJ OA[21-23], was assessed for each individual and addressed with patient-specific mobilisations and taping.

The lack of benefit following an additional 6 months of no treatment might indicate that interventions involving exercise, education, manual-therapy and taping for this patient population need to be extended. The targeted physiotherapy group was instructed to maintain their home exercise programme. However, the programme was not supervised or progressed over the following 6 months. Furthermore, adherence to the unsupervised programme is unknown. Considering that OA is a chronic disease, our results indicate the need for trials with either an extended supervised treatment duration, or additional means to ensure adherence to an unsupervised programme.

This study has a number of important strengths. To facilitate recruitment of those with predominant PFJ OA, our eligibility criteria included history, examination and radiographic criteria. The studied treatment was evidence-based and incorporated recommendations from clinical guidelines. Our comparison group (physiotherapist-delivered OA-education) controlled for the patient-therapist interaction inherent within our targeted physiotherapy intervention and sought to reduce performance bias. Participants and assessors were blinded to treatment allocation, to reduce the treatment bias and/or response bias. Adherence to the interventions was high and adverse events were mild.

There are some limitations to our study, with the main one being a loss of 21% of participants to follow up at 9-months. The worse-case scenario imputation for missing data implemented in the analysis lead to a conclusion of no benefit of exercise, education, manual-therapy and taping over OA education alone. The impact on the interpretation of the long-term outcomes might undermine the potentially real benefits of the exercise, education, manual-therapy and taping, because analysis without worse case scenario imputation showed a beneficial effect of the education, exercise, manual-therapy and taping program. While there was a 12% loss of participants to follow up on the primary outcome at 3 months, the effect of the exercise, education, manual-therapy and taping program was still present on imputing missing data on a worst-case scenario basis. As with other

non-pharmacological trials, it is not possible to blind the physiotherapists providing the treatment. Furthermore, the results of this trial cannot be extrapolated to those with different clinical features or patterns of radiographic OA, and the long-term effects cannot be assumed and should be evaluated.

In conclusion, after 3-months an 8-session multi-modal treatment of exercise, OA education, manual-therapy and taping that was targeted to the PFJ and tailored to individual patients resulted in superior outcomes for patient-perceived change and pain compared to OA-education alone in people with predominant PFJ OA. However, there was no significant difference in physical function and the positive effects observed after 3 months of treatment were not maintained after 6 months of no treatment. Conservative management of PFJ OA may be enhanced by targeting interventions to the PFJ compartment.

Competing interests

The authors declare that they have no competing interests

Author's contributions

KMC, RSH, BV, MGP, and AGS conceived the project and KMC co-ordinated the trial. KMC, RSH, BV, MGP, and AGS developed the protocol and procured the project funding. KMC, RSH and BV designed the physiotherapy and control treatments and KMC trained the physiotherapists. BV performed the sample size calculations and designed the statistical analyses. JL and HO recruited and screened participants. BV randomised participants to groups. All authors provided feedback on drafts of this paper and read and approved the final manuscript.

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The funding body (Australian National Health & Medical Research Council) had no role in the study design or data analyses.

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Figure 1: CONSORT 2010 Flow Diagram (modified for individual randomized, controlled trials of non-pharmacologic treatment)

Participants lost to follow-up at 3 months were not followed up at 9 months

Figure 2: Percentage of participants reporting perceived improvement across categories from 'much improved' to 'much worse'.

Table 1: Baseline characteristics of participants for Physiotherapy and OA-education groups. Values are mean (SD) unless stated otherwise

	Physiotherapy (n=44)	**OA-education (n= 48)**
Age (years)	56 (10)	53 (10)
Height (m)	1.69 (0.08)	1.70 (0.10)
Mass (kg)	78 (14)	81 (16)
BMI (m.kg-2)	27.2 (4.0)	27.9 (4.6)
Female gender n (%)	24 (45	29 (55)
KL grade n(%)		
-Grade 0	23 (52)	26 (54)
-Grade 1	11 (25)	9 (18)
-Grade 2	10(23)	13 (27)
PFJ O/P severity n(%)		
-Grade 1	31 (70)	30 (63)
-Grade 2	8 (18)	12 (25)
-Grade 3	5 (12)	5 (10)

BMI body mass index

€: Physiotherapy n=42; Control n=45

KL Kellgren and Lawrence grading scale [35] for the tibiofemoral joint measured from an anteroposterior radiograph)

PFJ O/P severity: Severity of lateral patellar osteophyte measure from a skyline x-ray [33]

Table 2: Mean (SD) scores for continuous primary and secondary outcomes at baseline, 3months and 9 months (adjusted for baseline scores), according to group

	Baseline		3 months		9 months	
	Physiotherapy (n=44)	**OA-education (n= 48)**	**Physiotherapy (n=39)**	**OA-education (n= 42)**	**Physiotherapy (n=35)**	**OA-education (n= 34)**
Primary Outcomes						
Knee pain on aggravating activity (0-100)	58 (26)	68 (27)	29 (28)	45 (31)	33 (30)	44 (29)
KOOS-ADL (100-0)	72.2 (14.9)	70.8 (16.9)	83.8 (12.8)	76.6 (14.6)‡	82.1 (14.8)	77.7 (16.0)
Secondary Outcomes						
KOOS-Pain (100-0)	64.0 (14.7)	63.4 (14.3)	76.3 (13.4)	69.4 (14.2) ‡	75.5 (16.5)	73.5 (14.4)
KOOS-Symptoms (100-0)	64.5 (14.7)	61.2 (17.5)	74.9 (13.7)	68.7 (17.8) ‡	74.3 (12.6)	71.6 (18.0)
KOOS-SR (100-0)	42.4 (20.4)	43.4 (21.5)	56.4 (23.3)	48.7 (22.2) ‡	58.5 (20.7)	53.3 (25.0)

KOOS-QoL (100-0)	44.3 (14.2)	9.5 (15.5)	54.7 (20.0)	49.8 (13.8) ‡	56 (19.6)	52 (15.2)

Knee pain on aggravating activities measured with a visual analogue scale (mm: 100 = maximal pain possible)

KOOS-ADL = Activities of daily Living subscale of the Knee injury and Osteoarthritis Outcome Score (100 = best possible score)

KOOS-Pain = Pain subscale of the Knee injury and Osteoarthritis Outcome Score (100 = best possible score)

KOOS-Symptoms = Symptoms subscale of the Knee injury and Osteoarthritis Outcome Score (100 = best possible score)

KOOS-SR = Sport and recreation subscale of the Knee injury and Osteoarthritis Outcome Score (100 = best possible score)

KOOS-QoL = Quality of Life subscale of the Knee injury and Osteoarthritis Outcome Score (100 = best possible score)

‡ n=41

Table 3: Estimated between-group differences, adjusted for the baseline value of the measure (mean difference and 95% confidence intervals), in the change scores from baseline to 3 months and from baseline to 9 months

	Baseline – 3 months	**Baseline – 9 months**
Primary Outcomes		
Knee pain on aggravating activity (0-100)	-15.2 (-27.0 to -3.4)*	-10.5 (-22.7 to 1.8)
KOOS-ADL (100-0)	5.5 (-0.6 to 11.2)	3.0 (-3.7 to 9.7)
Secondary Outcomes		
KOOS-Pain (100-0)	6.0 (0.1 to 12.6)*	1.4 (-5.2 to 8.0)
KOOS-Symptoms (100-0)	3.0 (-3.1 to 8.9)	-0.6 (-6.9 to 5.8)
KOOS-SR (100-0)	8.7 (-1.2 to 18.6)	6.2 (-4.2 to 16.5)
KOOS-QoL (100-0)	-0.1 (-7.1 to 7.0)	-0.9 (-8.3 to 6.5)

Knee pain on aggravating activities measured with a visual analogue scale (mm: 100 = maximal pain possible)

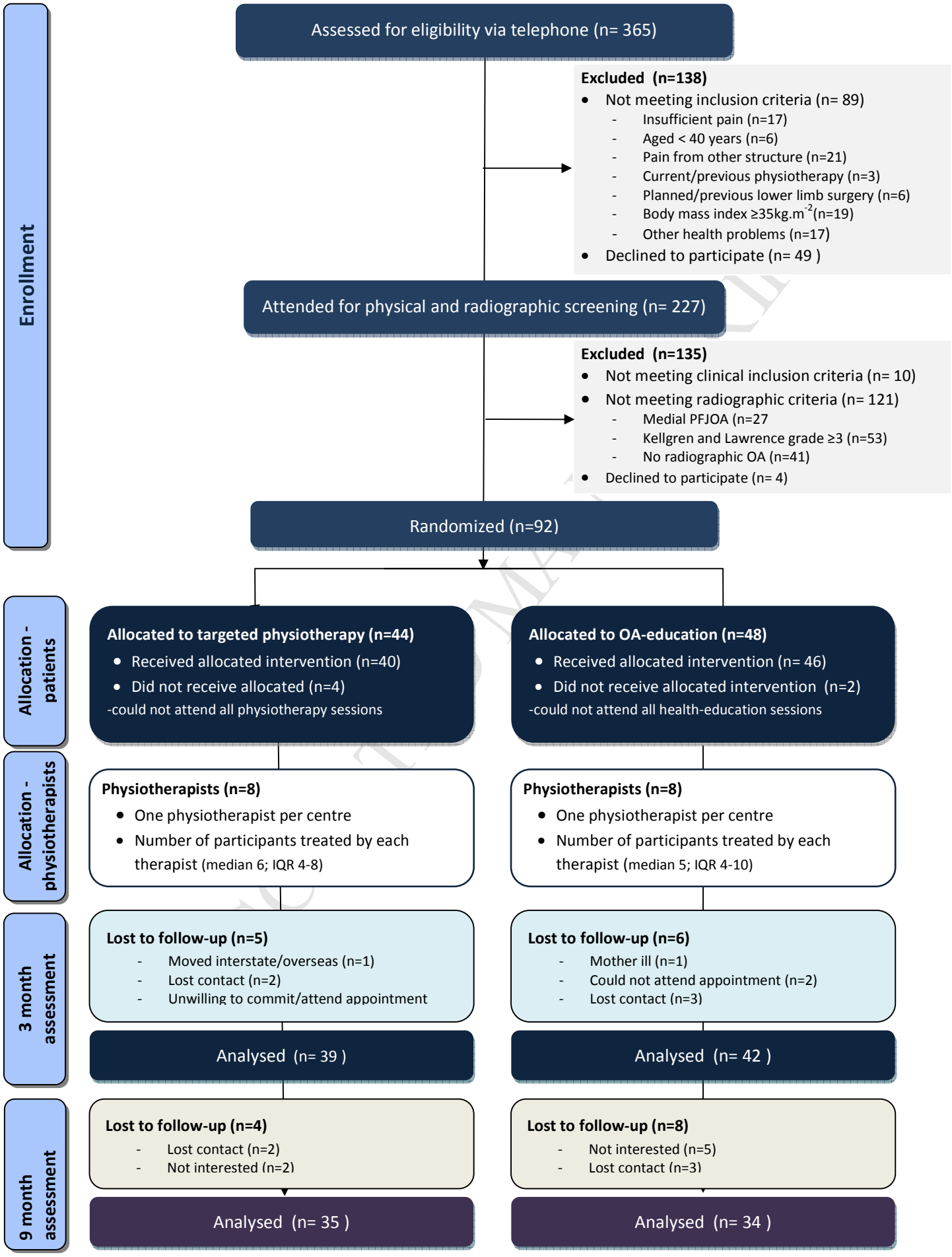
KOOS-ADL = Activities of daily Living subscale of the Knee injury and Osteoarthritis Outcome Score (100 = best possible score)

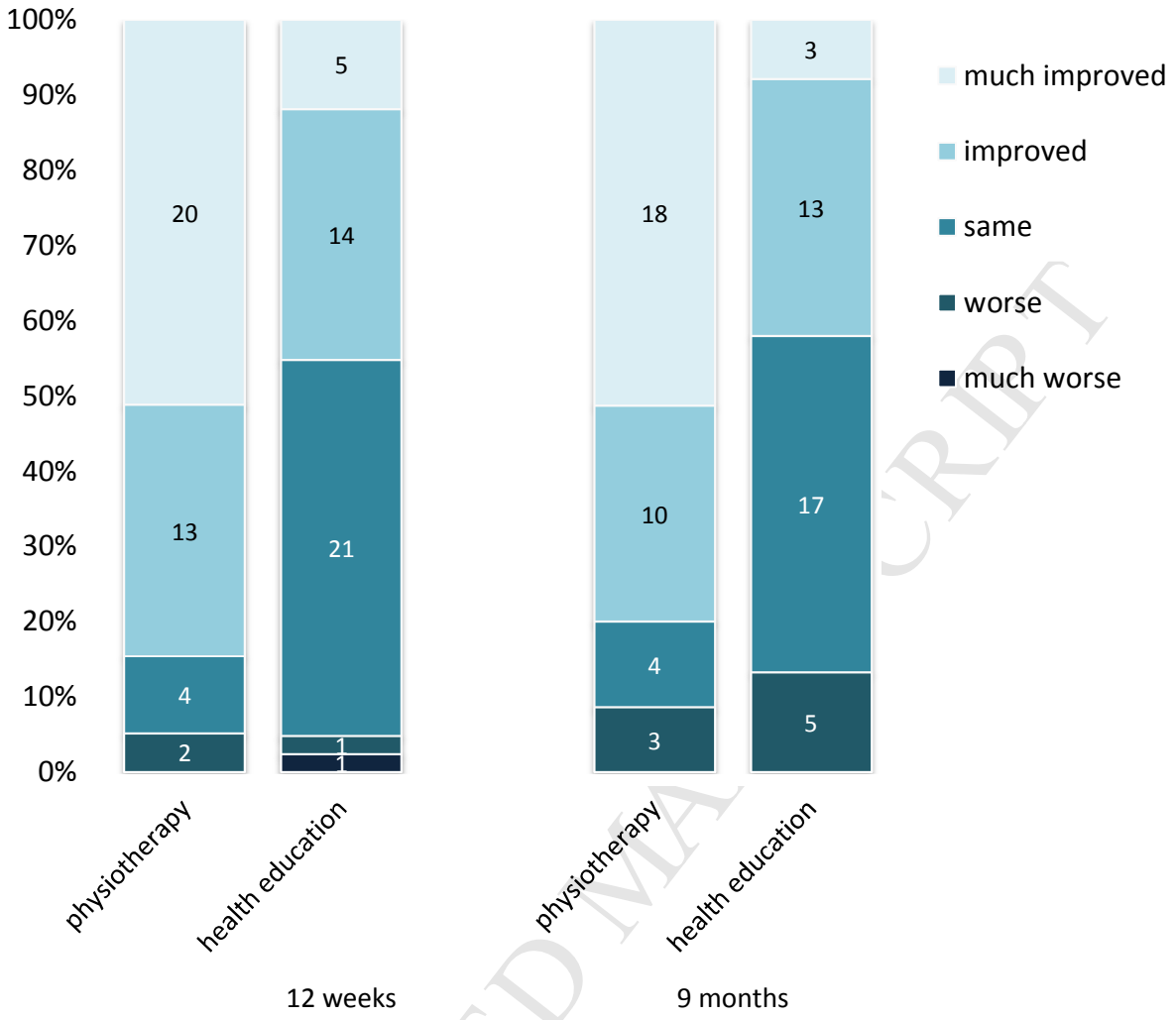
KOOS-Pain = Pain subscale of the Knee injury and Osteoarthritis Outcome Score (100 = best possible score)

KOOS-Symptoms = Symptoms subscale of the Knee injury and Osteoarthritis Outcome Score (100 = best possible score)

KOOS-SR = Sport and recreation subscale of the Knee injury and Osteoarthritis Outcome Score (100 = best possible score)

KOOS-QoL = Quality of Life subscale of the Knee injury and Osteoarthritis Outcome Score (100 = best possible score)





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Targeted physiotherapy for patellofemoral joint osteoarthritis: A protocol for a randomised, single-blind controlled trial

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Abstract

Background: The patellofemoral joint (PFJ) is one compartment of the knee that is frequently affected by osteoarthritis (OA) and is a potent source of OA symptoms. However, there is a dearth of evidence for compartment-specific treatments for PFJ OA. Therefore, this project aims to evaluate whether a physiotherapy treatment, targeted to the PFJ, results in greater improvements in pain and physical function than a physiotherapy education intervention in people with symptomatic and radiographic PFJ OA.

Methods: 90 people with PFJ OA (PFJ-specific history, signs and symptoms and radiographic evidence of PFJ OA) will be recruited from the community and randomly allocated into one of two treatments. A randomised controlled trial adhering to CONSORT guidelines will evaluate the efficacy of physiotherapy (8 individual sessions over 12 weeks, as well as a home exercise program 4 times/week) compared to a physiotherapist-delivered OA education control treatment (8 individual sessions over 12 weeks). Physiotherapy treatment will consist of (i) quadriceps muscle retraining; (ii) quadriceps and hip muscle strengthening; (iii) patellar taping; (iv) manual PFJ and soft tissue mobilisation; and (v) OA education. Resistance and dosage of exercises will be tailored to the participant's functional level and clinical state. Primary outcomes will be evaluated by a blinded examiner at baseline, 12 weeks and 9 months using validated and reliable pain, physical function and perceived global effect scales. All analyses will be conducted on an intention-to-treat basis using linear mixed regression models, including respective baseline scores as a covariate, subjects as a random effect, treatment condition as a fixed factor and the covariate by treatment interaction.

Conclusion: This RCT is targeting PFJ OA, an important sub-group of knee OA patients, with a specifically designed conservative intervention. The project's outcome will influence PFJ OA rehabilitation, with the potential to reduce the personal and societal burden of this increasing public health problem.

Trial Registration: Australia New Zealand Clinical Trials Registry ACTRN12608000288325

Background

Osteoarthritis (OA) is the leading cause of musculoskeletal pain and disability and is the third leading cause of life-years lost due to disability in Australia, only behind depression and dementia [1]. The annual total cost of arthritic disease in Australia is estimated at $24 billion [2], with the knee joint contributing substantially to this overall cost. The prevalence of OA in people aged over 55 years is 20–26% and rising, with arthritis rates expected to increase by 30% over the next 40 years [2]. The pain and suffering endured by patients as a result of OA decreases their quality of life, with the annual burden of disease costs ($12 billion in Australia) being half the total costs associated with this condition [2]. Pain associated with daily activities such as walking and stair-climbing ultimately leads to profoundly reduced functional independence [2].

The patellofemoral joint (PFJ) is one of the three knee joint compartments. Awareness of its importance in the OA process has been raised by the increasing use of lateral and skyline x-rays in recent times. Research has revealed that PFJ OA is more common than previously thought. In a community-based study of knee OA (N = 218), the frequency of radiographic osteophytes was greater in the PFJ (65% knees) than in the tibiofemoral joint (TFJ) (55% knees) [3]. Furthermore, in people with knee pain (N = 777), the most common compartmental distribution of radiographic OA was a combination of TFJ and PFJ disease (40%), followed by isolated PFJ OA (24%), and isolated TFJ disease (4%) [4]. Within the PFJ, the lateral compartment is more frequently affected by the OA process than the medial [5,6]. Importantly, the presence of baseline PFJ OA predicts structural deterioration in the TFJ compartment over 30 months (OR 2.31, 95% CI 1.37, 3.88) [7].

The PFJ is an important source of symptoms associated with knee OA [8]. Knee pain has been found to be significantly associated with PFJ osteophytes (OR 2.25, 95%CI 1.06, 4.77), but not TFJ osteophytes (OR 1.19, 95% CI 0.46, 3.09) [9], suggesting that the PFJ may be a more important source of knee pain than the TFJ. Hunter et al [10] noted that increased pain and poorer function was associated with reduced cartilage volume in the patella, but not in the femur nor the tibia. Other authors have confirmed the relationship between radiographic PFJ OA and knee pain [11-13].

Management strategies for knee OA have traditionally focussed on alleviating symptoms, primarily using drug therapies or surgery. A meta-analysis of OA trials highlights this, with most trials evaluating drug treatments (60%) or surgical procedures (26%) [14]. OA experts have highlighted the overall dearth of quality evidence to support the use of non-pharmacological interventions such as physiotherapy. Despite this, knee OA clinical guidelines recommend that conservative treatments be included as a first line strategy for the optimal management of the disease [15,16]. Physiotherapy is a conservative intervention, which is non-toxic, inexpensive and promotes physical activity and self management through exercise. Therefore, rigorous randomised clinical trials (RCTs) that evaluate the efficacy of physiotherapy are clearly needed, to better guide clinical decision-making.

Given the heterogeneity of knee OA with regard to aetiology, clinical presentation and natural history, guidelines also recommend the tailoring of knee OA treatments to the location of joint damage in order to optimise treatment outcomes [15,16]. However, most trials of physiotherapy for knee OA have not been targeted to disease subgroups, with participant selection typically based on the presence of non-specific knee pain and radiographic changes anywhere on an anteroposterior radiograph. While a plethora of evidence attests to the benefits of exercise for patients with predominant TFJ OA [17] there is no level I evidence and only one RCT [18] specifically addressing the problem of PFJ OA. The dearth of evidence for a compartment-specific treatment for PFJ OA necessitates our proposed study to establish the efficacy of a compartment-specific physiotherapy treatment using the rigour of a RCT.

While there is little known about the physical impairments associated with PFJ OA, there are several RCTs that have evaluated physical interventions for PFJ pain in younger adults (patellofemoral pain syndrome, or anterior knee pain). We have previously conducted a double blind, placebo-controlled RCT [19], which demonstrated the efficacy of a targeted physiotherapy program for this patient population. The targeted treatment involved (i) quadriceps muscle retraining; (ii) patellar taping; (iii) manual PFJ and soft tissue mobilisation; and (iv) hip muscle retraining. We have recently confirmed the beneficial effects of this targeted physiotherapy approach on pain and physical function in another population of young adults with PFJ pain [20]. Therefore, we are proposing to evaluate a similar, targeted physiotherapy intervention for people with PFJ OA.

This project aims to evaluate whether a physiotherapy treatment, targeted to the PFJ and based on successful treatment for PFJ pain in younger populations, results in greater improvements in pain and physical function than a physiotherapy education intervention in participants with symptomatic and radiographic PFJ OA.

Methods

Experimental design

A randomised, single-blind, controlled clinical trial conforming to CONSORT [21] guidelines will be conducted, comparing a multimodal physiotherapy intervention to a physiotherapy education intervention (Figure 1). A Project Investigator will screen for eligibility based on history, clinical and radiographic examination.

Ethical approval has been obtained from the University of Melbourne Human Research Ethics Committee (HREC No. 0721163) and from the Department of Human Services Victoria, Radiation Safety Committee. All participants will provide written informed consent.

Participants

Ninety people with lateral PFJ OA will be recruited from the community via advertisements, medical practitioners and our own research database. To be included in the study, participants must fulfil the following criteria: (i) aged > 40 years; (ii) anterior- or retro-patellar knee pain aggravated by at least two activities that load the PFJ (eg stair ambulation, squatting and/or rising from sitting); (iii) pain severity ≥ 4 on an 11 point numerical pain scale during aggravating activities; (iv) pain during these activities present on most days during the past month; (v) osteophyte grade ≥ 1 in the lateral PFJ compartment on skyline x-ray [22].

Exclusion criteria will include: (i) concomitant pain from other knee structures, hip or lumbar spine; (ii) current or previous physiotherapy for knee pain (prior 12 months); (iii) contra-indications to the treatments (eg tape allergy); (iv) recent knee injections (prior 3 months); (v) planned lower limb surgery in the following 9 months; (vi) body mass index ≥ 35 kg.m^2; (vii) medial PFJ OA (osteophytes

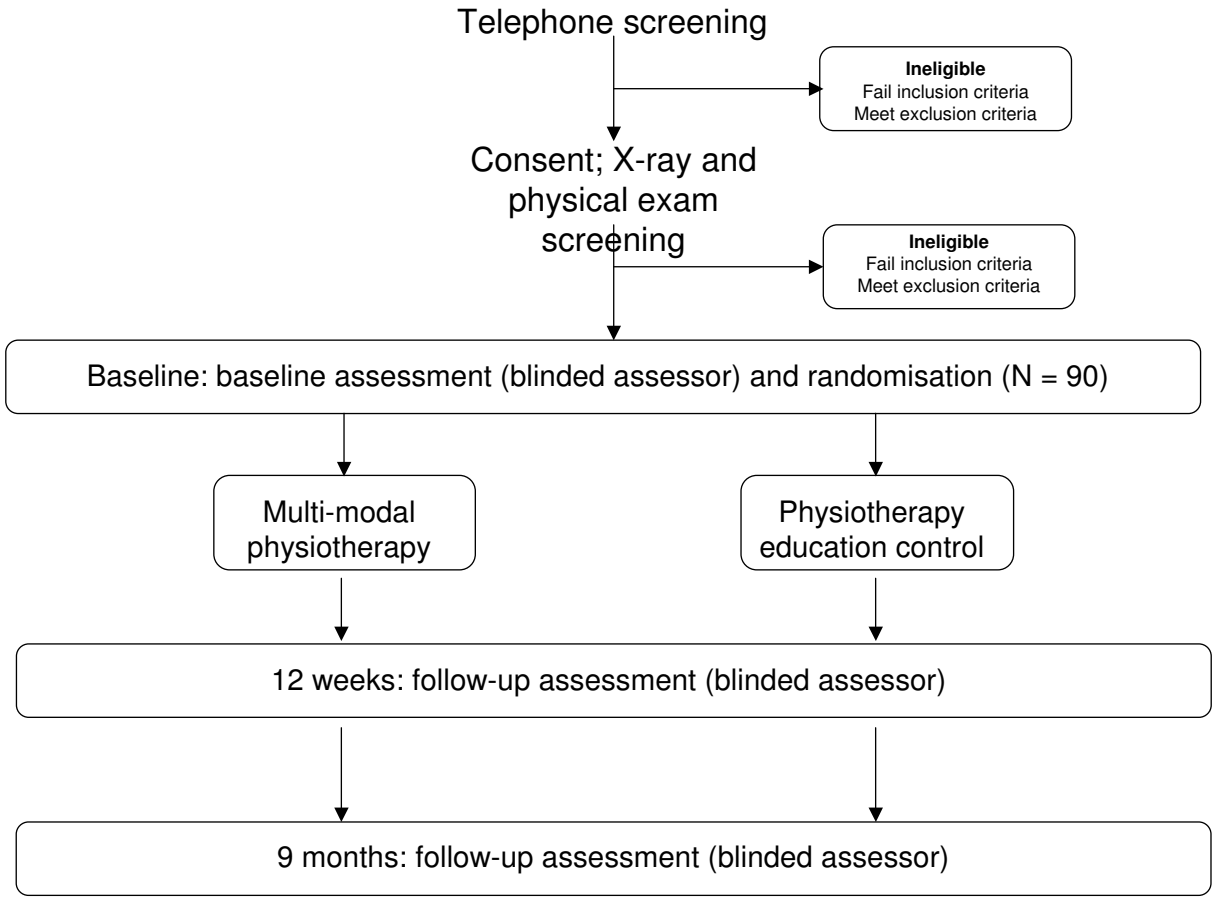

Figure 1
Flow of participants through the randomised controlled trial.

or joint space narrowing on a skyline x-ray) that is more severe than lateral PFJ OA; (viii) moderate to severe concomitant TFJ OA (Kellgren and Lawrence grade ≥ 3 on an anteroposterior radiograph) [23]; (ix) knee or hip arthroplasty or osteotomy; (xi) physical inability to undertake testing procedures or; (x) inability to understand written and spoken English.

Sample Size

Treatment efficacy will be evaluated by comparing change on primary outcome measures between groups. We aim to detect the minimum clinically important improvement on these outcomes as reported by Tubach et al [24]. Specifically, a sample of 90 will provide a minimum of 90% power ($\alpha = 0.05$) to detect a difference in pain on visual analogue scale (VAS) of 19.9 (21.5) mm and a difference in physical function on the Western Ontario MacMaster Universities Osteoarthritis Index (WOMAC) [25] of 9.1 (13.9) normalised units. This sample size also allows for an estimated 10% drop-out rate.

Procedure

The randomisation schedule (permuted blocks of 8 to 12) will be generated and maintained centrally by one of the investigators (BV), who will not be involved in assessment of participants. The randomisation schedule will be revealed via telephone following baseline assessment. A blinded investigator will perform outcome assessments (Table 1) at baseline, 12 weeks and 9 months, and participants will be instructed not to divulge their group allocation. Security of the blinding system will be evaluated to ensure integrity.

Outcome assessment

Age, gender, duration of knee OA symptoms, previous treatment, surgery and medication use for knee OA will be obtained at the baseline assessment.

Primary outcome measures: Pain and physical function

Overall average *knee pain* in the previous week on movement and during an aggravating activity nominated by the participant will be self-assessed with a 0–100 mm horizontal visual analogue scale (VAS) with terminal descriptors of (0 = no pain; 10 = maximal pain). Self-reported

Table 1: Outcome measures used in the randomised controlled trial

Primary Outcome	**Measurement**
Usual pain on movement in the previous week	0–100 mm visual analogue scale (VAS) with terminal descriptors: 0 = no pain; 10 = maximal pain
Usual pain during nominated aggravating activity in the previous week	0–100 mm visual analogue scale (VAS) with terminal descriptors: 0 = no pain; 10 = maximal pain
Self reported difficulty with physical function	Physical Function subscale of the Western and Onatario MacMasters University (WOMAC) Osteoarthritis Index (Likert version)
Secondary Outcomes	**Measurement**
Symptoms	
Pain and stiffness	Pain and Stiffness subscales of the WOMAC
Perceived global effect score	5 point ordinal scale (1-much improved; 2-improved. 3-same; 4-worse; 5-much worse)
Sports and recreation function	Sports and recreation function dimension of the Knee Injury and Osteoarthritis Score (KOOS)
Symptoms	Symptoms dimension of the KOOS
Knee related quality-of-life	Knee related quality-of-life dimension of the KOOS
Function	
Lower extremity functional performance	One-leg rise test – maximum number of one-leg rises from sitting on a 0.48 m stool
Stair ambulation performance	Timed stair ascent and descent
Standing balance	Step test – number of times can step foot up and down off 15 cm step in 15 s
Other Outcomes	**Measurement**
Physical activity levels	Physical Activity Scale for the Elderly (PASE)
Adherence (physiotherapy group only)	Number of physiotherapy visits Completion of home exercises via log-book
Knee-related medication use	Log-book
Adverse effects	Log-book and open probe questioning

difficulty with *physical function* will be assessed using the physical function subscale of the Likert version of the WOMAC [25]. This disease-specific measure is reliable, valid and responsive and comprises 17 items, using a 5-point scale to score each, where higher scores indicate worse symptoms.

Secondary outcome measures

Pain and stiffness will be assessed using the relevant subscales of the WOMAC [25]. Participants will rate their perceived overall change in symptoms following treatment on a 5 point ordinal scale: 1-much improved, 2-improved, 3-no change, 4-worse, 5-much worse, giving a *perceived global effect score*. *Sports and recreation function, symptoms* and *knee-related quality-of-life* will be assessed using the relevant dimensions of the Knee Injury and Osteoarthritis Outcome Score (KOOS) [26].

Objective measures of function will include the one-leg rise test, a timed stair ambulation test and the step-test. The one-leg rise test is the maximum number of one-leg rises the participant can perform from sitting on a stool. The participant must hold their non-test leg out straight and cannot use their arms for assistance. The number of rises that the participant can complete will be recorded. This test is a measure of lower extremity functional performance that has been found to predict the development of radiographic knee OA in middle aged people with chronic knee pain [27]. The timed stair ambulation task involves the participant ascending and descending a set of nine standard steps at their usual pace and the total time taken recorded, with longer time taken indicating poorer physical function [28]. The step-test is a functional, dynamic test of standing balance, where the participants stands on one leg in front of a 15 cm step, and places the opposite foot on and off the step as quickly as possible over 15 seconds. The total number of successful steps are recorded, with higher scores indicating better balance [29].

Other measures

Disease severity of the TFJ from weight bearing anteroposterior knee x-rays taken at screening will be determined using the Kellgren and Lawrence grading system [23] where 0 = normal; 1 = possible osteophytes; 2 = minimal osteophytes and possible joint space narrowing; 3 = moderate osteophytes, some narrowing and possible sclerosis and; 4 = large osteophytes, definite narrowing and severe sclerosis. PFJ OA will be assessed from a skyline x-ray using a radiographic atlas [22]. The medial and lateral PFJ compartments will each be scored separately for the presence of osteophytes and joint space narrowing where 0 = normal; 1 = mild or 1–33% abnormal; 2 = moderate or 34–66% abnormal and; 3 = severe or 67–100% abnormal. *Co-interventions, adherence and adverse effects will also be recorded*. Participants will be asked to refrain from other forms of OA treatment, but stable drug doses will be permitted. Physiotherapists will record attendance, details of treatment progression (physiotherapy group) and adverse events. Participants will record adherence with home exercises (physiotherapy group), adverse events and any co-interventions, including knee-related medication use in a log-book.

Interventions

Each participant will be treated by an experienced and registered physiotherapist. Treating practitioners will be trained and proficient in both of the interventions (physiotherapy and education control). Each treatment will be delivered in 8 sessions over 12 weeks (once per week for four weeks, then once every two weeks for 8 weeks). Reasonable costs associated with treatments will be met by the project.

Physiotherapy Treatment

The physiotherapy treatment will be similar to that employed in our previous RCTs for patellofemoral pain in younger people [19,20]. Treatment will consist of (i) functional retraining exercises for the quadriceps muscle; (ii) quadriceps and hip muscle strengthening; (iii) patellar taping; (iv) manual PFJ and soft tissue mobilisation; and (v) OA education. The treatment will be tailored according to each participant's clinical presentation (eg strength, pain severity, swelling) as well as the presence of co-morbidities (eg back and hip pain or pathology), and will be progressed based on individual response to exercise load, thus optimising treatment effects. Exercises will be taught and supervised by the physiotherapist during each visit. A home exercise program will be prescribed, to be performed independently at home 4 times per week. An exercise manual for participants will be produced, with clear instructions and diagrams to ensure correct and safe performance of exercise. Specific aspects of the treatment are outlined in Table 2 and will include:

(i) Functional retraining exercises for the quadriceps muscle. The muscle retraining is designed to enhance the co-ordination (magnitude and onset timing) of the medial quadriceps, relative to the lateral utilising biofeedback within the sessions. In order to accommodate a patient group with heterogeneous symptoms, the functional retraining exercises may be performed statically and/or dynamically during various functional activities (eg step up, step down, sit to stand).

(ii) Quadriceps and hip abduction strengthening. The exercise selection will be based on baseline capacity of the individual and then progressed, based on response to exercise load, thus maximising the training effects. Resistance will be provided by weights, rubber tubing and/or body weight.

Table 2: Physiotherapy treatment components

Functional retraining exercises† performed four times/week – participants perform a contraction of medial quadriceps in two of the following functional activities
- sitting (isometric)
- sit-stand
- step up
- single leg squat
Quadriceps muscle strengthening† performed four times/week – participants complete one exercise in each of the following
- inner range (open kinetic chain)
- mid range (open kinetic chain)
- weight-bearing (wall squat)
Hip abduction strengthening† performed four times/week
- sidelying hip abduction
Patellar taping
- combination of tilt, medial glide and fat pad unloading – tape will be applied by the physiotherapist at each visit, worn continuously for one week and then removed -
Patellofemoral and soft-tissue mobilisation
- mobilisation of the patella (medial glides) performed by the physiotherapists
- massage to the painful and tight soft tissue structures, performed by the physiotherapist

†Exact exercise and its number of repetitions will be determined by the physiotherapist from a schedule of permissible exercises based on each participant's clinical presentation (eg strength, pain severity, swelling), presence of comorbidities (eg back and hip pain or pathology) and will be progressed based on individual response to exercise load

(iii) Patellar taping to reduce pain using the same standardised protocol as per our previous knee OA research [30,31]. The tape will be applied by the physiotherapist at each visit, worn continuously for one week and then removed.

(iv) Manual PFJ and soft tissue mobilisation, comprising medial patellar glides and massage to the lateral soft tissue structures, performed by the physiotherapist.

(v) OA education covering topics such as exercise, diet, weight loss etc.

Following cessation of supervised physiotherapy sessions at 12 weeks, participants will be instructed to continue with a home exercise program. Adherence to the program will be monitored from the diary recordings of exercise completions.

Physiotherapy Education Control

In order to control for the psychosocial contact inherent with the physiotherapy treatment, participants allocated to the control group will attend individualised OA education sessions covering topics such as exercise, diet, weight loss, etc, provided by the physiotherapist with the same frequency as the physiotherapy sessions.

Data quality and management

Strategies employed to ensure data quality include: (i) training of assessors and physiotherapists; (ii) assessment of procedural quality; (iii) random checks by investigators of adherence to study protocols; and (iv) random checks of forms for completeness and data for accuracy. All analyses will be conducted on an intention-to-treat basis. The primary outcomes measured at 12 weeks and 9 months will be analysed using linear mixed regression models, including their respective baseline scores as a covariate, subjects as a random effect, treatment condition as a fixed factor and the covariate by treatment interaction. Participant characteristics (eg; gender, radiographic severity of TFJ and PFJ OA) will also be included as covariates. Regression diagnostics will be used to check for normality of the measures and homogeneity of variance, where appropriate. Comparisons between group means will be performed using Bonferroni or Newman Keuls range tests. An alpha level of 0.05 will be used. Calculation of the number needed to treat index will be performed to facilitate the development of clinical guidelines.

Discussion and Conclusion

PFJ OA is emerging as a distinct clinical entity that is common, is associated with considerable pain and disability, and is an important and novel area of research, since little is known about the optimal management of this condition. This study uses a single-blind RCT design to investigate whether a multimodal physiotherapy treatment, targeted to the PFJ, is more effective in reducing pain and improving physical function than a physiotherapy education control intervention in people with PFJ OA. As a secondary aim, it will evaluate whether the targeted physiotherapy treatment results in greater perceived improvement, self-reported stiffness, pain, sport and recreational function, symptoms and knee-related quality of life, as well as performance on functionally relevant tasks (one-leg rises, timed stair ambulation, and step-test) than the physiotherapy education control intervention.

In contrast to OA primarily affecting the TFJ, comparatively little known about the features or impairments associated with OA of the PFJ, and hence designing a targeted intervention is challenging. Thus, we have chosen to investigate a physiotherapy intervention that is largely based on a program that we have previously found to be successful in younger people with PFJ pain (patellofemoral pain syndrome) [19,20]. Components of this targeted intervention include: (i) functional retraining of the quadriceps muscle; (ii) quadriceps and hip muscle strengthening; (iii) patellar taping; (iv) manual PFJ and soft tissue mobilisation; and (v) OA education. This intervention is currently considered to be "best-practice" in the management of PFJ pain, and is increasingly being employed clinically in the management of people with PFJ OA.

An impairment that has been the subject of recent evaluation in participants with generalised knee OA is patellar malalignment. Patellar malalignment is typically exhibited as lateral patellar tilt, displacement or subluxation and may be important in PFJ OA by reducing and lateralising the PFJ contact area [32], thus increasing stress in this compartment. In people with knee OA, PFJ malalignment has been shown to be associated with indices of OA (joint space narrowing and loss of cartilage thickness) [33,34] as well as progression of OA (joint space narrowing) [35] in the PFJ compartment and increased functional impairment [36]. Thus, PFJ malalignment is a key feature of PFJ OA that could be amenable to a targeted intervention such as physiotherapy. This supports the inclusion of patellar tape in our targeted treatment, since it has the potential to reduce patellar malalignment [37-39] and we have already shown that patellar tape can reduce knee pain in generalised knee OA populations [30,31]. Other treatment modalities (eg PFJ and soft tissue mobilisations), may assist in the treatment of PFJ pain and malalignment in this patient population.

The balance of medial and lateral quadriceps activity is essential to maintain PFJ alignment. Experimental studies confirm that reduced or delayed medial quadriceps activity (relative to the lateral quadriceps) increases lateral patellar malalignment, leading to areas of heightened contact stress across the lateral PFJ compartment [40,41]. Thus, the balance of muscle activation between the medial and lateral quadriceps may be important in PFJ disease. In our studies of younger people with PFJ pain [42,43], we have observed a temporal delay in medial quadriceps activity. Thus, it is likely that individuals with PFJ OA may require a specific retraining program designed to restore balanced quadriceps activity.

While the role of hip muscle function in PFJ OA has not been investigated, there is increasing evidence that hip muscle function is impaired (reduced strength [44], delayed hip muscle activity [45]; and altered hip movements during ambulation [46]) in other PFJ conditions. These studies indicate that hip abduction is particularly relevant in patients with PFJ pain and hence, this study is focusing on strengthening hip abduction. Furthermore, the inclusion of a hip abduction strengthening program in this study reflects contemporary clinical practice.

While the main goal of treatment for OA is to reduce pain and disability, it is not known how non-pharmacological interventions achieve this goal; such is the complex multifactorial nature of OA pain. Our intervention is based on reversing the compartment-specific impairments *likely* to be associated with PFJ OA. Furthermore, this intervention builds on our previous studies, which have established that: (i) taping the patella medially reduces pain and disability associated with non-specific knee OA [30,31,47] and may reduce PFJ malalignment [48] and (ii) a quadriceps retraining program can reduce pain and disability, as well as restore quadriceps muscle activation patterns in younger people with PFJ pain [19,49,50]. Our unique RCT is targeting PFJ OA, an important sub-group of knee OA, with a specifically designed intervention. The project's outcome will influence knee OA rehabilitation, thus reducing the personal and societal burden of this increasing public health problem.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

KC, RH, BV, MP, AS attained the project funding. KC, RH, BV conceived and designed the trial protocol. All authors contributed to the manuscript and have read and approved the final manuscript.

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Supplementary Table. PFJ-targeted physiotherapy treatment elements

Components	Explanation	Rationale and/or Dosage
Functional retraining exercises for the quadriceps and hip muscles†	Retraining of the vasti (aiming for similar or greater activation in the medial, relative to the lateral vasti) and hip abductor/external rotator activity was performed in one exercise from each of the following: Functional retraining A - Sitting (isometric) or - Sit to stand Functional retraining B - Stepping up or - Single leg squat Biofeedback to facilitate vastus medialis activation was only used in physiotherapy sessions.	Patellar malalignment from altered vasti function [46] or excessive femoral rotation [47, 48] can lead to altered patellofemoral stress. Retraining aims to address these impairments. The commencing level and progressions were determined as the highest level that the participant could complete with pain <2 (0-10 numerical rating scale (NRS)) and whilst exhibiting optimal postural control (determined by therapist). Dosage was progressed (e.g. from 1 set of 10 repetitions through to 3 sets of 10 repetitions) and resistance provided through increasing hold times (e.g. from 0 to 10 seconds) for the sit-stand exercise and with increasing knee flexion and handheld weights for the single leg squats. All exercises were checked and progressed during the physiotherapy visits, and were conducted unsupervised at home 4 times per week, adherence and pain checked at each physiotherapy visit.
Quadriceps muscle strengthening†	Participants completed one exercise in each of the following activities: (i)- inner range (open kinetic chain) (ii)- mid range (open kinetic chain) (iii)- weight-bearing (wall squat)	Greater quadriceps muscle strength can protect against patellar cartilage loss. [41]. Quadriceps atrophy is a feature of PFJ OA [26] and was addressed with a strengthening program. Commencing level and progressions were determined as the highest level that the participant could complete with pain <2 (0-10 NRS) and exertion at least 5 (0-10 NRS). Dosage was progressed through the phases (e.g. from 1 set of 5 repetitions through to 3 sets of 15 repetitions) and resistance provided through increasing hold times, weights or resistance tubing (different grades). All exercises were checked and progressed during the physiotherapy visits, and were conducted unsupervised at home 4 times per week, adherence, pain and exertion checked at each physiotherapy visit.

Hip abduction strengthening[†]	Side lying hip abduction exercises.	Hip abduction dysfunction is a feature of PFJ OA [24, 28], and was addressed with a strengthening program. Exercises were progressed in 12 phases, commencing at the highest level that the participant could complete with pain <2 (0-10 NRS) and exertion at least 5 (0-10 NRS). Dosage was progressed from 3 to 4 set of 10 repetitions) and resistance provided through increasing hold times or weights). All exercises were checked and progressed during the physiotherapy visits, and were conducted unsupervised at home 4 times per week, adherence, pain and exertion checked at each physiotherapy visit.
Patellar taping	The taping techniques were applied in a pre-determined order (combination of tilt, medial glide and fat pad unloading), until the participant's pain was reduced by 50%.	Patellar malalignment is a feature of PFJ OA that can be addressed with taping [23]. The regular rigid strapping tape was applied by the physiotherapist at each visit, worn continuously for one week and then removed.
Patellofemoral, tibiofemoral and soft-tissue mobilisation	Manual patellar (e.g. medial glides) and tibiofemoral mobilisations (antero-posterior glides) Massage to the painful and tight soft tissue structures (e.g. lateral retinacular/iliotibial band)	Mobilisations have potential to improve joint pain [49]. Since walking on a flexed knee can increase the patellofemoral joint load, mobilisations were used to restore knee extension when restricted [50]. Techniques were provided when deemed appropriate by the physiotherapist based on assessment findings (e.g. to provide pain relief to assist pain-free exercises or activities of daily living). Provided only during physiotherapy sessions
OA education	Information sheets from the Arthritis Victoria website (http://www.arthritisvic.org.au) provided in eight sessions: 1a. What is arthritis? 1b. Osteoarthritis 1c. Tips for osteoarthritis of the hip or knee 2. Healthy eating and arthritis 3. Physical activity	Education sheets provided and patient-identified issues discussed with physiotherapist.

4. Dealing with pain
5. Medicines and arthritis

6a. Complementary therapies
6b. Glucosamine and chondroitin
6c. Fish oils

7a. Arthritis and emotions
7b. Saving energy

8. Taking control of your Osteoarthritis (booklet)

[†]Exact exercise and its number of repetitions were determined by the physiotherapist from a schedule of permissible exercises based on each participant's clinical presentation (e.g. strength, pain severity, swelling), presence of comorbidities (e.g. back and hip pain or pathology) and were progressed based on individual response to exercise load. While each person was started and progressed at an individual level (based on their strength/control or pain), the phases (see dosage) were standardised.