Physical Therapy for People with Lateral Elbow Tendinopathy

Using the Evidence to Guide Musculoskeletal Rehabilitation Clinical Practice

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Lateral elbow tendinopathy (LET) is an overuse injury of the common extensor tendon that occurs in active people. Modifiable risk factors include repetitive movements of the elbow, forearm, and hand, and tasks like handling heavy tools, which may overload the tendon. The clinical course of LET varies considerably. Some people experience a single, brief episode of symptoms, whereas others have persistent or recurring episodes of LET. The clinical course likely depends on the extent to which the tendon is exposed to chronic irritation. The evidence for physical therapy management of LET is summarized in the clinical practice guideline "Lateral Elbow Pain and Muscle Function Impairments" published in the December 2022 issue of *JOSPT*.

WHAT WE KNEW

Physical therapy can reduce pain and disability for people with LET. We also knew that there was a large body of evidence of variable quality, but no recent synthesis of critically appraised literature to provide practical recommendations to guide physical therapists when diagnosing and treating patients with LET.

WHAT WE DID

Content experts conducted systematic reviews of the literature related to assessing and treating LET. Studies published in the 20 years prior to November 2021 were evaluated for inclusion in the clinical practice guideline and were assigned a level of evidence. The guideline development group summarized the information and formulated evidence-based recommendations to guide physical therapists who are supporting patients with LET.

WHAT WE FOUND

Fifteen systematic reviews of the literature yielded 60 studies on issues related to examination and 74 studies of interventions. The guideline developers focused on systematic reviews, high-quality randomized controlled trials, and observational studies. Where there were gaps in the literature, the guideline developers included the next highest level of evidence that was available. The strength of the recommendations was influenced by the quality of evidence based on critical appraisals. A flowchart summarizes key elements of a proposed model to guide physical therapists' clinical reasoning when supporting people with LET to make informed decisions about how to best manage their symptoms.

WHAT WE NOW RECOMMEND: THE BOTTOM LINE FOR CLINICAL PRACTICE

1. For symptom modulation, physical therapists should use strategies to off-load tissues (grades B, C, E, and F) and to manage impairments through a combination of regional joint mobilizations (grade C) and physical agents, if needed (grades C and E).
2. To address joint and soft tissue mobility, physical therapists should incorporate therapeutic exercise alone or in combination with other interventions such as local (grade B) or regional (grade C) joint mobilization, dry needling (grade B), or soft tissue mobilization (grade C).
3. To restore load capacity once symptoms are less irritable, physical therapists should advance progressive resistance exercises (grade B) including the upper extremity kinetic chain (grade C) as symptoms allow, until function is restored.

This *JOSPT* Perspectives for Practice is based on the guidelines by Lucado et al[1] and was produced by Ann Lucado (PT, PhD, CHT) and a team of *JOSPT*'s Special Features Editorial Board including Alex Scott, PhD, BSc (PT), and staff led by Editor-In-Chief Clare Ardern, PhD, PT. The flowchart was produced by Kate Minick, PT, DPT, OCS, of Intermountain Healthcare, Rehabilitation Services, Salt Lake City, UT.

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This *JOSPT* Perspectives for Practice is based on the guideline by Lucado et al.[1]

REFERENCE

1. Lucado AM, Day JM, Vincent JI, et al. Lateral elbow pain and muscle function impairments. *J Orthop Sports Phys Ther*. 2022;52:CPG1-CPG111. https://doi.org/10.2519/jospt.2022.0302

Lateral Elbow Pain and Muscle Function Impairments Care Guideline

Assessment

Outcome, Activity Limitations, Self-Report Measures

- Patient-Rated Tennis Elbow Evaluation (PRTEE) to assess pain/irritability and function and/or the region-specific Disabilities of the Arm, Shoulder and Hand (DASH) to assess arm function at baseline and at least one other follow-up point – **A**
- Patient-Specific Functional Scale (PSFS) for patients with high-demand activities and/or a scale that assesses activity-specific disability at baseline, and at least one other follow-up point – **A**

Physical Impairment Measures

- Physical impairment measures of elbow and wrist range of motion, pressure pain threshold, pain-free grip strength, and maximum grip strength and baseline, and at least one other follow-up point, including at discharge – **B**

Intervention Strategies

Therapeutic Exercise:

- Isometric, concentric, and/or eccentric therapeutic resisted exercises of the wrist extensors for **subacute** or **chronic** lateral elbow tendinopathy (LET) **– B**
- Phased approach to reintroduce stress, increase strength, improve endurance, and restore optimal motor control for people with high-demand occupations or athletic interests – **F**
- Resisted wrist extension strengthening exercises in combination with other therapeutic interventions, including manual therapy (MT), in **subacute** or **chronic** LET – **B**
- Shoulder and scapular stabilizer muscle training exercises, when needed, with other forms of resistance exercises – **C**

Manual Therapy Joint Mobilizations/Manipulations:

- Local elbow MT to reduce pain and increase grip strength, standalone or adjunctive, in improving short term outcomes – **B**
- MT directed at the cervical or thoracic spine and/or wrist as an adjunct for short-term pain relief – **C**

Soft Tissue Mobilizations (STM):

- STM, including manual release therapy, to improve pain and function in people with **chronic** LET – **C**
- Instrumented-assisted STM with exercise to improve pain and function in those with **chronic** LET – **C**

Taping:

- Rigid taping techniques for short-term pain relief and improvement in muscle function in people with irritable LET – **B**
- Kinesiology tape application as part of a multimodal treatment program for short-term management of pain and function – **C**

Dry Needling:

- Either tendon or trigger point dry needling for treating pain and function deficits associated with LET – **B**

Orthoses:

- Forearm counterforce or wrist support orthosis, worn during activity, to immediately relieve pain and boost strength in people with activity-aggravated LET – **F**

Transcutaneous Electrical Nerve Stimulation (TENS):

- Burst TENS applied to the painful region or high- or low-frequency TENS applied to acupuncture points for short-term pain relief – **C**

Cryotherapy:

- Cryotherapy combined with burst TENS for short-term pain relief for people with symptoms >30 days – **C**
- Cryotherapy for pain relief for people with irritable symptoms – **E**

Iontophoresis:

- Iontophoresis with an anti-inflammatory drug, early in the rehabilitation phase (no later than 2-4 weeks from onset), in people who present with highly irritable symptoms – **C**

Laser:

- Laser therapy to relieve pain and improve grip strength, seen in follow-up periods >4 weeks to 6 months – **C**

Ergonomics:

- Ergonomic interventions for managing symptoms; education, behavioral modification, ergonomic equipment, and workstation adjustments – **E**

Not Recommended

Phonophoresis:

- Clinicians should NOT use phonophoresis for treatment of LET – **C**

No Recommendation

A recommendation cannot be made regarding the use of the following:

- Deep transverse tendon cross friction massage **– D**
- Ultrasound as a stand-alone treatment – **D**
- Forearm counterforce or wrist orthosis for intermediate or long-term LET – **D**

Based on the guidelines, the grades in this flowchart are translated as A = strong evidence, B = moderate evidence, C = weak evidence, D = conflicting evidence, E = foundational evidence, F = expert opinion. Figure produced for *JOSPT* by Kate Minick, PT, DPT, PhD of Intermountain Healthcare, Salt Lake City, UT

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The Effect of Progressive Resistance Exercise on Knee Muscle Strength and Function in Participants with Persistent Hamstring Deficit Following ACL Reconstruction: A Randomized Controlled Trial

OBJECTIVE: To investigate the effect of progressive resistance exercise compared with low-intensity home-based exercises on knee-muscle strength and joint function in people with anterior cruciate ligament (ACL) reconstruction and persistent hamstring strength deficits at 12-24 months after surgery.

DESIGN: Randomized controlled superiority trial with parallel groups, balanced randomization (1:1), and blinded outcome assessment.

METHODS: People with ACL reconstruction (hamstring autograft) and persistent hamstring muscle strength asymmetry were recruited 1 to 2 years postsurgery and randomized to either 12 weeks of supervised progressive strength training (SNG), or 12 weeks of home-based, low-intensity exercises (CON). The primary outcome was between-group difference in change in maximal isometric knee flexor muscle strength at 12-week follow-up.

RESULTS: Fifty-one participants (45% women, 27 ± 6 years) were randomized to SNG (n = 25) or CON (n = 26), with 88% follow-up rate at 12 weeks. People in the SNG group improved their knee flexor muscle strength (0.18 N·m/kg, 95% confidence interval [CI]: 0.07, 0.29; *P* = .002) more than the CON group, from baseline to 12 weeks. The SNG group also had superior Knee Injury and Osteoarthritis Outcome Scores for Pain (4.6, 95% CI: 0.4, 8.7; *P* = .031) and daily living function (4.7, 95% CI: 1.2, 8.2; *P* = .010) compared to the CON group.

CONCLUSION: In people with persistent hamstring muscle strength deficits after ACL reconstruction, 12 weeks of supervised progressive strength training was superior to low-intensity home-based exercises for improving maximal knee flexor muscle strength and some patient-reported outcomes. *J Orthop Sports Phys Ther 2023;53(1):40-48. Epub: 17 October 2022. doi:10.2519/jospt.2022.11360*

KEY WORDS: *anterior cruciate ligament reconstruction, functional outcome, hamstring, muscle strength, rehabilitation*

Anterior cruciate ligament (ACL) tears remain one of the most common knee injuries in young active individuals.[11,37,50] One common ACL reconstruction (ACLR) technique involves hamstring (HS) tendon autograft harvesting, with 9 to 12 months of rehabilitation typically needed, before returning to sport (RTS).[5,15,17,54]

The HS muscles are important protagonists to the ACL.[7,39,61] Due to well-documented positive effects of low-intensity strength training and/or neuromuscular exercise, restoring knee muscle strength has become a central element of contemporary ACLR rehabilitation programs.[6,8,21,30,53,56]

However, persistent (postrehabilitation) strength deficits in the HSs and quadriceps after ACLR are common[4,24,51] and have been observed up to 2 years postsurgery.[22,38] Athletes who return to sport after ACLR are more likely to reinjure their ACL in the first 2 years than athletes with their ACL intact.[43,44] The elevated risk of recurrent ACL injury appears to be even greater in athletes who do not meet specific knee muscle strength criteria (limb symmetry index [LSI] more than 90% for quadriceps/Hop test) prior to RTS,[31] highlighting a need to better understand the potential

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This study was approved by the ethics committee in the Region of Southern Denmark (S-2016003034). This study was registered at www.clinicaltrials.gov (NCT02939677) on October 20, 2016. Grant support (funding support as part of the PhD [B.B.]): Faculty of Health Sciences, University of Southern Denmark; Department of Orthopaedic Surgery and Traumatology, Kolding Hospital; Region of Southern Denmark Research Fund; Odense University Hospital Research Fund; Region of Southern Denmark Research Fund; The Danish Rheumatism Association. One author (J.B.T.) reported a research grant from Pfizer outside the submitted work. The corresponding author affirms that no other financial affiliation (including research funding) or involvement with any commercial organization that have had direct financial interest in any matter was included in this manuscript, except as disclosed above. No other conflict of interest has been disclosed or cited in the manuscript. The present trial protocol is available as an open-access source, published online at https://doi.org/10.1186/s13063-018-2448-3 and https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5787267/. The online version of this article (https://doi.org/10.1186/s13063-018-2448-3) contains supplemental material, which is available to authorized users.
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benefits of late-phase strength rehabilitation after ACLR.[30,52]

Therefore, we aimed to investigate the effect of progressive strength training, including elements of neuromuscular exercise, compared to low-intensity home exercises (resembling usual care) on HS muscle strength and knee joint function in people with persistent HS muscle strength deficits 12-24 months after ACLR.

METHODS

Trial Design

This study adopts a randomized controlled superiority trial design with parallel intervention groups, balanced randomization (1:1), and blinded outcome assessments. The ethics committee in the Region of Southern Denmark approved the study (S-2016003034). This study was a priori registered at www.clinicaltrials.gov (NCT02939677)[10] and reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[9]

Participants

Participants with ACLR (semitendinosus/gracilis tendon autografts) were recruited from the Department of Orthopaedics and Traumatology, Odense University Hospital and Lillebaelt Hospital, Kolding, Denmark. Initially, recruitment was primarily planned to take place at the outpatient clinic at 1-year follow-up visit. However, due to a low recruitment rate, most recruitments were carried out through other channels (Facebook, local sports club advertisements). Therefore, participants were recruited 12-24 months postsurgery as outlined in our protocol.[10] In brief, participants aged 18-40 years with persistent maximal isometric knee flexor strength asymmetry (>10% leg-to-leg difference, in isometric testing angle of 90° knee flexion) were recruited.[10] Exclusion criteria were body mass index [BMI] more than 35 or known lower limb pathology (including previous and/or concomitant knee injuries requiring surgical intervention to either knee), affecting participation in the intervention and/or test procedures. Informed consent was collected prior to enrollment and baseline testing. Data collection was performed at the Odense University Hospital and Lillebaelt Hospital between December 2016 and May 2020.

Randomization

Following baseline assessments, participants were randomized to either supervised progressive strength training including elements of neuromuscular exercise intervention (SNG) or to a home-based low-intensity weight-bearing exercise protocol, with the latter considered a minimal yet active modality of a control intervention that would resemble usual care (CON). The randomization was performed by a central study coordinator, otherwise not involved in the trial, with a simple 1:1 allocation ratio using sealed opaque envelopes.

Intervention

Participants randomized to SNG performed training sessions (60-70 minutes) twice weekly, over a duration of 12 weeks, commencing 8 exercises for the lower extremities performed in 3 sets of 10 repetitions with an intensity of 12 repetitions maximum.[10] Individual progression, quality of exercise, number of sets, repetitions, and additional training weights were monitored and adjusted throughout the intervention period by experienced physiotherapists. Participants allocated to CON received written and verbal instructions regarding 4 home-based (low intensity), weight-bearing exercises for the lower extremities, to be performed twice weekly. This intervention was designed to resemble usual care in cases where persistent knee muscle strength deficits would be discovered and considered a clinical issue. Acceptable adherence (for both groups) was defined as participation in ≥75% of all scheduled training sessions.[10]Adherence and adverse events were registered using a designated exercise diary by the participants in the CON group and by the physiotherapists in the SNG group, respectively. For specific intervention details, see protocol.[10]

Outcomes Measures

Outcome assessments were performed at baseline (prior to randomization) and following the 12-week intervention period. Participant characteristics were recorded at baseline.

Primary Outcome The primary outcome was the between-group difference in change from baseline to follow-up, in maximal unilateral isometric knee flexor (HS) strength of the ACLR knee.

Isometric knee muscle strength was determined by stabilized static dynamometry at a 90° angle (0° = full anatomical extension), according to methods described previously[24,27] with high-to-excellent test-retest reliability[26,55] and generally considered a valid test procedure.[23,42] Recorded force values expressed in Newtons (N) were multiplied by lower limb length (eg, external moment arm, measured from the lateral femur epicondyle to the lateral malleolus) and divided by body weight to yield torque values expressed in N·m/kg.

Secondary Outcome Variables Between-group difference in change in maximum unilateral isometric knee extensor strength (quadriceps) and HS-to-quadriceps muscle strength (H:Q) ratio, assessed by stabilized dynamometry. The H:Q strength ratio is the ratio between the maximal strength of the knee flexors relative to the knee extensors, calculated by dividing the maximal isometric knee flexor torque by the maximal knee extensor torque.[1,2] The Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire was administered to assess self-reported knee function and related symptoms.[13,16,46,47] The KOOS is a 42-item, self-administered survey that covers 5 patient-relevant domains: pain, other symptoms, activities of daily living (ADL), function in sport and recreation (Sport/Rec), and knee-related quality of life (QOL), with a 0-100 scale, where 100 represents "no symptoms." KOOS is a validated questionnaire with good-to-acceptable reliability documented in various cohorts of young and/

or active participants with knee injury and/or knee osteoarthritis (OA).[13,14,16,46-48]

Exploratory Outcome Variables Limb symmetry index based on the assessments of maximal isometric quadriceps and HS strength, defined as peak muscle torque of the injured leg divided by peak muscle torque of the nonoperated leg × 100.[36]

Sample Size

Previously published data on maximal unilateral isometric knee flexor strength of the operated ACLR leg (primary outcome)[22] guided our sample size estimates. The statistical model contained an estimated correlation between follow-up measurements of 0.5. A HS maximal isometric strength of 1.27 ± 0.37 N·m/kg was considered as reference values for the ACLR limb, and a change of 0.31 N·m/kg resulting in improvement toward reduced interlimb asymmetry was considered clinically relevant.[24] To ensure statistical power of 80% (β = .80) and an α-level of .05 (2-tailed testing), a sample size of n = 23 was calculated for each group. We aimed to recruit 50 participants (in total) to allow for possible dropouts.

Blinding

All authors were blinded to participant group allocation and did not participate in testing, randomization, or the intervention procedures. The statistical analysis was performed based on allocation codes only, and thus, the outcome assessment and principal data analyst (B.B.) was blinded to intervention allocation.[10] Blinding to treatment allocation of participants, training supervisors (physiotherapists), and project nurses (health care providers) was not possible due to the nature of the intervention.

Statistical Analysis

All randomized participants were included in the analysis, in the groups to which they were originally assigned (intention-to-treat analysis) with the last value carried forward for missing observations.[10] Between-group differences in change scores of outcome measures were evaluated using a linear regression model. Adjustments for covariates (sex, age, BMI, baseline outcome) were used for each outcome, to increase the precision of the treatment effect.

Effect size (ES) was estimated by using eta squared (η2), as described by Lakens.[32] To determine the effect size of the intervention, the mean outcomes of the 2 treatment groups were indexed in percentage of variance of each effect as small (0.02), medium (0.13), and large (0.26).[12] Outcome measures were checked for Gaussian distribution by visual inspection of Q-Q (quantile-quantile) plots. All statistical tests used an α-level of.05 (2-tailed) with data presented as means and 95% confidence intervals (CIs). STATA 16.1, StataCorp™, Texas, US, was used for all statistical analyses.

Patient and Public Involvement

The idea for the study protocol was partly created on basis from patients' attendance, feedback, and discussions, in a previous study, based in our laboratory.[24] Participant feedback on the current intervention was continuously collected by the physiotherapists involved in the delivery of the intervention. In the event of a study outcome in favor of the intervention, we planned to incorporate feedback into a written recommendation for municipal rehabilitation centers.

RESULTS

Participants

Seventy-four potentially eligible participants were screened from December 2016 to December 2019. Twelve declined to participate and 8 participants did not meet the inclusion criteria (no asymmetry). Three participants were unable to participate due to relocation or excessive travel distance to the exercise facility (**FIGURE 1**). Finally, 51 participants (recreational athletes of various levels [by

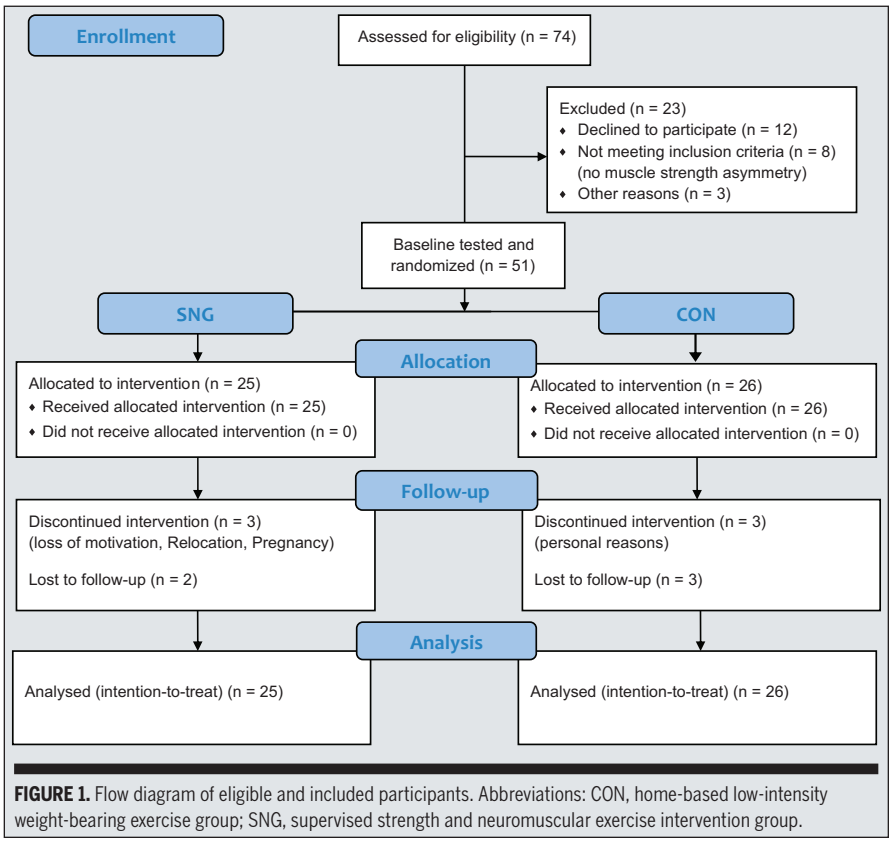

FIGURE 1. Flow diagram of eligible and included participants. Abbreviations: CON, home-based low-intensity weight-bearing exercise group; SNG, supervised strength and neuromuscular exercise intervention group.

chance/not part of inclusion criteria]) were randomized. Two and three participants in the SNG and CON, respectively, were lost to follow-up. One participant relocated, and one participant got pregnant and withdrew from the study. One participant in the SNG group lost motivation to participate after 2 training sessions and withdrew, while accepting the invitation for follow-up testing. In the CON group, 3 participants withdrew due to issues unrelated to the study and were not available for follow-up testing. Those participants retained in the study (n = 22 and n = 23 for the SNG and CON groups, respectively) had a training adherence exceeding 75% (92% and 100% for SNG and CON, respectively).

The SNG group participants (n = 25; 44% women) had a mean age of 27.7 years and a BMI of 25.6. The CON group participants (n = 26; 46% women) had a mean age of 27.0 years and a mean BMI of 24.5 (**TABLE 1**). Both groups included participants (3 and 2, respectively) with previous or concomitant meniscus injury, but none was surgically treated, and the meniscus injury did not affect (nonsurgical) treatment. Therefore, the injuries were not considered as part of exclusion criteria (**TABLE 1**).

TABLE 1 Baseline Characteristics of Study Participants

Baseline Characteristics	SNG (n = 25) Mean (SD)	CON (n = 26) Mean (SD)
Age (years)	27.7 (5.7)	27.0 (6.4)
Weight (kg)	78.7 (15.8)	77.3 (14.7)
Height (cm)	175.3 (9.3)	177.2 (8.9)
Body mass index (kg/m²)	25.6 (4.5)	24.5 (3.4)
Male-female ratio, n	14:11	14:12
Time since ACLR (months)	15 (3.3)	16 (3.0)
Meniscus injury		2
Injured leg, Do/non-Do	16/9	13/13
Primary Outcome:		
Maximal isometric knee flexor strength (N·m/kg)	1.28 (0.37)	1.42 (0.34)
[nonoperated limb]	[1.71 (0.33)]	[1.96 (0.34)]
Secondary Outcome:		
Maximal isometric knee-extensor strength (N·m/kg)	2.71 (0.69)	2.74 (0.59)
[nonoperated limb]	[3.02 (0.59)]	[3.16 (0.51)]
Hamstring-to-quadriceps ratio	0.48 (0.12)	0.54 (0.14)
KOOS–5[a] subscales score		
- Pain	83.0 (14.6)	79.39 (11.2)
- Symptoms	77.2 (17.4)	68.4 (12.7)
- ADL	88.6 (11.7)	87.9 (8.7)
- Sport/Rec	59.4 (26.3)	55.6 (22.4)
- QOL	49.1 (21.8)	55.0 (18.4)
Not Prespecified Explorative Outcomes:		
LSI hamstring (%)	74.25 (13.7)	72.26 (10.4)
LSI quadriceps (%)	89.49 (11.3)	86.18 (9.6)

Abbreviations: ACLR, anterior cruciate ligament reconstruction; ADL, activities of daily living; CON, home-based low-intensity weight-bearing exercise group; Do/non-Do, dominant/non-dominant; ES, effect size; KOOS, Knee Injury and Osteoarthritis Outcome Score; LSI, limb symmetry index in percent; QOL, quality of life; SD, standard deviation; SNG, supervised strength and neuromuscular exercise intervention group; Sport/Rec, sport and recreation.

[a]*KOOS consists of 5 subscales: pain, other symptoms, ADL, Sport/Rec, and knee-related QOL.*

Outcomes

Primary Outcome The SNG group had a greater improvement from baseline to follow-up in maximal isometric knee flexor strength of the ACLR limb compared with CON (0.18 N·m/kg, 95% CI: 0.07, 0.29; P = .002; ES = 0.30; **TABLE 2** and **FIGURE 2**). Within-group improvements in maximal isometric knee flexor strength were observed in both the SNG group (0.30 N·m/kg, 95% CI: 0.22, 0.39) and the CON group (0.09 N·m/kg, 95% CI: 0.02, 0.17) (**TABLE 2**).

Secondary Outcomes The SNG group had a greater improvement in the KOOS subscales for pain (4.6, 95% CI: 0.4, 8.7; ES = 0.27) and ADL (4.7, 95% CI: 1.2, 8.2; ES = 0.25) compared with the CON group. There were no between-group differences in change scores for knee extensor muscle strength, H:Q ratio, KOOS QOL, KOOS symptoms, and KOOS Sport/Rec at follow-up (**TABLE 2**). Within-group improvements for all secondary outcome variables were observed in the SNG group. In the CON group, there were improvements in maximal isometric knee extension strength, KOOS symptoms, and KOOS Sport/Rec (**TABLE 2**).

Exploratory Outcomes A larger between-group improvement toward reduced bilateral asymmetry was observed for quadriceps LSI in favor of SNG (4.6%, 95% CI: 0.57, 8.6). There was a within-group improvement for HS LSI in the SNG group (6.7%, 95% CI: 3.06, 10.25), but there were no significant differences between groups for changes in HS symmetry (**TABLE 2** and **FIGURE 2**).

Adverse Events

Two participants in the SNG group experienced transient episodes of acute knee joint pain (visual analog scale more than 50 mm) following a single training session. Loading and range of motion were adjusted in the following sessions, allowing training to resume after 1 and 2 weeks, respectively. Both participants managed to keep within the 75% threshold of acceptable adherence. During post-training testing, 2 participants (one from

TABLE 2 Mean Difference Within Groups and Difference Between Groups at Follow-up (Group Mean Values and 95% Confidence Intervals: mean [95% CI])[a,b]

	SNG Follow-up	SNG Within Group Change From Baseline	CON Follow-up	CON Within Group Change From Baseline	Between-Group Change From Baseline	Baseline Adjusted Between-Group Difference
Primary Outcome						
Maximal isometric knee flexor strength (N·m/kg)	1.58 [1.44, 1.73]	0.30 [0.22, 0.39]	1.51 [1.38, 1.65]	0.09 [0.02, 0.17]	0.21 [0.09, 0.33]	0.18 [0.07, 0.29]
[nonoperated limb]	1.96 [1.32, 2.80]	0.26 [0.18, 0.36]	2.02 [1.11, 2.57]	0.06 [0.03, 0.15]	0.20 [0.08, 0.31]	0.19 [0.07, 0.32]
Secondary outcome						
Maximal isometric knee extensor strength (N·m/kg)	3.07 [2.79, 3.35]	0.36 [0.24, 0.48]	2.94 [2.70, 3.18]	0.20 [0.05, 0.36]	0.16 [−0.04, 0.35]	0.15 [−0.03, 0.34]
[nonoperated limb]	3.32 [2.10, 4.45]	0.30 [0.16, 0.44]	3.39 [1.79, 4.78]	0.23 [0.08, 0.39]	0.07 [−0.14, 0.27]	0.06 [−0.27, 0.15]
Hamstring-to-quadriceps ratio	0.52 [0.48, 0.55]	0.04 [0.00, 0.08]	0.52 [0.48, 0.57]	−0.02 [−0.05, 0.04]	0.05 [0.00, 0.08]	0.03 [−0.01, 0.06]
KOOS–5[a] subscales score						
- Pain	88.3 [83.27, 93.29]	5.3 [1.33, 9.31]	81.2 [76.82, 85.64]	1.9 [−0.78, 5.89]	3.5 [−1.14, 8.09]	4.6 [0.43, 8.69]
- Symptoms	84.1 [79.31, 88.93]	6.9 [0.39, 13.37]	73.7 [68.20, 79.26]	5.3 [2.25, 8.37]	1.6 [−5.33, 8.47]	5.8 [−0.13, 11.63]
- ADL	94.8 [91.94, 97.66]	6.2 [2.98, 9.34]	89.5 [84.76, 94.30]	1.7 [−0.63, 3.94]	4.5 [0.72, 8.30]	4.7 [1.20, 8.22]
- Sport/Rec	71.6 [61.01, 82.19]	12.2 [5.70, 18.70]	63.2 [54.14, 72.32]	7.7 [1.55, 13.76]	4.6 [−4.14, 13.23]	5.4 [−2.94, 13.66]
- QOL	62.2 [53.03, 71.29]	13.0 [7.75, 18.33]	59.7 [51.63, 67.83]	4.7 [−0.87, 10.34]	8.3 [−0.79, 15.83]	7.3 [−0.13, 14.73]
Not pre-specified explorative outcomes						
LSI (hamstrings, %)	80.90 [75.58, 86.23]	6.65 [3.06, 10.25]	75.38 [70.26, 80.51]	3.13 [−1.02, 7.27]	3.53 [−1.83, 8.89]	4.03 [−1.13, 9.19]

Abbreviations: ADL, activities of daily living; CON, home-based low-intensity weight-bearing exercise group; KOOS, Knee Injury and Osteoarthritis Outcome Score; LSI, limb symmetry index in percent; QOL, quality of life; SNG, supervised strength and neuromuscular exercise intervention group; Sport/Rec, sport and recreation.

[a]*A forest plot of the between-group changes for primary, secondary, and exploratory outcome variables is available in the supplemental file.*

[b]*Adjusted = covariate and baseline adjusted, all values in mean (95% confidence interval).*

[c]*Changes in maximal isometric knee flexor and extensor strength are expressed relative to body mass (N·m/kg).*

[d]*KOOS consists of 5 subscales: pain, other symptoms, ADL, Sport/Rec, and knee-related QOL, increase in points on subscale (0-100).*

[e]*KOOS, for pain, symptoms, ADL, Sport/Rec, and knee-related QOL, increase in points on subscale (0-100).*

each group) experienced dizziness and nausea. In both cases, tests were terminated and completed 1 week later.

DISCUSSION

Twelve weeks of supervised progressive training intervention (SNG) was superior to low-intensity home based exercises (CON) for improving knee flexor muscle strength in people with ACLR and persistent HS muscle deficits. In addition, the people in the SNG group also had greater improvements in patient-reported pain and ADL function compared with people in the CON group. Consequently, knee flexor (HS) strength could be improved by a combination of progressive strength training and neuromuscular exercise, even when initiated at a late stage following ACLR, providing a potential basis for improved clinical and functional outcomes in this patient population.

Interpreting Strength Tests After ACLR Late Rehabilitation Previous efforts have been made to enhance maximal knee muscle strength in people with ACLR by applying accelerated or supervised rehabilitation (physiotherapy) protocols. However, these physiotherapy protocols did not elicit benefits in muscle strength compared to home-based exercise protocols.[18,19,33] After 9 to 12 months of postsurgical rehabilitation, a majority (approximately 70%-75%) of people with ACLR have persistent signs of interlimb HS muscle strength asymmetry that exceeds reported RTS thresholds.[24,51,59] Thus, based on previous reports, we question whether traditional ACLR protocols are sufficiently effective when it comes to regaining, and then maintaining, HS muscle strength in the longer term (>9 months).

Despite a large effect size for the observed pre-to-post training effect, the change score was somewhat low in magnitude (0.18 N·m/kg, 95% CI: 0.07, 0.29) compared with the anticipated and a priori defined clinically relevant change (0.31 N·m/kg).[10] A similar pattern was observed for KOOS subscale scores (pain and ADL), where the observed differences in change scores

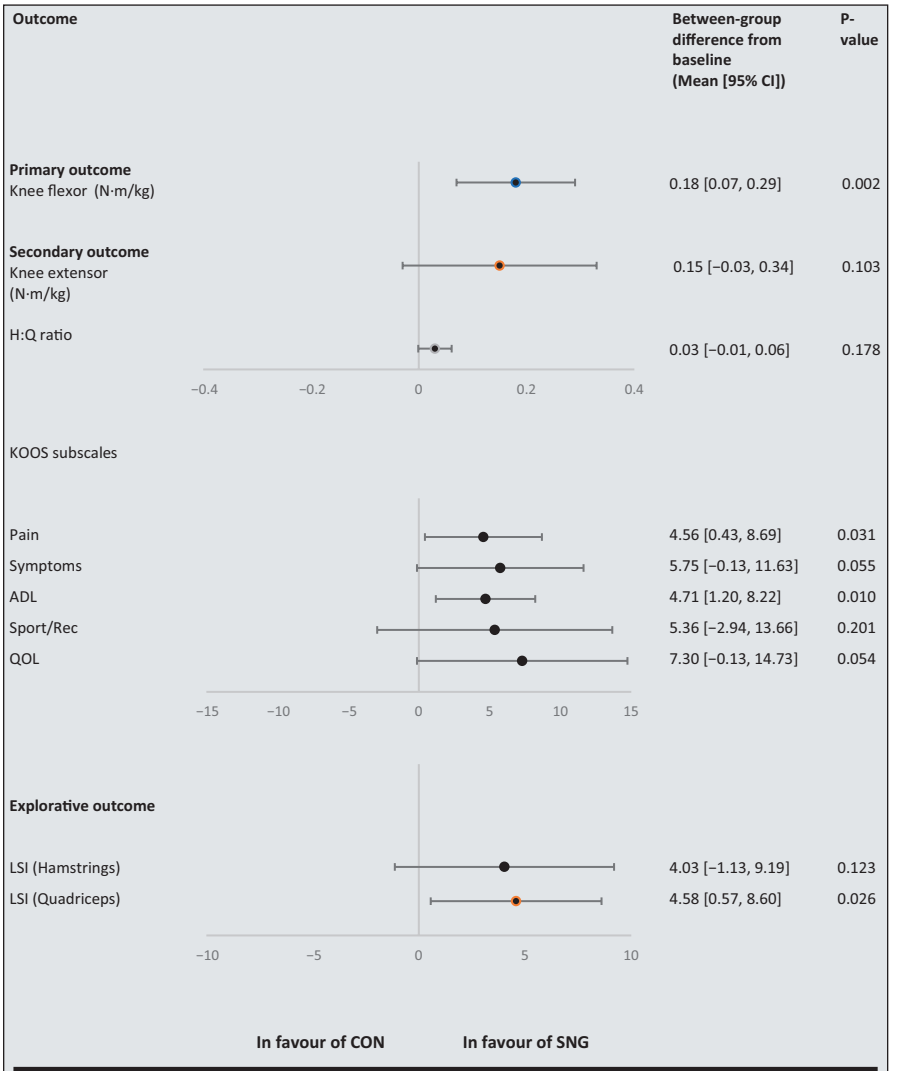

FIGURE 2. Effect size of between-group changes for primary, secondary, and explorative outcome variables at follow-up. The values are presented as between-group eta squared ($\eta 2$) differences from baseline and 95% confidence intervals (mean [95% CI]). Abbreviations: ADL, activities of daily living; CON, home-based low-intensity weight-bearing exercise group; H:Q, hamstring-quadriceps ratio; KOOS, Knee Injury and Osteoarthritis Outcome Score; LSI, limb symmetry index; QOL, quality of life; SNG, supervised strength and neuromuscular exercise intervention group; Sport/Rec, sport and recreation.

remained below 10 points, which is generally interpreted as not being clinically relevant.[46]

In contrast, the (postintervention) absolute values for maximal flexion and extension muscle strength (both groups) exceeded reference values previously reported for healthy soccer and handball players (compared with the original, not adjusted, muscle strength data [in Newton])[57] and by Šarabon et al reporting isometric knee flexor and extensor muscle strength in women and men.[49]

The SNG group demonstrated clinically relevant within-group improvements in KOOS scores (Sport/Rec and QOL), emphasizing that deficits in knee muscle strength and patient-reported knee function are modifiable by exercise-based intervention procedures even when initiated more than a year after ACLR.

Additional Late Rehabilitation Phase as Part of the RTS Decision When returning to sport following ACLR, the risk of re-injury remains high.[20,58,60] Prospects for RTS are somewhat low given that only 53% of ACLR patients pass RTS criteria 1 year after surgery[35] and only 55% return to competitive level sport.[3] Furthermore, persistent deficits in lower limb muscle strength might elevate the risk of posttraumatic knee OA,[28,41] with up to 50% of patients with ACLR developing knee OA.[40] Thus, there is a need to develop, promote, and examine the effect of designated late-phase rehabilitation efforts.

Despite significant training-induced improvements (SNG) characterized by a large effect in maximal HS strength (primary outcome variable), these gains appeared to be of insufficient magnitude to fully eliminate the presence of pathological LSI values based on maximal HS muscle strength. Of note, strength gains in the contralateral (nonoperated) limb (**TABLE 2**) might also contribute to the continued pathologic LSI values. We speculate that longer duration and/or a more intensive intervention protocol may evoke changes that could reach or exceed clinically significant thresholds of improvement, although this is not supported in a healthy/uninjured population.[29,45]

Generalizability Our inclusion criteria were broad, covering sex, a wide age range, and multiple types and level of sports participation. Participant characteristics (including strength measures) were well matched and consistent with previous studies of the same population.[24,25,34] Thus, the study findings are considered generalizable to the ACLR population.

Limitations The data analyst (B.B.) and the research assistants conducting all physical tests were carefully trained in the laboratory test protocol and blinded to randomization. However, blinding of participants for intervention allocation was not possible due to the nature of the study. In addition, the present results, especially those from the SNG group, may suffer from attention bias due to the sessions of supervised training.

Due to COVID-19–related shutdowns at follow-up, tests for 3 participants (2 in SNG, 1 in CON) were postponed for 2 weeks after completing the intervention. In addition, research staff were replaced during the intervention period as we required a longer than anticipated recruitment phase.

Five participants had concomitant meniscus injury of minor severity, which did not require surgery. We could not account for the potential influence of meniscus injury or concomitant bone marrow edema in our analyses. Notably, these injuries were distributed equally between the treatment and control groups and therefore were deemed unlikely to have affected our conclusions.

Although assessing muscle strength is a typical part of the early-phase rehabilitation program, such evaluation at 1-2 years post-ACLR is not part of usual care rehabilitation, and thus, additional muscle strengthening activities are not offered to ensure full late-phase recovery. Furthermore, no previous studies have investigated the effect of late-phase rehabilitation programs in patients after ACLR, nor has this aspect been addressed in current consensus statements related to treating ACL injury. However, as pathological asymmetry of the knee flexors was observed at inclusion, participants in our trial (CON) were offered a low-resistance exercise regimen to mimic a realistic clinical treatment option that could address signs of pathological deficits in knee muscle strength (if identified) at 12-month postoperative ACLR follow-up.

While not the purpose of our study, to optimize late-phase ACLR rehabilitation, the influence of differences in specific intervention parameters between SNG and CON (supervision, neuromuscular exercises, progression, frequency, volume etc) could be examined in future studies.

The minimal clinically important difference for our primary outcome variable (maximal HS muscle strength) is not supported by anchor-based definitions, and consequently, the current threshold of 0.31 N·m/kg was based upon qualified estimations obtained from previous reports in a comparable patient group.[24]

CONCLUSION

In people with persistent HS muscle deficits after ACLR, 12 weeks of supervised progressive strength training was superior compared to low-intensity home-based exercises (usual care) for improving knee flexor muscle strength and some patient-reported outcomes. Persistent HS muscle deficits can improve at late stages of postsurgical ACLR rehabilitation. However, it is unclear whether current improvements were of clinical importance and sufficient magnitude to fully eliminate deficits in maximal HS muscle strength. ◉

KEY POINTS

FINDINGS: Supervised strength training was superior to home-based weight-bearing exercise training in improving maximal unilateral isometric knee flexor strength after ACLR with HS tendon autograft and persistent muscle strength deficits. Both intervention groups improved their objective and subjective knee outcomes after treatment. Deficits in knee muscle strength and patient-reported knee function can improve, more than 1 year after ACLR

IMPLICATIONS: In patients with HS strength deficits more than 12-month post-ACLR, clinicians can consider strength and neuromuscular exercises to improve strength and patient-reported outcomes.

CAUTIONS: Despite significant training-induced improvements in maximal HS strength, these gains were of insufficient magnitude to fully eliminate the presence of pathological LSI in maximal HS muscle strength.

STUDY DETAILS

AUTHOR CONTRIBUTIONS: B.B., A.H.L., N.N., M.W.C., T.T., P.A.A., J.B.T., and C.J. designed the study. B.B. recruited participants, analyzed data, and wrote the manuscript. A.H.L. cosupervised inclusion, study flow, and technical support in the laboratory. J.B.T. helped in analyzing data and statistical assistance. C.J. and N.N. offered technical support, in terms of data analysis and inclusion. All authors (except N.N. [deceased in June 3, 2019]) reviewed and helped finalize the manuscript.

DATA AVAILABILITY AND SHARING STATEMENT: Data of the individual participant data collected during the trial, after deidentification, are available upon reasonable request. Data are available immediately following publication (no end date), to researchers who provide a methodologically sound proposal. Proposals should be directed to bo.bregenhof2@rsyd.dk. To gain access, data requestors will need to sign a data access agreement.

PATIENT AND PUBLIC INVOLVEMENT: The study protocol was partly created on the basis of patients' attendance, feedback, and discussions, in a previous study.[24] Participant feedback on the intervention was continuously collected by the physiotherapists involved in implementing the intervention. In the event of a study outcome in favor of the intervention, the feedback was planned to be incorporated into a written recommendation for municipal rehabilitation centers.

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Patient-Reported Outcome Measures for Adults and Adolescents with Patellofemoral Pain: A Systematic Review of Content Validity and Feasibility Using the COSMIN Methodology

People with patellofemoral pain (PFP) often report poor long-term outcomes and recurrence rates as high as 90%.[14,42,67] Clinicians and researchers need tools they can trust to accurately capture the patient's experience of PFP.[73] Given that the diagnosis of PFP relies on symptom location and pain during functional activities, a patient-reported outcome measure (PROM) that assesses pain and function is critical.[77]

OBJECTIVE: To assess the content validity and feasibility of patient-reported outcome measures (PROMs) used to assess pain and function in adults and adolescents with patellofemoral pain (PFP).

DESIGN: Systematic review.

LITERATURE SEARCH: We searched the databases PubMed, CINAHL, Scopus, SPORTDiscus, and the Cochrane Library from inception to January 6, 2022.

STUDY SELECTION CRITERIA: We included studies that described the development or evaluation of the content validity of English-language PROMs for PFP, as well as their translations and cultural adaptations to different languages.

DATA SYNTHESIS: Using the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) methodology, we determined overall ratings and quality of evidence for the relevance, comprehensiveness, and comprehensibility of PROMs. We extracted data related to feasibility for clinical use (eg, administration time and scoring ease).

RESULTS: Forty-three studies for 33 PROMs were included. The overall quality of most studies was "inadequate" due to failure to engage stakeholders and/or ensure adherence to rigorous qualitative research procedures. Of all PROMs evaluated, the Knee injury and Osteoarthritis Outcome Score–Patellofemoral subscale (KOOS-PF), was the only PROM with *sufficient* content validity components. Quality of evidence for content validity of the KOOS-PF was low. Most PROMs were rated feasible for clinical and research purposes.

CONCLUSION: Most PROMs used to measure pain and function in patients with PFP have inadequate content validity. The KOOS-PF had the highest overall content validity. We recommend the KOOS-PF for evaluating pain and function (in research and clinical practice) in adults and adolescents with PFP. *J Orthop Sports Phys Ther 2023;53(1):23-39. Epub: 18 October 2022. doi:10.2519/jospt.2022.11317*

KEY WORDS: *assessment, clinical measurement (clinimetrics), function, knee, patellofemoral joint, psychometrics*

PROMs are tools used in clinical practice and research to measure the impact of conditions on a patient's health status, pain, function, and quality of life.[75] PROMs for assessing health-related status may be disease-specific, body region-specific, or generic.[26] Valid assessment of the patient's perspective requires well-constructed PROMs with strong measurement properties.[71,73] Content validity, reported to be the most important PROM measurement property, is "the degree to which the content of an instrument is an adequate reflection of the construct to be measured."[70] The Consensus-based Standards for the selection of health Measurement INstruments (COSMIN) group recommends that content validity be the first measurement property of a PROM to be evaluated.[18,70] Use of a PROM with insufficient content validity can lead to inappropriate conclusions regarding the impact of a disease on the patient.[29]

A clinical practice guideline for managing PFP[77] and a recent international

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consensus statement[7] strongly recommend use of PROMs to measure the impact of PFP from the patient's perspective. Several PFP disease-specific PROMs exist, but researchers and clinicians have used a variety of PROMs.[20,26] Clinicians treating patients with a range of lower extremity conditions may use a knee- or lower extremity–specific PROM.[74] Similarly, researchers comparing patients with different diseases may select a region-specific or generic PROM.[15] However, these PROMs may not adequately address impairments and functional limitations associated with PFP. Therefore, it is imperative that the content validity of these instruments is established for use with patients with PFP.[18,70]

While not considered a measurement property, aspects related to feasibility (eg, administration time and ease of score calculation) deserve consideration when selecting a PROM for research and clinical use.[24,40,41,51,60] PROM feasibility is also important when developing a recommended *core outcome set* for use in clinical trials.[60]

Little is known about the content validity and feasibility of PROMs for PFP.[7,77] Although 2 systematic reviews have examined content validity of PFP PROMs,[24,30] they did not use the updated COSMIN methodology.[18,70] Therefore, we aimed to appraise and synthesize the evidence for the content validity of PFP PROMs according to the current COSMIN procedures and, when available, the content validity of translated and culturally adapted versions.[66] A secondary purpose was to appraise and synthesize the feasibility of the included PFP PROMs according to COSMIN methodology.

METHODS

This systematic review was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines and the *COSMIN Methodology for Systematic Reviews of PROMs User Manual* (version 1.0, dated February 2018).[16,48,49,56,61,70] The review of included studies followed the *COSMIN Methodology for Assessing the Content Validity of PROMs User Manual* (version 1.0).[18,70] The protocol was prospectively registered with PROSPERO (registration number CRD42018118247). The implementing PRISMA in Exercise, Rehabilitation, Sport medicine and SporTs science (PERSiST) guideline was used for guidance when summarizing the findings.[5]

Eligibility Criteria

This systematic review included cohort, case-control, and cross-sectional studies that reported the development or evaluation of the content validity of PFP PROMs initially developed and published in the English language. Per COSMIN, a PROM development study reports the initial development of a PROM. Content validity studies are those that examine PROM content validity in a different sample from the original PROM development study, including translations to different languages.[18,70] Studies that modified PROMs (eg, altered number or phrasing of items and/or instructions) and translations adapted to different cultures (ie, cultural adaptations) were considered development studies.[18] Inclusion as a content validity study required that ≥50% of participants were adults and/or adolescents (≥12 years) with a clinical diagnosis of PFP.[20,62] Included development studies were PROMs (1) developed with ≥50% of participants with PFP aged ≥12 years or (2) had at least one published study that examined the PROM's measurement properties with ≥50% of participants with PFP aged ≥12 years.[18] We included studies involving translations and cultural adaptations of English-language PFP PROMs. Exclusion criteria were (1) >50% of participants aged <12 years, (2) >50% of participants with nonmusculoskeletal or other musculoskeletal causes of anterior knee pain (eg, patellar tendinopathy or instability), and (3) systematic reviews, review articles, case reports/series, conference proceedings, non–peer-reviewed articles, and articles not published in English. We will report a systematic review on additional PFP PROM measurement properties (eg, internal consistency, structural and construct validity, reliability, measurement error, responsiveness, and interpretability) in a separate article.

Searches

PubMed, Scopus, CINAHL, SPORTDiscus, and the Cochrane Library databases were electronically searched from inception to January 6, 2022. A medical librarian assisted in developing and conducting all searches. Keywords and Medical Subject Headings (MeSH) related to PFP, outcome measures, and psychometric properties were combined with a search filter for finding studies on measurement properties of PROMs.[69] **SUPPLEMENTAL FILE 1** summarizes the search strategies for all databases. Search results were combined and duplicates removed.

Article Selection and Quality Appraisal

Two reviewers (L.T.H. and D.A.S.) independently screened titles and abstracts of retrieved articles for eligibility. We obtained the full text for studies meeting inclusion criteria and for articles where inclusion was unclear based on only title and abstract.[16] Pairs of reviewers (L.T.H. and L.A.B.; D.A.S. and D.J.J.) screened full-text articles. Hand searching of retrieved systematic reviews, narrative reviews, and reference lists of included studies located eligible studies not retrieved by our search.[16,61] To become familiar with the COSMIN appraisal methodology and improve consistency, all reviewers appraised 3 articles: a development study,[39] a translation study,[13] and a measurement properties study.[74] Ratings were compared and, following discussion, reviewers came to consensus.[18] A qualitative researcher (S.F.W.) participated and guided the group in this practice. Two reviewers independently appraised the quality of each included study using the COSMIN Risk of Bias checklist and COSMIN manuals for conducting systematic reviews of PROMs.[49,61,70] Quality appraisal scores were organized using standardized spreadsheets downloaded from the COSMIN website.[31] Ratings were discussed between the 2 reviewers to reach

consensus. A third reviewer (S.F.W.) was consulted to resolve any differences when consensus could not be reached.[18] Characteristics of the included studies and PROMs were independently extracted by 2 reviewers using standardized data extraction tables downloaded from the COSMIN website.[31] Extracted data were compared by 2 reviewers to reach consensus.

Ratings of the quality of PROM development began by searching the COSMIN website for previous development quality appraisal of any PFP PROMs identified in our search; none were previously appraised.[17] Box 1 of the COSMIN checklist was used to appraise risk of bias of PROM development studies, including cultural adaptations and modifications of existing PROMs (**SUPPLEMENTAL FILE 2**).[70] Quality of content validity studies was appraised using Box 2 of the COSMIN checklist, including translations of existing PROMs where no adaptation was made (**SUPPLEMENTAL FILE 2**).[70] Checklist items were rated according to COSMIN criteria as Very Good, Adequate, Doubtful, Inadequate, or Not Applicable. These items considered whether the PROM was applied to patients or professionals and whether qualitative or survey methods were used. The lowest scoring item on the COSMIN Risk of Bias checklist determined final ratings for measurement properties (ie, "the worst score counts").[49,61]

Three aspects of content validity were evaluated separately: (1) relevance, (2) comprehensiveness, and (3) comprehensibility. Relevance included whether PROM items were significant for the target population, construct of interest, and context of use.[70] Comprehensiveness determined whether all important concepts were included in the PROM.[70] Comprehensibility included whether PROM instructions, items, and responses were appropriately phrased and understood by the target population.[70]

Strategy for Data Synthesis

After study appraisal, overall content validity of each PROM was determined using the 10-criteria COSMIN checklist: 5 concerning relevance, 1 concerning comprehensiveness, and 4 concerning comprehensibility (**SUPPLEMENTAL FILE 2**).[18,70] Ratings for each of the 10 content validity criteria considered quality scores for development studies, any content validity studies, and the reviewer rating of the PROM itself.[70] Two reviewers independently rated and scored each criterion as Sufficient, Insufficient, Inconsistent, or Indeterminate.[70] Pairs of reviewers discussed ratings to achieve consensus. The qualitative reviewer (S.F.W.) resolved any differences. Following COSMIN guidelines, the overall ratings of PROM relevance, comprehensiveness, and comprehensibility were determined.[70] Content validity studies provided the highest evidence, followed by development studies, and last, by reviewer ratings.[70]

Finally, quality of evidence for overall PROM content validity ratings for the 3 aspects of content validity was graded using a modified Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach described by COSMIN (high, moderate, low, or very low quality).[70] Two reviewers independently assessed quality of evidence using the modified GRADE approach; agreement was reached through consensus. This approach began with evidence quality considered *high* and downgraded for issues with risk of bias in the studies, inconsistency between studies, and indirectness of the evidence (eg, study populations other than PFP).[18,70] The COSMIN-modified GRADE approach weighed evidence from content validity studies over development studies.[18]

PROM feasibility was determined using data extraction tables created by COSMIN and available on the COSMIN website.[31] COSMIN guidelines defined feasibility as "the ease of application of the PROM in its intended context of use."[16] Factors included completion time, instrument standardization, ease of score calculation, cost of use, and copyright. We also extracted the following data: type and ease of administration, instrument length, patient's required mental and physical ability level, required equipment, availability in different settings, and regulatory agency's requirement for approval. **SUPPLEMENTAL FILE 3** presents a full list of extracted data items.

Patient and Public Involvement

There was no involvement from patients or the public in the design, conduct, interpretation, and/or translation of our review.

RESULTS

Literature Search and Study Selection

The search yielded 10 962 records and 7066 records remained following duplicate removal. We retrieved 85 full-text records after screening titles and abstracts. Thirty-four of the 85 full-text records met the inclusion criteria. Nine articles were added from screening retrieved systematic reviews, review articles, and citations of included articles. This resulted in 33 development studies and 10 content validity studies (**FIGURE**).

Characteristics of Studies and PROMs

Characteristics of included studies, including study sample descriptions, are in **TABLE 1**. Studies were published between 1975 and 2021 and included participants from 23 countries: Australia,[19] Belgium,[10] Brazil,[4,21] Canada,[9,12,23,33,43,47] China,[13] Columbia,[46] Finland,[39] France,[35] Greece,[57,58] Iran,[53-55] Japan,[35] Jordan,[32] the Netherlands,[72] Norway,[34] the Republic of Korea,[44] Saudi Arabia,[1,2,6] South Africa,[22] Spain,[28] Sweden,[45,68] Thailand,[3,64] Turkey,[11,25] the United Kingdom,[65] and the United States.[9,27,35-37,52,59,63,76,78]

Characteristics of the 33 PROMs are summarized in **TABLE 2**. Sixteen PROMs were developed and reported in English-language development studies.[9,12,19,22,23,27,35,36,39,43-45,47,63,65,76] Six PROMs were modifications of items or responses[33,68] or reduced number of items.[37,52,59,78] Eleven PROMs were both a translation and cultural adaptation.[1,4,6,11,28,32,53,55,58,64,72] Twenty

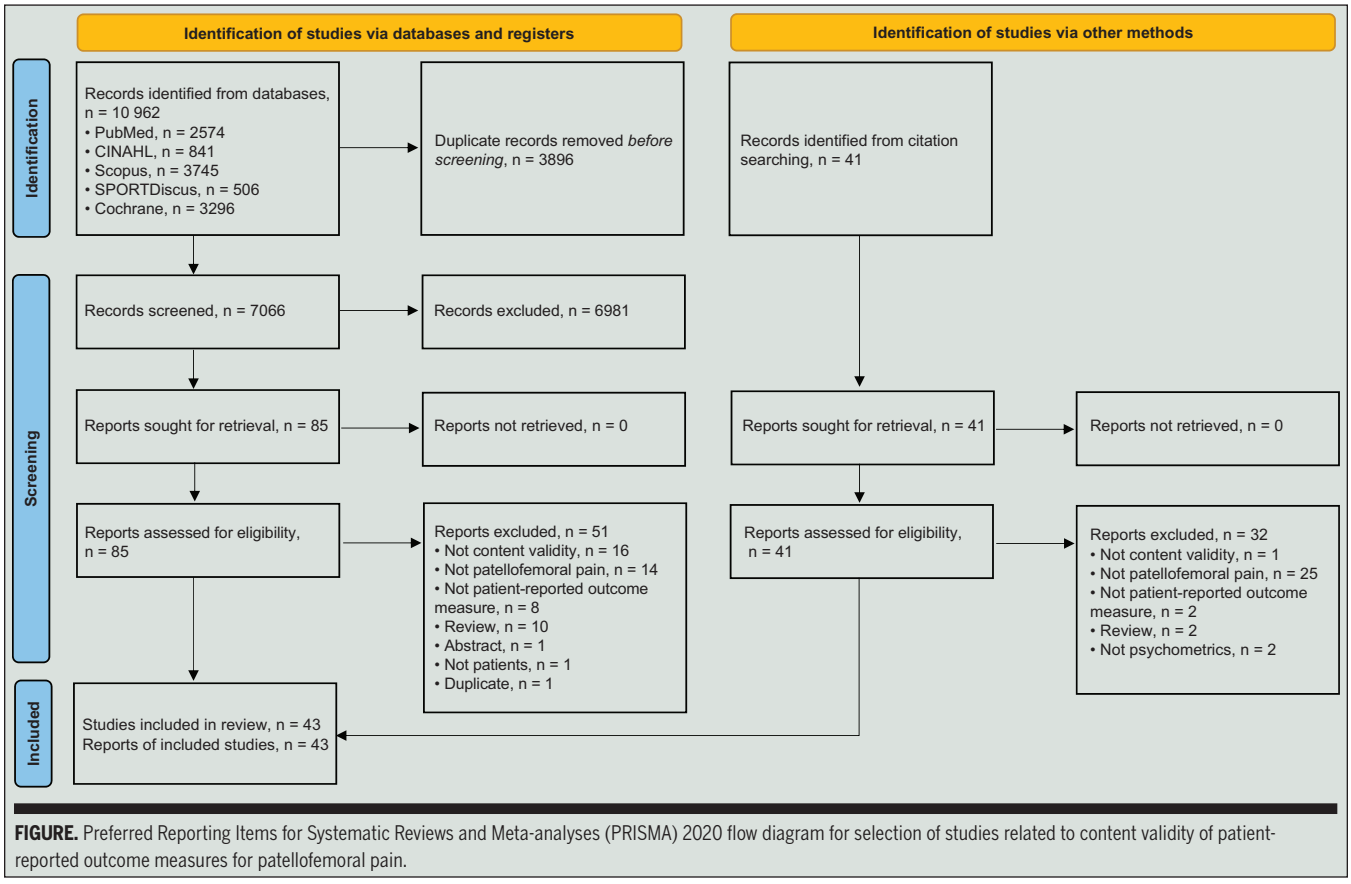

FIGURE. Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) 2020 flow diagram for selection of studies related to content validity of patient-reported outcome measures for patellofemoral pain.

PROMs were condition specific for PFP,[4,6,12,19,22,23,28,32,33,37,39,43,44,52,55,58,64,65,72,78] 10 were region-specific targeting patients with various musculoskeletal conditions of the knee,[1,11,27,35,36,45,59,63,68,76] 2 PROMs were region specific for lower-limb musculoskeletal conditions,[9,53] and 1 PROM focused on clinical pain.[47]

Ten studies (**TABLE 1**) were classified as content validity studies. The Anterior Knee Pain Scale (AKPS) was examined in 7 studies,[2,3,10,13,21,34,57] and the Functional Index Questionnaire (FIQ) was examined in 2 studies.[21,54] Content validity of the PFP Severity Scale (PSS), Knee Outcome Survey – Activity of Daily Living Scale (14-item) (KOS-ADLS – 14-item), Knee injury and Osteoarthritis Outcome Score–Patellofemoral subscale (KOOS-PF), and Modified Functional Index Questionnaire (MFIQ) were each examined in 1 study.[21,25,46,54]

Content Validity: Quality of Development Studies and Content Validity Studies

The quality of most PROM development studies was rated "inadequate" for the 3 components of content validity: relevance (n = 29; 88%), comprehensiveness (n = 32; 97%), and comprehensibility (n = 26; 79%).

Relevance of Development Studies

Four (12%) exceptions for relevance were all rated "doubtful" for development study quality: the KOOS-PF, a cultural adaptation of the KOOS-PF to the Saudi dialect of Arabic (KOOS-PF – Saudi Arabian adaptation), a cultural adaptation of the Lower Extremity Functional Scale (LEFS) to Persian (LEFS – Persian adaptation), and the cultural adaptation of the PSS to Greek (PSS – Greek adaptation).[6,19,53,58] Most PROM development studies (n = 32; 97%) did not use qualitative research methods or ensure rigorous qualitative methodology (eg, patient focus groups, skilled interviewers, standardized interview guides to elicit patient perspectives).[38] PROM developers frequently relied on health care professionals to identify items thought to be relevant to patients with PFP. The KOOS-PF development study was the only study that used some qualitative research methods to elicit items for the PROM.[19] The KOOS-PF developers determined relevant items by surveying individuals with PFP using open-ended questions. Procedures reported in this article suggested that it was "doubtful" if researchers used rigorous qualitative data collection and analysis methods.[38]

Comprehensiveness of Development Studies

All but one (97%) development study had "inadequate" quality for the comprehensiveness component of content validity.

TABLE 1 Characteristics of the Included Studies

Variable	PROM	N	Age, y[a]	Sex (Female)	Disease[b]	Country	Language
Development Studies[c]							
Algarni et al[1]	KOS-ADLS – 14-item – Arabic adaptation	280	54.6 ± 10.5	57.1%	Knee OA (88.2%), PFP (7.9%), RA (3.9%)	Saudi Arabia	Modern Standard Arabic
Aquino et al[4]	AKPS – Portuguese adaptation	40	Lay persons, 32.6 ± 9.76; PTs, 27.3 ± 4.19	Lay persons: 65.0% PTs: 70.0%	NA (no patients)	Brazil	Portuguese
Ateef[6]	KOOS-PF – Saudi Arabian adaptation	95	49.8 ± 9.9	0.0%	AKP	Saudi Arabia	Saudi dialect of Arabic
Binkley et al[9]	LEFS	107	44.0 ± 16.2	71.0%	Surgical and nonsurgical lower extremity conditions (PFP = 5.6%)	USA, Canada	English
Çelik et al[11]	IKDC – Turkish adaptation	103	34.9 ± 11.9	49.5%	Knee ligament injury ± surgery (42.7%), PFP (40.8%), meniscal injury ± surgery (7.8%), knee OA (4.9%)	Turkey	Turkish
Chesworth et al[12]	FIQ	18	29.0 ± NR	66.7%	PFP	Canada	English
Crossley et al[19]	KOOS-PF	138	38.6 ± 10.3	63.8%	PFP	Australia	English
Dippenaar et al[22]	PPSS	80	NR; range 18-55	38.8%	PFP	South Africa	English
Eng and Pierrynowski[23]	VAS activity	20	14.8 ± 1.2	100.0%	PFP	Canada	English
Flandry et al[27]	Flandry Scale	117	NR	NR	Surgical knee conditions	USA	English
Gil-Gámez et al[28]	AKPS – Spanish adaptation	130	21.2 ± 3.6	71.5%	PFP	Spain	Spanish
Haddad et al[32]	AKPS – Arabic adaptation	94	43.7 ± 14.5	70.2%	PFP	Jordan	Arabic
Harrison et al[33]	FIQ – modification	56	Male, 25.3 ± 9.9; female, 24.3 ± 8.1	NR	PFP	Canada	English
Irrgang et al[35]	IKDC	533	37.5 ± 16.2	47.4%	Knee ligament injury (28.1%), meniscal injury (20.3%), PFP (17.4%), patellar dislocation (2.8%), knee OA (17.3%), other knee conditions (4.1%), not recorded (15.6%)	USA, France, Japan	English
Irrgang et al[36]	KOS-ADLS – 17 item	397	33.3 ± NR	42.3%	Surgical and nonsurgical conditions: ligamentous and meniscal injury (57%), PFP (20%), knee OA (9%), other knee conditions (14%)	USA	English
Ittenbach et al[37]	AKPS – 6 item ordinal modification	414	13.9 ± 1.7	100.0%	PFP	USA	English
Kujala et al[39]	AKPS	68	AKP; 28.5 ± NR; subluxation, 23.9 ± NR; dislocation, 23.8 ± NR; control, 28.6 ± NR	92.7%	AKP, patellar subluxation, patellar dislocation	Finland	English
Laprade et al[43]	PSS	29	32.0 ± 8.9	24.1%	PFP	Canada	English
Lee et al[44]	SMC-PFS	179	NR	NR	PFP or patellofemoral joint OA (68.7%), meniscal tear (15.6%), healthy volunteers (15.6%)	Republic of Korea	English

Table continues on next page.

TABLE 1 Characteristics of the Included Studies (continued)

Variable	PROM	N	Age, y[a]	Sex (Female)	Disease[b]	Country	Language
Lysholm and Gillquist[45]	Lysholm Scale	51	NR	NR	Knee ligament injury	Sweden	English
Melzack[47]	MPQ	248	NR	NR	Wide variety of pathology	Canada	English
Myer et al[52]	AKPS – 6-item dichotomous adaptation	499	14.1 ± 1.8	100.0%	PFP	USA	English
Negahban et al[53]	LEFS – Persian adaptation	304	35.0 ± 14.4	37.8%	Nonsurgical musculoskeletal lower extremity conditions: ligament sprain (26.6%), degenerative joint disease (20.7%), PFP (15.5%), muscle strain (9.5%), meniscal injury (7.9%), other conditions (19.8%)	Iran	Persian
Negahban et al[55]	AKPS – Persian adaptation	100	25.3 ± 7.0	71.0%	PFP	Iran	Persian
Papadopoulos et al[58]	PSS – Greek adaptation	87	25.9 ± 17.1	58.6%	PFP	Greece	Greek
Piva et al[59]	KOS-ADLS – 14-item	60	29.9 ± 9.6	55.0%	PFP	USA	English
Roos et al[63]	KOOS	21	32.0 ± NR	57.1%	ACL injury and reconstruction	USA	English
Sakunkaruna et al[64]	AKPS – Thai adaptation	40	NR; range 18-56	90.0%	AKP	Thailand	Thai
Selfe et al[65]	MFIQ	77	Male, 29.0 ± 12.8; female, 24.0 ± 12.4	66.2%	PFP	United Kingdom	English
Tegner and Lysholm[68]	Lysholm Scale –modified	76	27 ± NR	27.6%	ACL injury and surgery	Sweden	English
Ummels et al[72]	AKPS – Dutch adaptation	50	27.8 ± 13.1	68.0%	PFP	Netherlands	Dutch
Williams et al[76]	SANE	130	21.0 ± 1.0	16.9%	ACL injury and reconstruction	USA	English
Worrell et al[78]	PHSQ	206	32.0 ± 14.1	57.0%	PFP	USA	English
Content Validity Studies[d]							
Alshehri et al[2]	Arabic AKPS	40	34.7 ± 9.3	35.0%	PFP	Saudi Arabia	Arabic
Apivatgaroon et al[3]	Thai AKPS	49	46.6 ± 10.8	79.6%	PFP	Thailand	Thai
Buckinx et al[10]	French AKPS	101	34.5 ± 11.4	58.4%	PFP	Belgium	French
Cheung et al[13]	Chinese AKPS	64	30.2 ± 6.1	40.6%	PFP	China	Chinese
da Cunha et al[21]	Brazilian Portuguese AKPS, FIQ, and PSS	83	31.3 ± 11.2	71.0%	PFP	Brazil	Brazilian Portuguese
Evcik et al[25]	Turkish KOS-ADLS – 14-item	67	57.7 ± 11.5	86.6%	Knee OA (76.1%), PFP (23.9%)	Turkey	Turkish
Hott et al[34]	Norwegian AKPS	112	27.6 ± 7.3	65.0%	PFP	Norway	Norwegian
Martinez-Cano et al[46]	Spanish KOOS-PF	5	NR	NR	PFP	Columbia	Spanish

Table continues on next page.

TABLE 1 Characteristics of the Included Studies (continued)

Variable	PROM	N	Age, y[a]	Sex (Female)	Disease[b]	Country	Language
Negahban et al[54]	Persian FIQ and MFIQ	100	25.3 ± 7.0	71.0%	PFP	Iran	Persian
Papadopoulos et al[57]	Greek AKPS	130	20.1 ± 6.2	48.0%	AKP	Greece	Greek

Abbreviations: ACL, anterior cruciate ligament; AKP, anterior knee pain; AKPS, Anterior Knee Pain Scale; FIQ, Functional Index Questionnaire; IKDC, International Knee Documentation Committee Subjective Knee Form; KOOS, Knee Injury and Osteoarthritis Outcome Score; KOOS-PF, Knee Injury and Osteoarthritis Outcome Score–Patellofemoral Pain and Osteoarthritis subscale; KOS-ADLs, Knee Outcome Survey–Activities of Daily Living Scale; LEFS, Lower Extremity Functional Scale; MFIQ, Modified Functional Index Questionnaire; MPQ, McGill Pain Questionnaire; N, number; NA, not applicable; NR, not reported; OA, osteoarthritis; PFP, patellofemoral pain; PHSQ, Patellofemoral Health Status Questionnaire; PPSS, Piloted Patellofemoral Pain Severity Scale; PROM, patient-reported outcome measure; PSS, Patellofemoral pain syndrome Severity Scale; PTs, physical therapist/physiotherapist; RA, rheumatoid arthritis; SANE, Single Assessment Numerical Evaluation; SMC-PFS, Samsung Medical Center Patellofemoral Score; VAS, visual analog scale.
[a]*Values are mean ± standard deviation.*
[b]*Disease characteristics of study sample; may differ from target population.*
[c]*Defined as the first study reporting (1) development of an English-language patient-reported outcome measure, (2) studies examining modifications of PROMs by modifying items or instructions, and (3) translation-adaptations of English-language patient-reported outcome measures to different languages and cultures when items or instructions have been modified during translation.*
[d]*Defined as follow-up studies to initial development studies in which the relevance, comprehensiveness, and/or comprehensibility of a patient-reported outcome measure is examined in a new population.*

The KOOS-PF development study was the only study with "doubtful" quality for comprehensiveness.[19]

Comprehensibility of Development Studies

Seven (21%) development studies scored better than "inadequate" quality for comprehensibility.[1,6,19,28,55,58,72] All but one (86%) of these 7 studies were cultural adaptations of English-language PROMs, and participants were asked about their comprehension of the PROM in the translated language.[1,6,28,55,58,72] The KOOS-PF development study was the only English-language PROM study to be scored better than "inadequate" quality for comprehensibility of the PROM, receiving a score of "doubtful" quality.[19]

Relevance, Comprehensiveness, and Comprehensibility of Content Validity Studies

Ten content validity studies of existing PROMs were conducted in translations of English-language PROMs (**TABLE 1**). One (10%) content validity study examined relevance of the AKPS.[3] No content validity studies examined comprehensiveness of the PROM. All content validity studies translated 6 English-language PROMs and examined their comprehensibility in different languages.[2,3,10,13,21,25,34,46,54,57] The quality of these studies was "doubtful" as none followed proper qualitative study data collection or analysis procedures.

Content Validity: Overall PROM Rating and Quality of the Evidence

Evidence to support the 3 components of content validity for the majority of PROMs was rated "indeterminate" due to "inadequate" study quality. The KOOS-PF, KOOS-PF – Saudi Arabian adaptation, LEFS – Persian adaptation, and PSS – Greek adaptation (**TABLE 3**)[6,19,53,58] received "sufficient" ratings for relevance based upon their development studies. PROM comprehensiveness based on development studies were all rated "indeterminate" (n = 32; 97%) except for the KOOS-PF that was rated "sufficient" (**TABLE 4**).[19] Five (15%) PROMs were rated "sufficient" for comprehensibility based on 3 content validity studies: the AKPS, FIQ, KOS-ADLS – 14-item, MFIQ, and PSS (**TABLE 5**).[21,25,54] Seven (21%) PROMs were rated "sufficient" for comprehensibility based on their development studies: AKPS – Persian adaptation, AKPS – Spanish adaptation, AKPS – Dutch adaptation, KOOS-PF, KOOS-PF – Saudi Arabian adaptation, KOS-ADLS – 14-item – Arabic adaptation, and PSS – Greek adaptation (**TABLE 5**).[1,6,19,28,55,58,72] Overall ratings of several PROMs for relevance (n = 22; 67%), comprehensiveness (n = 22; 67%), and comprehensibility (n = 24; 73%) were "sufficient." In most cases, the "sufficient" score for these studies was based solely upon the reviewer rating (relevance, n = 18, 82%; comprehensiveness, n = 21, 96%; comprehensibility, n = 12, 50%) rather than on research study evidence (**TABLES 3-5**).

Quality of the evidence was either "very low" (n = 30; 91%) or "low" (n = 3; 9%) for relevance and comprehensiveness according to the COSMIN-modified GRADE approach (**TABLES 3 and 4**).[70] Most PROMs (n = 27; 82%) had no research evidence examining content validity other than the development study, which was generally of "inadequate" quality (n = 29; 88%). Quality of the evidence for comprehensibility was "very low" (n = 22; 67%), "low" (n = 8; 24%), or "moderate" (n = 3; 9%) (**TABLE 5**). The KOOS-PF was the only PROM with evidence to support ratings of "sufficient" for relevance, comprehensiveness, and comprehensibility content validity components; however,

TABLE 2 Characteristics of the Patient-Reported Outcome Measures

PROM	PFP Condition Specific	Administration Mode	(Sub)scale(s) (number of items)	Range of Scores	Response Options	Original Language
AKPS[39]	Yes	Self-report	13 items	0-100[a]	Variable Likert scale	English
AKPS (6-item ordinal modification)[37]	Yes	Self-report	6 items	0-50[a]	Variable Likert scale	English
AKPS (6-item dichotomous modification)[52]	Yes	Self-report	6 items	0-6[a]	Dichotomous scale	English
AKPS (Arabic adaptation)[32]	Yes	Self-report and telephone interview	13 items	0-100[a]	Variable Likert scale	Arabic
AKPS (Dutch adaptation)[72]	Yes	Self-report	13 items	0-100[a]	Variable Likert scale	Dutch
AKPS (Persian adaptation)[55]	Yes	Self-report	13 items	0-100[a]	Variable Likert scale	Persian
AKPS (Portuguese adaptation)[4]	Yes	Self-report	13 items	0-100[a]	Variable Likert scale	Portuguese
AKPS (Spanish adaptation)[28]	Yes	Self-report	13 items	0-100[a]	Variable Likert scale	Spanish
AKPS (Thai adaptation)[64]	Yes	Self-report	13 items	0-100[a]	Variable Likert scale	Thai
FIQ[12]	Yes	Self-report	8 items	0-16[a]	6-point Likert scale	English
FIQ (modification)[33]	Yes	Self-report	8 items	0-2[a]	4-point Likert scale	English
Flandry Scale[27]	No	Self-report	28 items	0-100 mm[b]	Multiple VAS	English
IKDC[31]	No	Self-report	18 items	18-87[c]	5-point Likert scale and VAS	English
IKDC (Turkish adaptation)[11]	No	Self-report	18 items	18-87[c]	5-point Likert scale and VAS	Turkish
KOOS[62]	No	Self-report	42 items	0%-100%[a]	5-point Likert scale	English and Swedish versions
KOOS-PF[16]	Yes	Self-report	11 items	0-44[c]	5-point Likert scale	English
KOOS-PF (Saudi Arabian adaptation)[6]	Yes	Self-report	11 items	0-44[c]	5-point Likert scale	Arabic-Saudi Arabian dialect
KOS-ADLS (14-item)[59]	No	Self-report	14 items	0-70[c]	6-point Likert scale	English
KOS-ADLS (14-item Arabic adaptation)[1]	No	Self-report	14 items	0-70[c]	6-point Likert scale	Modern Standard Arabic
KOS-ADLS (17-item)[36]	No	Self-report	17 items	0-80[c]	6-point Likert scale	English
PHSQ (modification of KOS-ADLS)[78]	No	Telephonic interview	10 items	Not reported[a]	Variable Likert scale	English
LEFS[9]	No	Self-report	20 items	0-80[a]	5-point Likert scale	English
LEFS (Persian adaptation)[53]	No	Self-report	20 items	0-80[a]	5-point Likert scale	Persian
Lysholm Scale[45]	No	Interview	8 items	0-100[a]	Variable Likert scale	English
Lysholm Scale (modification)[68]	No	Interview	8 items	0-100[a]	Variable Likert scale	English
MFIQ[65]	Yes	Self-report	10 items	0-100[b]	Variable Likert scale	English
MPQ[47]	No	Interview	4 classes of pain subscales	0-78[b]	Variable Likert scale of spatial pain descriptors	English
PPSS[19]	Yes	Self-report	10 items	0-50[b]	Dichotomous scale	English
PSS[39]	Yes	Self-report	10 items	0-100[b]	VAS	English
PSS (Greek adaptation)[58]	Yes	Self-report	10 items	0-100[b]	VAS	Greek
SANE[78]	No	Self-report	1 item	0-100[a]	Single number	English
SMC-PFS[40]	Yes	Self-report	17 items	0-170[b]	5-point Likert scale	English
VAS activity[23]	Yes	Self-report	6 items	0-60[b]	VAS	English

Abbreviations: AKPS, Anterior Knee Pain Scale; FIQ, Functional Index Questionnaire; IKDC, International Knee Documentation Committee Subjective Knee Form; KOOS, Knee Injury and Osteoarthritis Outcome Score; KOOS-PF, Knee Injury and Osteoarthritis Outcome Score–Patellofemoral Pain and Osteoarthritis subscale; KOS-ADLs, Knee Outcome Survey–Activities of Daily Living Scale; LEFS, Lower Extremity Functional Scale; MFIQ, Modified Functional Index Questionnaire; MPQ, McGill Pain Questionnaire; PROM, patient-reported outcome measures; PFP, patellofemoral pain; PHSQ, Patellofemoral Health Status Questionnaire; PPSS, Piloted Patellofemoral Pain Severity Scale; PSS, Patellofemoral pain syndrome Severity Scale; SANE, Single Assessment Numerical Evaluation; SMC-PFS, Samsung Medical Center Patellofemoral Score; VAS, visual analog scale.

[a] *A higher score means higher functional ability.*

[b] *A higher score means lower functional ability.*

[c] *All scores transformed to a 0%-100% scale.*

TABLE 3 Relevance Component of Content Validity for Patient-Reported Outcome Measures and Quality of Evidence

	PROM Content Validity				
PROM	Development Study	Content Validity Studies	Reviewer Rating	Overall Rating	Quality of Evidence
AKPS[39]	Indeterminate	Indeterminate	Sufficient	Sufficient	Very low
AKPS[3]					
AKPS (6-item ordinal modification)[37]	Indeterminate		Inconsistent	Inconsistent	Very low
AKPS (6-item dichotomous modification)[52]	Indeterminate		Inconsistent	Inconsistent	Very low
AKPS (Arabic adaptation)[32]	Indeterminate		Sufficient	Sufficient	Very low
AKPS (Dutch adaptation)[72]	Indeterminate		Sufficient	Sufficient	Very low
AKPS (Persian adaptation)[55]	Indeterminate		Sufficient	Sufficient	Very low
AKPS (Portuguese adaptation)[4]	Indeterminate		Sufficient	Sufficient	Very low
AKPS (Spanish adaptation)[28]	Indeterminate		Sufficient	Sufficient	Very low
AKPS (Thai adaptation)[64]	Indeterminate		Sufficient	Sufficient	Very low
FIQ[12]	Indeterminate		Sufficient	Sufficient	Very low
FIQ (modification)[33]	Indeterminate		Sufficient	Sufficient	Very low
Flandry Scale[27]	Indeterminate		Inconsistent	Inconsistent	Very low
IKDC[31]	Indeterminate		Inconsistent	Inconsistent	Very low
IKDC (Turkish adaptation)[11]	Indeterminate		Sufficient	Sufficient	Very low
KOOS[62]					
Symptoms Subscale	Indeterminate		Inconsistent	Inconsistent	Very low
Pain Subscale	Indeterminate		Sufficient	Sufficient	Very low
ADL Subscale	Indeterminate		Inconsistent	Inconsistent	Very low
Sport Subscale	Indeterminate		Sufficient	Sufficient	Very low
Quality-of-Life Subscale	Indeterminate		Sufficient	Sufficient	Very low
KOOS-PF[16]	Sufficient		Sufficient	Sufficient	Low
KOOS-PF (Saudi Arabian adaptation)[6]	Sufficient		Sufficient	Sufficient	Low
KOS-ADLS (14-item)[59]	Indeterminate		Sufficient	Sufficient	Very low
KOS-ADLS (14-item Arabic adaptation)[1]	Indeterminate		Inconsistent	Inconsistent	Very low
KOS-ADLS (17-item)[36]	Indeterminate		Inconsistent	Inconsistent	Very low
PHSQ (modification of KOS-ADLS)[78]	Indeterminate		Sufficient	Sufficient	Very low
LEFS[9]	Indeterminate		Sufficient	Sufficient	Very low
LEFS (Persian adaptation)[53]	Sufficient		Sufficient	Sufficient	Very low
Lysholm Scale[45]	Indeterminate		Insufficient	Insufficient	Very low
Lysholm Scale (modification)[68]	Indeterminate		Insufficient	Insufficient	Very low
MFIQ[65]	Indeterminate		Sufficient	Sufficient	Very low
MPQ[47]	Indeterminate		Insufficient	Insufficient	Very low
PPSS[19]	Indeterminate		Insufficient	Insufficient	Very low
PSS[39]	Indeterminate		Sufficient	Sufficient	Very low
PSS (Greek adaptation)[58]	Sufficient		Sufficient	Sufficient	Low
SANE[76]	Indeterminate		Inconsistent	Inconsistent	Very low
SMC-PFS[40]	Indeterminate		Sufficient	Sufficient	Very low
VAS activity[23]	Indeterminate		Sufficient	Sufficient	Very low

Abbreviations: AKPS, Anterior Knee Pain Scale; FIQ, Functional Index Questionnaire; IKDC, International Knee Documentation Committee Subjective Knee Form; KOOS, Knee Injury and Osteoarthritis Outcome Score; KOOS-PF, Knee Injury and Osteoarthritis Outcome Score–Patellofemoral Pain and Osteoarthritis subscale; KOS-ADLs, Knee Outcome Survey–Activities of Daily Living Scale; LEFS, Lower Extremity Functional Scale; MFIQ, Modified Functional Index Questionnaire; MPQ, McGill Pain Questionnaire; PHSQ, Patellofemoral Health Status Questionnaire; PPSS, Piloted Patellofemoral Pain Severity Scale; PROM, patient-reported outcome measure; PSS, Patellofemoral pain syndrome Severity Scale; SANE, Single Assessment Numerical Evaluation; SMC-PFS, Samsung Medical Center Patellofemoral Score; VAS, visual analog scale.

TABLE 4 Comprehensiveness Component of Content Validity for Patient-Reported Outcome Measures and Quality of Evidence

	PROM Content Validity				
PROM	Development Study	Content Validity Studies	Reviewer Rating	Overall Rating	Quality of Evidence
AKPS[39]	Indeterminate		Sufficient	Sufficient	Very low
AKPS (6-item ordinal modification)[37]	Indeterminate		Insufficient	Insufficient	Very low
AKPS (6-item dichotomous modification)[52]	Indeterminate		Insufficient	Insufficient	Very low
AKPS (Arabic adaptation)[32]	Indeterminate		Sufficient	Sufficient	Very low
AKPS (Dutch adaptation)[72]	Indeterminate		Sufficient	Sufficient	Very low
AKPS (Persian adaptation)[55]	Indeterminate		Sufficient	Sufficient	Very low
AKPS (Portuguese adaptation)[4]	Indeterminate		Sufficient	Sufficient	Very low
AKPS (Spanish adaptation)[28]	Indeterminate		Sufficient	Sufficient	Very low
AKPS (Thai adaptation)[64]	Indeterminate		Sufficient	Sufficient	Very low
FIQ[12]	Indeterminate		Insufficient	Insufficient	Very low
FIQ (modification)[33]	Indeterminate		Insufficient	Insufficient	Very low
Flandry Scale[27]	Indeterminate		Sufficient	Sufficient	Very low
IKDC[31]	Indeterminate		Sufficient	Sufficient	Very low
IKDC (Turkish adaptation)[11]	Indeterminate		Sufficient	Sufficient	Very low
KOOS[62]					
Symptoms Subscale	Indeterminate		Sufficient	Sufficient	Very low
Pain Subscale	Indeterminate		Sufficient	Sufficient	Very low
ADL Subscale	Indeterminate		Sufficient	Sufficient	Very low
Sport Subscale	Indeterminate		Sufficient	Sufficient	Very low
Quality-of-Life Subscale	Indeterminate		Sufficient	Sufficient	Very low
KOOS-PF[16]	Sufficient		Sufficient	Sufficient	Low
KOOS-PF (Saudi Arabian adaptation)[6]	Indeterminate		Sufficient	Sufficient	Low
KOS-ADLS (14-item)[59]	Indeterminate		Sufficient	Sufficient	Very low
KOS-ADLS (14-item Arabic adaptation)[1]	Indeterminate		Sufficient	Sufficient	Very low
KOS-ADLS (17-item)[36]	Indeterminate		Sufficient	Sufficient	Very low
PHSQ (modification of KOS-ADLS)[78]	Indeterminate		Sufficient	Sufficient	Very low
LEFS[9]	Indeterminate		Sufficient	Sufficient	Very low
LEFS (Persian adaptation)[53]	Indeterminate		Sufficient	Sufficient	Very low
Lysholm Scale[45]	Indeterminate		Insufficient	Insufficient	Very low
Lysholm Scale (modification)[68]	Indeterminate		Insufficient	Insufficient	Very low
MFIQ[65]	Indeterminate		Sufficient	Sufficient	Very low
MPQ[47]	Indeterminate		Insufficient	Insufficient	Very low
PPSS[19]	Indeterminate		Insufficient	Insufficient	Very low
PSS[39]	Indeterminate		Sufficient	Sufficient	Very low
PSS (Greek adaptation)[58]	Indeterminate		Sufficient	Sufficient	Low
SANE[76]	Indeterminate		Insufficient	Insufficient	Very low
SMC-PFS[40]	Indeterminate		Insufficient	Insufficient	Very low
VAS activity[23]	Indeterminate		Insufficient	Insufficient	Very low

Abbreviations: AKPS, Anterior Knee Pain Scale; FIQ, Functional Index Questionnaire; IKDC, International Knee Documentation Committee Subjective Knee Form; KOOS, Knee Injury and Osteoarthritis Outcome Score; KOOS-PF, Knee Injury and Osteoarthritis Outcome Score–Patellofemoral Pain and Osteoarthritis subscale; KOS-ADLs, Knee Outcome Survey–Activities of Daily Living Scale; LEFS, Lower Extremity Functional Scale; MFIQ, Modified Functional Index Questionnaire; MPQ, McGill Pain Questionnaire; PHSQ, Patellofemoral Health Status Questionnaire; PPSS, Piloted Patellofemoral Pain Severity Scale; PROM, patient-reported outcome measure; PSS, Patellofemoral pain syndrome Severity Scale; SANE, Single Assessment Numerical Evaluation; SMC-PFS, Samsung Medical Center Patellofemoral Score; VAS, visual analog scale.

TABLE 5 Comprehensibility Component of Content Validity for Patient-Reported Outcome Measures and Quality of Evidence

	PROM Content Validity				
PROM	Development Study	Content Validity Studies	Reviewer Rating	Overall Rating	Quality of Evidence
AKPS[39]	Indeterminate				
AKPS[2]		Indeterminate			
AKPS[3]		Sufficient			
AKPS[10]		Indeterminate	Insufficient	Sufficient	Low
AKPS[13]		Indeterminate			
AKPS[21]		Indeterminate			
AKPS[34]		Indeterminate			
AKPS[57]		Indeterminate			
AKPS (6-item ordinal modification)[37]	Insufficient		Insufficient	Insufficient	Very low
AKPS (6-item dichotomous modification)[52]	Insufficient		Insufficient	Insufficient	Very low
AKPS (Arabic adaptation)[32]	Indeterminate		Sufficient	Sufficient	Very low
AKPS (Dutch adaptation)[72]	Sufficient		Sufficient	Sufficient	Low
AKPS (Persian adaptation)[55]	Sufficient		Sufficient	Sufficient	Low
AKPS (Portuguese adaptation)[4]	Indeterminate		Sufficient	Sufficient	Very low
AKPS (Spanish adaptation)[28]	Sufficient		Sufficient	Sufficient	Low
AKPS (Thai adaptation)[64]	Indeterminate		Sufficient	Sufficient	Very low
FIQ[12]	Indeterminate				
FIQ[21]		Sufficient	Sufficient	Sufficient	Moderate
FIQ[54]		Sufficient			
FIQ (modification)[33]	Indeterminate		Sufficient	Sufficient	Very low
Flandry Scale[27]	Indeterminate		Insufficient	Insufficient	Very low
IKDC[31]	Indeterminate		Sufficient	Sufficient	Very low
IKDC (Turkish adaptation)[11]	Indeterminate		Sufficient	Sufficient	Low
KOOS[62]					
Symptoms Subscale	Indeterminate		Sufficient	Sufficient	Very low
Pain Subscale	Indeterminate		Sufficient	Sufficient	Very low
ADL Subscale	Indeterminate		Sufficient	Sufficient	Very low
Sport Subscale	Indeterminate		Sufficient	Sufficient	Very low
Quality-of-Life Subscale	Indeterminate		Sufficient	Sufficient	Very low
KOOS-PF[16]	Sufficient		Sufficient	Sufficient	Low
KOOS-PF[42]		Indeterminate			
KOOS-PF (Saudi Arabian adaptation)[6]	Sufficient		Sufficient	Sufficient	Low
KOS-ADLS (14-item)[59]	Indeterminate		Sufficient	Sufficient	Moderate
KOS-ADLS (14-item)[25]		Sufficient			
KOS-ADLS (14-item Arabic adaptation)[1]	Sufficient		Sufficient	Sufficient	Very low
KOS-ADLS (17-item)[36]	Indeterminate		Sufficient	Sufficient	Very low
PHSQ (modification of KOS-ADLS)[78]	Indeterminate		Sufficient	Sufficient	Very low
LEFS[9]	Indeterminate		Sufficient	Sufficient	Very low
LEFS (Persian adaptation)[53]	Indeterminate		Sufficient	Sufficient	Very low
Lysholm Scale[45]	Indeterminate		Insufficient	Insufficient	Very low
Lysholm Scale (modification)[68]	Indeterminate		Insufficient	Insufficient	Very low
MFIQ[65]	Indeterminate		Sufficient	Sufficient	Moderate
MFIQ[54]		Sufficient			
MPQ[47]	Indeterminate		Insufficient	Insufficient	Very low

Table continues on next page.

TABLE 5 Comprehensibility Component of Content Validity for Patient-Reported Outcome Measures and Quality of Evidence (continued)

PROM	PROM Content Validity: Development Study	Content Validity Studies	Reviewer Rating	Overall Rating	Quality of Evidence
PPSS[19]	Indeterminate		Insufficient	Insufficient	Very low
PSS[39]	Indeterminate		Insufficient	Sufficient	Low
PSS[18]		Sufficient			
PSS (Greek adaptation)[58]	Sufficient		Insufficient	Sufficient	Very low
SANE[76]	Indeterminate		Insufficient	Insufficient	Very low
SMC-PFS[40]	Indeterminate		Inconsistent	Inconsistent	Very low
VAS activity[23]	Indeterminate		Sufficient	Sufficient	Very low

Abbreviations: AKPS, Anterior Knee Pain Scale; FIQ, Functional Index Questionnaire; IKDC, International Knee Documentation Committee Subjective Knee Form; KOOS, Knee Injury and Osteoarthritis Outcome Score; KOOS-PF, Knee Injury and Osteoarthritis Outcome Score–Patellofemoral Pain and Osteoarthritis subscale; KOS-ADLs, Knee Outcome Survey–Activities of Daily Living Scale; LEFS, Lower Extremity Functional Scale; MFIQ, Modified Functional Index Questionnaire; MPQ, McGill Pain Questionnaire; PHSQ, Patellofemoral Health Status Questionnaire; PPSS, Piloted Patellofemoral Pain Severity Scale; PROM, patient-reported outcome measure; PSS, Patellofemoral pain syndrome Severity Scale; SANE, Single Assessment Numerical Evaluation; SMC-PFS, Samsung Medical Center Patellofemoral Score; VAS, visual analog scale.

the quality of evidence was "low" for all three.

PROM Feasibility

Feasibility of PROM use was determined using data extracted from the development studies, the PROMs themselves, and the overall patient comprehensibility ratings (**TABLE 6**). Most PROMs (n = 29; 88%) were self-report questionnaires; however, 3 (9%) were interview based (the McGill Pain Questionnaire [MPQ], Lysholm Scale, and modified Lysholm Scale)[45,47,68] and 1 (3%) was telephonic interview based (the Patient Health Status Questionnaire [PHSQ]).[78] Instruments ranged in length from 1 item (Single Assessment Numerical Evaluation [SANE]) to 42 items (Knee injury and Osteoarthritis Outcome Score [KOOS]).[63,76] Completion time ranged from 1 minute (SANE) to 20 minutes in 1 interviewer-based PROM (MPQ).[47,76] The majority (n = 24; 73%) of PROMs were judged sufficient for patients' comprehensibility, based on our content validity appraisal of studies examining comprehensibility.[18] The reviewers judged clinician comprehensibility as sufficient (n = 31; 94%) for all PROMs except two that had poor instructions for administration and scoring (the PSS and the PPSS).[22,43] All PROMs were free and capable for use in different settings.

DISCUSSION

Clinicians and researchers have used many PROMs to assess the symptoms and functional status of adults and adolescents with PFP, but evidence to support the content validity of these PROMs is severely limited. Most PROM development studies had "inadequate" quality due to insufficient input from patients and failure to follow rigorous qualitative research methods (**TABLES 3-5**). In addition, follow-up content validity studies have only examined 6 PROMs, which did not incorporate proper qualitative data collection and analysis methods (**TABLE 1**). Overall, PROMs currently used for clinical and research purposes were rated either "very low" or "low" for quality of evidence for relevance, comprehensiveness, and comprehensibility. This suggests that many PROMs used with patients with PFP could have excluded important aspects of pain and function needed to fully understand the patient's experience. The reader should consider the following recommendations as preliminary, while acknowledging the need for ongoing works to determine valid PROMs appropriate for individuals with PFP.

Although the KOOS-PF had higher overall ratings than the other PROMs, its overall quality of evidence was rated "low." It was the only English-language PROM rated "sufficient" for all components of content validity for its development study.[19] The KOOS-PF also received the highest quality of evidence scores of English-language PROMs in our review; it was the only PROM scored "sufficient" with "low" or above evidence quality for all aspects of content validity. These findings support using the KOOS-PF to assess the patient's perspective in adults and adolescents with PFP. The KOOS-PF development study,[19] published in the same year as the current COSMIN guidelines, did not include all qualitative data collection and analysis methods listed in the current COSMIN content validity Risk of Bias checklist.[70] However, it followed the prior COSMIN checklist for PROM development and validation,[50] and included patient input for item reduction and measurement property evaluation. Finally, the KOOS-PF was one of the most feasible PROMs

TABLE 6 Feasibility of the Patient-Reported Outcome Measures

	Comprehensibility				
Feasibility Aspects[a,b,c]	Patient[d]	Clinician[e]	Completion Time	Instrument Standardization[f]	Ease of Score Calculation[g]
AKPS[39]	Sufficient	Sufficient	5 min	Good	Easy
AKPS (6-item ordinal modification)[37]	Insufficient	Sufficient	2 min	Good	Easy
AKPS (6-item dichotomous modification)[52]	Insufficient	Sufficient	2 min	Good	Easy
AKPS (Arabic adaptation)[32]	Sufficient	Sufficient	5 min	Good	Easy
AKPS (Dutch adaptation)[72]	Sufficient	Sufficient	5 min	Good	Easy
AKPS (Persian adaptation)[55]	Sufficient	Sufficient	5 min	Good	Easy
AKPS (Portuguese adaptation)[4]	Sufficient	Sufficient	5 min	Good	Easy
AKPS (Spanish adaptation)[28]	Sufficient	Sufficient	5 min	Good	Easy
AKPS (Thai adaptation)[64]	Sufficient	Sufficient	5 min	Good	Easy
FIQ[12]	Sufficient	Sufficient	5 min	Good	Easy
FIQ (modification)[33]	Sufficient	Sufficient	5 min	Good	Moderate
Flandry Scale[27]	Insufficient	Sufficient	10 min	Fair	Moderate
IKDC[31]	Sufficient	Sufficient	10 min	Good	Moderate
IKDC (Turkish adaptation)[11]	Sufficient	Sufficient	10 min	Good	Moderate
KOOS[62]	Sufficient	Sufficient	10 min	Good	Easy-Moderate
KOOS-PF[16]	Sufficient	Sufficient	5 min	Good	Easy-Moderate
KOOS-PF (Saudi Arabian adaptation)[6]	Sufficient	Sufficient	5 min	Good	Easy-Moderate
KOS-ADLS (14-item)[59]	Sufficient	Sufficient	5 min	Good	Easy-Moderate
KOS-ADLS (14-item Arabic adaptation)[1]	Sufficient	Sufficient	5 min	Good	Easy-Moderate
KOS-ADLS (17-item)[36]	Sufficient	Sufficient	5 min	Good	Moderate
PHSQ (modification of KOS-ADLS)[78]	Sufficient	Sufficient	Interviewer Dependent	Unknown	Moderate
LEFS[9]	Sufficient	Sufficient	5 min	Good	Easy
LEFS (Persian adaptation[53]	Sufficient	Sufficient	5 min	Good	Easy
Lysholm Scale[45]	Insufficient	Sufficient	Interviewer Dependent	Poor	Easy
Lysholm Scale (modification)[68]	Insufficient	Sufficient	Interviewer Dependent	Poor	Easy
MFIQ[65]	Sufficient	Sufficient	5 min	Good	Easy
MPQ[47]	Insufficient	Sufficient	10-20 min	Poor	Moderate
PPSS[19]	Insufficient	Insufficient	5 min	Poor	Unknown
PSS[39]	Sufficient	Insufficient	5 min	Fair	Moderate
PSS (Greek adaptation)[58]	Sufficient	Sufficient	5 min	Fair	Moderate
SANE[76]	Insufficient	Sufficient	1 min	Good	Easy
SMC-PFS[40]	Inconsistent	Sufficient	5 min	Poor	Easy
VAS activity[23]	Sufficient	Sufficient	5 min	Good	Moderate

Abbreviations: AKPS, Anterior Knee Pain Scale; FIQ, Functional Index Questionnaire; IKDC, International Knee Documentation Committee Subjective Knee Form; KOOS, Knee Injury and Osteoarthritis Outcome Score; KOOS-PF, Knee Injury and Osteoarthritis Outcome Score–Patellofemoral Pain and Osteoarthritis subscale; KOS-ADLs, Knee Outcome Survey–Activities of Daily Living Scale; LEFS, Lower Extremity Functional Scale; MFIQ, Modified Functional Index Questionnaire; MPQ, McGill Pain Questionnaire; PHSQ, Patellofemoral Health Status Questionnaire; PPSS, Piloted Patellofemoral Pain Severity Scale; PSS, Patellofemoral pain syndrome Severity Scale; SANE, Single Assessment Numerical Evaluation; SMC-PFS, Samsung Medical Center Patellofemoral Score; VAS, visual analog scale.

[a]*Patients must be able to read, write, and follow directions for all of the listed patient-reported outcome measures with the exception of those administered by an interviewer (PHSQ,[78] Lysholm Scale,[41] Lysholm Scale modification,[67] SANE[76]).*

[b]*None of the listed patient-reported outcome measures has any copyright provision and all are readily available on the internet for use.*

[c]*All of the listed patient-reported outcome measures are available free of cost.*

[d]*Patient comprehensibility rating is the overall rating for the comprehensibility component of content validity.*

[e]*Clinician comprehensibility rating was determined by the reviewers from the patient-reported outcome measure including its instructions for administration and score calculation.*

[f]*Instrument standardization refers to how specific instructions were given and the recall period (ie, average pain over the last 24 hours, worse pain over the past week, or average pain over the past week). Good means that the instructions were specific and delineated the recall period. Fair means poorly written instructions or lack of a recall period. Poor means poorly written instructions and lack of a recall period.*

[g]*Ease of score calculation is rated as easy, easy-moderate, or moderate. Easy requires summing the numerical value for each item of the patient-reported outcome measure. Easy-moderate requires summing numerical values for each item in multiple subscales and mathematical adjustments for skipped items. Moderate requires either excessive measurement technique for each item (multiple VAS for the Flandry Scale,[24] PSS,[39] PSS-Greek adaptation,[57] and VAS activity[20]), lack of scoring directions on outcome measure (FIQ modification[29]), multiple scoring options for items and mathematical calculations to obtain score (IKDC,[31] IKDC Turkish adaptation,[11] KOS-ADLS-17 item,[32] PHSQ,[78] MPQ[43]).*

identified in this systematic review. It incorporated 11 Likert-scale items, required only 5 minutes to complete, and was easy to score.

Only 4 studies in our review were published since publication of the 2018 COSMIN content validity guidelines, all translations or cultural adaptations of the KOOS-PF or AKPS.[6,32,34,46] Of these, only the KOOS-PF – Saudi Arabian adaptation was rated "sufficient" for any aspect of content validity, and only for relevance and comprehensibility.[6] Nineteen studies in our review were published before 2010, when the earlier COSMIN checklist was published.[50] All received ratings of "indeterminate" for all 3 content validity components with the exception of 1 translation study, which was rated "sufficient" for comprehensibility of the Turkish KOS-ADLS – 14-item.[25]

Clinicians and researchers also should consider aspects related to PROM feasibility. Instrument administration feasibility is important because clinicians need a PROM to collect valid information in an easy and timely manner. Previous systematic reviews and studies of PROMs for PFP addressed ease of questionnaire completion and scoring, highlighting the importance of feasibility for PROM selection.[8,24,52,65,74] Considerations include ease of administration and scoring, time to complete the PROM, number of items, and patient and clinician comprehensibility.[41] Health care practitioners typically choose PROMs based on feasibility factors.[40] Reported reasons for not using PROMs have included excessive time for the patient to complete and for the clinician to score the instrument.[40]

Our results differed in several ways from earlier systematic reviews conducted prior to the current 2018 COSMIN guidelines.[24,30] We used different methodologies, including different risk of bias checklists and methods to rate quality of evidence, which may explain why we found different results. Our systematic review builds on the findings of previous systematic reviews,[24,30] as we included 21 PROM development and content validity studies published more recently. Our review found the highest evidence to support use of the KOOS-PF, not published at the time of earlier reviews. We benefited from the use of the 2018 COSMIN methodology to assign overall content validity quality ratings separately for relevance, comprehensiveness, and comprehensibility.[18] Despite these differences, our findings align with previous systematic reviews in that the quality of evidence to support content validity of PROMs for patients with PFP was generally "very low" to "low."

Clinical Implications

The KOOS-PF was the best PROM available and was most appropriate for measuring pain and function in adults with PFP. This disease-specific PROM had the highest overall rating for all components of content validity, receiving ratings of "sufficient" quality for relevance, comprehensiveness, and comprehensibility from research studies. Although the quality of evidence was "low," the KOOS-PF was rated higher than other commonly used measures like the AKPS and LEFS.[9,39] The KOOS-PF development study included patient input and best reflected content validity for patients with PFP.[19] The KOOS-PF also had sufficient feasibility for clinical use (eg, short administration time, easy score calculation, and ready availability at no cost[60]).

Research Recommendations

Researchers should continue to examine content validity of the KOOS-PF and employ rigorous qualitative research methods (eg, patient focus groups, trained interviewers using interview guides, and coding of responses for data analysis[38,70]). Researchers should consider updating current PROMs using current COSMIN guidelines or developing a new PROM with "sufficient" content validity in accordance with COSMIN guidelines. Additional information regarding other measurement properties are important considerations when selecting a PROM. An updated systematic review of reliability, responsiveness, and interpretability of the KOOS-PF is needed to guide clinicians to assess pain, function, and meaningful change in patients with PFP. Finally, instruments designed to address factors specific to children and adolescents deserve attention. Researchers should consider examining content validity of the KOOS-PF in younger patients.

Limitations

It is possible we have excluded some PROMs due to the inclusion criteria. However, we performed a broad search of 5 databases and examined retrieved systematic and narrative review articles to include all English-language PROMs evaluating pain and functional status in individuals with PFP. Another limitation was inclusion of development studies for region-specific or generic PROMs used to assess pain and function of patients with PFP. These studies were added from reference searching (ie, not in the bibliographic database search). Including development studies, which were generally of lower quality as they predated the current COSMIN guidelines, increased the number of PROMs in our systematic review.[4,27,45,47,63,68,76]

CONCLUSION

Quality of evidence for content validity of PROMs was generally "very low" due to development study "inadequate" quality and few follow-up content validity studies. Most instruments commonly used in clinical practice and research lacked sufficient content validity, rendering them less effective to accurately assess an individual's experience with PFP. Although the KOOS-PF had limitations, it was the best PROM to date. The KOOS-PF content validity was "sufficient," supporting its use to measure pain and function in those with PFP. The KOOS-PF also had features to support its feasibility for clinical and research use since it is brief in length, is freely available, and is easy to administer and score. ◉

KEY POINTS

FINDINGS: Most patient-reported outcome measures (PROMs) used to measure pain and function in patients with patellofemoral pain (PFP) have "inadequate" content validity. The PROMs are free, appropriate for use in different settings, and have acceptable clinician and patient comprehensibility.

IMPLICATIONS: While clinicians and researchers use many PROMs to measure the patient's perspective of PFP, many PROMs do not have sufficient content validity to support their use. Based on the best available evidence, we recommend the KOOS-PF for use by clinicians and researchers to measure pain and function in individuals with PFP.

CAUTION: Although the development study for the KOOS-PF received a quality score of "sufficient," there is currently "low" quality of evidence for its content validity.

STUDY DETAILS

AUTHOR CONTRIBUTIONS: Lisa T. Hoglund and David A. Scalzitti designed the study and performed the screening of titles and abstracts. The George Washington University provided library facilities and recruited the librarian for the search. Susan F. Wainwright guided the group in appraisal of qualitative study methods. All authors contributed to the acquisition, analysis, and interpretation of data in the review. All authors contributed to the writing, reviewing, editing, and final approval of the manuscript.

DATA SHARING: All data relevant to the study are included in the article or are available as **SUPPLEMENTAL FILES**.

PATIENT AND PUBLIC INVOLVEMENT: There was no patient or public involvement in this research.

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LEVERAGING THE SHORT-TERM BENEFITS OF MANUAL THERAPY WHICH INCLUDES EXERCISE OVER EXERCISE THERAPY ALONE APPEARS JUSTIFIED FOR KNEE OSTEOARTHRITIS

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We would like to congratulate the authors on their meta-analysis assessing the added benefit of manual therapy (MT) to exercise alone for hip and knee osteoarthritis (OA).[5] We have several points for consideration when interpreting these results:

(1) The conclusion of no additional benefits of MT long term was based on only 3 trials (out of 18). The implications that "clinicians should focus on exercise and education first before considering MT" seem unjustified. Even if changes are not maintained long term, patients receiving MT were not worse off. Very few interventions for knee or hip OA have benefits that are maintained long term, including the core intervention of exercise therapy.[2] The recommendation to "clearly communicate with patients that added MT has no additional benefit over exercise along in the long term" is the interpretation of the authors. Another equally justified and perhaps more helpful recommendation is to clearly communicate that greater pain reduction and improved function are likely in the short term when MT is added to exercise, even if long-term outcomes are no better than someone receiving only exercise. This would be similar to advising our patients against receiving exercise therapy based on a meta-analysis, suggesting exercise therapy is no different than usual care in the long term (as early as 9 months).[2]

(2) The label "manual therapy" as used in this meta-analysis, "any hands-on therapy delivered by a clinician," can limit external validity. The statement, "clinicians should focus on exercise and education first before considering the addition of MT" would be most relevant to cases where MT is delivered as a singular procedure, but less generalizable to cases where MT instead describes a process "using highly specific treatment approaches, including manual techniques and therapeutic exercise."[4] The latter is how MT is defined by several professional organizations (eg, International Federation of Orthopaedic Manipulative Physical Therapists, American Academy of Orthopedic Manual Physical Therapists). Using this definition, MT would no longer be the same intervention without the exercise component. In reading descriptions of these approaches, passively moving the joint alone does not constitute MT. Therefore, attempts to separate the exercise component from MT in these cases may have questionable relevance. Additionally, the reader should consider the large variability of MT labels and missingness of dosing parameters (see appendix 2 in the work of Shepherd et al),[6] which is not uncommon due to poor reporting and affects our ability to properly understand its treatment effect.

(3) The authors mention the heterogeneity associated with pathophysiological differences of knee and hip OA and potential bias of looking at these conditions collectively, which merits further consideration when interpreting results. Only 2 of 18 trials included participants with solely hip OA (showing no additional benefit of MT), 1 trial had a mixed population of hip and knee OA, and 15 trials had only participants with knee OA (showing large additional benefits of MT). Also consider that added MT was cheaper (with booster)[1] and cost effective[3] for knee OA in the long term in 2 studies with low risk of bias included with heavier weight in this meta-analysis.[1,3]

These points merit consideration when interpreting the results of this meta-analysis and their implications for clinical practice. While we fully agree that exercise and education should be core treatment components for hip/knee OA, MT is not always mutually exclusive of these core components.[4] Pain is the primary reason patients seek treatment for OA, and short-term changes are meaningful for them, potentially improving adherence to long-term programs. From a patient perspective, offering a treatment with short-term benefits and long-term cost effectiveness (eg, MT and exercise) seems to represent about the best we have for knee OA in both the short and long terms. Questioning whether more research would change the conclusion of the long-term benefit of adding MT to exercise may be premature.

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RESPONSE TO THE LETTER TO THE EDITOR-IN-CHIEF REGARDING THE PAPER "THE BENEFITS OF ADDING MANUAL THERAPY TO EXERCISE THERAPY FOR IMPROVING PAIN AND FUNCTION IN PATIENTS WITH KNEE OR HIP OSTEOARTHRITIS: A SYSTEMATIC REVIEW WITH META-ANALYSIS"

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We would like to thank the Editor-in-Chief for the opportunity to respond to the comments by Rhon et al[3] about our systematic review. We appreciate the insightful remarks regarding some of the conclusions we drew and respond to the issues raised.

Our conclusion about the lack of long-term effectiveness for manual therapy (MT) as an adjunct to exercise is based on 3 trials. We believe it is appropriate to score the certainty of evidence as high as the studies were of high quality, and had reasonable sample sizes and no aspect of GRADE required downgrading. Rhon et al question our conclusion that "clinicians should focus on exercise and education first before considering MT," given the low number of studies for the long-term meta-analyses and findings that "patients receiving MT were not worse off." In most studies (2 of 3 studies in the long-term meta-analyses), participants received MT in additional time. Offering an intervention in addition to other treatments with the argument that people were not worse off is, in our view, not good practice, especially if treatment time is restricted as it is in many physiotherapy settings. We based our conclusion on the lack of long-term benefits and on the very low-certainty evidence of the short-term effectiveness of additional MT on pain and the lack of short-term effectiveness on function. We strongly disagree that our recommendation would be like advising patients against exercise therapy. Unlike additional MT, exercise therapy did show relevant long-term benefits for function[1]; there are also other health benefits that come with exercise treatment.[2]

Rhon et al note that modern MT practice includes manual techniques in combination with exercise (and other) components, and suggest that our research question itself is of doubtful relevance as MT would not be used without exercise. We believe we investigated the additional benefit of MT to exercise versus exercise alone and not the other way around (ie, the addition of exercise to MT versus MT alone). However, considering the wider definitions of MT as a process, we acknowledge that the addition of the word "techniques" after "manual therapy" throughout the manuscript could have given more clarity to what was investigated in our review. We agree that there is poor reporting of techniques and dosing parameters in the included primary studies. We have suggested improvements in these areas in our research recommendations.

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We are glad to see that we agree with Rhon et al about exercise and education as core treatments for knee and hip OA. We also agree that the results of this review should not discourage clinicians from using MT. Rather, we encourage clinicians to spend their time wisely, use shared decision-making, and communicate the current evidence base clearly with patients. However, considering the very low-certainty evidence for the benefits of additional MT to exercise for short-term pain and high-certainty evidence not showing an additional benefit for the long term on pain and function, we are not confident that adding MT to exercise "represent(s) about the best we have for knee OA."

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LEVERAGING THE SHORT-TERM BENEFITS OF MANUAL THERAPY WHICH INCLUDES EXERCISE OVER EXERCISE THERAPY ALONE APPEARS JUSTIFIED FOR KNEE OSTEOARTHRITIS

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We would like to congratulate the authors on their meta-analysis assessing the added benefit of manual therapy (MT) to exercise alone for hip and knee osteoarthritis (OA).[5] We have several points for consideration when interpreting these results:

(1) The conclusion of no additional benefits of MT long term was based on only 3 trials (out of 18). The implications that "clinicians should focus on exercise and education first before considering MT" seem unjustified. Even if changes are not maintained long term, patients receiving MT were not worse off. Very few interventions for knee or hip OA have benefits that are maintained long term, including the core intervention of exercise therapy.[2] The recommendation to "clearly communicate with patients that added MT has no additional benefit over exercise along in the long term" is the interpretation of the authors. Another equally justified and perhaps more helpful recommendation is to clearly communicate that greater pain reduction and improved function are likely in the short term when MT is added to exercise, even if long-term outcomes are no better than someone receiving only exercise. This would be similar to advising our patients against receiving exercise therapy based on a meta-analysis, suggesting exercise therapy is no different than usual care in the long term (as early as 9 months).[2]

(2) The label "manual therapy" as used in this meta-analysis, "any hands-on therapy delivered by a clinician," can limit external validity. The statement, "clinicians should focus on exercise and education first before considering the addition of MT" would be most relevant to cases where MT is delivered as a singular procedure, but less generalizable to cases where MT instead describes a process "using highly specific treatment approaches, including manual techniques and therapeutic exercise."[4] The latter is how MT is defined by several professional organizations (eg, International Federation of Orthopaedic Manipulative Physical Therapists, American Academy of Orthopedic Manual Physical Therapists). Using this definition, MT would no longer be the same intervention without the exercise component. In reading descriptions of these approaches, passively moving the joint alone does not constitute MT. Therefore, attempts to separate the exercise component from MT in these cases may have questionable relevance. Additionally, the reader should consider the large variability of MT labels and missingness of dosing parameters (see appendix 2 in the work of Shepherd et al),[6] which is not uncommon due to poor reporting and affects our ability to properly understand its treatment effect.

(3) The authors mention the heterogeneity associated with pathophysiological differences of knee and hip OA and potential bias of looking at these conditions collectively, which merits further consideration when interpreting results. Only 2 of 18 trials included participants with solely hip OA (showing no additional benefit of MT), 1 trial had a mixed population of hip and knee OA, and 15 trials had only participants with knee OA (showing large additional benefits of MT). Also consider that added MT was cheaper (with booster)[1] and cost effective[3] for knee OA in the long term in 2 studies with low risk of bias included with heavier weight in this meta-analysis.[1,3]

These points merit consideration when interpreting the results of this meta-analysis and their implications for clinical practice. While we fully agree that exercise and education should be core treatment components for hip/knee OA, MT is not always mutually exclusive of these core components.[4] Pain is the primary reason patients seek treatment for OA, and short-term changes are meaningful for them, potentially improving adherence to long-term programs. From a patient perspective, offering a treatment with short-term benefits and long-term cost effectiveness (eg, MT and exercise) seems to represent about the best we have for knee OA in both the short and long terms. Questioning whether more research would change the conclusion of the long-term benefit of adding MT to exercise may be premature.

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RESPONSE TO THE LETTER TO THE EDITOR-IN-CHIEF REGARDING THE PAPER "THE BENEFITS OF ADDING MANUAL THERAPY TO EXERCISE THERAPY FOR IMPROVING PAIN AND FUNCTION IN PATIENTS WITH KNEE OR HIP OSTEOARTHRITIS: A SYSTEMATIC REVIEW WITH META-ANALYSIS"

J Orthop Sports Phys Ther 2023;53(1):50-51. doi:10.2519/jospt.2023.0201-R

We would like to thank the Editor-in-Chief for the opportunity to respond to the comments by Rhon et al[3] about our systematic review. We appreciate the insightful remarks regarding some of the conclusions we drew and respond to the issues raised.

Our conclusion about the lack of long-term effectiveness for manual therapy (MT) as an adjunct to exercise is based on 3 trials. We believe it is appropriate to score the certainty of evidence as high as the studies were of high quality, and had reasonable sample sizes and no aspect of GRADE required downgrading. Rhon et al question our conclusion that "clinicians should focus on exercise and education first before considering MT," given the low number of studies for the long-term meta-analyses and findings that "patients receiving MT were not worse off." In most studies (2 of 3 studies in the long-term meta-analyses), participants received MT in additional time. Offering an intervention in addition to other treatments with the argument that people were not worse off is, in our view, not good practice, especially if treatment time is restricted as it is in many physiotherapy settings. We based our conclusion on the lack of long-term benefits and on the very low-certainty evidence of the short-term effectiveness of additional MT on pain and the lack of short-term effectiveness on function. We strongly disagree that our recommendation would be like advising patients against exercise therapy. Unlike additional MT, exercise therapy did show relevant long-term benefits for function[1]; there are also other health benefits that come with exercise treatment.[2]

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