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# Measurement properties of patient-reported outcome measures (PROMS) in Patellofemoral Pain Syndrome

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# Accepted Manuscript

Measurement Properties of Patient-Reported Outcome Measures (PROMS) in Patellofemoral Pain Syndrome: A Systematic Review

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#### <u>Title</u>

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Patellofemoral Pain Syndrome: A Systematic Review

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Patellofemoral Pain Syndrome, Patient Reported Outcome Measures, Systematic Review, Measurement Properties.

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#### ABSTRACT

This systematic review investigated the measurement properties of disease-specific patientreported outcome measures used in Patellofemoral Pain Syndrome. Two independent reviewers conducted a systematic search of key databases (MEDLINE, EMBASE, AMED, CINHAL+ and the Cochrane Library from inception to August 2013) to identify relevant studies. A third reviewer mediated in the event of disagreement. Methodological quality was evaluated using the validated COSMIN (Consensus-based Standards for the Selection of Health Measurement Instruments) tool. Data synthesis across studies determined the level of evidence for each patient-reported outcome measure. The search strategy returned 2177 citations. Following the eligibility review phase, seven studies, evaluating twelve different patient-reported outcome measures, met inclusion criteria. A 'moderate' level of evidence supported the structural validity of several measures: the Flandry Questionnaire, Anterior Knee Pain Scale, Modified Functional Index Questionnaire, Eng and Pierrynowski Questionnaire and Visual Analogue Scales for 'usual' and 'worst' pain. In addition, there was a 'Limited' level of evidence supporting the test-retest reliability and validity (cross-cultural, hypothesis testing) of the Persian version of the Anterior Knee Pain Scale. Other measurement properties were evaluated with poor methodological quality, and many properties were not evaluated in any of the included papers. Current disease-specific outcome measures for Patellofemoral Pain Syndrome require further investigation. Future studies should evaluate all important measurement properties, utilising an appropriate framework such as COSMIN to guide study design, to facilitate optimal methodological quality.

5	4
5	5

#### **INTRODUCTION**

56	Patellofemoral pain syndrome (PFPS) is a common knee disorder, with a typical
57	pattern of symptoms characterised by anterior peripatella or retropatella knee pain
58	(Heintjes et al., 2009; Collins et al., 2010; Hossain et al., 2011). Aggravating factors
59	include activities or movements which either increase patellofemoral joint
60	compression and/or produce mechanical forces in the surrounding soft tissue
61	structures; for example: ascending/descending stairs, sitting with a flexed knee for
62	prolonged periods, squatting, running, jumping or kneeling (Witvrouw et al., 2000;
63	Crossley et al., 2002; Barton et al., 2008; Thijs et al., 2008; Tan et al., 2010). As
64	many of these activities are an important part of daily life, PFPS may have a
65	considerable impact on an individual's wellbeing (Collins et al., 2008; Tan et al.,
66	2010). This impact may be especially debilitating as PFPS symptoms often reoccur,
67	becoming chronic (Nimon et al., 1998; Stathopulu and Baildam, 2003; Collins et al.,
68	2008; Boling et al., 2010).
69	
70	Whilst the aetiology of PFPS is debated, there is some consensus that its
71	development may be secondary to a functional or structural mal-alignment at the
72	patellofemoral joint, or of the lower extremity as a whole (Powers, 2003; Barton et al.,
73	2008; Heintjes et al., 2009; Carry et al., 2010; Hossain et al., 2011). There may be
74	multiple interacting factors which cause mal-alignment, such as muscle strength or

timing issues, altered tissue extensibility or bony morphology (Powers, 2003; Barton
et al., 2008; Heintjes et al., 2009; Bennell et al., 2010).

77

Physiotherapy is the most common intervention in PFPS (Crossley et al., 2001;

Heintjes et al., 2003), however, there is no clear consensus regarding the optimal

- 80 components of a management programme. As a consequence, a wide variety of
- 81 treatment techniques are employed by therapists including: quadriceps

82 strengthening, vastus medialus obliques (VMO) muscle retraining, biofeedback, hip 83 muscle strengthening, proximal strengthening, spinal manipulation, mobilisation, 84 taping, knee supports, foot orthoses and stretching of the hamstrings, illiotial band, 85 patella retinaculum or anterior hip (Crossley et al., 2002; Iverson et al., 2008; 86 Heintjes et al., 2009; Earl and Hoch, 2011; Hossain et al., 2011; Callaghan and Selfe, 87 2012). In the absence of guidelines outlining the most favourable PFPS treatment options, physiotherapists should appraise their own management, utilising high 88 89 guality, disease-specific, PFPS outcome measures to guide and evaluate patient 90 care, so they may deliver efficacious treatment tailored to the individual (DoH, 2010; 91 CSP, 2012; HCPC, 2013).

92

93 A number of patient-reported outcome measures (PROMs) have been developed to 94 assess symptoms and function in patients with PFPS. These disease-specific 95 measures are designed to be more sensitive to change in their target population than 96 region-specific measures, which evaluate general knee disorders. When making the 97 choice of which PROM to use in practice, it is important to examine their respective 98 measurement properties, so that the optimal instrument can be confidently employed. 99 These properties should at least satisfy existing minimum standards for PROMs, 100 such as those presented by the International Society for Quality of Life research 101 (Reeve et al., 2013). Previous systematic reviews that have evaluated the 102 measurement properties of knee PROMs, have tended to focus on region-specific 103 measures used in general knee conditions (Bellamy et al., 1997; Sun et al., 1997; 104 Wang et al., 2010), or non-PFPS-specific musculoskeletal disorders (Smith et al., 105 2008; Howe et al., 2012), and not all reviews have used a validated tool to determine 106 the guality of the included studies, for example, the COSMIN (Consensus-based 107 Standards for the Selection of Health Measurement Instruments) tool (Mokkink et al., 108 2010a) or OMERACT (Outcome Measures in Rheumatology) filter (Boers et al., 109 1998). The purpose of this study was to evaluate the measurement properties of

- 110 disease-specific PROMs for PFPS, using a validated measure of methodological
- 111 quality.
- 112

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113	METHODOLOGY
114	
115	Design
116	A systematic review of outcomes was conducted according to a pre-defined protocol
117	informed by the PRISMA guidelines (Liberati et al., 2009), the Cochrane Handbook of
118	Systematic Review Interventions (Higgins and Green, 2011) and the COSMIN group
119	(Mokkink et al., 2010b).
120	
121	Search strategy
122	The MEDLINE, EMBASE, AMED, CINHAL+ and Cochrane Library electronic
123	databases were searched from inception to August 2013 (the MEDLINE search
124	strategy is presented in Appendix I). All records were downloaded into Endnote $\ensuremath{\mathbb{C}}$
125	version 15, and duplicates removed. Two authors (DK, CL) independently screened
126	all citations by title/abstract, before retrieving potentially eligible full text articles for
127	review. Disagreements were resolved through discussion, with a third reviewer on
128	hand to mediate if required. The strength of agreement between investigators was
129	established using Cohen's kappa statistic (Cohen, 1960) and interpreted using set
130	criteria (Landis and Koch, 1977). Remaining articles were subjected to a citation
131	search. Finally, a hand-search of all reference lists was conducted.
132	
133	Identification of eligible studies
134	Full text original articles were included if they evaluated at least one PROM

135 measurement property (reliability, validity, responsiveness or interpretability (Mokkink

136 et al., 2010a)) in a cohort of PFPS patients. There are no universally agreed

137 diagnostic criteria for PFPS, therefore, this review used criteria employed by several

138 high-quality randomised controlled trials, each demonstrating treatment efficacy in a

139 PFPS cohort (Collins et al., 2008; van Linschoten et al., 2009; Collins et al., 2010).

140 Thus, studies had to include participants that presented with a main complaint of

141	patellofemoral pain (defined as anterior peripatellar or retropatellar knee pain) with
142	symptoms that were provoked by at least two of the following: prolonged sitting or
143	kneeling, stair walking, running, squatting, hopping, a positive Clarke's sign or grind
144	test, a positive patellar compression test and recognisable painful symptoms on
145	palpation of the patellar facets (Collins et al., 2008; Syme et al., 2009; van
146	Linschoten et al., 2009). Internationally agreed definitions for each measurement
147	property Mokkink et al.,(2010a) informed the eligibility review. Non-English language
148	papers were excluded.
149	
150	Data Extraction
151	Two authors (AG, CL) independently extracted data regarding the following
152	measurement properties: reliability, internal consistency, measurement error), validity

153 (including content, construct, criterion and cross-cultural validity), responsiveness

and interpretability (Mokkink et al., 2010a). Disagreements were resolved through

155 discussion with the intervention of a third author (DK) if needed.

156

#### 157 Measurement Properties

158 Reliability examines the degree to which a measurement is free from error, and can 159 be considered in three categories: test-retest reliability (the degree to which results 160 can be replicated over time within a stable environment), this can be further divided 161 into inter-rater reliability (between individuals) and intra-rater reliability (within the 162 same individual); internal consistency (correlation between items that are 163 interrelated); and measurement error (systematic and random error within a patient's 164 outcome score that is not attributed to a true change) (Mokkink et al., 2010b). 165 Validity encompasses: content validity (is the PROM an adequate reflection of the 166 construct to be measured); construct validity (how a PROM performs against predefined hypotheses); criterion validity (how a PROM compares to a 'gold standard' if 167 168 available); and cross-cultural validity (how well the translated PROM reflects the

169	original version) (Mokkink et al., 2010b). Responsiveness is the ability of an outcome
170	measure to detect a clinically meaningful change in a patient's condition over time
171	(Mokkink et al., 2010b). In addition, a PROM must demonstrate adequate
172	interpretability, to ensure that the meaning and significance of changes in score can
173	be easily understood (Mokkink et al., 2010a).
174	
175	Quality assessment and evidence synthesis
176	Methodological quality of the included studies was evaluated in order to determine
177	their trustworthiness. Two investigators (AG, CL) independently assessed each
178	study, rating the quality of methods employed to evaluate individual measurement
179	properties, using the validated COSMIN framework (Mokkink et al., 2010a).
180	Disagreements were resolved through discussion with a third author (DK). Papers
181	were rated using a 4-point scale ('poor', 'fair', 'good', 'excellent') (Terwee et al 2012).
182	Synthesis across studies combined findings for each measure and measurement
183	property, taking into account the quality of studies, to determine the level of evidence
184	for each PROM (Schellingerhout et al., 2012). The overall level of evidence was
185	rated as 'strong', 'moderate', 'limited' or 'conflicting', in-line with the criteria proposed
186	by the Cochrane Back Review Group (van Tulder et al., 2003).
187	
188	

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189	RESULTS
190	
191	Study selection
192	The search strategy returned 2177 citations. 2155 studies were excluded by
193	title/abstract and 22 full-text articles were retrieved for further review. Of these, 15
194	full-text articles were excluded as they utilised non-PFPS cohorts, PFPS was not the
195	major complaint of the participants, or because the PFPS diagnostic criteria used by
196	the paper did not meet the defined standards, or was missing altogether. Inter-rater
197	agreement between the investigators during title/abstract screening was 'good'
198	(k=0.68, 95% CI 0.557-0.806) (Cohen, 1998). No additional full-text articles were
199	included following either the citation search or the hand search of reference lists,
200	therefore, 7 papers were included in the final analysis (Figure. 1). The included
201	studies evaluated 12 PROMs, including: the Activity of Daily Living Scale (ADLS)
202	(Irrgang et al., 1998); the Eng and Pierrynowski Questionnaire (EPQ), also known as
203	the Visual Analogue Pain Scale during Activity (Eng and Pierrynowski, 1993); the
204	Flandry Questionnaire (Flandry et al., 1991); the Kujala/Anterior Knee Pain Scale
205	(AKPS) (Kujala et al., 1993); the Modified Functional Index Questionnaire (MFIQ)
206	(Chesworth et al., 1989); the Persian Version Kujala/AKPS (Negahban et al., 2012);
207	the Patellofemoral Function Scale (PFS) (Reid, 1992); the PFPS Severity Scale
208	Syndrome (PSS) (Laprade and Culham, 2002); the Visual Analogue Pain Scale
209	(VAS), also referred to as the Numerical Pain Rating Score (NPRS); and the Visual
210	Analogue Pain Scales for least pain (VAS-L), usual pain (VAS-U) and worst pain
211	(VAS-W).

## 213 Study characteristics

214 Study characteristics are presented in Table 1. The 7 studies examined 384 215 symptomatic PFPS subjects, largely recruited from the general population, with 1 216 study recruiting from the military (Laprade and Culham, 2002). The mean age of participants ranged from 23.8 to 32 years old. Average duration of symptoms was 217 218 reported in 3 papers (Bennell et al., 2000; Crossley et al., 2004; Negahban et al., 219 2012) and ranged from 12.0 to 38.6 months. No study provided details regarding the 220 severity of participant symptoms. Details of each PROM evaluated across the 7 221 studies is presented in Table 2. Measurement property data are presented in Table 222 3. The methodological quality of the studies is presented in Table 4 and the results. presented per PROM, are discussed below. 223

224

#### 225 Activity of Daily Living Scale (ADLS)

226 Contains 14 items investigating general daily activities and specific functional tasks

227 (e.g. stair descent). Each item is scored 0-5 to provide an overall percentage score.

Higher scores indicate better functioning. One study (Piva et al., 2009) found the

ADLS responsive, demonstrating a moderate change in score (effect size 0.63).

However, this property was evaluated with 'poor' methodological quality.

231

232 Eng and Pierrynowski questionnaire (EPQ)

An activity-related pain-rating tool using a 0-10 visual analogue scale. Higher scores

indicate more pain. Two studies (Bennell et al., 2000; Crossley et al., 2004)

supported reliability (ICC<sub>3,1</sub> 0.83-0.92), one study (Crossley et al., 2004) found the

EPQ responsive (RTE 0.76), and one study (Bennell et al., 2000) reported a Minimal

237 Clinically Important Difference (MCID) of 14 points (23%). However, measurement

238 properties were evaluated with 'poor' methodological quality. Structural validity of the

EPQ was supported by Bennell et al. (2000), with a 'moderate' correlation (r=0.66)

- 240 with the Flandry questionnaire. This property was evaluated with 'moderate'
- 241 methodological quality.
- 242

243 Flandry Questionnaire

- 244 Consists of 28 visual analogue scale items which investigate the severity of knee
- symptoms and the ability to perform physical activities. One study (Bennell et al.,
- 246 2000) supported test-retest reliability (ICC<sub>3,1</sub> = 0.95) and structural validity (r = 0.66)
- and also reported a Standard Error of Measurement (SEM) of 34 points (27.6%).
- However, these measurement properties were evaluated with 'poor' methodological
- 249 quality.
- 250
- 251 Kujala/Anterior Knee Pain Scale (AKPS)
- A 13-item knee function questionnaire, scored out of 100, with higher scores
- indicating less disability. Two studies (Bennell et al., 2000; Crossley et al., 2004)
- supported reliability (ICC<sub>3,1</sub> = 0.81-0.90) and responsiveness (treatment effect size =
- 255 1.15 for responders), however, these measurement properties were evaluated with
- 256 'poor' methodological quality. Bennell et al. (2000) reported a moderate correlation

for structural validity (r = 0.58); this property was evaluated with 'good'

258 methodological quality.

259

260 Modified Functional Index Questionnaire (MFIQ)

261 Consists of 8 items that measure the ability to perform various functional activities. A

262 maximum score of 16 indicates optimal functioning. Three studies (Chesworth et al.,

- 263 1989; Bennell et al., 2000; Crossley et al., 2004) supported test-retest reliability (ICC
- 264 = 0.48; ICC<sub>3,1</sub> = 0.49-0.94); one study (Harrison et al., 1995) demonstrated a 'very

265 good' level of internal consistency (pre-treatment  $\alpha$  = 0.85 and post-treatment  $\alpha$  = 266 0.88); one study (Bennell et al., 2000) reported the MCID as 2.8 points (16%); two 267 studies (Harrison et al., 1995; Crossley et al., 2004) found the MFIQ responsive with 268 a moderate effect sizes (0.49 and 0.59)., However, all these properties were 269 evaluated with 'poor' methodological quality. Bennell et al. (2000) supported the 270 validity of the MFIQ, evidenced by a moderate correlation (r = -0.66); this property 271 was evaluated with 'good' methodological quality.

272

273 The PFPS Severity Scale Syndrome (PSS)

A 10 item visual analogue instrument, examining the effect of PFPS on an
individual's functional activities. One study (Laprade and Culham, 2002) supported
the test-retest reliability (r = 0.95), however, this property was evaluated with 'poor'
methodological quality.

278

#### 279 Visual Analogue Scale (VAS)/ Numerical Pain Rating Scale

280 This scale - scored from 0 (no pain) to 10 (max pain) - evaluates levels of pain. Other

versions include: (1) VAS-L (pain at its *least*), (2) VAS-U (*usual* level of pain), and (3)

VAS-W (pain when at its *worst*). Five studies (Chesworth et al., 1989; Harrison et al.,

1995; Bennell et al., 2000; Crossley et al., 2004; Piva et al., 2009) supported both

test-retest reliability (ICC = 0.56-0.77; ICC<sub>3,1</sub> = 0.56-0.79) and responsiveness (effect

- size for improved responders = 0.70-1.22; RTE = 0.95-1.09) of the VAS, VAS-L,
- 286 VAS-U and VAS-W, however, these properties were evaluated with 'poor'
- 287 methodological quality in all studies. One study (Bennell et al., 2000), found a

288 minimum change of 3.3cm (33%) on the VAS-U was required to detect a real change

in a patient's condition, again methodological quality was 'poor'.

290

291 Bennell et al. (2000) established that the VAS-U and VAS-W were moderately

292 correlated (r = 0.63), providing evidence of their structural validity; this property was

293 evaluated with 'good' methodological quality.

294

295 The Patellofemoral Function Scale (PFS)

296 Contains 9 items, scored from 0-100, examining both PFPS signs/symptoms and the

ability of the patient to perform functional activities; higher scores indicating less

disability. One study (Harrison et al., 1995) found the scale was responsive (effect

size = 0.81 for responders) and demonstrated a 'minimally acceptable' to

300 'acceptable' internal consistency (pre-treatment  $\alpha$  = 0.65 and post-treatment  $\alpha$  =

301 0.77), however, these properties were evaluated with 'poor' methodological quality.

302

#### 303 Persian Version Kujala/AKPS

304 One study (Negahban et al., 2012) reported 'excellent' test-retest reliability (ICC<sub>2.1</sub> = 305 0.96) and confirmed the accuracy of the hypothesis that the Persian Kujala 306 questionnaire would correlate more highly with the SF-36 physical questionnaire than 307 the SF-36 mental questionnaire (correlation 0.34-0.51 and 0.25-0.37 respectively); 308 these properties were evaluated with 'fair' methodological quality. Negahban et al. 309 (2012) also reported high levels of internal consistency ( $\alpha = 0.81$ ), however, for this 310 component of the study, methodological quality was 'poor'. Cross-cultural validity was 311 also examined with the authors concluding that no major translation modifications 312 were required, this aspect of the study demonstrated 'good' methodological quality 313 (Negahban et al, (2012).

314

315 As this questionnaire was a translated version, it was not synthesised with English

316 language AKPS as the respective findings may not be directly comparable

317 (Schellingerhout et al., 2012), hence presented separately in Table 5.

318

#### 319 Synthesis of results across studies

- 320 Synthesis of results for each questionnaire with the associated level of evidence is
- 321 presented in Table 5. There was a 'moderate' level of evidence to support the
- 322 structural validity of the: EPQ, Flandry Questionnaire, AKPS, MFIQ, VAS-U and VAS-
- 323 W. In addition, there was a 'limited' level of evidence supporting the reliability (test-
- retest) and validity (cross-cultural and hypothesis testing) of the Persian version of
- 325 the AKPS, based on the findings of one paper.

326

- 327 It was not possible to identify supporting evidence for the following PROM
- 328 measurement properties due to poor methodological quality across the included
- 329 papers: ADLS (responsiveness); EPQ and AKPS (test-retest reliability, measurement
- 330 error, responsiveness); Flandry Questionnaire (test-retest reliability, measurement
- 331 error); MFIS (internal consistency, test-retest reliability, measurement error,
- 332 responsiveness); PSS (internal consistency); VAS and VAS-L (test-retest reliability,
- 333 responsiveness); VAS-U (test-retest reliability, measurement error, hypothesis
- testing, responsiveness); VAS-W (internal consistency, test-retest reliability,
- 335 responsiveness).

336

337 There was no information available for the following PROM measurement properties:

338	ADLS (internal consistency, test-retest reliability, measurement error, structural
339	validity, hypothesis testing); EPQ and AKPS (internal consistency, hypothesis
340	testing); Flandry Questionnaire (internal consistency, hypothesis testing,
341	responsiveness); MFIQ (hypothesis testing); PSS (test-retest reliability, measurement
342	error, structural validity, hypothesis testing, responsiveness); VAS and VAS-L
343	(internal consistency, measurement error, structural validity, hypothesis testing);
344	VAS-U (internal consistency) and VAS-W (internal consistency, hypothesis testing).
345	In addition, no PROM was examined for the measurement property of interpretability.
346	DISCUSSION
347	The chiestive of this evolution to view was to evolute the manufacturement even attice
348	The objective of this systematic review was to evaluate the measurement properties
349	of disease-specific PROMs for PFPS, to aid clinicians in choosing the best
350	instrument to inform patient management. Unfortunately, the poor methodological
351	quality with which measurement properties were evaluated across the PROMs,
352	makes recommending an optimal instrument problematic.

353

#### 354 Principal findings

We found a 'moderate' level of evidence to support the construct validity (structural 355 356 validity) of six PROMs: the Flandry Questionnaire, AKPS, MFIQ, EPQ, VAS-U and 357 VAS-W. We also found a 'limited' level of evidence supporting the reliability (test-358 retest) and validity (cross-cultural and hypothesis testing) of the Persian version of 359 the AKPS, based on the findings of one paper. Unfortunately, many other important 360 PROM measurement properties were either evaluated with poor methodological 361 quality (e.g. measurement error), or were not evaluated at all (e.g. interpretability). 362 Common methodological shortcomings included: small sample sizes, absent a priori 363 hypotheses, missing details/references for comparator instruments during the

evaluation of responsiveness and a failure to check the uni-dimensionality of a scaleprior to the evaluation of internal consistency.

366

Structural validity, as a component of construct validity, has been identified as a
critical element of the overall validity of a PRO instrument (Reeve et al., 2013), it is
therefore encouraging that over half of the tools we investigated demonstrated this
feature. Unfortunately, no measure was able to satisfy all of the recently agreed
minimum standards for PROMs advocated by the International society for Quality of
Life research (Reeve et al., 2013).

373

374 Comparing these results to those of other authors is difficult. As mentioned previously, there is a lack of systematic reviews focusing on PFPS-specific PROMs 375 used exclusively in PFPS cohorts. Howe et al. (2012) did review the measurement 376 properties of a number of PROMs that arguably could be employed in PFPS, but did 377 378 so alongside other musculoskeletal disorders, including osteoarthritis, ligament injuries and meniscal lesions. Although the results are not directly comparable, the 379 findings from this study appear similar to ours with regard to the AKPS PROM, which 380 381 was reviewed in both studies. Using the OMERACT filter, Howe et al. 2012 382 determined that the tool demonstrated construct validity, however, they also 383 supported its responsiveness, which the current study did not. Our use of the 384 COSMIN tool instead of the OMERACT filter may explain this difference. Finally, 385 Smith and colleagues (2008) evaluated several outcome measures used to assess 386 patellar instability, of which, only the AKPS was included in our study. The findings 387 from both reviews are consistent, namely that poor methodological quality precluded definitive conclusions regarding the measurement properties of the PROMs they 388 389 investigated.

390

391	One of the main purported benefits of disease-specific PROMs is that they may be
392	more sensitive to subtle changes in a patient's condition (i.e. more responsive) than
393	more generic tools (Garratt et al., 2001; Walsh et al., 2003). It is particularly
394	disappointing, therefore, that evidence of responsiveness was lacking in the PROMs
395	we evaluated. Until such time as they are evaluated and validated with greater
396	methodological quality, it is not possible to recommend a disease-specific PROM
397	over an evidence-supported region-specific measure.
398	
398 399	Strengths and limitations
	Strengths and limitations A strength of this study is its use of systematic methods to investigate the
399	
399 400	A strength of this study is its use of systematic methods to investigate the
399 400 401	A strength of this study is its use of systematic methods to investigate the measurement properties of PROMs employed in PFPS, taking into account the

some articles that were potentially relevant, but used different diagnostic parameters.

406 Further work is needed to develop definitive PFPS diagnostic criteria.

## CONCLUSIONS

410	Several PROMs used in PFPS demonstrate structural validity including: the Flandry
411	Questionnaire, AKPS, MFIQ, EPQ, VAS-U, and VAS-W. In addition there is limited
412	level of evidence supporting the test-retest reliability and validity (cross-cultural and
413	hypothesis testing) of the Persian version of the AKPS, based on one study.
414	However, no instrument possesses supporting evidence for all important
415	measurement properties (Reeve et al., 2013). The measurement properties of
416	PROMs in PFPS are commonly evaluated with poor methodological quality, and
417	many are yet to be investigated. Current PFPS measures should be subjected to
418	further scrutiny and future studies should evaluate all important measurement
419	properties, utilising an appropriate framework such as COSMIN to guide study
420	design, to facilitate optimal methodological quality.
421	

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#### Table 1 588

#### Characteristics of Included Studies 589

Study	Country	<b>Subjects</b> (num. of females)	<b>Participants</b> Mean (SD or range)	Duration of Symptoms (months) Mean (SD) unless stated.
Bennell et al., 2000 <sup>a</sup>	Australia	50 (33)	23.8 ± 8.9 yrs	17.1 (25.2)
Chesworth et al., 1989 <sup>a</sup>	Canada	18 (12)	29.0 yrs (20-50)	not reported
Crossley et al., 2004 <sup>a</sup>	Australia	71 (46)	27.5 yrs (14-40)	38.6 (42.6) [Rx Gr]
				31.1 (32.2) [Placebo Gr]
Harrison et al., 1995 <sup>a</sup>	Canada	56 (7)	24.8 yrs (12-41)	not reported
Laprade and Culham, 2002 <sup>b</sup>	Canada	29 (71)	32.0 yrs (20-48)	Range: 3-72
Negahban et al., 2012 <sup>a</sup>	Iran	100 (0)	25.3 ± 7.0 yrs	Median & interquartile range: 12 (6-24)
Piva et al., 2009 <sup>c</sup>	USA	60 (33)	29.9 ± 9.6 yrs	Distribution: 1-3 (38%); 4-6 (22%), 7-12 (10%), 13-24 (18%), >25 (12%).

Settings: <sup>a</sup> = General population, <sup>b</sup> = Military population, <sup>c</sup> = Unknown population. tion, <sup>c</sup> = Uma... 590

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Instrument Name	Study ID	Summary of Instrument	Scoring Method
Activity of Daily Living Scale (ADLS)	Piva et al., 2009	14-item scale assessing how patient's knee symptoms affect their ability to perform general daily activities (6 items) and specific functional tasks (8 items).	Each item scored 0-5 (0 = unable; 5 = no difficulty to perform); max score = 70. Percentage calculated (score/70 x 100).
Eng & Pierrynowski Questionnaire/Visual Analogue Pain Scale during Activity (EPQ)	Bennell et al., 2000; Crossley et al., 2004	Visual rating scale that is used to indicate the perception of the level of pain during activity.	10cm horizontal line drawn with annotations along the line for example 'no pain'. Score is the measurement from left hand side to patient's mark.
Flandry Questionnaire	Bennell et al., 2000	Questionnaire to evaluate subjective components of unspecific knee complaints; 28 items relating to severity of symptoms and the ability to perform activities.	Each item (i.e. 28) scored on a VAS (0 – 10); max score = 280.
Kujala/Anterior Knee Pain Scale (AKPS)	Bennell et al., 2000; Crossley et al., 2004	13 item multiple-choice PFPS questionnaire relating to the patient's knee function.	3-5 response choices depending on item; each response allocated a score. Scores vary between 0 and 10; max score = 100.
Modified Functional Index Questionnaire (MFIQ)	Bennell et al., 2000; Chesworth et al., 1989; Crossley et al., 2004; Harrison et al., 1995	8-item questionnaire relating to the ability to perform functional activities on that day.	Each item scored on a 3-point scale: $0 -$ unable to do; $1 -$ can do with a problem; $2 -$ no difficulty; max score = 16.
Persian Version Kujala	V Negahban et al., 2012	Translated version of Kujala – Persian (more info see Kujala)	Same as Kujala.
The Patellofemoral Function Scale (PFS)	Harrison et al., 1995.	16 multiple-choice item scale with 9 PROs and 7 CROs. Items are based on pain, ability to perform functional activities and cardinal signs associated with	Items have multiple choice answers (e.g. Jogging $- 6 = no$ restriction; $0 =$ restricted.) Response scores vary between 0 and 10; max score

## 592 **Table 2**

593 Characteristics of Patient reported Outcome Measures

		PFPS.	= 100.	
The PFPS Severity Scale Syndrome (PSS)	Laprade and Culham, 2002	10 items assessing pain and the ability to perform functional activities.	Each item scored using 10cm VAS; max score = 100.	
Visual Analogue Pain Scale (VAS)/	Chesworth et al., 1989;	Visual rating scale that is used to indicate the perception of the	As in Eng/VAS-A	
Numerical Pain Rating Score (NPRS)	Piva et al., 2009	current level of pain.	A A	
Visual Analogue Pain Scale when Least pain (VAS-L)	Harrison et al., 1995	Visual rating scale that is used to indicate the perception of the level of pain when at its least.	As in Eng/VAS-A	
Visual Analogue	Bennell et al., 2000;	Visual rating scale that is used	As in Eng/VAS-A	
Pain Scale when Usual pain (VAS-U)	Crossley et al., 2004;	to indicate the perception of the usual level of pain i.e. average level of pain.		
	Harrison et al., 1995			
Visual Analogue	Bennell et al., 2000;	Visual rating scale that is used	As in Eng/VAS-A	
Pain Scale when Worst pain (VAS-W)	Crossley et al., 2004;	to indicate the perception of the level of pain when at its worst.		
	Harrison et al., 1995			

594 PFPS – Patellofemoral Pain Syndrome; VAS – Visual Analogue Scale; PRO –
595 Patient-Reported Outcome; CRO – Clinician-Reported Outcome.

Table 3Results of the measurement properties for the patient reported outcome measures.

			Measurement Property			
Study ID	Study size	Internal Consistency	Test-Retest Reliability (& Standard Error of Measurement)	Validity	Responsiveness	
<b>DLS</b> va et al., 2009	n = 60	_		5	Effect Size: 1.19(I), 0.03 (NI), 0.63 (overall) Guyatt Index: 1.4 Area under ROC curve: 0.83 MCID = 7.1% (5 pts)	
PQ			O Y			
ennell et al., 2000	n = 50	-	$ICC_{(3,1)} = 0.92$ Paired <i>t</i> test = 2.298 (0.03) <sup>a</sup> SEM: 4.8 (14 points; 23%)	vs Flandry, Pearson r = 0.66 (BC) <sup>S</sup>	_	
rossley et al., 2004	n = 71	-	$ICC_{(3,1)} = 0.83$ Paired <i>t</i> test = -0.10 (0.92) <sup>a</sup>	_	Median score: 1(NI) vs -19(I) RTE = 0.76 RE = No figure provided	
<b>landry</b> ennell et al., 2000	n = 50	_	$ICC_{(3,1)} = 0.95$	vs Eng,		
			Paired <i>t</i> test = 0.991 (0.33) <sup>a</sup> SEM: 120 (34 points; 27.6%)	Pearson r = $0.66 (BC)^{S}$		

Kujala/AKPS					
Bennell et al., 2000	n = 50	_	$ICC_{(3,1)} = 0.90$	vs FIQ,	_
			Paired <i>t</i> test = $-0.673 (0.51)^{a}$	Pearson r = 0.58 (BC) <sup>s</sup>	
Crossley et al., 2004	n = 71		SEM: 4.7 (13 points; 14%) ICC <sub>(3,1)</sub> = 0.81		Median score: 2(NI) vs 15.5(I)
		—	Paired <i>t</i> test = $-1.35 (0.20)^{a}$		RTE = 1.15
					RE = 1.24
MFIQ				5	
Bennell et al., 2000	n = 50	_	ICC <sub>(3,1)</sub> = 0.94	vs Flandry,	_
			Paired <i>t</i> test = $1.796 (0.09)^{a}$	Pearson r = $-0.66$ (BC) <sup>s</sup>	
			SEM: 1.0 (2.8 points; 16%)		
Chesworth et al., 1989	n = 18	_	ICC = 0.483	_	ANOVA <sup>a</sup> : F = 21.09; 2,20 df; p<0.001
					Newman-Keuls <sup>a</sup> : Pre-Rx: p >0.05
Oreceleu et el 2004					Post-Rx: p<0.01
Crossley et al., 2004	n = 71	_	$ICC_{(3,1)} = 0.49$ Paired <i>t</i> test = -1.34 (0.20) <sup>a</sup>	_	Median score: -0.5(NI) vs 3(I) RTE  = 0.49
			Pared $i$ test = -1.34 (0.20)		RTE = 0.49 RE = 0.18
Harrison et al., 1995	n = 56	Pre-Rx:	Pre-Rx: Spearman r = 0.69-		ANOVA <sup>a</sup> : Pre-Rx: no significant
	n = 00	Cronbach's $\alpha =$	0.77	_	differences (p<0.05) & post Rx:
		0.85	Post-Rx: Spearman r = 0.84-		significant differences (p<0.05)
		Post-Rx:	0.92		between I & NI.
		Cronbach's $\alpha =$			Effect Size: Pre-Rx: -0.17
		0.88			Effect Size: Post-Rx: 0.59(I), -0.50(NI)
Persian Version Kujala		×,	7		
Negahban et al., 2012	n =	Cronbach's $\alpha =$	$ICC_{(2,1)} = 0.96$	Correlations higher	_
Negahban et al., 2012	n =	Cronbach's $\alpha =$	$ICC_{(2,1)} = 0.96$	Correlations higher	_

	100	0.81		between Kujala & SF36 physical than Kujala & SF36 mental <sup>H</sup>	
<b>PFS</b> Harrison et al., 1995	N = 56	Pre-Rx: Cronbach's $α =$ 0.65 Post-Rx: Cronbach's $α =$ 0.77		Society	Effect Size: Pre-Rx: no results Effect Size: <i>Post-Rx:</i> 0.81(I), -0.31(NI)
PSS		0.11			
Laprade and Culham, 2002	n = 29	Spearman r = 0.95		_	_
VAS/ NPRS					
Chesworth et al., 1989	n = 18	_	ICC = 0.603	_	ANOVA <sup>a</sup> : F = 19.72; 2,20 df; p< 0.001
Piva et al., 2009	n = 60	-		_	Newman-Keuls <sup>a</sup> : Pre-Rx: p >0.05 Effect Size: 1.22(I), 0.26(NI) Guyatt Index: 1.9 Area under ROC curve: 0.84 MCID = 1.2 pts
VAS-L					

Harrison et al., 1995	n = 56	<i>Pre-Rx:</i> ICC = 0.64 <i>Post-Rx:</i> ICC = 0.74		ANOVA <sup>a</sup> : Pre-Rx: no significant differences (p<0.05) & post Rx: significant differences (p<0.05) between I & NI
VAS-U				
Bennell et al., 2000	n = 50	ICC <sub>(3,1)</sub> = 0.77 Paired <i>t</i> test = 0.517 (0.61) <sup>a</sup> SEM: 1.2 (3.3cm; 30%)	vs VAS-W, Pearson r = 0.63 (BC) <sup>s</sup>	_
Crossley et al., 2004	n = 71 _	$ICC_{(3,1)} = 0.56$ Paired <i>t</i> test = -0.40 (0.69) <sup>a</sup>	_	Median score: -1(NI) vs -3(I) RTE = 0.95 RE = 1
Harrison et al., 1995	n = 56 _	Pre-Rx: ICC = 0.58 Post-Rx: ICC = 0.77	_	ANOVA <sup>a</sup> : Pre-Rx: no significant differences (p<0.05) & post Rx: significant differences (p<0.05) between I & NI Effect Size: <i>Pre-Rx:</i> -0.20 Effect Size: <i>Post-Rx:</i> 0.75(I), -0.15(NI)
VAS-W				
Bennell et al., 2000	n = 50 _	ICC <sub>(3,1)</sub> = 0.79 Paired <i>t</i> test = $3.301 (0.03)^{a}$ SEM: 1.1 (3.0cm; 30%)	vs VAS-U, Pearson r = 0.63 (BC) <sup>s</sup>	_
Crossley et al., 2004	n = 71 _	$ICC_{(3,1)} = 0.76$	_	Median score: 0.5 (NI) vs -3.5(I)

		Paired <i>t</i> test = $1.65 (0.12)^{a}$	RTE = 1.09
Harrison et al., 1995	n = 56	Pre-Rx: ICC = 0.56 Post-Rx: ICC = 0.70	RE = No figure provided ANOVA <sup>a</sup> : Pre-Rx: no significant differences (p<0.05) & post Rx: significant differences (p<0.05) between I & NI. Effect Size: <i>Pre Rx:</i> 0.02 Effect Size: <i>Post Rx:</i> 1.15(I), 0.09(NI)

<sup>S</sup> – Structural validity; <sup>H</sup> – Hypothesis validity.

ROC = Reciever Operating Characteristic; MCID = minimum clinical important difference; ICC = Intraclass Correlation Coefficient; SEM = Standardised Error of Measurement; BC = Best Correlation; NI = Not Improved; I = Improved; RTE = Relative Treatment Effect; RE = Relative Efficiency; ANOVA = A repeated measures analysis of variance; df = degrees of freedom; CI = Confidence Interval; Rx = treatment; WOMAC = Western Ontario and McMaster Universities;

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a Statistical Significant Difference (p = 0.05).

## Table 4

Methodological quality of each study per measurement property and patient reported outcome measure

	Measurement Property							
	Internal Consistency	Test-retest Reliability	Measurement Error	Validity	Responsiveness	Interpretability		
ADLS			~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~					
Piva et al., 2009	_	_		_	Poor	_		
EPQ								
Bennell et al., 2000	_	Poor	Poor	Good <sup>s</sup>	_	_		
Crossley et al., 2004	_	Poor	<b>)</b> -	_	Poor	_		
Flandry								
Bennell et al., 2000	_	Poor	Poor	Good <sup>s</sup>	_	_		
Kujala/AKPS								
Bennell et al., 2000		Poor	Poor	Good <sup>s</sup>	_	_		
Crossley et al., 2004	C	Poor	_	_	Poor	_		
MFIQ	<b>V</b>							
Bennell et al., 2000	_	Poor	Poor	Good <sup>s</sup>	_	_		
Chesworth et al., 1989	_	Poor	_	_	Poor	_		

Crossley et al., 2004	_	Poor	_	_	Poor	_
Harrison et al., 1995	Poor	Poor	_		Poor	_
Persian Version Kujala <sup>*</sup>						
Negahban et al., 2012	Poor	Fair	_	Fair <sup>H</sup> ; Good <sup>C</sup>	_	_
PFS <sup>**</sup>				$\cup$		
Harrison et al., 1995	Poor	_	- 2	_	Poor	_
PSS						
Laprade and Culham, 2002	_	Poor	$\sim$	_	_	_
VAS/ NPRS						
Chesworth et al., 1989	_	Poor	y _	_	Poor	_
Piva et al., 2009	_	-	_	_	Poor	_
VAS-L						
Harrison et al., 1995	_	Poor	_	_	Poor	_
VAS-U	~					
Bennell et al., 2000	_	Poor	Poor	Good <sup>s</sup>	_	_
Crossley et al., 2004		Poor	_	_	Poor	_

Harrison et al., 1995	_	Poor	_	_	Poor	_
VAS-W						
Bennell et al., 2000	_	Poor	Poor	Good <sup>s</sup>	_	_
Crossley et al., 2004	_	Poor	-	₽-	Poor	_
Harrison et al., 1995	_	Poor	- ~	)	Poor	_

<sup>s</sup> – Structural validity; <sup>H</sup> – Hypothesis validity; <sup>C</sup> – Cross-cultural validity <sup>\*</sup>As a translated version cannot be analysed alongside the other PROM

-- As this measure has components of PRO and CRO measures this cannot be analysed alongside the other PROM

CERTED Y

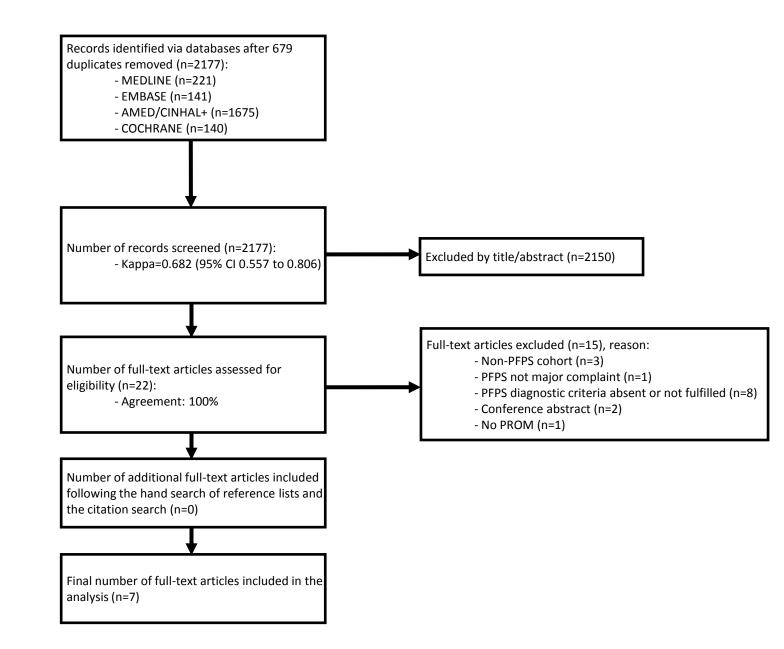
## Table 5

Quality of measure	ment properties per questionnair	e		R		
		Measurem	ent Properties			
	Internal Consistency	Test-retest Reliability	Measurement Error	Validity	Responsiveness	Interpretability
ADLS	nr	nr	nr	nr	?	nr
EPQ	nr	?	?	++ <sup>S</sup>	?	nr
Flandry	nr	?	?	++ <sup>S</sup>	nr	nr
Kujala/AKPS	nr	?	?	++ <sup>S</sup>	?	nr
MFIQ	?	?	?	++ <sup>S</sup>	?	nr
PSS	?	nr	nr	nr	nr	nr

VAS/ Numeric Pain Rating Scale	nr	?	nr	nr	?	nr
VAS-L	nr	?	nr	nr	?	nr
VAS-U	nr	?	?	++ <sup>\$</sup>	?	nr
VAS-W	nr	?	?	++ <sup>\$</sup>	?	nr
Persian Version Kujala <sup>*</sup>	?	+	nr	+ <sup>H,C;f</sup>	nr	nr
PFS **	?	nr	nr	nr	?	nr

Abbreviations: <sup>S</sup> – Structural validity; <sup>H</sup> – Hypothesis validity; <sup>C</sup> – Cross-cultural validity; nr – not reported. Evidence grading: +++ or --- strong' evidence of a positive/negative result, ++ or -- 'moderate' evidence of a positive/negative result, + or --'limited' evidence of a positive/negative result, ± 'conflicting' evidence, ? unknown due to poor methodological quality.

<sup>‡</sup> Measured against SF 36 physical.
 <sup>\*</sup> Translated version of Kujala questionnaire.
 <sup>\*\*</sup> Measure has PRO and CRO components.



#### <u>APPENDIX I</u>

#### MEDLINE search strategy Aug 2013

1. knee joint or knee or patella or patellofemoral.mp

2. arthralgia or pain.mp

3. Combine 1. And 2.

4. anterior knee pain.mp

5. ((patell\$ or femoropatell\$ or femoro-patell\$ or retropatell\$) adj (pain or syndrome or dysfunction)).mp. [mp = title, original title, abstract, name of substance word, subject heading word]

6. ((lateral compression or lateral facet or lateral pressure or odd facet) adj (pain or syndrome or dysfunction)).mp. [mp = title, original title, abstract, name of substance word, subject heading word]

7. ((chondromalac\$ or chondropath\$) adj (knee\$ or patell\$ or femoropatell\$ or femoropatell\$ or retropatell\$)).mp. [mp = title, original title, abstract, name of substance word, subject heading word]

8. or/3-7

9. Clinometric/ or Psychometric.mp (clinomet\$/ or psychometr\$.mp)

10. (Reliability/ or reliable).mp

- 11. Validity adj (content or construct or criterion).mp
- 12. Responsiveness.mp
- 13. clinical sensitivity.mp
- 14. Internal adj consistency.mp
- 1. Measurement adj error.mp
- 2. Interpretability.mp

17. or/9-16.

18. outcome measur\$.mp

19. Questionnair\$.mp

20. (patient reported or patient-reported or self-reported) adj (questionnair\$ or scale or measure or outcome or outcome measure\$).mp

21. (clinician reported or clinician-reported or performance based or performance-based)

adj (questionnair\$ or scale or measure or outcome ot outcome measur\$).mp

22. or/ 18-21

23. 8 and 17 and 22

24. Limit 23 (humans)