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1 **Title**

2 Does a bespoke education session change levels of catastrophizing, kinesiophobia and pain
3 beliefs in patients with patellofemoral pain? A feasibility study.

4

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8

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14

15 Word Count: 3545

16

17 *Key words:* Patellofemoral pain, anterior knee pain, education, kinesiophobia, catastrophising.

18

19 **Abstract**

20 **Objectives:** To assess the feasibility of a 30-minute education session for patients with
21 patellofemoral pain on levels of catastrophizing and kinesiophobia.

22 **Design:** Randomised feasibility study

23 **Setting:** Three sites within a single NHS Organisation in England.

24 **Participants:** Thirty-one adult patients were screened for inclusion, resulting in twenty-four
25 who had a clinical diagnosis of patellofemoral pain being randomised equally to either the
26 intervention or control group.

27 **Intervention:** Participants were randomised to either control or intervention conditions; both
28 received standardized physiotherapy while the intervention/experimental group received a 30-
29 minute educational session addressing causes of pain, beliefs about noise that comes from the
30 joint, the impact of the pain on activity, the influence of other family members' experience
31 and beliefs about knee pain. Intervention participants were also given an *education leaflet*:
32 'Managing My Patellofemoral Pain'.

33 **Main outcomes:** recruitment, retention, intervention fidelity.

34 Patient reported outcome measures (PROMs): Knee injury and Osteoarthritis Outcome Score
35 for patellofemoral pain and osteoarthritis (KOOS-PF), Pain Catastrophizing Scale (PCS) and
36 Tampa Scale for Kinesiophobia (TSK).

37 **Results:** The study was successful in recruiting and retaining participants and was delivered
38 as intended. In addition, sufficient clinical data were generated to calculate the required
39 sample size for a future study of efficacy

40 **Conclusions:** This study which featured a 30-minute education session targeting levels of
41 catastrophizing and kinesiophobia is feasible and identified that the TSK may be the most
42 appropriate PROMs for a future study of efficacy of this intervention. Allowing for a drop out

43 of 20% as identified in similar studies, 86 participants (per arm) in a two-arm study would be
44 required for a traditional randomised controlled trial design.

45

46

47 **Introduction**

48 Patellofemoral pain (PFP) is characterised by peri or retropatellar knee pain, which is
49 reproduced upon activities of daily-living when there is load or stress on the patellofemoral
50 joint such as when climbing stairs, squatting and sitting (1). The impact of PFP may extend to
51 social engagements and participation in physical activities including sports and occupational
52 tasks (2).

53 One in five of the general population will have experienced PFP within the last year (3) and
54 there is a poor prognosis with 91% reporting pain and dysfunction four years post-diagnosis
55 (4). Symptoms may persist for decades after their first onset; with estimates ranging from 16
56 to 20 years (4-7), therefore it is appropriate to consider PFP can become a chronic
57 musculoskeletal condition in some instances. Forty to 57% of patients will experience
58 unfavourable long-term outcomes despite receiving evidence-based treatments (2) including
59 strengthening exercises, often prescribed to address biomechanical faults during activities (8,
60 9). A significant number of patients who have PFP have been found to have lower levels of
61 strength in their quadriceps and gluteal muscles than individuals without PFP (10). However,
62 research by Selfe et al (2016) (11) identified a subgroup of PFP patients, predominantly
63 males with higher levels of hip abductor and quadriceps strength who were classed as
64 'strong'. This might help to explain why some patients who receive evidence-based
65 strengthening exercises continue to have poor outcomes. Similar to other chronic
66 musculoskeletal conditions, chronic PFP is associated with high pain intensity, low quality-
67 of-life and increased risk of ceasing participation in sports (12). The psychological impact of
68 PFP (13) offers a challenge to the traditional biomedical approach to the management of PFP.
69 The most recent Consensus Statement from the International Patellofemoral Pain Research
70 Retreat (10) recommends a greater emphasis be placed on addressing psychosocial factors and
71 pain sensitization.

72 Robertson et al (2017) (14) explored the beliefs of patients with PFP about crepitus and the
73 impact of this on their behaviour. The key emergent themes influencing behaviour were:
74 patients' beliefs that crepitus was damaging, the influence of others and avoiding the noise.
75 Patients, with PFP have also been found to have higher levels of catastrophizing,
76 kinesiophobia (15) and mental distress (16) than people without PFP. Smith et al (2017) (17)
77 demonstrated, the importance of understanding the significant negative effects of living with
78 PFP on peoples lifestyles and how it impacted on their well-being. The study highlighted the
79 possibility that improved outcomes could potentially be achieved by supporting people living
80 with PFP to overcome psychological barriers.

81 Biopsychosocial interventions targeting catastrophizing and kinesiophobia are yet to be fully
82 explored in patients with PFP. Research from other chronic pain conditions suggest that
83 focusing on reducing kinesiophobia might be promising as it is moderately associated with
84 lower pain and higher function following appropriate education (15, 18). Similar to the
85 traditional clinical management of PFP, the usual patient education approach for PFP is also
86 through a biomedical lens where anatomy and biomechanics are the main foci (18). However,
87 pain is complex; it is a sensory and emotional experience (18, 19) which can have a longer
88 term impact on behaviour (19). Therefore, the intervention in this feasibility study adopted a
89 biopsychosocial approach focussing on catastrophizing and kinesiophobia, whereby the
90 participants own lived experience and beliefs were discussed in reference to how they manage
91 and respond to their pain.

92

93 **Methods**

94 The primary aim of this study was to determine the feasibility of a RCT comparing
95 standardised physiotherapy with an education intervention addressing patients'

96 catastrophizing and kinesiophobia. Both groups received the same standardized
97 physiotherapy while the experimental group also received a 30-minute educational session
98 addressing kinesiophobia and catastrophizing. The specific uncertainties for this study were
99 recruitment, retention, intervention fidelity (20), which meant that a feasibility study in the
100 first instance was appropriate. Secondary objectives were to generate data that would inform
101 a sample size calculation for a future study by collecting data from three different patient
102 reported outcome measures (PROMs) (21).

103

104 *Study design and participants*

105 In this single site feasibility study, twenty-four patients were recruited via an NHS teaching
106 hospital. The study was approved by the North West – Liverpool Central Research Ethics
107 Committee and HRA (18/NW/0725) and all participants provided written informed consent.
108 The study was registered with Clinicaltrials.gov NCT03784339.

109 Patients who had been clinically diagnosed in a Musculoskeletal Clinical Assessment Service
110 (MCAS) with PFP at 3 sites within an NHS teaching hospital trust were approached to take
111 part in the study. Recruitment began in April 2019, patients were provided with information
112 about the study by a participant identification physiotherapist. The research physiotherapist
113 contacted patients interested in taking part to discuss and made arrangements to obtain
114 informed consent as appropriate. Once enrolled onto to the study, randomisation software
115 (Research randomizer: randomizer.org) was used to allocate participants to either intervention
116 or control groups.

117

118

119 Eligibility was assessed by the research physiotherapist prior to taking written informed
120 consent.

121 *Inclusion criteria:*

- 122 • Adults aged 18-40 years
- 123 • Able to understand written and spoken English.
- 124 • Clinical diagnosis of PFP (2)
- 125 • Able to attend for up-to 12 weeks of physiotherapy

126 *Exclusion criteria:*

- 127 • Patients who presented with referred pain from the spine or hip, or who had
128 tibiofemoral pathology of any nature on the ipsilateral side.
- 129 • A diagnosis of PFJ osteoarthritis as confirmed by x-ray or MRI.
- 130 • Previous surgery to the symptomatic knee.

131

132 ***Outcome Measures***

133 The PROMs used in this study were Knee injury and Osteoarthritis Outcome Score –
134 Patellofemoral subscale (KOOS-PF) (22, 23), Pain Catastrophising Scale (PCS) (24) and
135 Tampa Scale of Kinesiophobia (TSK) (25).

136 The KOOS-PF includes five subscales; Pain, other Symptoms, Function in daily living
137 (ADL), Function in sport and recreation (Sport/Rec) and knee related Quality-of-life (QOL).
138 It also includes the 11-item patellofemoral pain and osteoarthritis subscale, developed for use
139 with PFP patients. Items are scored 0-4; the sub-scales are calculated independently, and
140 transformed to give a score from 0-100 with 0 indicating worse scores. The reported
141 minimum clinically important change (MCIC) is 16 points (22).

142 The PCS is a 13-item questionnaire describing thoughts and feelings that individuals
143 experience when they have pain. Participants reflect on their pain experience and indicate one
144 of the 13 thoughts or feelings perceived at the time of pain. The scale ranges from 0-52,
145 where 52 represents greatest catastrophic pain (24); scores greater than 24 being associated
146 with higher pain ratings (26). The reported MCIC is 9 points for low back pain (27)
147 The TSK is a 17 item questionnaire used to quantify fear of movement and re-injury due to
148 movement and physical activity on a scale of 0-68, where 68 indicates greatest fear of re-
149 injury due to movement (25, 28). A score of thirty seven has been suggested as the boundary
150 for high and low fear (29). The reported MCIC is 4 points (30)

151

152 ***Sample size***

153 The sample size was informed by previous research (17, 31, 32), suggesting a total of n=24
154 participants (n=12 per group) would be required to answer the feasibility objectives.
155 Therefore in this 2 arm randomised feasibility study each group comprised 12 participants.

156

157 ***Baseline measures***

158 Participants were asked to self-report their baseline characteristics including age, sex, and
159 duration of symptoms, which were collected alongside baseline PROMs: KOOS-PF, TSK and
160 PCS. These questionnaires were repeated after 12 weeks.

161

162 ***Study design***

163 Participants were randomised to either the intervention (n=12) or the control group (n=12).
164 All participants in both groups received their treatment directly from the research
165 physiotherapist only.

166 ***Control Conditions***

167 Participants in the control group underwent standardised treatment, comprising an explanation
168 of the diagnosis of PFP with a management plan and an individualised home exercise
169 programme.

170 ***Experimental conditions***

171 Participants in the experimental group (the intervention group) received the same intervention
172 as participants in the control group plus an individual education session. The individual
173 education session, lasted for 30 minutes and allowed a two-way face-face conversation to take
174 place between the research physiotherapist and the participant. Topics covered in the
175 education session were

- 176 • The causes of pain
- 177 • Beliefs about pain
- 178 • Beliefs about noises from the joint
- 179 • The impact of the pain on activity
- 180 • The influence of other family members' experience and beliefs about knee pain

181 A patient education leaflet was also provided (33) as part of the intervention. Following the
182 intervention session, participants received the same standardised physiotherapy as control
183 participants. At 12 weeks, participants from both groups were asked to repeat the PROMs.

184

185 ***Recruitment***

186 The study objectives were to assess recruitment, retention and intervention fidelity.
187 Recruitment was assessed by keeping a log of all patients identified as having PFP by the
188 clinicians in MCAS and the number of those who met the inclusion criteria by the research
189 physiotherapist against the number of participants recruited to the study.

190

191 ***Retention***

192 To optimise retention participants who were lost to follow up were telephoned and PROMs
193 sent in the post with paid return envelopes enclosed. A log was kept of those who responded
194 to telephone and PROMs.

195

196 ***Intervention fidelity***

197 Self-assessment was used by the research physiotherapist to assess intervention fidelity (34).
198 The study protocol was reviewed to check if the pre-defined topics were discussed and if
199 intervention participants received the education leaflet.

200

201 **Results**

202 (Insert Figure 1 CONSORT flow diagram here)

203

204 ***Recruitment***

205

206 As illustrated by the CONSORT diagram, thirty-one patients were screened; seven of whom
207 were ineligible (n=1 did not speak English, n=2 had undergone previous knee surgery, n=4
208 declined to participate). The remaining twenty-four were recruited and consented from April
209 to November 2019 at a rate of three per month.

210 (Insert table 1 Baseline characteristics here).

211

212

213 Mean age was higher in the intervention group and both groups had more females. Mean
214 duration of symptoms was longer in the intervention group. The group also had higher mean
215 scores on PCS and TSK. As this was a randomised design, baseline characteristics were not
216 analysed for significant differences. This was because we already know that these would
217 have arisen by chance. Furthermore this practice of analysing for baseline differences is
218 actively discouraged in randomised designs (35).

219 The average (mode) number of treatment sessions attended was three and four in the
220 intervention and control group respectively. There were no specific or fixed number of
221 treatment sessions predefined for both intervention and control group participants.

222

223 ***Retention***

224 Nineteen out of the 24 participants were retained in the study. One (female) was lost to
225 follow-up in the intervention group, four (3 female and 1 male) were lost to follow-up in the
226 control group.

227

228 ***Intervention Fidelity***

229 This self-audit identified that the intervention was delivered as planned, all pre-determined
230 topics were covered in the intervention session (experimental conditions), and thus fidelity
231 was 100% with every participant.

232

233 ***Outcome measures***

234 All participants improved their scores on each of the three PROMs; KOOS-PF, TSK and PCS,
235 except for one whose KOOS-PF score deteriorated. Mean pre-intervention, post-intervention
236 and change scores are presented for each outcome measure (table 2).

237 (Insert Table 2 here)

238

239 Pre and post-scores for each of the questionnaires for the intervention and control groups are
240 shown in box plots in figures 2-4. Figure 2 shows that both groups improved their KOOS-PF
241 scores, with the range being greater post-intervention in the intervention group.

242 PCS scores in figure 3 shows reduced post-intervention scores in both of the groups, with the
243 same pattern as the post-intervention KOOS-PF in the intervention group. TSK scores in
244 figure 4 demonstrated the same pattern, although the spread of the data was not as wide.

245 Inspecting the raw data identified an outlier in the intervention group, which appears to be
246 responsible for the large spread, as seen in figure 2. The participant's pre-intervention
247 KOOS-PF score was 25.0, but this reduced to 9.09 which was contrary to the participant's
248 subjective report that her symptoms had improved prior to completing the questionnaire.

249 Once this outlier was removed, the central tendency and distribution of the data was more
250 consistent with the anticipated results.

251

252

253

254

255

256 *Results including outlier*

257 (Insert figure 2 here)

258 (Insert figure 3 here)

259 (Insert figure 4 here)

260 The time taken to complete the KOOS-PF was within the suggested time frame of 10
261 minutes (23) with the TSK and PCS taking less than five minutes each. Patients were
262 able to complete the three questionnaires without assistance in 15 to 20 mins.

263

264 ***Sample size calculation***

265 The data from the results for each of the outcome measures was used in the following
266 equation (Equation 1). This was used to determine the number of participants required
267 for a larger study with $\alpha=0.05$ and $\beta=0.2$ (36) to calculate sample size for a two arm
268 efficacy study.

269 (Insert equation 1 here)

270

271 Post-intervention means and standard deviations for each of the outcome measures in
272 each of the groups (table 2) were used in the equation. The participant who was an
273 outlier on KOOS-PF was included in all sample size calculations. Each total sample
274 size has been inflated to include a 20% drop out allowance:

275 • KOOS-PF: 2124

276 • PCS: 150

277 • TSK: 172

278 Although the dropout rate for this current study was slightly higher at 20.8%, a 20%
279 drop out rate has been used in the sample size calculations as this is consistent with
280 other PFP research.

281 **Discussion**

282 This randomised feasibility study achieved its primary objective by demonstrating that it

283 would feasible to evaluate the intervention in a future study. Additionally, it also addressed
284 the secondary objective and informed a series of sample size calculations for a future
285 study by collecting data from three different patient reported outcome measures
286 (PROMs)

287 This study was necessary because research shows that patients diagnosed with PFP have
288 elevated levels of kinesiophobia and catastrophizing (37), however the optimal treatment
289 approach to influence these psychological factors has not been identified.

290 ***Recruitment***

291 Prior to the study commencing, audit data suggested 104 patients would be eligible to
292 participate over a 12-month period, with a recruitment rate of eight per month from
293 three sites in one NHS hospital trust. However, participants were recruited at a slower
294 rate of three per month.

295 Recruitment to the study was conducted by participant identification physiotherapists in
296 the MCAS service. Review of referrals to the study identified that more participants
297 (n=16) were recruited by the most senior rather than the junior participant identification
298 physiotherapists (n=8). This was unexpected as there was a ratio of 1:4 for these staff
299 groups. This might have been because junior clinicians were less confident in their
300 diagnosis of PFP, as opposed to it being an issue of competence. Research has
301 identified that physiotherapists' with one years' experience are competent at diagnosing
302 knee disorders (38), which is supported by this study where only three of the 31
303 participants screened were ineligible, suggesting that the participant identification
304 physiotherapists were competent. Time management could have been an issue, with
305 junior clinicians having less time available to discuss the study, again this is consistent
306 with previous research, which identified that time can impact on recruitment into RCTs

307 (39). A potential solution would be to utilise research clinicians, who are experienced
308 in screening patients and whose sole role is to recruit to research.

309

310 ***Retention***

311 Five participants were lost to follow up (control n=4, intervention n=1), representing
312 ~20.8% of participants, which is similar to other studies (40).

313 In this study, recruitment and retention may have been affected by the intervention
314 being at one site only. This was a pragmatic decision as the research physiotherapist
315 was based there, but it did mean that only patients able and willing to travel could
316 participate.

317 Future studies are likely to have multiple physiotherapists delivering the intervention at
318 different sites, or alternatively employ online or digital platforms. Both of these
319 strategies would reduce the burden on patients and might encourage their participation
320 in research (37). These strategies might then translate into enhanced recruitment and
321 retention.

322 If there is concern about slow recruitment and borderline retention, a future study could
323 also use an adapted RCT design whereby an internal pilot with clear progression rules
324 are used to assess if the study should continue onto a main trial, thereby ensuring the
325 research is robust and resources are not wasted (41).

326

327 ***Intervention fidelity***

328 Self-reflection of the intervention identified fidelity, with multiple sites, would continue
329 to be ensured with ongoing training and monitoring within and between sites, this is
330 particularly important if multiple clinicians deliver the intervention. Another potential
331 strategy to promote fidelity might include using treatment manuals (42) or video to

332 deliver the intervention as it would ensure that every participant receives the same
333 information regardless of the clinician. This strategy has been used successfully to
334 reduce maladaptive belief in adolescents with PFP (37), although, the results should be
335 interpreted with caution as this study was underpowered. If videos are considered this
336 should be done with caution to ensure that it does not change the intervention to the
337 point that the findings of this feasibility study are compromised.

338 *Sample size for a future two arm efficacy study*

339 Alternative sample sizes for a future two arm efficacy study were calculated using each
340 of the outcome measures using the post-intervention means and standard deviations;
341 which resulted in different sample sizes for each measure.

342 The MCIC for KOOS-PF is recommended as 16 (22). In this study an average change
343 greater than 16 was found in both the control and intervention groups respectively (19.3,
344 16.5). Removing the outlier's scores increased the mean change in the intervention
345 group to 19.8; this might indicate that some participants may struggle to complete the
346 KOOS-PF. It should be made clear to participants that they must ask if there is anything
347 that they do not understand with the research physiotherapist readily available. Using
348 the KOOS-PF to calculate a sample size for a future study suggested 2124 participants
349 would be needed. This would be a significant challenge in terms of recruitment even if a
350 multicentre approach were to be conducted

351 The PCS MCIC is reported to be 9 points (27). In this study the average change for the
352 control and intervention was -9.3 and -8.4 respectively demonstrating a greater change
353 in the control group. However the PCS MCIC for PFP has not been identified and the
354 score of 9 was recommended for lower back pain patients (27).

355 Scott et al (2014) (26) has stated that a high score for the PCS was considered to be
356 greater than 24. In this study the average pre-scores, 18.4-23.3 for PCS was considered

357 at the low end; in which case the educational based intervention may have had less of an
358 impact as there was less room for improvement in patients with PFP. This has
359 implications when considering future suitability of this outcome as a primary outcome
360 measure in a larger study.

361 The TSK cut off point between individuals with high and low fear is 37 (29). This
362 study had a pre-score of 43.2 in the intervention and 39.9 for the control, placing both in
363 the high fear grouping. There were 9 in the control group and 12 in the intervention
364 group with pre-TSK scores of 37 or more.

365 The average post-intervention change for the TSK score was -3.5 for the control and -
366 4.5 for the intervention. Therefore, only the intervention group achieved the reported
367 MCIC of 4 (30). Priore et al (2019) (43) reported a change of -5.64 in TSK when using
368 a knee brace with PFP participants, although this study was limited to 6 weeks. The
369 changes in the TSK scores are in line with those from this feasibility study. Although
370 this was a feasibility study and not powered to detect differences between the 2 groups
371 the TSK was able to identify a clinically important change in the intervention group.

372 In this study, the TSK appeared to be the most appropriate outcome tool for assessing
373 the education session delivered to this patient population and yielded a suggested future
374 sample size of 172 which with appropriate resourcing could be achievable through a
375 multicentre study.

376

377 **Strengths and limitations**

378 *Risk of bias*

379 There are inherent risks of bias in this study. It was not possible to mask or blind
380 participants to their group allocation due to the nature of the intervention and the

381 outcome measures were also self-reported. In addition, the research physiotherapist
382 collected participants' outcome data and delivered the intervention, which might also
383 have introduced social desirability bias if participants felt compelled to report better
384 outcomes than they were actually experiencing. This could be mitigated by having
385 sufficient funding to ensure the involvement of multiple research physiotherapists; e.g.
386 one to deliver the intervention and one to assist in outcome data collection.

387 ***Recruitment***

388 Recruitment was slower than anticipated, thus prolonging the duration of the study,
389 however this finding was beneficial as it should provide a more realistic recruitment
390 timescale for a future appropriately powered study.

391

392 ***Retention***

393 The drop out from this study was consistent with similar studies which also had a
394 dropout rate of 20% (44). Retention may have been impacted by participants' ability to
395 regularly attend the intervention site for treatment. A future study should consider
396 'releasing' participants back to the original site once they have completed the
397 intervention to undergo usual care or the use of supportive digital technology.

398 Greater involvement of patients with PFP as part of patient and public involvement
399 (PPI) would be essential in taking the results of this study and refining the design for
400 future research. This is particularly important because it is likely that the PPI group
401 would identify potential difficulties and solutions to the proposed design, which would
402 have a positive impact. This is particularly important if multiple-centres are to be
403 considered for an efficacy study, which would be pragmatic as the required sample size

404 to assess efficacy is large, and would not be realistic to conduct in a timely fashion at
405 one site only.

406

407 ***Intervention fidelity***

408 A limitation of this study was that it was delivered solely by the research
409 physiotherapist who was restricted to a satellite clinic and there were no resources
410 available to fund an independent assessment of intervention fidelity. Furthermore our
411 fidelity assessment focused only on delivery and not other aspects of fidelity, such as
412 receipt; ensuring participants understood the information provided in the intervention
413 (experimental conditions), and enactment; whether or not the participant applies the
414 information and knowledge they have acquired to their own lives (34). However, the
415 study protocol was pre-registered with Clinicaltrials.gov NCT03784339 was used to
416 review if the intervention had been delivered as intended.

417

418 **Future research recommendations**

419 This feasibility study has answered some of the uncertainties around the feasibility of
420 conducting this research. Following amendments highlighted from this study it should
421 now be tested further in a pilot study, guided by the MRC framework (20) prior to a
422 larger suitably powered study to assess efficacy. An appropriately powered future study
423 should endeavour to identify if the education session is effective across varying degrees
424 of chronicity. In this study the mean duration of pain was over 3 years in both the
425 control and intervention groups.

426 The control group in this study had a greater improvement in the KOOS-PF and PCS,
427 but the intervention group had a greater improvement in the TSK. Future studies should

428 consider only including participants with high scores on the identified pre-intervention
429 outcome measures, or at least analyse large data sets further to see if the intervention
430 has a greater effect on patients with high TSK scores and thus supports the theoretical
431 proposition for the mode of action of the intervention. This would potentially
432 demonstrate greater change in pre-post-intervention scores which would influence the
433 sample size calculation. Furthermore, Machlachlan's (2017) (37) systematic review
434 into the psychological features of PFP recommends subgrouping patients to guide
435 treatment, as although there is emerging evidence of the
436 benefits of subgrouping and targeted physical intervention (10, 45) (9 & 44) it remains
437 unknown if a similar approach would be useful for psychological features.

438 The stated aims of this study were to; determine the feasibility of a future two arm
439 efficacy RCT comparing standardised physiotherapy with an education intervention
440 addressing patients' catastrophizing and kinesiophobia. A limitation of the study was
441 that we did not include a specific outcome measure to identify levels of mental distress.
442 However, the PCS has been found to have a significant degree of overlap, identified on
443 correlation matrix, among all measures of emotional distress (24). The secondary
444 objectives were to generate and analyse clinical data from three different outcome
445 measures to inform the appropriate sample size that would be required for such a future
446 study.

447 This study has demonstrated that a larger study would be feasible based on the findings.
448 The TSK appears to be the most appropriate outcome tool and yielded a suggested
449 future sample size of 172 patients. A future pilot RCT would benefit from the inclusion
450 of strict progression criterion in view of the challenges associated with recruitment and
451 retention. The study has achieved its secondary objectives of generating enough clinical
452 data to inform a sample size calculation for all outcome measures used.

453

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460 Declaration of interest statement

461 The authors have no interests to declare.

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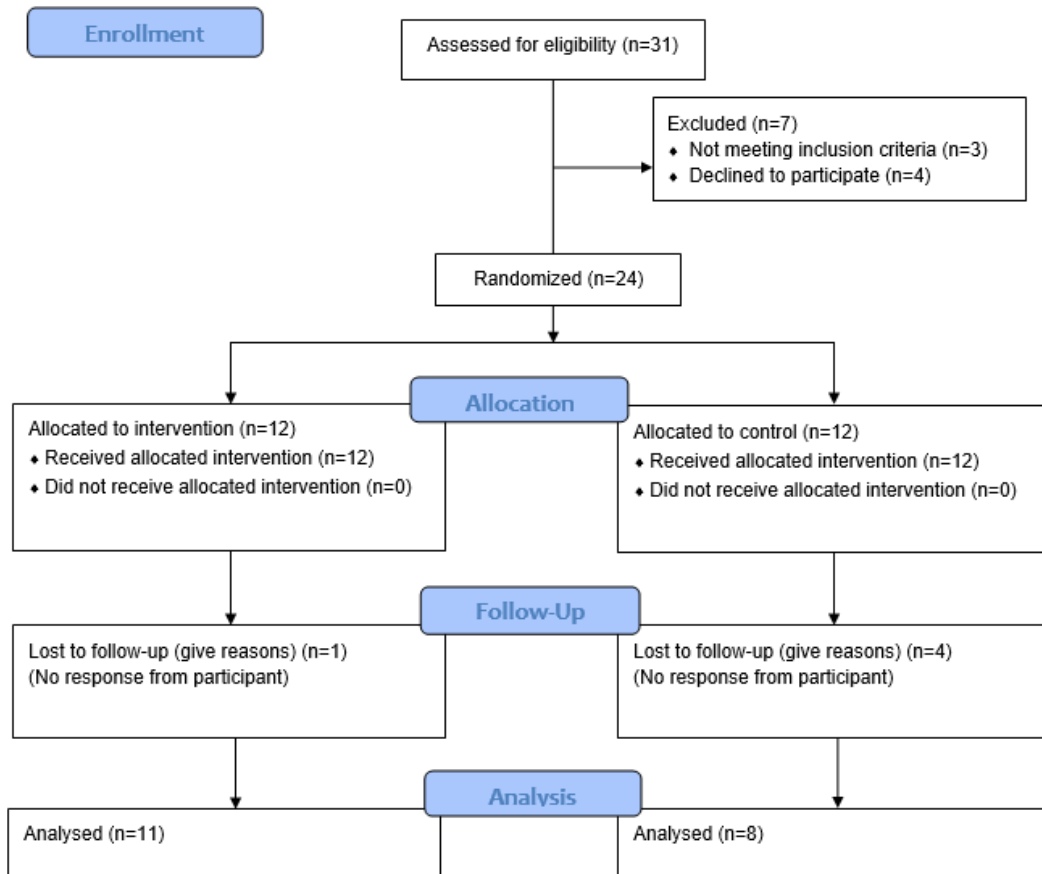
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CONSORT 2010 Flow Diagram



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Table 1 Baseline characteristics: means (standard deviations) indicated.

Baseline Characteristics	Intervention (n=12) Mean (SD)	Control (n=12) Mean (SD)
Female	10	8
Age (years)	28.9 (5.9)	24.8 (5.6)
Pain Duration (months)	42.66 (59.00)	38.75 (33.09)
KOOS-PF	47.1 (13.90)	47.2 (15.20)
PCS	23.3 (12.82)	18.4 (11.55)
TSK	43.2 (4.93)	39.9 (3.64)

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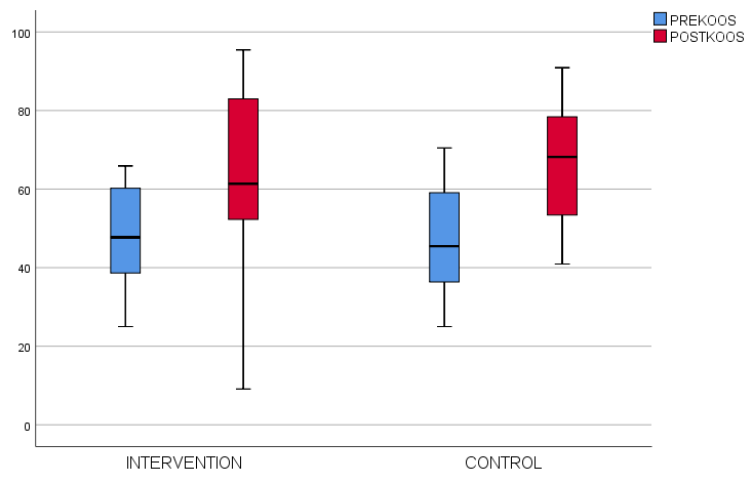
589 Table 2 Pre, post and change scores for outcome measures: mean (standard deviation)
 590 and minimally clinically important change (MCIC) score.

	Pre	Post	Change	MCIC
KOOS-PF Intervention	47.1 (13.90)	63.6 (25.89)	+16.5 (16)	16
KOOS-PF Control	47.2 (15.20)	66.5 (16.70)	+19.3 (16)	
PCS Intervention	23.3 (12.82)	14.8 (14.04)	-8.4 (9)	9
PCS Control	18.4 (11.55)	9.1 (7.75)	-9.3 (9)	
TSK Intervention	43.2 (4.93)	38.7 (4.45)	-4.5 (4)	4
TSK Control	39.9 (3.64)	36.4 (5.31)	-3.5 (4)	

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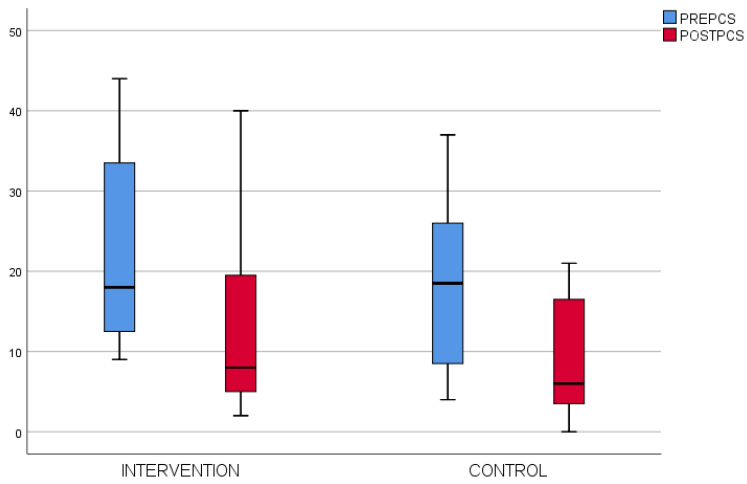
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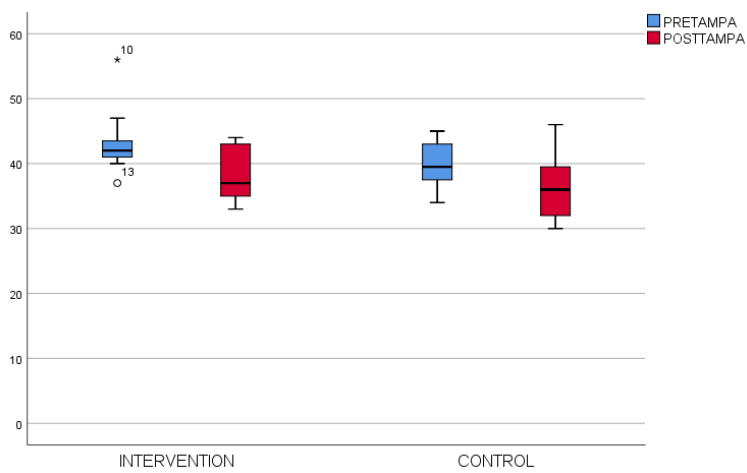
Figure 2 Pre and post-intervention KOOS scores for each group



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Figure 3 Pre and post-intervention PCS scores for each group



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Figure 4 Pre and post-intervention TSK scores for each group

$$k = \frac{n_2}{n_1} = 1$$

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2/K)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

$\Delta = |\mu_2 - \mu_1|$ = absolute difference between two means
 σ_1, σ_2 = variance of mean #1 and #2
 n_1 = sample size for group #1
 n_2 = sample size for group #2
 α = probability of type I error (usually 0.05)
 β = probability of type II error (usually 0.2)
 z = critical Z value for a given α or β
 k = ratio of sample size for group #2 to group #1

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Equation 1 Sample size calculation

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