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1 **A single-arm, non-randomized investigation into the short-term effects and follow up of**
2 **a 4-week lower limb exercise programme on kinesiophobia in individuals with knee**
3 **osteoarthritis.**

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16 **AUTHOR CONTRIBUTIONS**

17 **Concept and design. Molyneux, Herrington, Riley, Jones.**

18 **Analysis and interpretation of data. Molyneux, Herrington, Jones.**

19 **Critical revision of the article for important intellectual content. Molyneux, Herrington,**
20 **Jones.**

21 **Final approval of the article. Molyneux, Herrington, Jones.**

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29 **Abstract**

30 **Objective**

31 To investigate the short-term effects and follow-up of a 4-weeks lower limb exercise
32 programme on kinesiophobia in individuals with knee osteoarthritis.

33 **Design**

34 Participants diagnosed with knee OA clinically against the American College of
35 Rheumatology criteria (ACR) were recruited. Participants completed a 4 weeks lower limb
36 exercise programme. Each participant completed two questionnaires, the Tampa
37 kinesiophobia scale (TSK) and the knee injury and osteoarthritis outcome score (KOOS).
38 Each measurement was completed at the baseline assessment, at session 4 of the programme,
39 at session 8 of the programme, and 6-weeks after the exercise programme. Perceived levels of
40 exertion (RPE) were measured after each exercise session using the modified Borg scale.

41 **Results**

42 Fifty-four participants took part in the study. Kinesiophobia decreased from the baseline
43 assessment to 6-weeks after the exercise programme. KOOS pain, symptoms, sports and

44 recreation, quality of life and activities of daily living score increased, therefore showed
45 improvement. Correlational analysis highlighted a moderate negative correlation between the
46 KOOS pain and kinesiophobia at baseline and 6- weeks after the exercise programme (0.44,
47 0.48 respectively).

48 **Conclusions**

49 Understanding baseline kinesiophobia scores could provide an important resource for health
50 professionals who manage individuals with knee osteoarthritis to improve the quality of care
51 due to the correlation with pain changes and may improve exercise related outcomes for a
52 longer duration.

53 **CONTRIBUTION OF THE PAPER**

54 -Kinesiophobia is prevalent in individuals diagnosed with knee osteoarthritis.

55 -Kinesiophobia decreased in 75% of individuals with knee osteoarthritis after a 4-
56 weeksexercise programme.

57 -Correlation between pain and kinesiophobia at baseline and 6-weeks after an exercise
58 programme.

59 -An understanding of an individual's kinesiophobia level before an exercise programme is
60 important for future prognosis of changes in pain.

61 **CLINICAL TRIAL NUMBER**

62 NCT02734342

63

64

66 Introduction

67 Osteoarthritis (OA) is one of the leading causes of pain and musculoskeletal disability (1) and
68 represents a typical chronic musculoskeletal condition (2). The management of knee
69 osteoarthritis can be categorized into pharmacological, surgical, and conservative
70 management. Usage of pharmacological treatments such as paracetamol and intra-articular
71 injections provide a reduction in pain (1). However, both have complications e.g. renal
72 toxicity, septic arthritis, and joint degradation (3). Surgical interventions may be required,
73 such as arthroscopic resection, osteotomies, and joint replacements, but come with risks such
74 as infection, deep vein thrombosis and revision surgery (4). Non-pharmacological core
75 interventions recommended via the NICE guidelines (1) include local muscle strengthening,
76 general aerobic exercises, and education for their effectiveness in reducing pain and
77 increasing function.

78 Increasing muscle strength can significantly reduce knee OA symptoms, pain and therefore
79 improve the quality of life and activities of daily living. Exercise has been recommended as a
80 core treatment for knee osteoarthritis (1). Despite positive evidence regarding exercise (7)
81 individuals with knee OA avoid exercise to prevent pain (12) and are not achieving the
82 recommended level of exercise (13). Psychological factors such as kinesiophobia are as
83 important as the physical characteristics in driving this behaviour (14). Kinesiophobia is a
84 psychological impairment that results from a feeling of vulnerability to a painful injury or re-
85 injury and therefore prevents individuals completing an activity (15). Kinesiophobia is
86 prevalent in individuals with knee OA with greater pain and functional limitations being
87 reported in individuals with increased kinesiophobia (16, 17). Therapeutic exercise has the
88 potential to improve knee instability and psychological factors (23, 35).

89 There is little research exploring kinesiophobia in knee OA with only one recent study
90 investigating the effects of dynamic balance and exercise in forty individuals diagnosed with
91 medial knee OA (28). Kinesiophobia was measured as a secondary outcome using the brief
92 fear of movement scale questionnaire with positive effects after completing a 10-weeks
93 partially supervised exercise programme. The study undertaken is the first study to measure
94 the short-term effects of kinesiophobia using the Tampa Scale of Kinesiophobia throughout a
95 4 weeks exercise programme at baseline, session 4, session 8 and 6-weeks after the exercise
96 programme in individuals with knee OA. The Tampa Scale of Kinesiophobia (TSK) is a
97 brief, reliable and a valid measure to link fear of movement with knee OA (26). We
98 hypothesized that a short-term exercise programme reduces kinesiophobia in individuals
99 diagnosed with knee OA.

100 **Participants and Methods**

101 The study is a level one prospective clinical trial (clinical trial number NCT02734342)
102 whereby ethical approval was obtained from the South West Research Ethics Committee
103 (16/SW/0036).

104 *Participants*

105 Individuals referred to physiotherapy were invited to participate who had a clinical diagnosis
106 of knee OA using the American College of Rheumatology guidelines, which are 95%
107 sensitive and 69% specific for the diagnosis of osteoarthritis (18). Individuals aged 45 and
108 above were invited into the study, as per national guidelines (1) with specific sign and
109 symptoms to include stiffness for less than thirty minutes; crepitus; bony tenderness; bony
110 enlargement and no palpable joint warmth, individuals must elicit three of the six to be
111 included in the study. Individuals who had a radiographic diagnosis were also included in the
112 study, as x-rays are gold standard in the diagnosis of OA with a greater specificity (18).

113 Reasons for exclusion from the study included previous lower limb joint injection within
114 three months; previous bilateral hip or knee joint replacement; any severe cognitive, cardio-
115 respiratory, musculoskeletal or neurological diagnosis that prevents participants from
116 exercising. Individuals with a body mass index (BMI) over 40 had a choice of being involved
117 in the study or be referred to the NHS weight management service, as per service
118 specification. Other minor health related issues were assessed prior to the commencement of
119 the study to ensure safe practice. All participants provided written informed consent.

120 *Intervention*

121 *Procedures*

122 Participants were asked to attend eight exercise sessions within a group class environment
123 that lasted for 1 hour per session. Participants attended each class, twice per week for four
124 weeks. Four-weeks was chosen due to time and workload constraints within the
125 physiotherapy department. Clinical guidelines suggest two to three exercise sessions per
126 week are required to attain a positive response in symptoms (20). During the hour, all
127 participants completed a 5-minute warm up and then commenced the 14-station exercise
128 programme, which were specifically orientated to strengthen the lower limb and improve
129 aerobic capacity. Exercises included cycling, treadmill walking, cross trainer, step machine,
130 wall squats with a swiss ball, mini- squats with an elastic band, trampette, step-ups, heel
131 raises, hip extension over a plinth, crab walking with an elastic band, monster walking with
132 an elastic band, balancing on a tilt board and single leg stands. Participants recorded the
133 number of repetitions, and progression of exercises was patient led based on pain and
134 perceived exertion. Each exercise was timed for two minutes with approximately one minute
135 in between each exercise. After seven exercises, a 5-minute hydration break occurred. After
136 each exercise class, a cool down was completed, with the participant completing the Borg

137 scale for patient specific maximal exertion. Participants were advised to have a recovery day
138 to prevent overloading (21). The group class operated from the physiotherapy department
139 gymnasium and was supervised by a specialist physiotherapist, who received three hours
140 training by the principal investigator, which consisted of reviewing each exercise station,
141 outcome measurements, and documentation. Both the principal investigator and specialist
142 physiotherapist offered telephone support to any of the participants during department open
143 times. Participants also received text message reminders the day before each exercise class to
144 increase attendance, which is cost effective (22). Other forms of interventions during the
145 study were not permitted such as the provision of injections or orthotics.

146 All individuals completed the Knee Injury and Osteoarthritis Outcome Score (KOOS) and the
147 Tampa Scale of Kinesiophobia (TSK) at the baseline assessment. TSK Scores range from 17-
148 68 points, with high kinesiophobia being classified with a score above 37 (15). Although no
149 evidence has been reported in relation to the minimal clinical detectable change for the TSK
150 in knee OA, a 4.6-point change in kinesiophobia was found using the brief fear of movement
151 with medial knee OA (28), with a 5.6-point change for generalised chronic pain (26) and 9.2
152 point for low back pain (38). Furthermore, a minimal clinical detectable change of 13.4
153 points has been suggested for the KOOS pain scale in knee OA (29-30).

154 The questionnaires were repeated at session 4 and session 8 of the exercise programme. At
155 the end of the allocated sessions, all participants were issued with a six-week follow up
156 assessment and referred to a local leisure centre for further exercise. Perceived level of
157 exertion was measured after each exercise programme using the modified Borg scale.

158 *Statistical Analysis*

159 Statistical analysis was performed using Statistical Package for Social Sciences (SPSS
160 version 24.0) with the significance level set at $p < 0.05$. Data were reviewed for normality

161 prior to data analysis with the Kolmogorov-Smirnov tests being completed. The KOOS data
162 were normally distributed; therefore, a repeated measure of analysis of variance (ANOVA)
163 was completed to investigate the mean variability within the participants' scores. Normal
164 distribution was not found in the TSK; therefore, a Friedman test was completed with a post
165 hoc Wilcoxon sign ranks test. A Spearman's correlation coefficient was completed to analyse
166 the TSK and KOOS.

167

168 **Results**

169 Ninety- five individuals diagnosed with knee OA were invited into the study. Thirty-one
170 individuals did not consent to the exercise programme and were re-appointed with another
171 physiotherapist. Ten individuals completed the 60-minute assessment and then e-
172 mailed/telephoned directly after to decline participation. Therefore, Fifty- four individuals
173 with knee OA participated in the study, 27 males and 27 females with a mean age of 63.35
174 (SD 8.1) years; mean height 1.64 (SD 0.34) metres; mean mass 78.37 (SD 21.22) kilograms;
175 mean body mass index 27.12 (SD 4.08). Seventeen participants (31.5%) were diagnosed with
176 grade 2 Kellgren and Lawrence scale (KL); 19 participants (35.2%) diagnosed with grade 3
177 KL; 12 participants (22.2%) diagnosed with grade 4 KL, all with medial compartment OA,
178 and six participants (11.1%) diagnosed without x-ray but with specific clinical symptoms
179 using the American College of Rheumatology criteria (ACR).

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Insert Table 1 here

183 Table 2 shows the median points scored after completing the TSK at baseline, session 4,
184 session 8 and 6-weeks after the exercise programme. Participants' baseline scores recorded a
185 median of 37 (IQR 9.25), at session 4, median score 33.5 (IQR 11), at session 8, median
186 score 32 (IQR 8.5) and 6-weeks post-exercise programme, median score 33 (IQR 12).
187 Therefore, an overall median change score of four was recorded from baseline to 6-weeks
188 post-exercise programme. Secondary analysis using the Wilcoxon signed ranks test data
189 indicated a non-significant change from baseline to session 4 ($p= 0.052$), however from
190 baseline to session 8 ($p= 0.002$) and baseline to 6-weeks post-exercise programme ($p= 0.001$)
191 there was a statistically significant change. Over half of the participants' recorded high levels
192 of kinesiophobia at baseline (52% scored 37 and over). Fourteen participants' remained high
193 after 6-weeks post-exercise programme, 12 scored highly at baseline and remained high
194 throughout the exercise programme. Two participants scored low at baseline, but had a re-
195 occurrence of their symptoms at the 6-week follow-up. Those participants whose
196 kinesiophobia remained high, the pain levels minimally reduced (baseline 46.69, 6-weeks
197 post-exercise programme 45.88).

198 **Insert Table 2 here**

199 Table 3 shows the KOOS mean scores at baseline, session 4, session 8 and 6-weeks after the
200 exercise programme. Participant's baseline KOOS pain score recorded a mean of 41.06 (SD
201 17.46) at session 4, mean score 47.79 (SD 14.83) at session 8, mean score 51.18 (SD 21.82)
202 and 6-weeks post-exercise programme, mean score 56.53 (SD 22.21). A non-significant
203 change from baseline to session 4 ($p= 0.06$) occurred, however from baseline to session 8
204 ($p=0.009$) and baseline to 6-week post- exercise programme ($p= 0.001$) the change was
205 statistically significant. Participant's baseline KOOS symptoms score recorded a mean of
206 41.67 (SD 18.78) at session 4, mean score 49.34 (SD 14.09) at session 8, mean score 49.03
207 (SD 20.29) and 6-weeks post-exercise programme, mean score 56.48 (SD 19.19). With

208 significant changes occurring from baseline to session 4 ($p= 0.001$), from baseline to session
209 8 ($p=0.05$) and baseline to 6-week post-exercise programme ($p= 0.001$). Participant's baseline
210 KOOS activities of daily living score recorded a mean of 46.9 (SD 21.62) at session 4, mean
211 score 54.33 (SD 18.04) at session 8, mean score 57.44 (SD 25.31) and 6-weeks post-exercise
212 programme, mean score 61.39 (SD 20.97). There was a non-significant change from baseline
213 to session 4 ($p= 0.09$) was recorded, however from baseline to session 8 ($p=0.038$) and
214 baseline to 6-week post- exercise programme ($p= 0.01$) the change was statistically
215 significant. Participant's baseline KOOS sport and recreation score recorded a mean of 21.39
216 (SD 29.71) at session 4, mean score 29.07 (SD 21.06), at session 8, mean score 32.41 (SD
217 26.22) and 6-weeks post-exercise programme, mean score 32.94 (SD 27.13). There was a
218 non-significant change from baseline to session 4 ($p= 0.25$), however from baseline to session
219 8 ($p=0.010$) and baseline to 6-week post-exercise programme ($p= 0.029$) the change was
220 statistically significant. Participant's baseline KOOS quality of life score recorded a mean of
221 24.15 (SD 19.39) at session 4, mean score 37.06 (SD 17.74) at session 8, mean score 40.33
222 (SD 24.21) and 6-weeks post -exercise programme, mean score 43.08 (SD 23.47). A
223 significant change occurred from baseline to session 4 ($p= 0.001$), baseline to session 8 ($p=$
224 0.0001) and baseline to 6 week post-exercise programme ($p= 0.001$). Mean scores throughout
225 the 8-session exercise programme ranged from 13.22 to 14.07. Baseline scores for the
226 participants perceived exertion was 13.5, with the greatest increases at session 4 (13.98) and
227 session 5 (14.07), then the score levels decreased to 13.29 at session 8. Correlational analysis
228 suggests that the KOOS pain and TSK have a moderate negative correlation at baseline
229 (coefficient -0.48) and at 6-weeks after the exercise programme (coefficient -0.44). Mean
230 scores for the Borg scale ranged from 13.22 to 14.07 throughout the programme.

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Insert Table 3 here

232 **Discussion**

233 The study aimed to understand whether kinesiophobia was altered following an 8 session
234 physiotherapy intervention. To the authors' knowledge, this is the first study to demonstrate
235 that an 8-session exercise programme in the national health service setting reduces
236 kinesiophobia, pain, and symptoms, increases quality of life, sporting and recreation
237 activities. Kinesiophobia has a negative influence on the outcome of rehabilitation with a
238 high level of kinesiophobia presenting poorer rehabilitation outcomes (34) with an increased
239 level of disability and a reduction in strength being reported (37). Kinesiophobia interferes
240 with descending pain-inhibitory systems and facilitates neuroplastic changes in the spinal
241 cord during painful stimulation, which ends with pain sensitisation (38). Consequently, this
242 pain sensitisation causes functional decline that in turn causes depression and disturbed sleep
243 that can increase psychological distress (19). Over half of the participants' recorded high
244 levels of kinesiophobia at baseline (23), therefore assessing for kinesiophobia during an
245 initial assessment is important to allow the therapist and patient to collaborate a physical
246 activity programme with specific goals that will reduce the fear of movement sooner and
247 potentially reduce the chronic processes that can be related to kinesiophobia.

248 Previous research into kinesiophobia using the TSK for functional disability reported an
249 average score of 24.5 with osteoarthritis (39), which is much lower than our study. However,
250 a mean reduction of 4.6 points in kinesiophobia was found using the brief fear of movement
251 scale after an exercise programme in individuals with medial knee OA (28), which aligns
252 with our findings. Furthermore, the difference in this study is lower than the average score for
253 other musculoskeletal conditions, which is 42 (24). Higher levels of kinesiophobia have been
254 reported at baseline in individuals with chronic low back pain, which reduced after 6 months
255 of physical activity (25). Although no evidence has been reported in relation to the minimal
256 clinical detectable change for kinesiophobia in knee OA, the median change of 4 during this
257 study does not appear to meet the minimal clinical detectable change of 5.6 for generalised

258 chronic pain (26) or even 9.2 for low back pain (27). Correlational analysis between the TSK
259 and KOOS pain highlighted a moderate negative correlation at baseline and 6-weeks post
260 programme, therefore, the reduction in pain might be potentially related to the reduction in
261 kinesiophobia, but it is unlikely this is the only reason and future study should attempt to
262 investigate this in detail. Identifying individuals who have high TSK at the start of the
263 exercise programme may help to stratify different strategies to increase physical activity
264 levels, reduce chronic behaviour patterning, and improve the rehabilitation process. Similarly,
265 pain coping strategies and exercise programmes have been positively associated in
266 individuals with knee OA (17, 35), however not cost effective (17).

267

268 At the 6-week review compared to baseline, the KOOS pain subscale significantly improved.
269 However, between baseline and session 4 no significant improvement was found, this could
270 be related to the individuals starting an exercise programme or even commencing exercises
271 that they had never completed before and after the first few sessions developing pain due to
272 working the muscles. From session 4 onwards, the exercise programme provided the
273 individuals with reduced pain. With a mean change of 15.47, which is clinically significant
274 (29, 30). Further KOOS subscale scores highlighted statistically significant scores reducing
275 symptoms, increasing quality of life, increasing sport and recreation and increasing activities
276 of daily living. However, between baseline and session 4 no significant improvement was
277 found in the individual's activities of daily living, with the exercise programme reducing the
278 individuals' activities, which could be down to pain and reduced function (32). Perceived
279 exertion was recorded whilst using the Borg scale, with scores ranging from 13.22 to 14.07,
280 which can significantly influence knee OA (33). Moderate activity has been linked with
281 improved function and reduced pain for up to 6-months (34).

282 The main limitation of this study relates to the multiple factors that are associated with
283 kinesiophobia, as it is considered a psychological behavioural factor with sociological, lack
284 of confidence and previous experience being as important as the physical characteristics. We
285 have assumed that the exercise programme had a positive impact on kinesiophobia; however,
286 the interaction with the physiotherapist could have influenced the results and reduced
287 kinesiophobia. Therefore, a control group is an essential part of research to minimize the
288 effects of the intervention; future studies should include a control group with a matched
289 alternative therapy. Understanding individual exercise behaviours and habits should be
290 established as part of the routine examination and treatment for chronic musculoskeletal
291 conditions especially in relation to physical activity.

292

293 In conclusion, our findings demonstrate that kinesiophobia and pain reduces after completing
294 an exercise programme in participants with knee OA. During the exercise programme, as
295 kinesiophobia reduced, so did the participant's pain, therefore an understanding an
296 individual's kinesiophobia level before an exercise programme is important for future
297 prognosis of changes in pain, as individuals who interpret pain as none threatening confront
298 the situation, maintain daily activities, and are more likely to recover quicker and are less
299 likely to experience problems.

300 **ETHICAL APPROVAL**

301 The study is a level one prospective clinical trial (clinical trial number NCT02734342)
302 whereby ethical approval was obtained from the South West Research Ethics Committee
303 (16/SW/0036).

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307 **Table 1: Descriptive characteristics. Data presented as mean (SD) unless otherwise**
308 **indicated.**

Characteristics	N=54
Age (years)	63.35 (SD 8.1) Range: 47-79
Gender	Male: 27 Female: 27
Weight (kg)	78.37 (SD 21.22) Range: 57.15 – 120.6
Height (m)	1.64 (SD 0.34) Range: 1.49- 1.91
Body Mass Index (BMI)	27.12 (SD 4.08)

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317 **Table 2: Friedman Test. Median change (IQR), percentage difference between sessions,**
318 **p-values, and changes in kinesiophobia using the TSK (* Significant value)**

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	TSK	P-value from baseline	% of change between session
Baseline Score	37 (9.25)		
Session 4 Score	33.5 (11)	0.052	-9.46%
Session 8 Score	32 (8.5)	0.002*	-4.48%
6-week post Score	33 (12)	0.002*	+3.13%
Total change	4		-10.81%

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329 **Table 3: Repeated Analysis of Variance. Mean (SD) changes in the KOOS**
330 **questionnaire at baseline, session 4, session 8, and 6-week post exercise programme (***
331 **Significant value) .**

KOOS Subscale	Baseline score	Session 4 score	Session 8 score	6-week post score	Total change from baseline	P-value from baseline
Pain	41.06 (17.46)	47.79 (14.83)	51.18 (21.82)	56.53 (22.21)	15.47	0.001*
Symptoms	41.67 (18.78)	49.34 (14.09)	49.03 (20.29)	56.48 (19.19)	14.81	0.001*
Activities of daily living	46.9 (21.62)	54.83 (18.04)	57.44 (25.31)	61.39 (20.97)	14.49	0.002*
Sport/Recreation	21.89 (29.71)	29.07 (29.07)	32.41 (26.22)	32.94 (27.13)	11.55	0.011*
Quality of life	24.15 (19.39)	37.06 (17.74)	40.33 (24.21)	43.08 (23.47)	18.93	0.001*

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