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This is the peer-reviewed, manuscript version of an article published in *Physical Therapy in Sport*. The version of record is available from the journal site: <u>https://doi.org/10.1016/j.ptsp.2018.05.018</u>.

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The full details of the published version of the article are as follows:

TITLE: The effects & mechanisms of increasing running step rate: A feasibility study in a mixed-sex group of runners with patellofemoral pain

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JOURNAL: Physical Therapy in Sport

PUBLISHER: Elsevier

PUBLICATION DATE: 31 May 2018 (online)

DOI: 10.1016/j.ptsp.2018.05.018



The effects & mechanisms of increasing running step rate: a feasibility study in a mixed-sex group of runners with patellofemoral pain

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Word count: 4789 (excluding Tables and Figures)

- 1 The effects & mechanisms of increasing running step rate: a feasibility study in a
- 2 mixed-sex group of runners with patellofemoral pain

4 <u>Abstract</u>

5 **Objectives:** To explore feasibility of recruitment and retention of runners with

6 patellofemoral pain (PFP), before delivering a step rate intervention.

7 **Design:** Feasibility study

8 Setting: Human performance laboratory

9 **Participants:** A mixed-sex sample of runners with PFP (n=11).

10 **Main Outcome Measures:** Average/worst pain and the Kujala Scale were recorded 11 pre/post intervention, alongside lower limb kinematics and surface 12 electromyography (sEMG), sampled during a 3KM treadmill run.

**Results:** Recruitment and retention of a mixed-sex cohort was successful, losing one participant to public healthcare and with kinematic and sEMG data lost from single participants only. Clinically meaningful reductions in average (MD=2.1, d=1.7) and worst pain (MD=3.9, d=2.0) were observed. Reductions in both peak knee flexion (MD=3.7°, d=0.78) and peak hip internal rotation (MD=5.1°, d=0.96) were observed, which may provide some mechanistic explanation for the identified effects. An increase in both mean amplitude (d=0.53) and integral (d=0.58) were observed for

20 the Vastus Medialis Obliqus (VMO) muscle only, of questionable clinical relevance.

21 **Conclusions:** Recruitment and retention of a mixed sex PFP cohort to a step rate 22 intervention involving detailed biomechanical measures is feasible. There are 23 indications of both likely efficacy and associated mechanisms. Future studies 24 comparing the efficacy of different running retraining approaches are warranted.

25 Key Words

26 Patellofemoral Pain, Running, Biomechanics, Electromyography

#### **INTRODUCTION**

Decreation

28

29 Recreational running positively influences cardiac, (Petrovic-Oggiano, Damjanov, 30 Gurinovic, & Glibetic, 2010) metabolic (Williams, 2014) and mental (Ghorbani, et al., 31 2014) health. Despite the reported benefits, recreational running is reported to bring 32 about an increased risk of musculoskeletal pain. (Saragiotto, et al., 2014; van Gent, 33 et al., 2007) Overall incidence of musculoskeletal pain amongst recreational runners 34 ranges from 19% to 94%, (van Gent, et al., 2007) with patellofemoral pain (PFP) 35 thought to be the most common. (Taunton, et al., 2002) Specific annual incidence of 36 PFP amongst recreational runners ranges from 4% to 21%, (Noehren, Hamill, & 37 Davis, 2013; Ramskov, Barton, Nielsen, & Rasmussen, 2015; Thijs, Van Tiggelen, 38 Roosen, De Clercq, & Witvrouw, 2007), with overall prevalence in sports medicine 39 facilities suggested to be 17%. (Taunton, et al., 2002)

40

41 Running biomechanics has been reported to be a risk factor for, and associated with, 42 running related PFP. Specifically, peak hip adduction during running has been 43 reported to be significantly higher in female runners who develop subsequent PFP 44 when compared to those who remain asymptomatic. (Neal, Barton, Gallie, 45 O'Halloran, & Morrissey, 2016; Noehren, et al., 2013) In addition, based on our 46 recent meta-analysis, (Neal, et al., 2016) peak hip adduction, peak hip internal 47 rotation and contralateral pelvic drop are also significantly higher in runners with 48 PFP when compared to asymptomatic controls. For neuromuscular function, females 49 with PFP have been reported to have a delayed gluteal onset prior to foot contact 50 and shorter gluteal activation duration compared to asymptomatic controls. 51 (Willson, Kernozek, Arndt, Reznichek, & Scott Straker, 2011)

53 At present, evidence suggests that exercise interventions, whilst effective at 54 reducing symptoms in runners with PFP in the short-term, do not result in full 55 symptom resolution. (Earl & Hoch, 2011; Ferber, Kendall, & Farr, 2011) Moreover, 56 exercise may not derive its effects by way of a kinematic mechanism, as multiple 57 studies have demonstrated that exercise programs designed to increase hip strength 58 do not alter running kinematics thought to be associated with PFP. (Earl & Hoch, 59 2011; Sheerin, Hume, & Whatman, 2012; Willy & Davis, 2011; Wouters, et al., 2012) 60 This brings into question the ability of an exercise intervention to provide long-term 61 resolution to running related PFP, as it fails to target factors known to be associated 62 with the development and persistence of the condition. It is this premise that 63 originally led to the development of what has been termed running retraining, 64 (Heiderscheit, 2011) or more specifically 'the implementation of any cue or strategy 65 designed to alter an individual's running technique'. (I. Davis, 2005)

66

67 Reports from observational studies, involving visual and verbal cues to reduce peak 68 hip adduction, indicates running retraining may reduce pain and improve function in 69 female runners with PFP who demonstrate more than 20° peak hip adduction during 70 running. (Neal, et al., 2016; Noehren, Scholz, & Davis, 2011; Willy, Scholz, & Davis, 71 2012) The key limitation of this work is that the results can only be extrapolated to a 72 minority of runners with PFP (i.e. females with high peak hip adduction). In addition, 73 a recently completed randomised controlled trial (RCT) has established efficacy for 74 cues to transition from rearfoot to forefoot strike in combination with a load 75 management running program in a mixed-sex, but again a predominantly female,

cohort. (Roper, et al., 2016) The limitation of this study is that cues to transition to a forefoot strike are only applicable to those who rearfoot strike at baseline. Additionally, it is thought that such a change to running mechanics may also be injurious by virtue of the increase in Achilles tendon load that is observed with forefoot strike running compared to rearfoot strike running. (Rice & Patel, 2017) This is reinforced by the fact that 25% (2/8) of the runners in this RCT who transitioned to a forefoot strike pattern reported ankle soreness at follow up. (Roper, et al., 2016)

83

84 It has been reported that cues to increase running step rate do not increase Achilles 85 tendon load (Lyght, Nockerts, Kernozek, & Ragan, 2016) and thus may be a more 86 widely applicable running retraining option to those previously studied. A recent 87 feasibility study has reported that a step rate increase of 10% combined with running 88 in a minimalist shoe was superior to foot orthoses at reducing pain and improving 89 function at 12 week follow up in runners with PFP. (Bonacci, Hall, Saunders, & 90 Vicenzino, 2017) An increase in step rate of 10% has also been reported to 91 favourably alter patellofemoral joint stress in both runners with PFP and 92 asymptomatic runners, (Willson, Sharpee, Meardon, & Kernozek, 2014), though the 93 actual reduction in step length reported was much greater (14%). In addition, no 94 evaluation of symptoms could be reported in this study due to the limitation of the 95 cross-sectional, observational design. Observational work in asymptomatic runners 96 also indicates that more modest increases in running step rate of 5% or 7.5% may 97 still reduce peak hip adduction (Heiderscheit, Chumanov, Michalski, Wille, & Ryan, 98 2011; Willy, et al., 2015), albeit of a smaller magnitudes.

99

100 A recent three-arm RCT (Esculier, et al., 2017) found that a running retraining 101 intervention to increase step rate was no more effective than education focused on 102 load management, or compared to the same education combined with exercise 103 therapy in runners with PFP. Whilst no treatment group had superior outcomes, the 104 step rate intervention did result in significant reductions in both worst and running 105 specific pain. All three groups remained symptomatic at the primary end point (20 106 weeks), and running-related pain was higher (2.5/10) in the step rate group 107 compared to previous studies where hip adduction (0.5/10) (Noehren, et al., 2011; 108 Willy, et al., 2012) and strike pattern (1.0/10) (Roper, et al., 2016) has been targeted. 109 This could be explained by the absence of a faded-feedback protocol to facilitate the 110 retraining intervention, (Irene Davis, 2017) which has been found to be effective by 111 previous studies. (Noehren, et al., 2011; Roper, et al., 2016; Willy, et al., 2012)

112

The primary aim of this study was to investigate the feasibility of a pragmatic 113 114 running retraining intervention, by cueing a 7.5% increase in running step rate using 115 a faded feedback protocol. Specific objectives included (i) the recruitment of an 116 appropriate number of both males and females from a clinical population and (ii) the 117 collection of both symptom and function data to determine an estimate of the 118 effects derived from the intervention. The secondary aim was to investigate the 119 potential kinematic and muscle function mechanisms explaining any effects induced 120 by the intervention.

122

#### <u>METHODS</u>

#### 123 Participants

124 Ethical approval for this study was granted by the Queen Mary Ethics of Research 125 Committee (QMREC2014/63). All participants provided written informed consent 126 prior to study commencement. Participants were recruited from local sports 127 medicine clinics. Sample size was based on the apriori power analysis conducted by 128 the authors of the previous work on running retraining, (Noehren, et al., 2011; Willy, 129 et al., 2012) leading to a total of 10 participants being sought. Participants were of 130 either sex, currently or previously running a minimum of 10 km/week and aged 131 between 18 and 45 years. To be included, participants were required to have 132 atraumatic retropatellar or peripatellar pain during running and one other activity 133 described by the most recent PFP consensus document, which includes squatting, 134 stair ambulation and jumping. (Crossley, et al., 2016) Patellofemoral symptoms 135 needed to be rated at a minimum of three (out of a maximum of 10) using a 136 numerical rating scale (NRS). Potential participants with patellofemoral instability, 137 previous surgery, tibiofemoral pathology or any pathology (musculoskeletal or 138 otherwise) that precluded running participation were excluded.

139

### 140 Experimental Protocol

141 Included participants were required to present to the Human Performance 142 Laboratory at Queen Mary University of London. In the presence of bilateral 143 symptoms, the knee that scored highest on the numerical rating scale was analysed. 144 In the presence of equivocal symptoms, the dominant limb that would be used to 145 kick a ball was analysed. (Willy, et al., 2012) Both limbs were not entered into the

146 analysis in the presence of bilateral symptoms given the potential for type I error. 147 (Menz, 2005) Prior to data collection, participants completed the Kujala Scale as a 148 subjective measure of function. (Kujala, et al., 1993) The Kujala Scale is a 13-question 149 appraisal of subjective function in those with PFP, with a score of 100 representing 150 no symptoms and a score of 0 indicating complete disability. Participants were also 151 required to rate their average and worst pain in the past week from 0 to 10 using an 152 NRS. Whilst there is no definitive outcome measure for use with a PFP cohort, the 153 NRS and Kujala Scale are reported to be the most valid and responsive measures for 154 detecting change at time of study commencement. (Crossley, Bennell, Cowan, & 155 Green, 2004)

156

### 157 <u>Kinematic Measures</u>

158 Participant movement data were collected during running using a four-camera, 159 infrared motion analysis system (CX-1, Codamotion, Charnwood Dynamics Limited, 160 Leicestershire, UK). (Lack, et al., 2014) 24 infrared markers, consisting of eight 161 individual markers and four rigid clusters of four markers, were placed on standard pelvic and lower limb anatomical landmarks using the CAST protocol. (Cappello, 162 163 Cappozzo, La Palombara, Lucchetti, & Leardini, 1997) Markers from the pelvis frame 164 to the knee joint centre tracked the thigh segment and markers from the knee joint 165 centre to the ankle joint centre tracked the shank segment. Individual markers were 166 applied using double-sided adhesive tape and secured with transparent surgical 167 tape, with the rigid clusters applied using adjustable elastic straps and secured with 168 cohesive self-adherent bandage. Virtual markers were also identified on the femoral 169 epicondyles and the ankle malleoli, to allow for the calculation of relevant joint

170 centers during an upright standing trial. The hip joint centre was estimated as a 171 projection within the pelvis frame using the methods described by Bell et al (Bell, 172 Pedersen, & Brand, 1990) and did not vary between male and female subjects. The 173 knee joint centre was estimated as the mid-point between the femoral epicondyle 174 markers.

175

176 Participants were asked to run in their usual running shoes and self-select their 177 typical 'steady state' running speed on the laboratory treadmill (Kistler Gaitway, 178 Kistler Group, Winterthur, Switzerland). Participants were instructed to run for a 179 total of three kilometers (KM), with the option to cease if symptoms increased to 180 four or greater on the NRS. 10 seconds of data sampled at 200Hz were collected at 181 0.8/1.8/2.8KM, with distance as opposed to time chosen to act as a constant 182 measure across a cohort of participants running at differing speeds. Multiple data 183 collections were completed to increase reliability of gait analysis. (Monaghan, 184 Delahunt, & Caulfield, 2007) Based on between group differences identified in our 185 recent meta-analysis, (Neal, et al., 2016) variables of interest included peak hip 186 adduction, internal rotation and flexion, peak knee flexion and contralateral pelvic 187 drop, given their retrospective association with PFP.

188

### 189 <u>Electromyography Measures</u>

Surface muscle electromyography (sEMG) were collected simultaneously with the kinematic data using a wireless Delsys TRIGNO system (DELSYS Inc., Natick, Massachusetts, USA). Prior to application, participant's skin was marked, shaved and cleaned with an alcohol swab. Self-contained bipolar electrodes were placed at the

194 motor points of the Gluteus Maximus (GMAX), Gluteus Medius (GMED), 195 Semitendinosus (ST) and Vastus Medialis Obliqus (VMO) adhering to SENIAM 196 guidelines. (Hermens, Freriks, Disselhorst-Klug, & Rau, 2000) 10 seconds of sEMG 197 data sampled at 1926Hz were collected at three specific distance points as described 198 above, but were not synchronised to the kinematic data.

199

#### 200 <u>Running Retraining Intervention</u>

201 Participants completed 18 retraining sessions over the course of six weeks. Each 202 week involved a total of three individual runs, equating to 18 runs in total. For the 203 first four weeks, the initial run was completed in a supervised fashion with the 204 primary investigator (BSN). During the retraining sessions, participants were cued via 205 an audio metronome set at 7.5% above their baseline step rate (calculated during 206 data acquisition), based on the previous work of Willy et al (Willy, et al., 2015). The 207 additional two runs each week were completed independently. A faded feedback 208 protocol successfully used previously was adopted. (Noehren, et al., 2011; Willy, et 209 al., 2012) Feedback exposure was gradually reduced and treadmill run time was 210 gradually increased from 10 minutes to 30 minutes (see figure 1), to facilitate skill 211 acquisition. A slower progression from 10-30 minutes was used (18 sessions over six 212 weeks) compared to previous work (8-10 sessions over two to four weeks), to better 213 adhere to contemporary training progression approaches. (Gabbett, 2016) Further, 214 this pace of progression is used clinically in the chosen recruitment centre, 215 minimising ethical issues from varying usual care. For the final two weeks, all 216 completed sessions were performed independently, without any metronome

217 feedback. All data were collected prior to, and after completion of, the running



218 retraining intervention.

219

Figure 1: running retraining schedule depicting the faded feedback protocol employed.

- 222
- 223

## 224 Kinematic Data Analysis

225 Data were analysed offline using a custom written Matlab program (version 2015, 226 Mathworks, Natick, Massachussets, USA). Initial foot contact and toe off were 227 identified using the heel marker on the calcaneal tuberosity and the metatarsal 228 marker on the fifth metatarsal head in the vertical (Z) plane. Consistent with 229 previously described methods, initial foot contact was defined as the point at which 230 the heel marker ceased its descent in the vertical plane. (Zeni, Richards, & Higginson, 231 2008) Toe off was identified using a combination of the heel and metatarsal markers. 232 Specifically, peak acceleration of the metatarsal marker was identified within a 233 specific time point defined by the 70% or greater of the absolute maximum velocity 234 region of the heel marker. (Zeni, et al., 2008) All kinematic data were aligned to 235 initial foot contact, interpolated and normalised to percentage of stride cycle (0% =

236	initial contact, 100% = terminal stance) to facilitate data analysis. Clinical relevance
237	of kinematic data was interpreted with reference to the minimum detectable change
238	data reported by Noehren et al. (Noehren, Manal, & Davis, 2010)

239

#### 240 <u>sEMG Data Analysis</u>

241 sEMG data were processed using an in-built band-pass filter from 25-500 Hz. Raw 242 sEMG data were decomposed using wavelets. (Reaz, Hussain, & Mohd-Yasin, 2006) 243 Post-wavelet decomposition, data were cut into strides using the mean total wavelet 244 power of the VMO muscle, as the typical activation pattern of this muscle 245 (onset/offset) during running is known to align closely to the initial contact (onset) 246 and toe off (offset) phases of running gait. (Flynn & Soutas-Little, 1993) These stride 247 cycle timings were then applied to all sEMG data. Pre and post retraining data were 248 cut into strides independently, but were not used to describe sEMG data as though it 249 were synchronised to the true kinematic gait cycle of the participant. As participants 250 are unlikely to reach signal intensity akin to maximal voluntary isometric contraction 251 (MVIC) during steady state running, data were normalised to the mean of the peak 252 dynamic signal intensity across a single set of strides (0.8KM trial, pre-retraining), 253 which has been reported to be more valid than normalizing to maximal dynamic 254 signal peak. (Bolgla & Uhl, 2007)

255

#### 256 Statistical Analysis

All statistical testing were performed offline using Microsoft Excel (Microsoft Corporation, Albuquerque, New Mexico, USA). A Cohen's *d* was calculated to determine the size of all identified interactions, alongside the reporting of mean

differences and 95% confidence intervals (CI). Cohen's *d* was interpreted as small ( $\leq$  0.2), medium (>0.5) and large (>0.8) respectively. (Sullivan & Feinn, 2012) As a feasibility study, not powered apriori to detect statistical significance, dependent sample *t-tests* were not performed and p-values for differences not reported because of the potential for type II error and to avoid giving the impression of there being robust findings from a feasibility study design. The main outcomes were those of recruitment, retention and measurement feasibility.

<u>RESULTS</u>

268

A total of 10 (out of 11) participants (four male, six female) completed the study. One female participant was lost to follow up due to a switch of care provision to the National Health Service. Demographics and baseline characteristics of the participants who completed the study are described in table 1.

273

274 <u>Table 1</u>

Variable	Mean (SD)
Sex (Male/Female)	4/6
Age (Years)	31.6 (5.5)
Height (cm)	170.6 (7.8)
Mass (kg)	67.7 (9.8)
Symptom duration (Months)	45.1 (32.1)
Average run volume (KM)	17.0 (9.8)
Step rate (SPM)	163.6 (4.7)
Kujala scale	86.4/100 (6.9)
Average NRS	3.0/10 (1.6)
Worst NRS	6.8/10 (1.5)

275 Participant characteristics

276 Key: cm=centimeters; kg=kilograms; KM=kilometers; SPM=steps per minute;

277 NRS=numerical rating scale.

278

280 <u>Effects</u>

Large reductions in both average (d=1.7) and worst (d=2.0) pain were identified postretraining. The mean difference (MD) of these reductions was 2.1 and 3.9 NRS points respectively and individual participant worst pain responses to the retraining intervention ranged from 1 to 8 NRS points (see figure 2). A modest improvement in function measured with the Kujala Scale was also identified (d=0.12), with a mean difference of 4.4 points.



287

Figure 2: mean pooled and individual worst pain responses at baseline (pre) and six weeks follow up (post).

290

291 <u>Mechanisms</u>

292 Spatiotemporal

293 An increase in running step rate at six weeks follow up was observed, with a mean

increase of 7.8% (range 2.3% - 11.1%). 3 participants did not achieve a step rate of ≥

295 7.5% post retraining.

296

## 297 Kinematics

298 One participant was found to have consistently corrupted marker data throughout 299 their trials and was therefore removed from the kinematic analysis. This resulted in a 300 kinematic sample of nine participants (five females, four males). Moderate 301 reductions in both peak knee flexion (MD= $3.7^\circ$ , d=0.78) (see figure 4a) and peak hip 302 adduction (MD=2.4°, d=0.54) (see figure 4b) were identified post-retraining. A large 303 reduction in peak hip internal rotation was also identified post retraining (MD=5.1°, 304 d=0.96) (see figure 4c). A full breakdown of the kinematic analysis can be seen in 305 table 2 and individual participant spatiotemporal and kinematic responses in relation 306 to average/worst pain at six-week follow up are presented in table 3.



Figure 4a: mean pattern of hip knee flexion throughout stance at baseline (pre) and six week follow up (post). Knee flexion is positive. Solid line = mean. Dashed line = 95% confidence intervals.





Figure 4b: mean pattern of hip adduction throughout stance at baseline (pre) and six
week follow up (post). Hip adduction is positive. Solid line = mean. Dashed line = 95%
confidence intervals.



Figure 4c: mean pattern of hip internal rotation throughout stance at baseline (pre)
and six week follow up (post). Hip internal rotation is positive. Solid line = mean.
Dashed line = 95% confidence intervals.

319

## 320 <u>Table 2</u>

Variable	Variable Pre Post		Mean Difference	95% CI	Cohen's d
	Mean (SD)	Mean (SD)			
Average Pain	3.0/10 (1.6)	0.90/10 (0.9)	2.1 (*)	0.88, 3.32	1.7
Worst Pain	6.8/10 (1.5)	2.9/10 (2.3)	3.9 (*)	2.08, 5.72	2.0
Kujala Scale	86.4/100 (6.9)	90.8/100 (5.4)	4.4	-10.22, 1.42	0.1
Peak KFLEX	36.2° (5.3)	32.5° (4.2)	3.7°	-1.08, 8.48	0.78
Peak HFLEX	26.7° (9.3)	23.1° (4.9)	3.6°	-3.83, 11.03	0.51
Peak HADD	15.6° (3.5)	13.2° (5.4)	2.4°	-2.15, 6.95	0.54
Peak CLPD	4.3° (2.7)	2.8° (2.4)	1.5°	-1.05, 4.05	0.59
Peak HIR	9.1° (7.7)	4.0° (2.9)	5.1° (*)	-0.71, 10.91	0.96

321 Pre and post retraining means, standard deviations, mean differences, 95%322 confidence intervals and effect sizes

323

324 Key: (\*)=mean difference exceeds MDC; SD=standard deviation; CI=confidence

interval; HADD=hip adduction; HIR=hip internal rotation; CLPD=contralateral pelvic
 drop; KFLEX= knee flexion; HFLEX= hip flexion.

	Tal	ble	3
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Participant	Peak	Peak	Peak HIR	Peak	Baseline	Step Rate %	Average	Worst
	KFLEX at	HADD at	at Follow	KFLEX at	Step Rate	Increase	Pain at	Pain at
	Follow	Follow	Up	Follow Up			Follow Up	Follow Up
	Up	Up					(x/10)	(x/10)
1	¥	¥	↓???	¥	160	11.1%	1	6
2	♥???	♦???	↓???	▶???	172	2.3%	2	5
3	¥	♦???	↓???	$\bullet$	168	7.7%	0	0
4	▶???	♥???	▶???	▶???	164	8.9%	0	3
5	¥	<b>↑</b> ???	↓???	¥	168	7.7%	0	0
6	¥	♦???	1	¥	164	8.9%	2	2
7	1	1	↓???	1	164	5.7%	0	0
8	▶???	♥???	1	♥???	158	10.2%	1	4
9	1	¥	<b>↑</b> ???	1	158	6.0%	2	4

Individual participant kinematic, spatiotemporal and symptom responses to retraining

Key: (\*)=difference exceeds MDC; HADD=hip adduction; HIR=hip internal rotation; KFLEX=knee flexion; A-NRS= average pain; W-NRS=worst pain.

328 sEMG

329 One participant was found to have consistently corrupted sensor data throughout 330 their trials and was therefore removed from the sEMG analysis. This resulted in a 331 sEMG sample of 9 participants (6 females, 3 males). A mean of peak muscle 332 amplitudes, in addition to an integral (amplitude x duration) of each decomposed 333 signal were calculated for each muscle pre and post retraining. For mean amplitude, 334 minimal changes post-retraining were identified for GMAX (d=0.02), GMED (d=0.07) 335 and ST (*d*=0.05). However, for VMO, an increase in mean amplitude was observed 336 post-retraining, associated with a medium effect size (d=0.53, 95% CI -0.09, 0.03). 337 For muscle integral, a similar interaction was identified, with minimal changes seen 338 post-retraining for GMAX (d=0.04), GMED (d=0.04) and ST (d=0.09). For VMO, an 339 increase was observed, associated with a medium effect size (d=0.58, 95% CI -0.06, 340 0.02).

DISCUSSION

The results of this study suggest that a faded feedback protocol to increase running step rate by 7.5%, is feasible in a clinical setting. A mixed sex cohort was successfully recruited and a low dropout rate (n=1) was achieved. Furthermore, potential clinically relevant changes in both average and worst pain were identified postretraining, suggesting that the intervention has potential efficacy and warrants further appraisal in an adequately powered RCT.

349

350 The mean reductions in both average and worst pain seen within this study are 351 smaller than those identified by previous running retraining studies, (Noehren, et al., 352 2011; Roper, et al., 2016; Willy, et al., 2012) although no inference on average or 353 worst pain as individual outcomes were made by these studies and the feedback 354 employed was different. Further, both this feasibility study and the referenced works 355 were essentially underpowered for all but the most preliminary of conclusions. 356 When analysing the reductions in worst pain from this study, only 3/10 participants 357 were asymptomatic at six-week follow up and just one participant had pain  $\leq 3/10$ . 358 This means that the 6 remaining participants would continue to be eligible for 359 inclusion into a clinical trial using currently accepted criteria, (Crossley, et al., 2016) 360 meaning that the intervention could be defined as unsuccessful in 60% of our cohort 361 if using worst pain as the primary outcome.

362

A recent high quality RCT identified that a 7.5% step rate increase, with the option of transitioning to a forefoot strike pattern if deemed necessary, was no more effective than comparative education or exercise interventions. (Esculier, et al., 2017) When

342

366 comparing the symptom reductions achieved in this study (6 week follow up) to the 367 relevant time point in the Esculier et al RCT (8 week follow up), (Esculier, et al., 2017) 368 both average and worst VAS are comparable for our step rate intervention compared 369 to all 3 intervention groups (education, exercise plus education, running retraining 370 plus education). It could be suggested that running retraining is in fact a form of load 371 management or graded exposure, which may explain why it was found to be no 372 more effective than education on training loads by Esculier et al. (Esculier, et al., 373 2017) However, Roper et al (Roper, et al., 2016) reported efficacy of retraining from 374 rearfoot to forefoot strike running. Importantly, this retraining strategy produced larger pain reductions when delivered using a faded feedback protocol, over and 375 376 above an equivocal progressive duration running protocol. This suggests that a form 377 of feedback is required over and above a load management intervention where 378 there is a clinical need. A further potential explanation for the more modest 379 symptom responses to step rate retraining reported by Esculier et al, (Esculier, et al., 380 2017) is that feedback is likely to have needed to be subject or subgroup specific 381 and not all participants will have a baseline step rate amenable to an increase.

382

Previous studies on running retraining have established a potential kinematic mechanism at the hip to explain their positive effects, specifically a 5° reduction in peak hip adduction. (Noehren, et al., 2011; Willy, et al., 2012) The results of this study are in line with this, identifying a smaller but still clinically meaningful mean difference of 2.4° that was associated with a moderate effect size (Table 2). Our mixed-sex sample could explain this smaller mean difference, as the previous work of both Noehren et al (Noehren, et al., 2011) and Willy et al (Willy, et al., 2012)

390 purposefully recruited female participants with higher than average peak hip 391 adduction, which may be more amenable to change. However, as our results have 392 identified a reduction in peak hip adduction equivalent to a previous 7.5% step rate 393 increase study in asymptomatic runners, (Willy, et al., 2015) it is suggested that a 394 larger increase in step rate (10%) will result in greater reductions in peak hip 395 adduction equivalent to those seen in asymptomatic runners (Heiderscheit, et al., 396 2011). A 10% step rate increase is known to reduce both patellofemoral joint stress 397 (Willson, et al., 2014) and pain (Bonacci, et al., 2017) in runners with PFP, whereas a 398 7.5% step rate increase (Esculier, et al., 2017) resulted in non-significant changes in 399 both peak patellofemoral reaction force and average patellofemoral loading rate in a 400 recent RCT. Clinically, it may be sensible to start retraining with a more modest 7.5% 401 step rate increase, increasing to 10% or greater if tolerated, especially in those with 402 low baseline step rate.

403

404 In addition to reducing peak hip adduction, the results of this study have identified 405 two novel potential kinematic mechanisms, being a reduction in both peak hip 406 internal rotation and knee flexion. The identified mean difference in peak hip 407 internal rotation of 5.1° is above the MDC of 3.7° reported by Noehren et 408 al (Noehren, et al., 2010) and was associated with a large effect size (d=0.96). Peak 409 hip internal rotation is associated with running related PFP (Neal, et al., 2016) and 410 can result in increased patellofemoral joint stress by increasing contact pressures at the lateral patellar facet. (Salsich & Perman, 2007) Thus, given the plausibility for 411 412 reducing hip internal rotation during running gait to favourably alter PFP symptoms

413 and the size of the identified effect, one could argue that a clinically meaningful414 change has been identified.

415

A reduction in peak knee flexion of 3.7° is in line with the work of Lenhart et al, 416 417 (Lenhart, Thelen, Wille, Chumanov, & Heiderscheit, 2014) who reported a reduction 418 in peak knee flexion of 3.3° with a 10% step rate increase in a normative cohort. 419 Within this musculoskeletal model, (Lenhart, et al., 2014) peak knee flexion 420 correlates positively with patellofemoral joint force, indicating this finding may be 421 clinically relevant. This effect is likely due to changes in patella contact pressures, as 422 a subsequent modeling study reports that lateral patellar arthrokinematics were not 423 significantly altered by a 10% step rate increase. (Lenhart, et al., 2015) At an 424 individual level, kinematic changes seem to correlate poorly with symptom 425 improvements post-step rate retraining (see table 3). For example, two participants 426 (one male, one female) had an increased peak hip adduction post-retraining (see 427 table 3), with both participants asymptomatic for both average and worst pain 428 variables. For the female participant, the increase in peak hip adduction (6.6°) 429 exceeds the MDIC  $(2.6^{\circ})$  and is thus less likely to be related to measurement error. 430 Future studies should look to investigate alternative potential mechanisms of 431 running retraining, such as kinetic changes, load management or graded exposure.

432

Previous observational research investigating increasing step rate by 10% has
identified increased quadriceps activation (Chumanov, Wille, Michalski, &
Heiderscheit, 2012) comparable to the increase seen within this study. VMO activity
is known to be altered in some individuals with PFP (Chester, et al., 2008) and VMO

weakness is reported to correlate with lateral patella shift. (Sakai, Luo, Rand, & An,
2000) Whilst this study design prohibits inference of causality, this sEMG finding may
be associated with the reduction in pain seen post-retraining.

440

441 The lack of change in mean gluteal EMG identified by this study is perhaps not 442 surprising given the work of Willson et al, (Willson, et al., 2011) who report no 443 differences in mean gluteal sEMG when comparing female runners with PFP to 444 matched controls. Willson et al (Willson, et al., 2011) do however report that female 445 runners with PFP demonstrate a shorter GMED activation window and delayed onset 446 prior to foot contact in females with PFP. Additionally, Willy & Davis (Willy & Davis, 447 2013) reported earlier GMED activation and an increased GMED activation duration 448 in a small case series of 2 female runners with PFP post-mirror running retraining. 449 Combined with findings from our study, this indicates that changes to gluteal muscle 450 activation patterns rather than magnitude may provide mechanistic explanation for 451 the reduction in pain. Further research is needed to explore this and a limitation of 452 the current study is the fact that the sEMG were not synchronised to the kinematic 453 system, meaning not all variables of interest from the previous literature could be 454 investigated.

455

### 456 Future Directions

457 Based on the results of this feasibility study, a future RCT should look to compare a 458 step rate intervention against an exercise therapy control and investigation of effects 459 to long-term follow up (~12 months) is advocated. Future work on running retraining 460 should seek to use a faded feedback protocol, as it appears to result in superior

outcomes. Recruitment of participants with a step rate of <160 (>1 SD below the mean of this cohort) who are more likely to be amenable to step rate retraining or stratifying outcome analysis by baseline cadence is worth considering – a strategy that would require greater samples but produce more generalisable findings. Subgroup analysis by baseline kinematic variables associated with PFP such as hip adduction may also be indicated, though kinematic variables do not appear to be sensitive to predicting those who may respond to a step rate intervention.

468

469 Whilst this feasibility trial was not powered apriori to investigate these effects, a 470 post-hoc calculation using the mean difference of both average and worst pain 471 revealed that a sample of 10 participants is adequate to investigate symptom 472 changes post-step rate retraining with adequate statistical power ( $\alpha$ =0.05,  $\beta$ =0.20). It 473 is therefore advisable that future trials adhere to the so-called rule of 10, recruiting 474 10 participants per individual variable investigated to minimize risk of bias (Peduzzi, 475 Concato, Kemper, Holford, & Feinstein, 1996) 10% of the biomechanical data in this 476 study was lost due to data corruption and it is advisable that this be factored in to any sample size calculation for mechanistic outcomes in future studies. 477

478

Comparing the results of this study to the previous work on running retraining proved challenging given the heterogeneity of pain outcomes collected. It is advisable that future work collects data on both average/usual and worst/running related symptoms to allow for more clinically meaningful comparisons. The mean difference in the Kujala scale identified falls well below the accepted MCID of 10 points (Crossley, et al., 2004) and given the high baseline scores seen in the

485	population studied, a ceiling effect can be suggested. Future studies are advised to
486	consider an alternative measure of subjective function, with the lower extremity
487	functional scale (LEFS), used by previous studies, (Noehren, et al., 2011; Willy, et al.,
488	2012) and the recently developed patellofemoral subscale of the Knee Osteoarthritis
489	Outcome Score (KOOS), (Crossley, Macri, Cowan, Collins, & Roos, 2017) particularly
490	worthy of consideration.

492	CONCLUSION
493	The results of this study confirm that increasing running step rate using a faded-
494	feedback protocol is a feasible and effective intervention for use in a mixed sex UK
495	cohort. Future studies should focus on investigating the long-term efficacy of
496	running retraining in a cohort that have a clear treatment target (i.e. low step rate),
497	compared to an appropriate control. A sample size of ten participants per
498	group/variable is adequate to detect minimum clinically important differences with
499	adequate statistical power. In addition to future work establishing efficacy,
500	exploration of both forms of feedback and treatment mechanisms is encouraged.
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# (1) Conflict of Interest

The authors declare that they have no conflicts of interest in relation to this study.

# (2) Ethical Approval

Ethical approval was sought and subsequently granted by the Queen Mary Ethics of Research Committee (QMREC2014/63)

## (3) Funding

This project was part funded by the Private Physiotherapy Education Foundation Scheme A1 novice researcher grant (EMRG1E8R) awarded to the lead author. The funding body played no role in the study design, data collection, data analysis and interpretation, the writing of the report or the decision to submit the article for publication.