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1	1	Effect of time on biomechanical measures during exercise on the
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25 Effect of time on biomechanics during exercise on the Functional

Re-adaptive Exercise Device

28 Abstract

Mechanistic studies of the Functional Re-adaptive Exercise Device (FRED) have shown it automatically recruits Lumbar Multifidus (LM) and Transversus Abdominis (TrA) - two deep-spinal muscles that are atrophied and show altered motor control in low back pain (LBP). No studies have investigated the time required to familiarise to FRED exercise, which is required to inform future FRED based clinical trial protocols. This study therefore determined the effect of time, during FRED exercise, on biomechanical outcome measures, to establish the familiarisation period, and assess for loss of technique throughout a ten minute trial. A cohort comparison study of 148 participants, 70 experiencing low back pain, had lumbopelvic kinematics, exercise frequency and movement variability measured during a 10 minute trial. Magnitude-based inference was used to assess for familiarisation, using plots of variation over time with familiarised reference ranges. The no pain group took 170 seconds, and the back pain group took 150 seconds, to familiarise. A familiarisation period of at least 170 seconds (2.8 minutes) is recommended. This justifies, and provides a familiarisation time for use of the FRED as a motor control intervention.

Keywords: Motor control, spinal rehabilitation, Lumbar Multifidus, Transversus
47 Abdominis

Manuscript metrics: Abstract words: 181. Main text (Introduction through the
49 discussion) words: 3415. References: 30. Tables: 2. Figures: 1.

50 Introduction

51	Low back pain (LBP) costs over £1billion per year (NICE, 2009) in addition
52	to psychosocial challenges, creating a need for low cost and effective treatments.
53	While LBP is multifactorial(Panjabi, 2006), spinal robustness at an inter-segmental
54	level (Panjabi, 1992a, 1992b) and changes in spinal mechanics (Panjabi, 2006) are
55	commonly reported elements. An adequate level of spinal robustness is required to
56	ensure static and dynamic stability of the spine with robustness referring to both
57	stability and how the spine, muscles and motor control system cope with
58	disturbances such as a perturbation (Reeves, Narendra, & Cholewicki, 2008). The
59	Lumbar Multifidus muscle (LM) provides segmental stiffness (Kiefer, Shirazi-Adl,
60	& Parnianpur, 1998; Panjabi, 1992a) and controls lumbar lordosis(Claus, Hides,
61	Moseley, & Hodges, 2009) while the Transversus Abdominis muscle (TrA) provides
62	segmental robustness by increasing intra-abdominal pressure (J. Hides, Stanton,
63	Mendis, & Sexton, 2011b; Hodges, 2004). Dysfunction and atrophy of both muscles
64	has been linked with a lack of spinal robustness and therefore LBP (J. Hides,
65	Lambrecht, Stanton, & Damann, 2015; J. Hides, et al., 2011b; Hodges and Moseley,
66	2003; Saunders, Coppieters, & Hodges, 2004; Wallwork, Stanton, Freke, & Hides,
67	2009). It is often difficult for individuals to voluntarily recruit these muscles,
68	especially LM(Van, Hides, & Richardson, 2006), which is a challenge for
69	rehabilitation.
70	Recently, the Functional Re-adaptive Exercise Device (FRED), that aims to
71	target recruitment of the LM and TrA muscles, has undergone mechanistic
72	investigations to assess its potential as an intervention for LBP and determine future
73	clinical trial protocol parameters (Caplan, Gibbon, Hibbs, & Debuse, 2014; Debuse,
74	Birch, Gibson, & Caplan, 2013; Gibbon, Debuse, & Caplan, 2013). Exercise on the
	3
	52 53 54 55 56 57 58 59 60 61 62 63 64 63 64 65 66 67 68 69 70 71 72 73

75	FRED involves a combination of weight-bearing, an unstable base of support (at the
76	feet) and an upright posture with a robust lumbo-pelvic region during functional
77	lower-limb cyclical motion at a slow target speed. The FRED is similar to an
78	elliptical trainer but with no resistance and a requirement to perform the movement
79	with minimal variability in movement speed. A more detailed description of the
80	movement on FRED and determination of target exercise speed, with images, is
81	available elsewhere (2017c). Recent studies of FRED exercise shows it
82	automatically recruits both LM and TrA (Debuse, et al., 2013; Winnard, et al.,
83	2017c) through a tonic contraction (Caplan, et al., 2014) with no conscious input, as
84	well increasing spinal robustness (Gibbon, et al., 2013) and placing the spine into a
85	more optimal position for LM and TrA activity compared to walking, which is a
86	similar upright functional exercise (Winnard, D., Wilkinson, Tahmosybayat, & N.,
87	2017b). These studies have justified clinical trials of FRED as an intervention for
88	LBP.
89	To date, FRED studies have included exercise familiarisation periods of two
90	to three minutes (Debuse, et al., 2013), or five minutes (Caplan, et al., 2014; Gibbon,
91	et al., 2013; Winnard, D., et al., 2017b; Winnard, et al., 2017c). These
92	familiarisation periods, however, have not been determined objectively. As a final
93	stage of the mechanistic studies, before a clinical trial, it was necessary to determine
94	the time required to familiarise to FRED exercise in terms of pelvic and spinal
95	kinematics, exercise frequency and movement variability. The same familiarisation
96	time could also be used clinically, should the device prove useful from clinical trials,
97	without clinicians having to rely on arbitrary or trial and error derived familiarisation
98	periods. The aim of this study was therefore determined the effect of time, during

- 99 FRED exercise, on biomechanical outcome measures, to establish the familiarisation
- 100 period, and assess for loss of technique throughout a ten minute trial.

103 Methods

104	The study protocol was approved by the Northumbria University ethics
105	committee. Participants provided written informed consent before participating.
106	One hundred and forty eight participants were recruited from the general public, with
107	a mean (±SD) age, height and mass of 36.7 (±9.0) years, 1.72 (±0.09) m, and 77.8
108	(± 17.5) kg, respectively. The study was conducted fully open to the general public
109	at a local science museum in Newcastle-Upon-Tyne as part of a "Meet the Scientist"
110	interactive exhibit and the general public visiting the museum over a four week
111	period were able to choose to take part in the study. Exclusion criteria included
112	being aged under 18 or over 55 years, having a history of neuromusculoskeletal
113	problems or injuries resulting in scoliosis or inability to exercise safely on the
114	FRED, being pregnant, having heart disease and having had abdominal or spinal
115	surgery in the last three years. In addition, four participants' kinematic data and
116	seven participants' FRED data were excluded due to technical errors with data not
117	having been recorded for them. All participants were required to pass the Physical
118	Activity Readiness Questionnaire prior to testing. Using the same method as earlier
119	FRED studies (Winnard, D., et al., 2017b), all participants were divided into two
120	groups for comparison, those with and those without back pain. This was done by
121	asking participants "how much back pain have you had in the past 4 weeks?"
122	(modified question 7 of the Short Form-36 (SF-36), standard, US version 2
123	(QualityMetric, 2000)). Participants indicated their pain score, ranging from 1 (no
124	pain) to 6 (very severe pain). Low-back pain scores of 2 or more designated
125	participants as having back pain for analysis. There were 78 participants who
126	reported no back pain, and 70 who reported at least very mild back pain.
127	

Protocol

129	Six hundred seconds of kinematic, exercise frequency and foot-movement
130	variability data were simultaneously collected during FRED exercise from the
131	moment participants began exercising on the device. Participants were first time
132	FRED users and did not undertake a pre-exercise familiarisation period. Explanation
133	was given of the visual feedback which the device provides to help users maintain a
134	target frequency of 0.42 Hz that produces a slow movement consistent across all
135	participants and FRED studies. The target frequency was designed to force users to
136	exercise in a slow and smooth movement, that is expected to me more useful than
137	fast or jerky movements, for promoting core stability and spinal robustness (details
138	published in previous paper (Winnard, et al., 2017c)). The foot movement amplitude
139	can be adjusted on the FRED and for this study was set to the smallest amplitude
140	(0.2 m) for all participants. The smallest amplitude setting was selected as it
141	considered to be the easiest setting for the first time users and is in line with our
142	other studies (Winnard, et al., 2017c; Winnard, Debuse, Wilkinson, Tahmosybayat,
143	& Caplan, 2017b).

Outcome measures

Lumbopelvic kinematics were assessed by measuring sagittal plane joint
angles at L5/S1, L3/L4, T12/L1 and T8/T9 and pelvic tilt. These measures are
relevant to LM and TrA training, as they provide an estimate of full lumbar lordosis,
lower thoracic kyphosis and sagittal plane pelvic tilt and were the same as those
measured in a previous study (2017b). Current clinical LM and TrA training aims to
promote and maintain lumbar lordosis within the lumbar spine (O'Sullivan et al.,
2006; Roussouly, Gollogly, Berthonnaud, & Dimnet, 2005) as LM controls the

153	lumbar lordosis (Claus, et al., 2009). Kinematics were assessed using a wearable-
154	motion-capture system (MVN, XSens, Enschede). The system consists of a series of
155	motion tracking devices placed at key locations within a wearable suit that was
156	placed over a single layer of participant's clothing, who wore t-shirt and trousers, in
157	line with published guidelines (Roetenberg, Luinge, & Slycke, 2013) and our
158	previous study methods (Winnard, D., et al., 2017b). Seventeen sensors containing a
159	3D gyroscope, 3D accelerometer and a magnetometer, were secured to the hands,
160	forearms, upper arms, head, scapulae, pelvis, upper legs, lower legs and feet. An
161	image of the exact tracker locations is available elsewhere (2017b). Participants
162	were required to remove footwear throughout the trials to prevent any confounding
163	effect of footwear design. Full body kinematic data were collected at 80 Hz, using
164	the default full body model and Kinematic Coupling Algorithm (KiC) fusion engine
165	setting. Local magnetic interference can cause drift over prolonged use of this
166	system, so the magnetometer input was disabled to minimise drift errors. For
167	modelling the spinal segments, data is taken from the sacrum, sternum, scapulae and
168	head trackers. The spine is divided into segments with joints estimating movements
169	at L5S1, L3L4, L1T12 and T9T8. The movements of these joints were estimated by
170	the software using interpolation between the trackers. This is the default setup
171	recommended by the XSens user manual, which states these segment definitions
172	match International Society of Biomechanics recommendations (XSens, 2012). Data
173	from the trackers is used to displace the default spinal model. The displacement
174	movement is divided across several segment joints based on a stiffness assigned to
175	each segment within the software.
176	

The Xsens system was reported as having up to two degrees of error for dynamic accuracy in roll, pitch and heading linked to centre of mass and pelvic tilt data, and an angular resolution for joint angle estimation of 0.05 degrees (Lebel, Boissy, Hamel, & Duval, 2015). The system has been validated against the gold standard VICON 3D system for measuring kinematic data (Roetenberg, et al., 2013) and shown to have good correlation with optical motion capture systems for estimated 3D kinematics at the L5S1 level (Faber, Chang, Kingma, Dennerlein, & van Dieen, 2016). Exercise frequency and foot movement variability were assessed using a rotary encoder built into the FRED (RP6010, ifm Electronic GmbH, Essen, Germany). Frequency was calculated as the number of crank cycles per second (Hz). Movement variability was quantified as the difference (%) between the instantaneous-angular velocity of movement and the mean-angular velocity over the previous second. This was recorded as a negative change if the live velocity was decreasing and positive if it was increasing. Movement variability data were made absolute for analysis, meaning a high movement variability value indicated uneven movement while a movement variability of zero represented perfectly even movement (i.e. constant angular velocity of the feet). The frequency and movement variability data were recorded at 5 Hz on a second PC, running custom software. This sampling rate was the fastest the FRED hardware and software was able to record. The frequency and movement variability data was collected over the same time period as the Xsens data. The data were imported into Microsoft Excel 2010

- 200 for analysis.

Data analysis:

Familiarisation time was defined as the time at which participants first achieved
correct technique after movement initiation. Correct FRED exercise technique
requires upright posture and a relatively stable lumbopelvic region, during slow and
controlled cyclical-functional movements of the lower limbs (Debuse, et al., 2013).
Poor exercise technique may therefore be defined as variation beyond the amount
measured during a period of familiarised exercise.

The mean and standard error of the mean (SEM), across each participant was calculated for every data point for both groups, as used in previous biomechanical familiarisation studies (Moore and Dixon, 2014). The mean \pm SEM range was plotted as a function of time for flexion angle at L5/S1, L4/L3, L1/T12, T8/T9, anterior pelvic tilt, exercise frequency and movement variability. To enable clear analysis, without losing the overall pattern, several filtering options were assessed. The smallest moving average which reduced noise sufficiently to allow clear analysis to be made was selected. A moving average filter was therefore selected for each variable with a time window of 2.5 seconds before and after each data point. All data appeared to have plateaued, indicating familiarisation, by 2.5 minutes and remained stable until at least 4.5 minutes, showing no loss of technique occurred within this period. Therefore the mean between 2.5 and 4.5 minutes was used as a familiarised reference. The familiarised reference mean \pm the mean SEM of each measure between 2.5 and 4.5 minutes was plotted as a familiarisation reference range based on the likely range of the true mean. Familiarisation was estimated to be the point (to the nearest 5 second interval) at which the mean \pm SEM

across all participants fully entered into the familiarisation reference range for each
variable. Any variables that crossed over the familiarised region, before the 2.5
minute point and continued to fluctuate while still overlapping the familiarised
range and before reaching an obvious plateau were not considered familiarised until
fluctuations decreased and the plateau was reached.

Magnitude based inference (MBI) was used to determine if the mean difference before and after the familiarisation point was at least as large as the familiarised reference SEM. Magnitude based inference has recently been proved a trustworthy alternative to traditional significance testing and outperforms in sample size, error rates and publication bias (W. G. Hopkins and Batterham, 2016). For all estimated points, the mean difference, 90% confidence intervals and probabilities (%) that the true values of the statistic were mechanistically positive, trivial or negative based on the smallest worthwhile change (familiarisation reference SEM) were reported and qualitatively defined by the following scale recommended by Hopkins, et al. (2008) as <0.5% is "most unlikely", <5% is "very unlikely", <25% is "unlikely", 25-75% is "possible", >75% is "likely", >95% is "very likely", and >99.5% is "most likely". All inferences which were at least likely (>75%) were highlighted using bold text in the results. Full raw data sets are available from the authors on request.

Results

Table 1 presents the pain and no pain group demographics. The group
demographics and any differences found with MBI are, therefore, presented taking
these exclusions into account. Any differences between the groups were *trivial*.

232	
253	Figure 1 illustrates the mean \pm SEM for L5/S1 kinematics as an example
254	variable, throughout the 600 second trials, compared to the familiarised reference
255	ranges, in both the pain and no pain groups. All other familiarisation figures can be
256	requested as supplementary data from the authors. The reference familiarisation
257	ranges are marked with horizontal dashed lines on the plots and any estimated
258	familiarisation points by vertical dotted lines. Table 2 presents the raw change in
259	mean and 90% confidence limits of each measure, before and after the estimated
260	familiarisation and loss of technique points, and MBI.
261	
262	All flexion angles were familiarised by 40 seconds, in the no pain group and
263	45 seconds in the pain group, and flexion decreased during the familiarisation period
264	in both groups. Table 2 shows it was <i>likely</i> that flexion angles were positive in both
265	groups before the estimated familiarisation point, compared to afterwards.
266	
267	Pelvic tilt appeared familiarised by 105 seconds in the no pain group and 110
268	seconds in the pain group, decreasing during the familiarisation period in the no pain
269	group and increasing in the pain group. However, Table 2 shows that it was unlikely
270	that anterior pelvic tilt was positive before the familiarisation point in the no pain
271	group and unlikely negative before familiarisation in the pain group, compared to
272	afterwards. The mean pelvic tilt data always overlapped the familiarised range and
273	so familiarisation was estimated to be the point of plateau within the range.
274	
275	Exercise frequency was familiarised by 70 seconds in the no pain group and
276	15 seconds in the pain group. Frequency decreased during the familiarisation period
	12

in the no pain group and increased in the pain group. Table 2 shows it was *likely* that
frequency was positive before the estimated 70 second familiarisation point in the no
pain group, compared to afterwards. However, it was only *possible* that frequency
was negative before the 15 second estimated familiarisation point in the pain group,
compared to afterwards. The mean pelvic frequency always overlaps the
familiarised range and so familiarisation was estimated to be the point of plateau
within the range.

Movement variability was familiarised by 130 seconds of exercise in the no pain group and 155 seconds in the pain group. Movement variability decreased during the familiarisation period in both the no pain and pain groups. Table 2 shows that before the estimated 130 and 150 familiarisation points, in the no pain and pain groups respectively, movement variability was *most likely* positive, compared to afterwards.

Discussion

The main finding of this study was that it took up to 170 seconds to familiarise to FRED exercise in the no pain group and up to 150 seconds in the pain group. Spinal positioning was the first element to familiarise in both groups. Spinal positioning started in a more flexed position and gradually extended at all measured angles during familiarisation. This agrees with a previous study of 130 participants that showed FRED promotes extension in the lower portion of the spine compared to walking (Winnard, D., et al., 2017b). Exercise frequency increased in the no pain group and decreased in the pain group, while movement variability gradually decreased in both groups, throughout familiarisation. No *likely* mechanistic change

in pelvic tilt orientation occurred throughout the 600 second trials. Previous research
(Gibbon, et al., 2013) and the reference data both showed that FRED exercise places
the pelvis into increased anterior tilt compared to walking, and so it appears from
this study that the shift in pelvic tilt occurs immediately on initiating exercise.

It is known that the LM and TrA muscles are active in a more tonic pattern during FRED exercise than walking(Caplan, et al., 2014), and more active than at rest(Debuse, et al., 2013). It is also known that LM has a role in spinal positioning, with increasing activity when the lumbar spine extends into a lordotic curve below the thoracolumbar junction (Claus, et al., 2009; O'Sullivan, et al., 2006; Roussouly, et al., 2005). As spinal posture is the first element to familiarise it is reasonable to imply that the LM muscle is likely to be active by 40 seconds of exercise in those without, and by 45 seconds in those with, back pain. The remaining familiarisation time then appears to be taken up by attempting to reach an even paced global movement pattern at the target frequency. In the no pain group, movement variability familiarised by 130 seconds followed by exercise frequency at 170 seconds. This suggests that device users focus first on achieving an even movement followed by reaching the correct frequency. However, those with back pain had no *likely* frequency familiarisation time suggesting they were able to reach the target frequency from initiating movement. The target frequency provided by the feedback was 0.42 Hz as per the rationale explained in Winnard et al.(2017c) and it is felt that users are familiarised once they are able to exercise close to this frequency with low movement variability. The familiarised frequency ranges were found to be 0.48±0.01 Hz for the no-LBP group and 0.50±0.01 Hz for the LBP group. The no-LBP group were, therefore, able to exercise closer to the target frequency, whereas

the LBP group had a frequency that was 0.12 Hz faster. This finding might suggest that those with no back LBP had better motor control. If so, this could be an indication of the FRED being a potentially useful intervention to improve motor control but this needs testing in clinical trials. Additionally, despite the much quicker frequency familiarisation time which led to a faster overall familiarisation time, the LBP group took 20 seconds longer to develop familiarised movement variability. As people with LBP often have reduced motor control of deep lumbopelvic muscles such as LM (J. A. Hides, Stokes, Jull, & Cooper, 1994; Hodges and Moseley, 2003; Panjabi, 2006) it is unsurprising that they took more time to develop the motor control required to refine the movement, and showed reduced ability to reach the target exercise frequency. This finding therefore adds to the justification of a clinical trial of the FRED as an intervention for challenging and training lumbopelvic motor control in LBP patients to test this possibility. Only six participants indicated experiencing severe or very severe pain. Therefore, the back pain results are mostly representative of populations with very mild to moderate back pain and should be treated with caution in populations with severe or worse pain. The back pain group does not necessarily represent a group that would all benefit from spinal motor control rehabilitation. For first time users of the FRED, it took 170 seconds to familiarise to the exercise in terms of pelvic and spinal kinematics, exercise frequency and movement variability, while overall familiarisation occurred 20 seconds earlier in participants

352	with back pain as they moved at the slow target frequency from the start of exercise.
353	Those with back pain took 20 seconds longer to achieve a consistent movement
354	pattern, probably due to reduced motor control, and demonstrated less ability to
355	modulate exercise frequency, suggesting the intervention might be useful as a motor
356	control intervention. Therefore, it is recommended that future FRED activites
357	include a familiarisation period of at least 170 seconds to allow correct lumbopelvic
358	positioning and control of the movement to be reached.
359	
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465	Figure captions
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467	Figure 1. Mean L5/S1 flexion angle across all participants throughout the 600 second
	trial in; a. the no pain group and b. the pain group. Familiarisation range shown on
	plots between dashed lines is no pain group: 2.7 ± 0.3 , pain group: 3.4 ± 0.3 (degrees).
	pious between dashed files is no pain group. 2.7±0.5, pain group. 5.+±0.5 (degrees).
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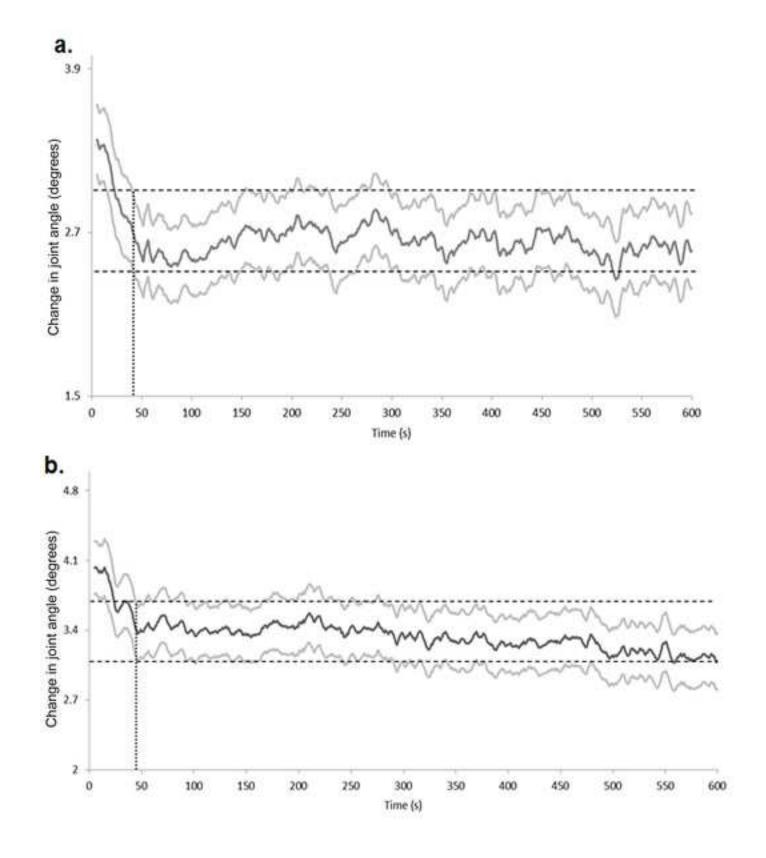


Table 1

		Gender	Age	Mass	Height	
	n	(M/F)	(years)	(kg)	(m)	BMI
Kinematic data						
All participants	144	73/71	36.5	77.8	1.72	26.3
Back pain	67	33/34	37.6	80.3	1.72	27.1
No pain	77	40/37	35.7	75.6	1.72	25.6
Chance (%) that difference between pain						
and no pain groups	s trivial		100	97	100	100
FRED data						
All participants	141	71/70	36.8	78.4	1.72	26.3
Back pain	67	33/34	37.6	81.1	1.72	27.2
No pain	74	38/36	36.1	75.9	1.72	25.6
Chance (%) that diff	ference bet	ween pain				
and no pain groups i	s trivial		100	94	100	98

Table 1. Group demographics and chance that any group differences are trivial using an inference threshold of 0.6 standardised mean change.

Group	Comparison time	Raw	90% confidence		Mechanistic
	point	change	limits		inference
L5/S1 flexion angle. Inference threshold: 0.3 degrees no pain and pain group					
No pain	40 s	0.4	0.6	0.2	Likely +ve
Pain	45 s	0.4	0.6	0.2	Likely +ve
L3/L4 flexion angle. Inference threshold: 0.1 degrees no pain and pain group					
No pain	40 s	0.2	0.3	0.1	Likely +ve
Pain	45 s	0.2	0.3	0.1	Likely +ve
T12/L1 flexion angle. Inference threshold: 0.1 degrees no pain and pain group					
No pain	40 s	0.2	0.3	0.1	Likely +ve
Pain	45 s	0.2	0.3	0.1	Likely +ve
T8/T9 flexion angle. Inference threshold: 0.1 degrees no pain and pain group					
No pain	40 s	0.1	0.2	0.0	Likely +ve
Pain	45 s	0.2	0.2	0.1	Likely +ve
Anterior pelvic tilt. Inference threshold: 0.1 degrees no pain and pain group					
No pain	105 s	0.4	0.4	0.0	Unlikely +ve
Pain	110 s	-0.4	0.1	-0.9	Unlikely -ve
Exercise frequency. Inference threshold: 0.014 Hz no pain and pain group					
No pain	170 s	-2.4	-1.5	-3.3	Very likely -ve
Pain	15 s	1.7	4.0	-0.7	Possibly +ve
Movement variability. Inference threshold: 1.5% no pain and 1.6% pain group					
No pain	130 s	4.2	4.8	3.6	Most likely +ve
Pain	155 s	3.2	3.6	2.7	Most likely +ve

Table 2. Differences in L5/S1. L3/L4, T12/S1 and T8/T9 flexion angles, pelvic tilt, exercise frequency and movement variability pre and post familiarisation point.

Threshold for inferences using mean SEM between 2.5 and 4.5 minutes is indicated in table. All raw change and confidence limits are in degrees.