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information services gwasanaethau gwybodaeth Immediate effect of a spinal mobilisation intervention on muscle stiffness, tone and elasticity in subjects with lower back pain – A randomized cross-over trial.

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Background: Despite the lack of objective evidence, spinal manual therapies have been common practice for many years, particularly for treatment of lower back pain (LBP). This exploratory study measured and analysed the effect of a spinal mobilisation intervention on muscle tissue quality in LBP sufferers.

Methods: 40 people with LBP participated in a within-subject repeated measures cross-over study with intervention and control conditions. A myometer was used to assess the change in para-spinal muscle tissue quality before and after the intervention. Analysis considered the magnitude of muscle response together with individual covariates as potential contributors.

Results: A significant post intervention reduction was observed in muscle stiffness (p = 0.012, $\eta^2_{partial} = 0.15$), tone (p = 0.001, $\eta^2_{partial} = 0.25$) and elasticity (p = 0.001, $\eta^2_{partial} = 0.24$). Significant increases were seen in 2 variables post control: stiffness (p = 0.004, $\eta^2_{partial} = 0.19$), tone (p = 0.006, $\eta^2_{partial} = 0.18$) and a significant decrease in elasticity (p < 0.000, $\eta^2_{partial} = 0.3$). Significant contributing covariates include baseline stiffness, BMI, waist circumference and sex. Baseline stiffness and tone were significantly correlated to their response levels.

Conclusions: The significant reduction in all muscle tissue qualities following the intervention provide preliminary data for an evidence-based LBP therapeutic. Baseline stiffness, BMI, waist circumference and sex could act as significant contributors to magnitude of response. The results warrant further investigation into spinal mobilisation therapies to further build the objective evidence base.

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1 Introduction

2

Lower back pain (LBP) is one of the most common and economically debilitating pain 3 4 conditions globally. It is associated with decreased levels of spinal mobility, limited lumbar 5 muscle flexibility and altered spinal kinematics (Ferreira et al., 2009; Goertz et al., 2016; 6 Powers et al., 2008). The likely result of this, is reduced function of the lumbar spine and 7 increased stiffness. This can have an impact on body movement capability and lead to the 8 development of chronic problems with posture, coordination and range of motion (RoM) 9 (Shum et al., 2013, 2007). Manual therapy (MT) is a physical-based therapeutic reportedly 10 used for LBP treatment which targets musculoskeletal structures through several different 11 techniques (Bishop et al., 2015). Commonly reported benefits from MT-based techniques are 12 improvements in RoM, pain relief and muscle stiffness. However, these are often subjectively assessed (Ferreira et al., 2009; George et al., 2006; Lopez-Lopez et al., 2015) with both positive 13 14 (Chiradejnant et al., 2003; George et al., 2006; Haas et al., 2014; Sterling et al., 2001) and 15 conflicting results (Assendelft et al., 2003; Childs et al., 2004; Goodsell et al., 2000; Stamos-16 Papastamos et al., 2011; Thomson et al., 2009). These inconsistencies may be explained by 17 methodological differences as well as variability in individual responses to treatment (Childs 18 et al., 2004; Shum et al., 2013). Further, although commonly used in clinical practice to treat 19 musculoskeletal pain, there is limited understanding of the mechanisms responsible for the 20 reported benefits of MT (Goertz et al., 2016; Voogt et al., 2015). The rationale to establish the efficacy of such treatments is supported by the National Institute of Clinical Excellence, given 21 22 their low risk of minor side effects and potential millions in economic savings (Carnes et al., 23 2010; National Institute for Health and Care Excellence, 2016; Powers et al., 2008; Stamos-24 Papastamos et al., 2011; Wong et al., 2016).

25

Spinal mobilisations is a MT technique used to treat such chronic pain (Chiradejnant et al., 2003; Goodsell et al., 2000; Sterling et al., 2001; Thomson et al., 2009), typically applied in a precise manner, using low velocity oscillatory movements to mobilise joints and passively stretch soft tissues (Maitland et al., 2013; Piekarz and Perry, 2015). While objective research on the efficacy of spinal mobilisations as an LBP treatment has been conducted in recent years, more efficacy based evidence is needed (Piekarz and Perry, 2016), and a better
understanding of the response to such treatment is required.

33

34 Nonetheless, lower back muscle stiffness appears to be a meaningful contributor to reduced 35 mobility and has seen a growth in investigative literature (Edgecombe et al., 2013; Ferreira et 36 al., 2009). However, information about other aspects of muscle quality that collectively 37 contribute to mobility are lacking but are required to aid improved muscle condition understanding (Kelly et al., 2018; Marusiak et al., 2012; Nair et al., 2016). The capacity of a 38 39 muscle to resist deformation, either by contraction or external force can be objectively 40 measured using a myometer to show stiffness or compliance. A muscle with higher stiffness 41 has a higher resistance to contraction (Viir et al., 2006). Muscle stiffness can be assessed by 42 palpation as well as characterised biomechanically. Muscle tone characterises the 43 background tension of the muscle in a resting state. Background tension is required to retain 44 stability, structure, and involuntary contractions. However, hypertonicity can cause high 45 intramuscular pressure and have a harmful effect on muscle recovery. Elasticity of a muscle describes its ability to return to original shape after deformation and can be a used as a 46 47 measure for mechanical stability and tissue changes (Kelly et al., 2018; Schneider et al., 2014). 48 In this study we seek to measure these tissue property changes to contribute to the 49 knowledge of the effectiveness of spinal mobilisation in people with LBP (Kelly et al., 2018; 50 Nair et al., 2016).

51

This study was an exploratory investigation of MT response and potential contributing factors. We measured the change in stiffness, tone and elasticity in response to a spinal mobilisation intervention within an LBP population to provide objective data for this. This is the first scientific investigation of a 30-minute sustained spinal mobilisation intervention and objective measures of muscular change. This is to provide a contribution to knowledge on MT effectiveness and their beneficial mechanisms within LBP and provide recommendations for further data collection to improve understanding.

59

We hypothesised that a reduction in paraspinal muscular stiffness and tone and increase in
elasticity after receiving a spinal mobilisation intervention could be objectively identified with
a validated protocol when compared to a sedentary scenario.

63 Methods

64 <u>Participants</u>

40 participants were recruited for this study (male: n = 18, female: n = 22) in a repeatedmeasures cross-over study design, similar to previous investigations (Goodsell et al., 2000; Jowsey and Perry, 2010; Pecos-Martín et al., 2017; Pentelka et al., 2012). Participants were recruited through posters and word of mouth advertised at Edinburgh Napier University and shared on social media.

70

71 Inclusion criteria for participation were: age range 18 to 80 and suffering from any form of 72 self-reported LBP (acute, chronic, diagnosed, undiagnosed, if pain was experienced in the region between the 12th rib and the gluteal folds within the time of recruitment). Participants 73 74 were excluded if they responded positively to any absolute contraindications for spinal 75 therapy (Liebenson, 2007; Olson, 2009). These include: segment instability, infectious 76 disease, osteomyelitis, bone tumours, neurological deficit, upper motor neuron lesion, spinal 77 cord damage, or cervical arterial dysfunction. Participants responding positively to relative 78 contra-indications were asked to contact their GP and excluded based on severity. These 79 include: osteoporosis, spinal instability, rheumatoid arthritis, inflammatory disease, active 80 history of cancer, hypermobile syndrome, segment hypermobility, cardiovascular disease, 81 cervical anomalies, nerve root disorder, spinal surgery, respiratory problems, thrombosis, 82 open wounds, local infection and fractures or dislocations (Maitland et al., 2013). Ethical 83 approval was obtained from the Edinburgh Napier University Research Integrity Committee, 84 following the ethical guidelines stated by the Declaration of Helsinki.

85

86 <u>Procedure</u>

Participants attended a control and a spinal mobilisation intervention session one week apart,
at the same time of day for each session. All participants were informed about study details
and provided written consent. Participants were randomly allocated into one of two groups
via a random group generator, alternating the order of session type they received. All data
collection took place in the same treatment room and on the same standard physiotherapy
plinth. Ambient room temperature was controlled (20°-23° Celsius) for all sessions.

94 All participants completed the Oswestry Disability Index (ODI) (Fairbank and Pynsent, 2000) 95 prior to their first session to categorise their level of LBP (Chou and Huffman, 2007; Fritz et 96 al., 2011; Kamali and Shokri, 2012; Savigny P Watson P, Underwood M, Ritchie G, Cotterell 97 M, Hill D, Browne N, Buchanan E, Coffey P, Dixon P, Drummond C, Flanagan M, Greenough, C, 98 Griffiths M, Halliday-Bell J, Hettinga D, Vogel S, Walsh D., 2009). Anthropometric measures of 99 height, mass, waist circumference and sex were also recorded. These were taken as pre-100 measures to investigate correlations as potential influencers on response and focus on muscle 101 tissue response as the main investigation.

102

103 The chartered physiotherapist performing the treatment had extensive experience in spinal 104 mobilisation therapy and as a working physiotherapist in practice at the time of the study. 105 They performed a 30-minute spinal mobilisation intervention, working at a specific rate 106 (0.37Hz) maintained by a metronome (on silent but within view of the therapist) set to the 107 equivalent 22 beats per minute. The physiotherapist worked at a grade lower than grade 1 108 and specific location (L1-L5), using posteroanterior (PA) mobilisations, oscillating the lumbar 109 vertebra, with both hands working on one side of the lumbar spine. Contact remained 110 consistent over the 30-minute period. These intervention parameters were based on previous 111 physiotherapy practice with anecdotal evidence of success within LBP. The intervention was 112 focussed on the lumbar spine to facilitate data collection.

113

Outcome measures for muscle stiffness, tone and elasticity were taken immediately before and after both sessions, with participants lying prone. The intervention was performed on one side of the lumbar spine (determined by pre-intervention stiffness values). The control session involved no physical touch. The participant lay on the plinth and was encouraged to relax for 30 minutes. The outcome measures were taken by the lead researcher who was not involved in performing the intervention but was there to oversee the session.

120

121 Outcome measures

Measurements for para-spinal muscle stiffness, tone and elasticity were taken using a myometer palpation device (MyotonPRO, Myoton Ltd., London UK). This previously validated handheld device has been documented to give reliable results for muscle stiffness, tone and elasticity (Bizzini and Mannion, 2003; Marusiak et al., 2012; Pruyn et al., 2015; Schneider et

al., 2014; Sohirad et al., 2017; Zinder and Padua, 2011). The myometer uses a series of low
force mechanical impulses (0.4N) registered as an oscillation in the form of an acceleration
signal. The muscle quality parameters are reported as a mean of these impulses along with
the coefficient of variation (CV), with recommended CV acceptance values of <3% (Kelly et al.,
2018; Schneider et al., 2014; Viir et al., 2006).

131

132 Measures were repeated 3 times on each side of the spine, to determine which side had higher levels of stiffness and therefore the side to receive treatment. This was due to 133 134 literature suggesting that greater initial stiffness levels were more likely to respond with a 135 greater stiffness reduction (Childs et al., 2004; Shum et al., 2013). The location for 136 measurements were identified on both sides of the spine on a central point of the erector 137 spinae by asking the participant to lift their head and feet at the same time contracting their 138 back muscles. This spot was then marked to ensure pre- and post-measures were taken at the 139 same location. The distance and width from the base of the spine was measured to locate the same spot for their 2nd session. The myometer was held perpendicular to the identified spot 140 141 and oscillations were sent through to the corresponding muscle.

142

143 <u>Analysis</u>

144 Analysis was exploratory and therefore carried out on each dependent variable (stiffness, 145 tone and elasticity) in separate 2-way repeated measure within participant ANOVAs to 146 determine any significant differences that occurred due to the independent variables; condition (control and intervention) and time (pre- and post-). Covariates were assessed in 147 separate ANCOVAs to determine significant factors contributing to muscle changes. Due to 148 149 previously reported differences in male and female muscle characteristics (Granata et al., 150 2002; Owens et al., 2007), the sex variable was investigated further with independent t-tests 151 and Pearson correlations, as well as within the ANCOVA analysis. All statistical analysis was 152 carried out using SPSS (version 23) with the alpha level set at 0.05.

153 Results

Pre- intervention anthropometric measures and ODI scores presented in table 1 for 40 LBP
 participants and demonstrate a wide LBP population recruitment. Shapiro Wilk tests revealed

- no normality violations in the dependent variable results. A post-hoc power calculation using
 G-power (version 3.1) revealed an accepted power level of 0.91 (alpha = 0.05, sample size =
 40, groups = 2, measurements = 3).
- 159

160 <u>Muscle stiffness</u>

A 2-way repeated measures ANOVA revealed a pre- to post- intervention significant main effect interaction (between condition and time). Pairwise comparisons were used to determine where specific differences lie in a pre- to post- comparison, revealing a significant stiffness increase within the control and a significant decrease within the intervention (table 2, fig. 1).

166

167 ANCOVA was performed using all covariates to explore their interaction with the change in 168 stiffness post intervention. Change in stiffness was used as the dependent variable. Pre 169 intervention stiffness, BMI, ODI, waist circumference, height and sex were added as 170 covariates. A backward elimination was conducted based on highest p-value. The only 171 covariate remaining with significant influence was pre-intervention stiffness (p = 0.002) with resultant model $R^2 = 0.22$ (adjusted = 0.2). There was a significant bivariate correlation 172 173 between pre intervention stiffness and change in stiffness (table 3). This results in a negative 174 correlation due to the reduction in stiffness seen in figure 1.

175

An independent t-test revealed a significant difference between male and female intervention stiffness change (p = 0.032). Bivariate correlations for pre-intervention stiffness and stiffness change carried out separately with male and female data displayed similar trends (table 3).

180

181 <u>Muscle tone</u>

A 2-way repeated measures ANOVA revealed a pre- to post- intervention significant main effect on muscle tone (condition) and the interaction (between condition and time). Pairwise comparisons revealed a significant tone increase within the control group and a significant tone decrease within the intervention group (table 2, fig. 2).

ANCOVA was performed using muscle tone as the dependent variable run in the same way as above. BMI (p = 0.048), waist circumference (p = 0.01) and sex (p = 0.005) were found to be significant contributors to tone change with resultant model R² = 0.253 (adjusted = 0.19). There was a significant bivariate correlation between pre intervention tone and change of tone (table 3), resulting in a negative correlation due to the reduction in tone (fig. 2).

192

An independent t-test revealed no significant difference between male and female tone change (p =0.052). Bivariate correlations for pre intervention tone and tone change conducted separately with male and female data show different patterns (table 3).

196

197 <u>Muscle elasticity</u>

A 2-way repeated measures ANOVA revealed a pre- to post- intervention significant main effect on muscle elasticity (time). Pairwise comparisons revealed a significant increase in muscle logarithmic decrement within the control from pre- to post-intervention and a significant increase within the intervention condition (table 2, fig. 3). This equates to a decrease in muscle elasticity due to its inversely proportional relationship to muscle decrement.

204

ANCOVA was performed using changes in elasticity as the dependent variable, in the same way as above. There were no covariates with a significant influence on decrement change. A bivariate correlation between pre-intervention decrement in elasticity and decrement change was not significant (table 3).

209

An independent t-test revealed no significant difference between male and female elasticity change (p = 0.162) and bivariate correlations for pre intervention decrement in elasticity and decrement change conducted for male and female data displayed no pattern (table 3).

213 Discussion

The previously reported benefits of MT range from reduced pain, stiffness, fatigue and improved RoM (Ferreira et al., 2009; Lopez-Lopez et al., 2015; Voogt et al., 2015). Greater knowledge of the mechanistic changes occurring due to MT will benefit LBP management and

inform treatment recommendations. The findings from this study suggest that a reduction in
lower back para-spinal stiffness can be measured after a 30-minute treatment session and
could be determined by initial stiffness levels. These results are an indication of an immediate
effect on muscle tissue quality after this specific 30-minute spinal mobilisation treatment.
However, differences in specific clinical practices should be taken into consideration for the
application of results.

223

224 We show for the first time an immediate, objective and significant reduction in para-spinal 225 stiffness with a large effect size (table 2) after a 30-minute spinal mobilisation treatment (fig. 226 1), supported by previous literature (Ferreira et al., 2009; Fritz et al., 2011; Shum et al., 2013; 227 Wong et al., 2015). However, large SEM values could have resulted from the exploratory 228 nature of the study and the wide recruitment. This reduces the confidence of the findings; 229 therefore, we recommend this stiffness reduction is investigated further with distinct LBP 230 population groups to achieve more meaningful results. Since stiffness characterises the 231 muscle's ability to resist deformation, and is associated with pain and reduced mobility (Fritz 232 et al., 2011; Haas et al., 2014; Lopez-Lopez et al., 2015; Vicenzino et al., 2001), a reduction in 233 stiffness of these muscles may allow greater compliance to muscle contraction and therefore 234 improve movement fluidity (Ferreira et al., 2009). This study demonstrates the impact of lying 235 stationary for 30 minutes can have on stiffness, reinforcing the recommendation to reduce 236 sedentary behaviour, a known risk factor for developing LBP and chronic stiffness (Hartvigsen 237 et al., 2018; Naraoka et al., 2017).

238

Improved knowledge of muscular stiffness has been identified as crucial to understand 239 240 underlying mechanistic changes in therapeutic interventions and apply them effectively to 241 the populations at most need (Bailey et al., 2013; Kelly et al., 2018). Potential mechanisms 242 responsible have been suggested to involve the activation of somatosensory signals. 243 Mechanical induction of sensory nerves may cause adaptive signalling in the muscle spindles 244 (stretch receptors) affecting muscle fibre ability to respond to changes in shape (Pickar and 245 Bolton, 2012; Reed et al., 2014). Differences between the mechanical induction of muscle 246 stretch response verses an active muscle stretch response could be further investigated in an 247 MT and stretching study to help decipher the benefits of each. Information on significant 248 influencers on stiffness change, such as initial stiffness levels and anthropometric measures,

249 may help to inform these mechanistic theories through predictive modelling in large scale MT250 studies.

251

252 While this exploratory study demonstrates the benefit of a single MT session, there is a lack 253 of statistical power describing the influencing factors and warrants further investigation. The 254 key influence of initial stiffness levels could be further investigated by taking into 255 consideration prior environmental influences on stiffness. As no significant differences were 256 found between the control and intervention condition pre-stiffness levels (fig. 1), it was 257 concluded that the protocol design had been successful in controlling for this. Further studies 258 investigating other stretching and movement related interventions may also contribute 259 insight into mechanistic changes and influencing factors.

260

261 Although the ANCOVA results showed that initial stiffness was a significant contributor to 262 stiffness response (and a significant correlation, table 3), results for sex as a covariate were 263 more complex. Sex did not account for the variance in stiffness within the ANCOVA model 264 and suggests that initial stiffness values have greater influence than sex on stiffness response, 265 supported by similar correlation trends for males and females (table 3). This could be further 266 investigated in a sex comparison study, given the known difference between male and female 267 muscle composition (Granata et al., 2002; Nair et al., 2016; Owens et al., 2007). It is important 268 to note that, while ODI, BMI, waist or height measurements do not contribute to stiffness 269 response, they could still influence the initial stiffness values. Though previous studies have 270 also found similar baseline and stiffness change correlations (Ferreira et al., 2009; Shum et al., 2013) this correlation has not been defined objectively as a clinical predictor for 271 272 intervention response (Fritz et al., 2011; Nim et al., 2020; Wong et al., 2015). The availability 273 of objective measurement tools for muscle health, such as a myometer, will enable 274 monitoring of intervention effectiveness for types of responders, potentially developing 275 stiffness thresholds for responders.

276

Similar results for muscle tone (fig. 2) and stiffness indicate that both variables respond to the intervention in a similar way. Pre- tone measures in the control and intervention conditions were very similar with less variation than pre- stiffness measures. Muscle stiffness and tone depict different aspects of muscle quality. The myometry form of muscle tone describes

resting muscle tension and is mechanically represented by the acceleration frequency of the oscillations induced and recorded. The reduced variation in tone baseline and SEM values compared to stiffness may be explained by its intrinsic nature (required for resting tension) as oppose to responsive (Bizzini and Mannion, 2003; Schneider et al., 2014; Viir et al., 2006).

The ANCOVA results for tone response revealed BMI, waist circumference and sex as 286 287 contributing factors, different to the contributing factors for stiffness response. Comparison 288 of male and female trend lines demonstrated different patterns in their pre-intervention and 289 tone change correlations (table 3) supporting sex as a contributing factor to muscle tone in 290 the ANCOVA model. Though stiffness and tone display similar pattern changes in previous 291 studies (Gervasi et al., 2017; Nair et al., 2016), the resultant difference in contributing factors 292 between them may indicate key underlying differences in their response mechanisms. The 293 electrical signals responsible for muscle tone, though likely still influenced by adaptive 294 signalling, may result in a greater number of influencing factors compared to tissue stiffness. 295

A reduction in both tone and stiffness can be beneficial to populations with chronic pain and limited movement (Chuang et al., 2012; Fröhlich-Zwahlen et al., 2014; Wong et al., 2015). Hypertonia is associated with mobility restrictions and chronic pain in conditions such as stroke and Parkinson's (Fröhlich-Zwahlen et al., 2014). It will therefore benefit clinicians to monitor these variables and relate to functional output in rehabilitative interventions together with changes in their patients' pain.

302

303 Elasticity results show a higher degree of variance compared to stiffness and tone (fig. 3) 304 which is consistent with previous literature (Gervasi et al., 2017; Schneider et al., 2014). An 305 increase in dissipation of mechanical energy (logarithmic decrement) equates to a lower level 306 of elasticity in the muscle and its ability to recover shape after deformation (Bailey et al., 307 2013; Chuang et al., 2012). Both control and intervention conditions resulted in decreased 308 elasticity in this study, suggesting that both stationary relaxing and MT affected the elasticity 309 of para-spinal muscles in a similar way. A similar report (Schneider et al., 2014) found a 310 decrease in stiffness and tone and an increase in decrement after testing muscles in 311 weightlessness conditions. The reason for this is unclear and was suggested to be the result 312 of a relaxed state. The passive nature of the therapy may have resulted in an elasticity

- decrease because of the participant lying still with no active movements. Therefore muscles
 may require active movements to have an improved effect on elasticity and could be explored
- in future studies with MT compared to exercise type therapies to investigate this further.
- 316

317 <u>Limitations and Future Study</u>

The results in reduced muscle stiffness and tone after a 30-minute MT intervention are encouraging. This prospective study has provided promising preliminary data and warrants further investigation to better understand the influencing factors to this muscular response and the mechanisms responsible.

322

Though BMI was measured in this study, this variable does not give an accurate depiction of muscle to fat ratio. Adipose tissue could be beneficial to measure in future studies as a covariate due to potential influence on stiffness results (Fröhlich-Zwahlen et al., 2014). Although the factorial, within-participant analysis should reduce this influence on stiffness due to the relative change within each participant between groups, it would be beneficial to accurately measure and investigate this variable.

329

Increasing the number of participants recruited with higher levels of pain, together with more 330 331 comprehensive methods to rate level of pain and post intervention pain, may assist in the 332 development of this area of research to investigate the relationship between pain and 333 stiffness. Physical activity levels were not controlled in this study and could be a factor in baseline levels of stiffness, tone and elasticity (Nair et al., 2016). Therefore, more 334 investigation into potential lifestyle contributions to pain in LBP could give added information 335 336 about potential influences on spinal stiffness. The previously reported optimum number of 337 treatment sessions has been 12 (Ferreira et al., 2009; Haas et al., 2014), therefore, further 338 investigation into treatment dose and number of sessions would contribute to knowledge on 339 MTs.

340

341 <u>Conclusions</u>

The 30-minute spinal mobilisation intervention had a significant immediate effect on muscle quality showing a stiffness and tone reduction in sufferers of LBP when compared to a control intervention. Initial levels of stiffness contributed to reduction levels post intervention and

there was more variance in contributing factors for tone and elasticity. Although significant differences between male and female stiffness results were found, sex was not a significant contributor to stiffness reduction and likely affected initial baseline levels. Preliminary results show an immediate muscular response after a MT intervention and further study could investigate an accumulated effect after repeated sessions with further explanatory measures.

351 <u>Clinical Relevance</u>

- Findings reported of an exploratory investigation providing new objective evidence of
 a spinal mobilisation intervention.
- Results reveal an immediate reduction in myometry measured muscle stiffness and
 tone with baseline stiffness, waist circumference, BMI and sex as significant
 contributors.
- Objective muscle data provided for an evidence-based contribution towards manual
 therapy treatments.
- 359
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- 361 Lower back pain
- 362 Spinal mobilisations
- 363 Myometry
- 364 Muscle stiffness
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- 371 Declaration of Interest

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- in study design, data collection and analysis.

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