Rehabilitation from Lumbopelvic Deconditioning on Earth and in Space

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Rehabilitation from Lumbopelvic Deconditioning on Earth and in Space

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FRED

i. Abstract

Astronauts experience low back pain (LBP) and heightened spinal injury risk due to lumbopelvic deconditioning following spaceflight. Atrophy and reduced control of the lumbar multifidus (LM) and transversus abdominis (TrA) muscles have been linked with LBP, and are commonly found in astronauts, as well as individuals with LBP in the general population. Many people have difficulty voluntarily recruiting LM and TrA, presenting a rehabilitation challenge. Previously, it was found that LM and TrA are recruited automatically during Functional Readaptive Exercise Device (FRED) exercise, and that the recruitment is tonic, which is the most effective way to train these muscles, suggesting it could be suitable for use post spaceflight and in LBP populations. However, the mechanisms underpinning the effect that FRED exercise has on LM and TrA needed to be investigated before clinical trialling the device to determine:

1. What current interventions are used to prevent or rehabilitate lumbopelvic deconditioning and what are their effects?
2. Do the underlying mechanisms of FRED exercise indicate that it may be a useful intervention to trial in the rehabilitation of lumbopelvic deconditioning resulting from microgravity exposure in astronauts and a sedentary lifestyle in the general population?
3. What are the requirements for a standard and progressive training protocol using the FRED?

Interventions preventing lumbopelvic deconditioning in human spaceflight simulation studies were systematically reviewed regarding effectiveness and future needs. Countermeasures during microgravity exposure were found ineffective for maintaining lumbopelvic health, presenting an immediate rehabilitation need, and future countermeasure refinement within the human

spaceflight community. Rehabilitation to recover lumbar lordosis and train LM and TrA was suggested as beneficial.

Recruitment of the LM and TrA muscles and movement variability was measured during FRED exercise using all available foot movement amplitudes on the device. Both muscles were recruited in all settings, and the challenge to the muscle and movement control was increased in larger amplitudes.

Four chapters measured lumbopelvic kinematics and movement variability. Assessment was made of kinematic effects, the usefulness of FRED generated visual exercise feedback, the exercise familiarisation time and the effect of using the device handle bars in people with and without LBP.

The FRED promotes increased lumbar extension and anterior pelvic tilt compared to over ground walking.

Increasing crank amplitude increased movement variability, ΔTrAmax, ΔLMmax and TrA muscle recruitment. There was more variation away from the target exercise frequency when visual feedback was not provided. It took 170 seconds for asymptomatic individuals to familiarise to FRED exercise and155 for those with LBP. Spinal positioning became more flexed with reduced movement variability when the handles were used during exercise.

There is now sufficient evidence that FRED exercise promotes beneficial lumbopelvic posture and deep muscle activity to justify a clinical trial of the device in astronaut and general deconditioned LBP populations. Following an eighty second familiarisation period, training should begin in the smallest exercise amplitude and increase in one amplitude setting intervals once FRED users can maintain a consistent movement speed, using visual feedback, but without using the handle bars.

Contents

ii. Acknowledgments

The following acknowledgements and thanks are given to those who have made contributions to the work undertaken within this thesis:

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It has been said that a PhD journey can be lonely, however the long list of acknowledgments is evidence that this one involved much companionship and collaboration. A final acknowledgement is made to those who stand to benefit from this work, LBP patients on Earth and those who carry our hopes and aspirations into space.

Ex astris, Scientia. Per aspera per audacia ad astra

iii. Declaration

The work for this thesis was undertaken at Northumbria University and the Newcastle Life Science Centre between October 2013 and July 2016. No material contained in this thesis has been used in any other submission for an academic award. Excepting where clearly identified and referenced, no material contained in this thesis has been published elsewhere (to be edited if works are accepted for publication by submission). All procedures for ethical approval have been followed throughout. Approval has been sought and granted by the Faculty Ethics Committee for all studies included in this thesis. The number of words contained in the thesis excluding table titles, figure legends, reference list and appendices is declared to be 44,396.

Signed: Date:

Andrew J Winnard

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1. Chapter One: Introduction

Physical inactivity and lumbopelvic deconditioning have been linked to increased incidence of non-specific LBP and spinal injury in those exposed to microgravity (e.g. Astronauts and long term bed rest) (Pavy-Le Traon et al. 2007), and in the general population (Verbunt, Smeets and Wittink 2010). Astronauts have been reported to have a 53-68% risk of experiencing moderate to severe LBP during microgravity exposure (Wing et al. 1991) and a four-fold increased risk of herniated intervertebral discs within one year following spaceflight (Johnston et al. 2010). The direct costs of non-specific LBP in the general population was estimated as £1 billion per year (NICE 2009), alongside the human costs of distress, pain, injury, loss of independence and potentially mortality in extreme cases. These costs justify the need to develop evidence based, economical and effective preventative and rehabilitation strategies. Understanding the underlying mechanisms of LBP and spinal changes during microgravity and sedentary lifestyle related deconditioning, and developing an effective rehabilitation programme to address these, is therefore required.

Atrophy and reduced motor control of the LM and TrA muscles resulting from periods of deconditioning is linked to non-specific LBP and spinal injury risk in both post flight astronauts and general populations (Hides et al. 1994; Hodges and Richardson 1996; Hides et al. 2007; Hides et al. 2015). Hides et al. 2016 also highlighted the parallels in muscular adaptation between astronauts and low back pain patients, suggesting LBP patients as a good ground based model for lumbopelvic deconditioning relevant to astronauts. However, voluntary recruitment of these two key muscles is difficult and presents a rehabilitation challenge (Van, Hides and Richardson 2006). A new Functional Readaptive Exercise Device (FRED) is being developed that shows potential to activate the LM and TrA muscles automatically and in a tonic fashion (Debuse et al. 2013; Caplan et al. 2014). This thesis therefore set out to investigate the mechanisms

of the FRED within a lumbopelvic deconditioning and non-specific LBP context, relevant to rehabilitation of both astronaut and general sedentary lifestyle populations.

1.1. How low back pain is linked with segmental spinal stability and upright sagittal spinal motor control

Non-specific LBP is experienced in the lower region of the spine and is not attributable to a known cause or specific pathology such as infection, systemic disease, fracture or cauda equina (Balague et al. 2012). The nature of non-specific LBP makes it complex and often multi factorial in relation to its cause, diagnosis and interventions. This is recognised in the hypothesis of Panjabi (2006), who suggested abnormal spinal mechanics may be a commonly reported factor in back pain patients, but suggests several potential triggers and causes of abnormal mechanics including: inflammation, biochemical and nutritional changes, immunological factors, structural changes in discs and endplates, adverse psycho-social factors and changes in neural structures.

Linked with the common symptom of altered mechanics is atrophy (Hides et al. 2008; Danneels et al. 2000; Hodges et al. 2006; Hodges and Richardson 1996; Ferreira, and Hodges 2004) and altered motor-control (Hodges & Richardson 1996) of the lumbar multifidus (LM) and transversus abdominis (TrA) muscles. Both muscles have a substantial body of evidence linking their dysfunction and atrophy with LBP (Hides et al. 2015; Hides et al. 2011b; Hodges and Moseley 2003; Hodges and Richardson 1996; Macdonald, Moseley and Hodges 2009; Saunders, Coppieters and Hodges 2004; Wallwork et al. 2009) and following microgravity exposure (Hides et al. 2015; Belavy et al. 2015; Evetts 2015; Hides et al. 2007).

1.1.1. Deep and superficial lumbopelvic muscles in spinal stability

The paraspinal muscles can be divided into deep and superficial muscles based on a structural model of the spine provided by Bergmark (1989) who provided the following definitions. Deep muscles all have their origin or insertion at the vertebrae and have an action that includes controlling the curvature and/or structural stiffness of spine. Deep muscles include the LM and TrA muscles. The LM muscle controls and stabilises lumbar lordosis (Claus et al. 2009) during force transfer through the spine (Macintosh et al. 1986; Moseley, Hodges and Gandevia 2002) and provides segmental stiffness (Panjabi 1992a; Kiefer, Shirazi-Adl and Parnianpur 1998). The TrA muscle provides a transverse force, therefore increasing stiffness and extrinsic stability of the spine (Hodges and Richardson 1996) by increasing intra-abdominal pressure (Hodges 2004; Hides et al. 2011b). Superficial muscles control the large spinal movements and transfer loads between the thorax and pelvis, they do not directly increase stiffness or stability of the spine at the segmental level (Bergmark 1989), but can increase global trunk stability (Hodges, Cholewicki and Van Dieen 2013). Superficial muscles include, superficial Erector Spinae, Internal and External Obliques, Rectus Abdominis, Quadratus Lumborum and Psoas. Bergmark (1989) also defined stability in engineering terms, as the ability of a loaded structure to maintain its equilibrium under loading. This definition was then extended to define clinical spinal stability as the ability of the spine, under physiological loads, to limit structural displacement in order to prevent damage to spinal structures including the discs, ligaments and neural structures. The spine gains passive stability from the bones, ligaments, tendons and fascia while it is suggested that active stability is provided by deep muscles (Bergmark 1989). Studies using in vitro cadaveric specimens of human spinal segments found that the specimens became mechanically unstable at loads much less than those experienced by in vivo spines (Panjabi 1992a).

This finding highlighted the importance of the stabilising force provided by the LM and TrA muscles in allowing the spine to function under everyday loading.

1.1.2. Spinal stabilising system and motor control

To achieve spinal stability requires the deep muscles be controlled by precise coordination of deep muscle activation and timing. The complete spinal stabilising system was, therefore, conceptualised by Panjabi (2003) as a neural control element, passive spinal column(and ligaments) and an active system of deep muscles. The control system assesses and directs the deep muscles to provide varying levels of extrinsic stability while the passive elements of the spinal column provide intrinsic stability (Figure 1-1). To successfully provide control, actions are based on feedback from both the active and passive components. Mechanoreceptors in the passive structures indicate levels of force and stress, while feedback on muscle activation patterns and stretch are provided by the active system.

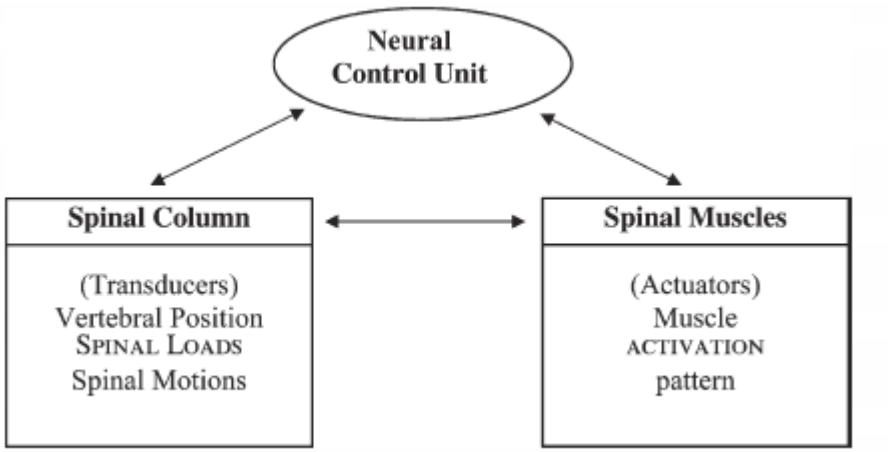


Figure 1-1 The Spinal stabilising system from Panjabi 2003

It is also theorised that once a successful motor control strategy of trunk muscle activiation has been learned, an anticipatory feed forward mechanism of activating an appropriate muscle response pattern ahead of movements can occur (Hodges, Cholewicki and Van Dieen 2013).

1.1.3. Segmental Stability and the Neutral Zone

During dynamic loads into spinal flexion and extension, there is displacement of each vertebra which provides flexibility. At low loads the spine was observed to be highly flexible and then stiffening as loads increased. A neutral zone was defined as the range of segmental displacement within which there is minimal resistance to the displacement (Panjabi 2003). This is represented graphically in Figure 1-2 with the neutral zone being represented by a ball in a bowl. The motion of the ball represents the displacement motion of the vertebral segment, while the steepness of the sides represents varying stability with steeper sides demonstrating increased resistance to displacement.

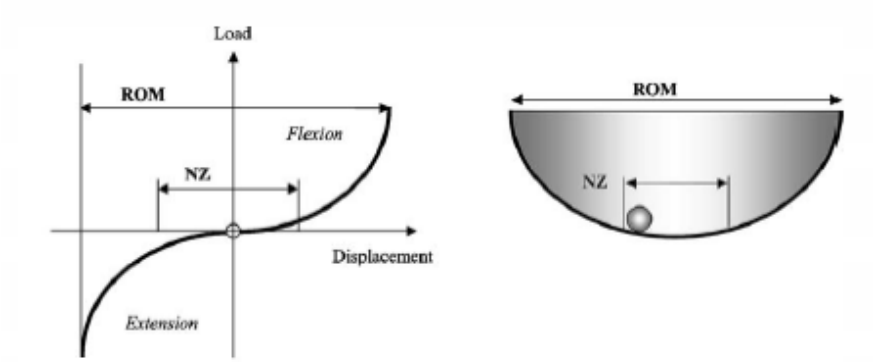


Figure 1-2 Load displacement curve of spinal segments (left) and a visual representation of the neutral zone (right) (Panjabi, 2003)

As segmental spinal stability increases, the neutral zone becomes smaller, demonstrated by placing the ball in a wine glass. As segmental spinal stability decreases the neutral zone gets larger, demonstrated by placing the ball in flat bowl, see Figure 1-3.

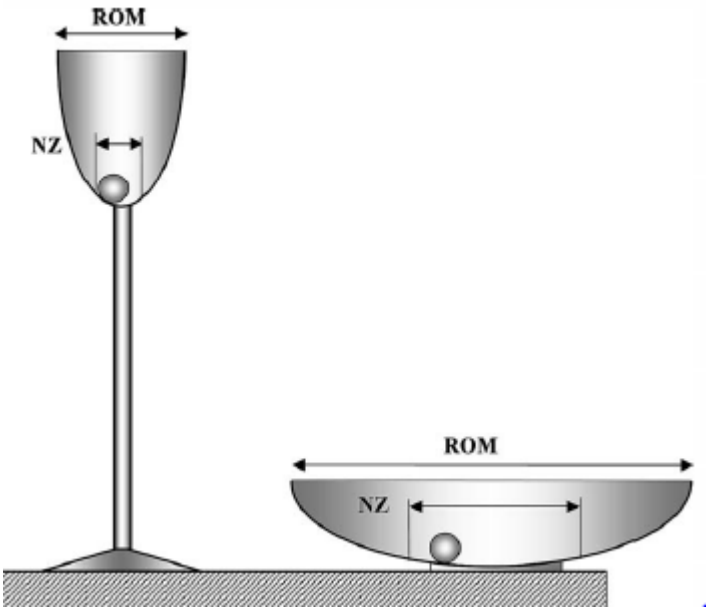


Figure 1-3 Varying degrees of spinal stability and neutral zone size represented using the ball in bowl analogy, high stability on the left, low stability on the right (Panjabi, 2003)

It was hypothesised that decreased stability may be caused either by damage to the passive stability system and/or abnormal activity or control of the active system that leads to a larger neutral zone. An increase in the neutral zone is likely to be associated with increased stress on spinal structures and so result in pain. Therefore, interventions were suggested for unstable painful spines which aimed at reducing the neutral zone through retraining control of the active stability system or through use of spinal fusion (Panjabi 2003). This theory is represented graphically in Figure 1-4, again using the ball in a bowl analogy.

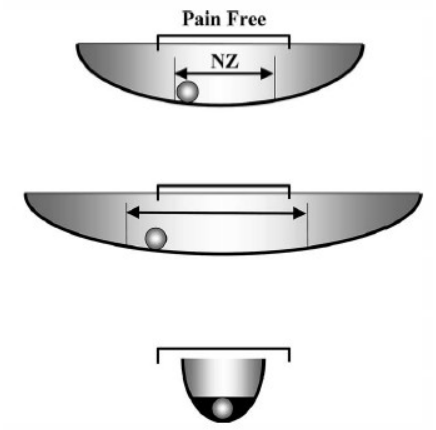


Figure 1-4 Pain free spinal range with neutral zone within pain free range (top), exceeding pain free range (middle) and after stabilising intervention (bottom) (Panjabi, 2003)

1.2. Theory linking low back injury with altered motor control and low back pain

More recently the theory for how LBP starts has been updated. It is still suggested the common feature is altered mechanics but with a deeper explanation for how this may arise. It was summarised by Panjabi (2006) as follows, with graphical representation in Figure 1-5:

1. Initial trauma occurs to spinal structures such as ligaments. This can be either a long term build-up of microtrauma or an acute injury.
2. During dynamic loading of the injured spine, mechanoreceptor signals sent to the neural control system, produced by the injured tissue are now corrupted due to injury.
3. The control unit finds a mismatch between expected signals and those actually being received. This causes control unit output to the active stability system in response to dynamic loading to also become corrupted.
4. Corrupted output from the control unit leads to the changes in the activation of the deep muscles in response to the dynamic load. These changes lead to abnormal activation and timing of the active stabilising deep muscles – LM and TrA. This then causes altered spinal mechanics.
5. Abnormal activation patterns of the deep muscles causes their returning feedback to also become corrupted, causing further mismatch in signals being received by the control unit.
6. Increased corruption of control unit output occurs in response to continued dynamic loading. This has great potential to lead to segmental instability, increased segmental neutral zone and higher stresses on spinal structures.
7. Inflammation of stressed spinal tissues around unstable segments is then likely to occur and nociceptive pain signals produced.

8. If left unchecked chronic non-specific LBP may develop.

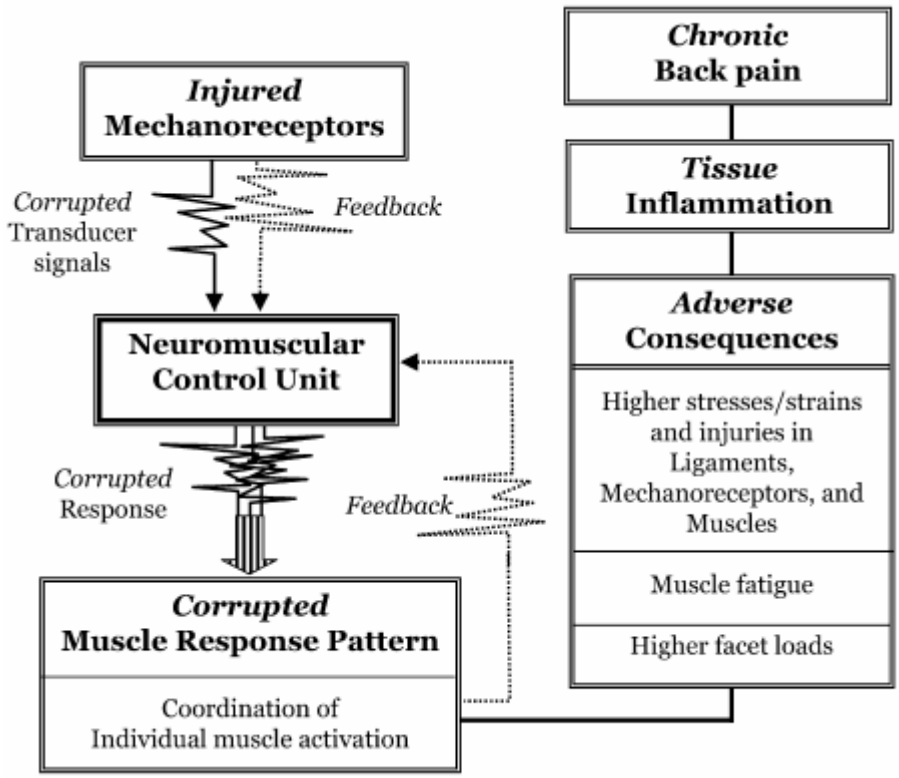


Figure 1-5 Graphical representation of pathway towards chronic back pain (Panjabi, 2003)

A more detailed synthesis of mechanisms and pathways that can lead to muscle changes within the motor control concept by Hodges, Cholewicki and Van Dieen (2013) is also provided in figure 1-6.

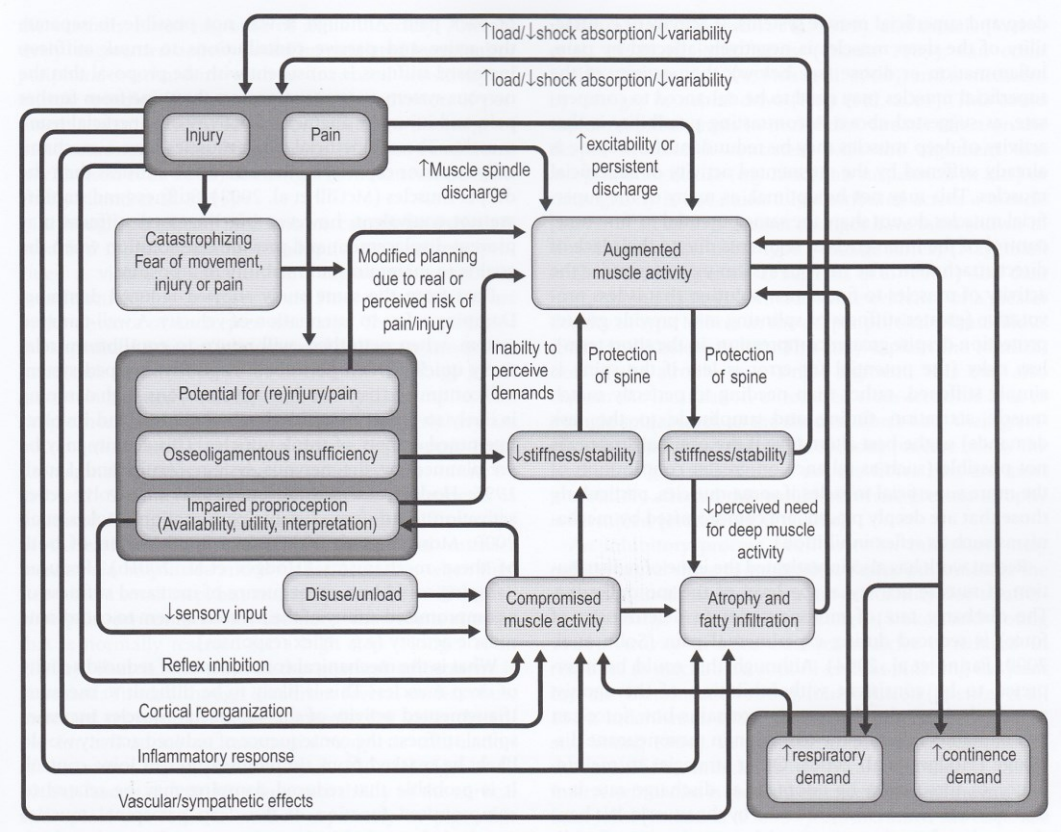


Figure 1-6 A more detailed graphical representation of possible mechanisms for changes in trunk muscles within the motor control concept (Hodges, Cholewicki and Van Dieen 2013)

Evidence supporting these hypotheses exists from several experimental studies. Danneels et al. (2000) did a comparison study of chronic LBP and matched no-LBP participants that found reduced cross sectional area of LM in the lower lumbar spine. In the study, 32 clinical participants were compared to 23 matched no-LBP volunteers and the LM cross sectional area measured using CT scans. A study in pigs by Hodges et al. (2006) found that induced L4 spinal disc lesions resulted in LM cross sectional area at the same level of the injury within three days, compared to no change in no-LBP controls. Injury to the L3 nerve root resulted in LM cross sectional area reduction at the affected level and down to L4, L5 and S1 levels in 15 induced injury pigs compared to six controls. The controls were, however, still subjected to a sham surgical procedure which involved all the same steps as the injured pigs apart from the inducing of the injury. A comparison study by Hides et al. (1994) of 26 first episode acute

unilateral low back patients with 51 health controls, found LM asymmetry in the back pain patients, isolated to the symptomatic level compared to symmetrical LM muscles in the no-LBP controls.

A comparison study by Hodges and Richardson (1996) of 15 LBP patients with 15 no-LBP matched controls used electromyography to assess the activation and timing of TrA in response to upper limb movements. It was observed that TrA activation was consistently delayed in the back pain patients. A comparison study by Ferreira and Hodges (2004), of ten low back patients with ten health matched controls found consistently reduced changes in TrA thickness in the back pain group during lower limb exercises measured using ultrasound imaging.

1.3. Management of low back pain using motor control interventions for segmental spinal stability

Management of segmental instability using specific motor control exercises aimed at normalising the recruitment patterns of the deep muscles was summarised by O'Sullivan (2000). The first stage of training is learning to isolate and correctly voluntarily contract the deep muscle system. The voluntary contractions are intended to be low level and at 30-40% maximal voluntary contraction. Contractions are taught in postures such as supine, prone and four-point-kneeling while patients are asked to perform abdominal drawing in using TrA while maintaining a neutral lumbar lordosis. In addition to this, patients are taught:

- Differentiation of lumbar, pelvic and hip movements.
- Diaphragmatic breathing and maintenance of neutral lordosis in different postural sets such as sitting and standing.

Live biofeedback with use of palpation, ultrasound imaging or possibly electromyography can be included to help isolate TrA and LM activation (Hides et al. 2008). Treatment is then progressed to the second stage where the deep muscle recruitment learned in stage one is incorporated into functional and previously faulty movement patterns. Patients are taught movements such as sit to stand, walking, bending and twisting while maintaining activation of deep muscles and keeping neutral lordosis. The third and final stage of training is for patients to carry the newly learned and stable functional movements into their activities of daily life. Further advice, practice and biofeedback may be given to facilitate this process. These stages of rehabilitation are represented graphically in Figure 1-7

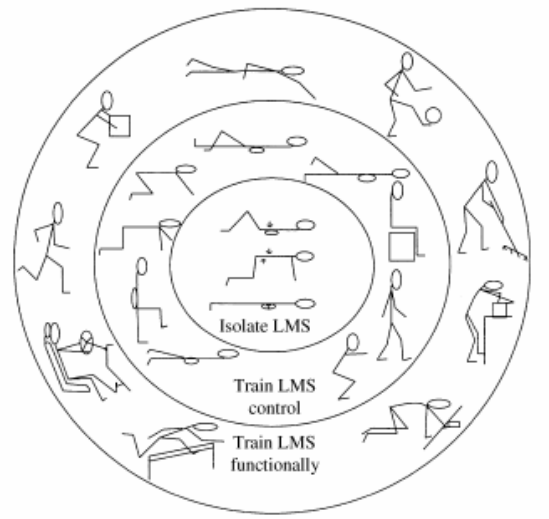


Figure 1-7 Graphical representation of deep muscle system (LMS) motor relearning (O'Sullivan, 2000)

A study was undertaken by Hides at al. (2008) to assess LM size in athletes with LBP and determine the effectiveness of a motor control intervention. Ten participants with back pain underwent a six week intervention programme of learning to correctly activate TrA and LM. Live biofeedback using ultrasound imaging was used during muscle activation teaching. Abdominal drawing in exercises were used to teach recruitment of the TrA while maintaining a normal, relaxed, breathing pattern, followed by participants attempting to swell the LM

muscle while holding a breath out and keeping the spine still with a neutral lumbar lordosis. Initially, activation was taught in lying and then progressed to upright sitting and standing, all while maintaining neutral lumbar lordosis. Further progression to functional movements was then performed. By the end of the programme pain scores had dropped from an average of 4.3 to 2.3 ($p<0.05$). Before treatment, asymmetry had been observed in LM cross sectional area, which also significantly decreased, while overall muscle size increased. This is evidence that suggests motor control exercises including recruitment of deep muscles can improve clinical outcomes.

1.4. Evidence based management of low back pain including use of motor control interventions in a wider context with a multi-lateral approach

A good quality systematic review by Ferriera et al. (2006) summarised a large portion of the remaining evidence surrounding motor control exercises for the treatment of spinal and pelvic pain. Motor control exercises were defined as those which retrain control of the deep muscles in the lumbopelvic region by specifically recruiting those muscles while gradually reducing over activity in superficial spinal muscles (Ferreira et al. 2006). Progression of motor control exercises involved recruitment of deep muscles during functional activities (Ferreira et al. 2006). Twelve discreet studies were identified and assessed for quality using PEDro scoring before the results were pooled and illustrated graphically as in Figure 1-8 to 1-11. All of the studies scored at least 4 out of 10 on PEDro.

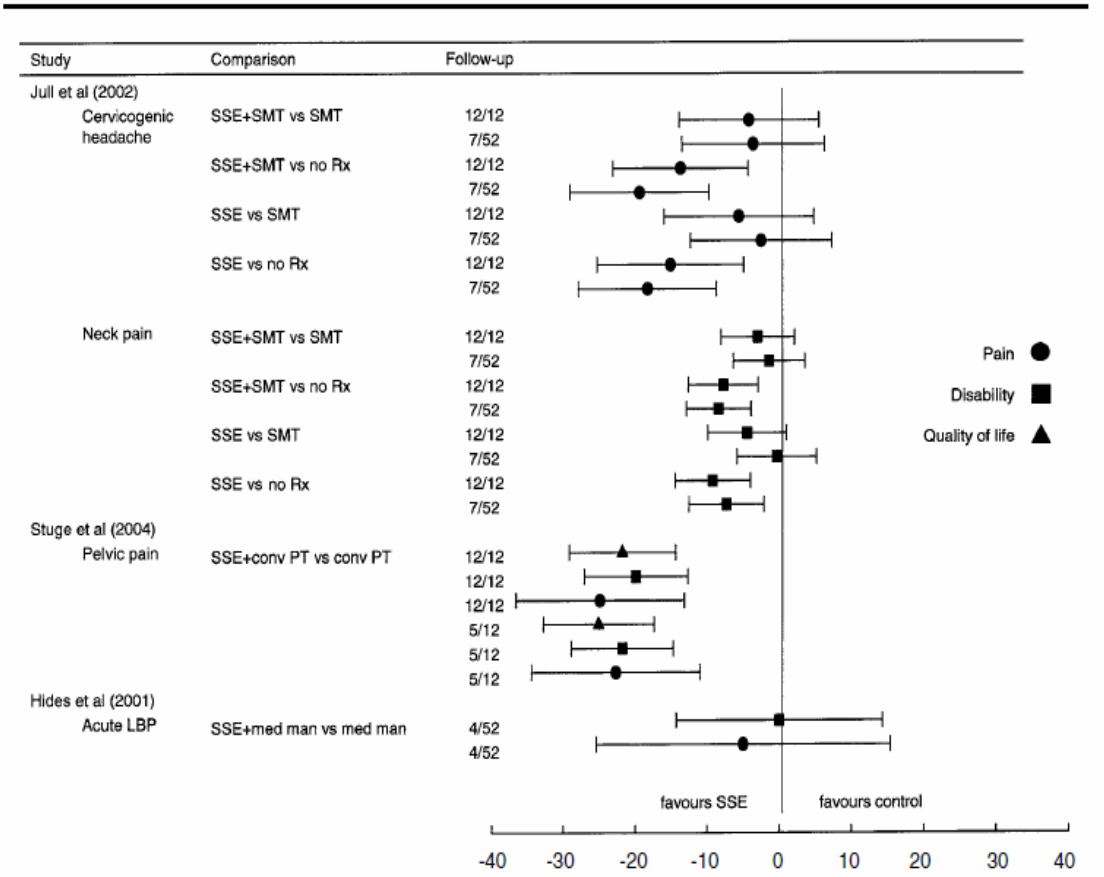


Figure 1-8 Effect of motor control exercise on pain, disability and quality of life outcomes for LBP and cervical pain. (Ferreira et al. 2006)). SSE = specific stabilisation exercises based on motor control approach defined earlier, SMT = spinal manipulative therapy, PT = conventional physiotherapy, med man = medical management and tails on the graph show 95% confidence intervals.

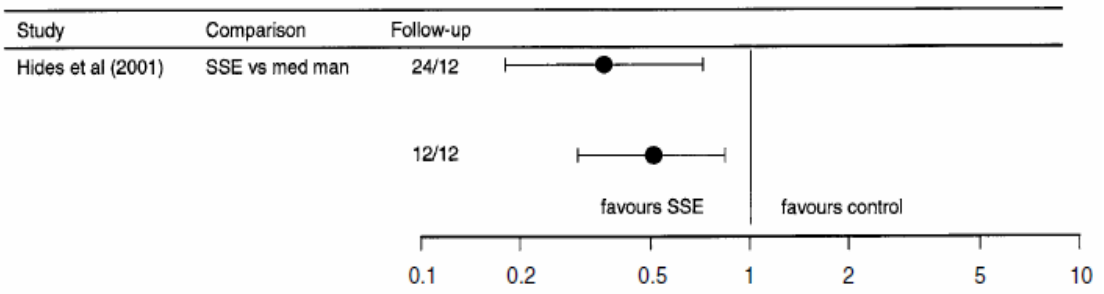


Figure 1-9 Effect of specific stabilisation exercise on risk of recurrence after acute episode of LBP. (Ferreira, et al., 2006). SSE = specific stabilisation exercises based on the motor control approach defined earlier, med man = medical management and tails on the graph show 95% confidence intervals.

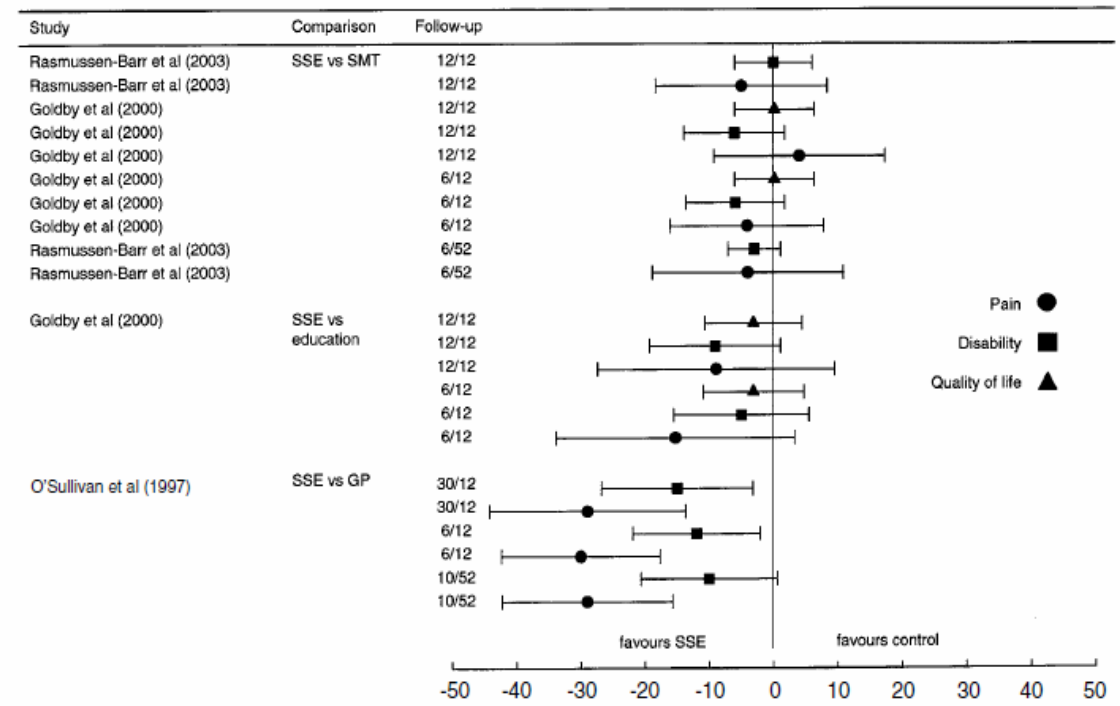


Figure 1-10 Effect of specific stabilisation exercise on pain, disability and quality of life outcomes for chronic LBP. (Ferreira, et al., 2006). SSE = specific stabilisation exercises based on the motor control approach defined earlier, SMT = spinal manipulative therapy and tails on the graph show 95% confidence intervals.

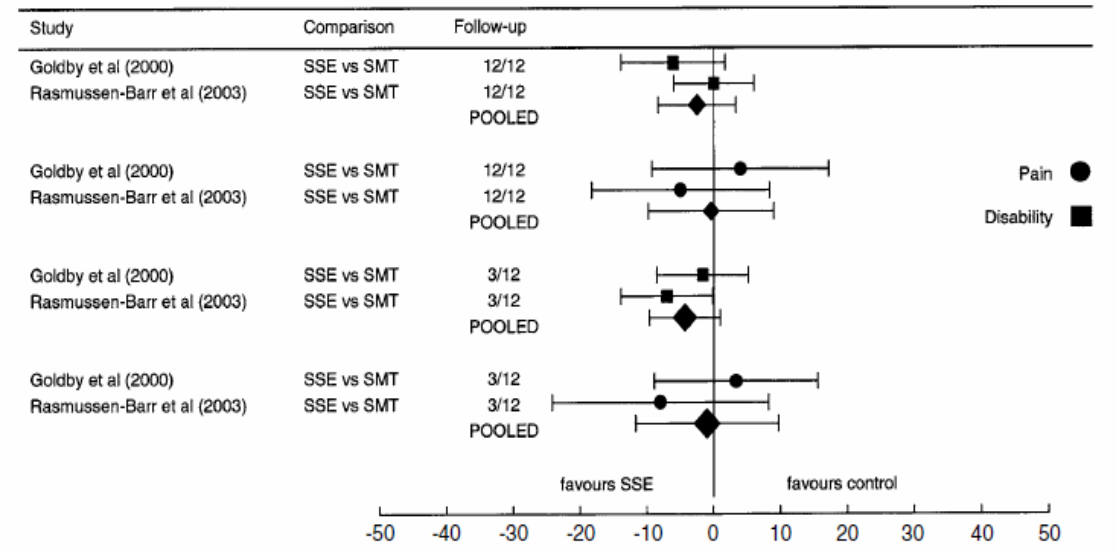


Figure 1-11 Effect of motor control exercise vs usual care on pain and disability outcomes for LBP. (Ferreira, et al. 2006). SSE = specific stabilisation exercises based on the motor control approach defined earlier, SMT = spinal manipulative therapy, and tails on the graph show 95% confidence intervals.

The overall evidence presented in the review shows that intervention programmes that include motor control exercises appear to be effective at improving back pain outcomes across much of the evidence. One study provided evidence that motor control exercises also improve long term outcomes in LBP patients compared to manual therapy approaches. However, motor control

exercises alone did not show much more improvement on immediate outcomes over manual therapy. The approaches that showed the best outcome improvements were motor control exercises in combination with conventional physiotherapy or manipulative therapy. It is possible that using a multi-lateral approach to treating LBP could fit into the previously presented theory from Panjabi et al. (2006). Having a motor control exercise would target the abnormal deep muscle patterns and normalise the corrupted feedback being sent to the control unit. Meanwhile the traditional physiotherapy, which included manual therapy, stretching and healing process education (which many of the physiotherapy control interventions included in Ferreira et al. (2006)), may promote soft tissue healing and normal spinal range of movement and so also normalise corrupted feedback from ligament or soft tissue mechanoreceptors. Combined with teaching correct neural control system output by isolating and relearning correct LM and TrA activation, this sort of multi-lateral approach targets most of the problem areas highlighted in Panjabi et al. (2006). However. it has long been established that LBP is heterogenic with respect to potential causes and that subgrouping to address specific issues is more likely to aid clinical diagnosis and selection of most appropriate treatments (Bouter, van Tulder and Koes 1998; Hancock, Herbert and Maher 2009). Therefore the combination approaches might have been treating more subgroups than individual treatments and the same effectiveness might be found if LBP patients had been sub grouped based on good assessment and received problem-based treatments.

In addition to this, it was suggested by Hodges, Cholewikci and Van Dieen (2013) that functional training is likely to have better carry-over of muscle activation into other functional movements used in daily activities. The implication being that improved activation in every day functional movements will be of higher benefit to patients. Additionally, new exercises such as using the FRED may have

potential to automatically recruit LM and TrA (Debuse et al. 2013; Caplan et al. 2014), which is a clinical challenge at present (Van, Hides and Richardson 2006).

1.5. Defining neutral posture for low back pain interventions

Maintaining a neutral spinal posture during movements and functional tasks is part of many spinal stability intervention programmes. As lordosis is an element of sagittal plane posture, it is necessary to define a neutral upright sagittal posture. Postures which include the following sagittal plane elements were considered to be well balanced in a large X-ray imaging study (Roussouly et al. 2005)

- An anteriorly tilted pelvis resulting in a sacral slope of 35 to 45 degrees.
- The thoracolumbar (T12L1) junction being the inflection point between lumbar lordosis and thoracic kyphosis.
- The inflection point being vertically aligned with the anterior superior edge of the S1 vertebrae.

An electromyography study by Claus et al. (2009) additionally found that sitting with a spinal posture very similar to the well-balanced posture defined in the x-ray study also impacts LM and TrA activity. An inflection point located at the thoracolumbar junction with lumbar lordosis also created the highest LM and TrA activity compared to long lordotic, flat back and slumped postures (Claus et al. 2009). Clinically, it is often not possible to assess sacral slope, due to the lack of sufficient imaging equipment. However, significant correlation was found between anterior pelvic tilt and both the location of the spinal inflection point and alignment of the inflection point with the S1 vertebrae (Roussouly et al. 2005). Therefore, it may be possible to clinically suggest correct posture has been achieved if there is a degree of anterior pelvic tilt to the extent that a lumbar lordosis exists throughout the lumbar vertebrae up to the thoracolumbar junction. This suggestion would

have more confidence if evidence of LM and TrA activation was also found concurrently.

1.6. Motor control with the biopsychosocial model

O'Sullivan (2005) identified many treatment options for LBP that only target a single potential causative element and suggested it is better to assess all potential biopsychosocial causes of back pain before selecting treatment options that address the range of potential underlying problems. Additionally, the high quality systematic review by Ferreira et al. (2006) found larger effect sizes with tailored multi-treatment LBP interventions such as treating LM and TrA and addressing psycho-social problems. Therefore, while this PhD considers LM and TrA interventions in detail, it is acknowledged they should be used as part of a biopsychosocial approach.

1.7. Summary

There is evidence linking atrophy and poor control of deep muscles to poor spinal mechanics and nonspecific LBP. Interventions that activate these muscles in functional positions and movements, while simultaneously promoting balanced upright sagittal postures, often called motor control exercises, are suggested to be beneficial. This is especially so when used as part of a multi-lateral approach.

1.8. Populations that are expected to benefit from spinal motor control exercises

Previous sections of the introduction have explained how injury to the spine and disuse atrophy of the LM and TrA can lead to motor control problems in the general population. Therefore it is clear that motor control interventions are likely to be of benefit in the general population who experience LBP due to a spinal motor control deficit. However, the focus of this research was astronauts that

experience the same deep spinal muscle and spinal motor control changes and have many parallels with the general population. There is also potential that this research could also benefit falls prevention rehabilitation in older adults. These additional populations are explained below.

1.8.1. Astronauts and Bed-Rest Study Participants

Astronauts returning from long duration space missions (~6-months duration) (Buckey 2006) and participants following bed-rest studies, which are commonly used to simulate microgravity exposure (Pavy-Le Traon et al. 2007), suffer a range of muscular and postural problems. These problems include decreased balance and proprioception, decreased muscle mass, force and power with increased loss of technique (specifically affecting lower limb antigravity muscles and lumbopelvic segmental control muscles) (Buckey 2006), decreased ability to control posture - specifically the ability to achieve balanced pelvic tilt and spinal curves in the sagittal plane (as defined in section 1.5), increased risk of spinal injury from poor spinal positioning during every-day activities - especially involving trunk flexion, and increased chance of poor global movement patterns and risk of injury from musculoskeletal weakness and atrophy (Hides et al. 2011; Hides et al. 2007; Belavy et al. 2011c; Belavy et al. 2015). Those in microgravity also experience lengthening of the spine due to swelling of the intervertebral discs which in turn become deconditioned resulting in increased risk of disc injury (Belavy et al. 2015). To date, the full list of musculoskeletal changes reported to occur during microgravity exposure and the effectiveness of in-flight countermeasures and post flight rehabilitation to prevent and reverse changes is unknown. An element of this PhD will be to establish a list of changes that occur due to microgravity exposure and review the effectiveness of relevant current interventions.

1.8.2. Older Populations and Falls

An etiological study of aging and muscle dysfunction stated that falls are the most common cause of accidental injury in older people with muscle weakness being a commonly found feature (Fiatarone and Evans 1993). The reasons given in the study for muscle weakness were: natural musculoskeletal changes due to age, increased prevalence of chronic diseases, increased use of medications, sedentary lifestyle leading to atrophy, and poor nutrition. Natural aging changes included reduced maximal contraction strength, decreased muscle mass, biochemical changes leading to reduced energy available to muscles and decreased neural recruitment capacity. Increased use of medications such as steroids due to higher prevalence of chronic disease in older people also contributes to muscle wasting. When this high incidence of muscle loss is combined with periods of immobility from bed-rest, wheelchair use or casting due to either acute or chronic illness, the overall loss of muscle and functional ability can accelerate (Fiatarone and Evans 1993).

A systematic review by Granacher et al. (2013) into falls prevention highlighted that historically balance and lower limb strength training have been used as interventions against falls in older people. While such training has improved outcomes related to strength testing, improvements in functional outcomes and ability to complete activities of daily living safely have been limited (Granacher et al. 2013). Based on the research being done on the role of motor control and deep muscles in spinal stability theories, it was suggested a similar approach may also be useful in falls prevention (Hwang et al. 2008). It was hypothesised that the effects of aging on the deep muscles and neural control system may compromise an older person's ability to stabilise the spine, particularly in response to sudden trunk loading and lower limb movements. To assess this, Hwang et al. (2008) conducted a comparison study of 23 young (<30 years age) individuals

with 15 healthy older (>60 years age) controls. Surface electromyography was used to investigate activation of LM in response to sudden expected and unexpected upper limb loading. LM activation was seen to be significantly later in the older individuals for both expected and unexpected loads, the difference was increased for expected loads (Figure 1-12).

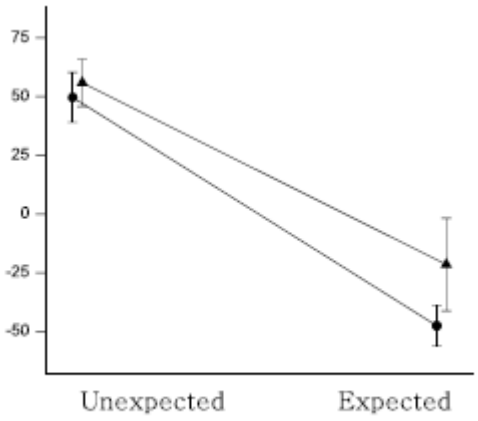


Figure 1-12 Latencies of LM (in ms) reflex to sudden loading, triangle represents older people and circle young from Hwang et al. (2008).

The systematic review by Granacher et al. (2013) also highlighted a correlation between increasingly flexed spinal postures in older people and falls. As it has already been shown that LM controls lordosis (extension) and is active in response to balanced sagittal posture including lordosis, flexed postures may also negatively impact on deep muscle activity. The conclusion of the systematic review was that stability was important for older people to successfully perform activities of daily living and that functional stability interventions are also likely to show improvements in falls relevant outcomes. It recommended including functional stability training in programmes for older people alongside traditional strength training.

1.8.3. Knowledge transfer between populations and levels of indirectness

The three main populations identified as being likely to benefit from motor control interventions are astronauts and bed rest (microgravity exposure), general population LBP due to deconditioning similar to that found in microgravity exposure and potentially older adults. Knowledge transfer between these groups is therefore recommended and is already being performed (Stokes, Evetts and Hides 2016). It has already been shown that LBP in the general population and those entering microgravity have the highest comparability and are therefore expected to have the lowest level of indirectness for knowledge transfer (Hides et al. 2007; Pool-Goudzwaard et al. 2015), with spinal lengthening due to intervertebral disc swelling being the only key difference other than from gravity loading. Techniques for motor control exercises are already being transferred successfully between general low back pain and microgravity populations (Hides et al. 2011; Evetts et al. 2014). Therefore this thesis applies to and recruits data from general LBP and astronaut populations and applies the results to both of these populations. However, in the thesis conclusion, areas where knowledge transfer could also apply to older adults are still highlighted.

1.9. The Functional Readaptive Exercise Device (FRED)

Many people have difficulty recruiting LM, in particular, voluntarily (Van et al. 2006), which presents a challenge to physiotherapists involved in motor control exercises.

Debuse et al. (2013) investigated a new exercise device, the FRED (Figure 1-13), that aims to recruit the LM and TrA muscles. FRED exercise constitutes a combination of weight-bearing, an unstable base of support (at the feet), an upright posture with a relatively stable lumbopelvic area, functional lower limb movement and real-time visual feedback of performance. This requires the participants' rearward leg to work to control the downward movement of the

forward leg, in order to achieve a smooth, controlled cyclical motion. Exercise on the FRED was shown to recruit LM and TrA automatically (i.e. with no conscious effort by participants) and to recruit them differentially (Debuse et al. 2013). More recently, FRED exercise has been shown to promote tonic activity of LM and TrA (Caplan et al. 2014), which is considered the most effective type of activity for retraining the stability function of these muscles (Richardson & Jull 1995). The FRED was also found to reduce lumbopelvic movement when compared to over-ground walking (Gibbon, Debuse & Caplan 2013).

Figure 1-13 Current Prototype Functional Readaptive Exercise Device (European Space Agency image)

It is hypothesised that the device uses several mechanisms in combination, to produce rehabilitation effects on several of the problems found in spinal instability simultaneously within one intervention (Table 1-1). Additional, potential, mechanisms also result from training on the FRED, which are also likely to be useful to relevant clinical populations are outlined in Table 1-2.

Table 1-1 Potential primary mechanisms in FRED training

Problem	FRED Mechanism
Poor lumbopelvic motor control of deep spinal muscles	1. a. Exercising using a pattern of moving the feet in a quasi-elliptical path in antiphase with minimal resistance from the device or support from the upper limbs b. Exercising while maintaining a stable pelvis and upright trunk while having to maintain an even speed within one revolution. The above points create a need for greater control of the lower limbs and pelvis during an unstable dynamic movement. Greater control is particularly needed in resisting a fast descent of the foot in the forward-most position of the cycle. The movement is functional and similar to over ground walking. Therefore, muscle activation training is learned in a functional movement, hoped to produce carry over into other functional daily activities. 2. Clinical observations seem to indicate that relatively greater rear foot loading in standing results in greater recruitment of LM whereas relatively greater front foot loading in standing has a deactivating effect on LM. It is hypothesised that correct exercise on FRED results in reduced front foot loading. REF? 3. FRED provides visual feedback which encourages users to exercise at a constant, controlled speed and frequency ratio which is hypothetically the most energy efficient movement (Taylor, Budds and Thomas 2003). Additional feedback encourages users to maintain even movements throughout the exercise, training control of the lumbopelvic area and lower limbs during dynamic, functional movements. It is thought that efficient and smooth controlled movement on FRED may improve LM and TrA neuro-motor control. The exercise has already been shown to activate LM and TRA without the need to consciously trigger the activation in non-symptomatic populations (Debuse et al. 2013). In addition to this, LM was shown to have constant tonic activity throughout exercise cycle on the device in an electromyography study. The muscle was active for more time than during over ground walking (Caplan et al. 2014).
Reduced ability to control spinal posture and balance	Previous kinematic research has shown FRED exercise promotes an increased degree of anterior pelvic tilt during upright posture (Gibbon, Debuse and Caplan 2013). Increased anterior pelvic tilt, within a range where the thoracolumbar junction remains the inflection point between lumbar lordosis and thoracic kyphosis, has been shown to create a well-balanced sagittal spinal posture (Roussouly et al. 2005). Electromyography data has also shown that this type of posture produces highest LM and TRA recruitment (Claus et al. 2009), though this study investigated sitting postures. Additionally, users of the device are required to exercise in an upright posture. It is hoped that these elements together mean FRED exercise promotes a balanced upright sagittal posture (defined in section 1.4) with recruitment of LM and TrA. Having improved control of balanced posture is also hoped to improve overall balance.

Table 1-2 Additional potential mechanisms in FRED training of use to Relevant Rehabilitation Populations

Atrophy of spinal extensors	EMG data from FRED exercise shows it promotes increased activation of spinal extensors over flexors (Caplan et al. 2014). This may be relevant to the rehabilitation of astronauts who show increased flexion postures when in space (Buckey 2006)
Weakness of lower limb anti-gravity muscles	Previous kinematic research shows FRED exercise involves constant hip and knee flexion in a dynamic and gravity loaded exercise, therefore, constantly loading lower limb extensor muscles (Gibbon, Debuse and Caplan 2013). This loading is expected to improve strength in the lower limb extensors which is a common aim of traditional older people falls risk interventions (Granacher et al. 2013)

The mechanisms show how the FRED has already demonstrated the ability to automatically activate both LM and TrA in an asymptomatic population without need for conscious muscle recruitment. This might have potential to solve the LM and TrA conscious recruitment difficulties found in traditional rehabilitation (Van, Hides and Richardson 2006). The exercise is dynamic, functional, weight-bearing, in an upright posture and relevant to common daily activities such as walking. These are all elements of motor control exercises covered in section 1.7. It appears, therefore, that the device might be a useful intervention to train the LM and TrA muscles and segmental spinal stability.

As the device is a prototype and its underlying mechanisms require investigation, a series of studies were planned to test the mechanisms and build the evidence base underpinning them. It was also decided to include relevant back pain populations in these studies. While the current rehab approaches in back pain are well documented and reviewed, this is not so for post spaceflight rehabilitation. Therefore, a review of the rehabilitation in this population was also included to establish current interventions and benchmark against the effectiveness of the new device.

1.10. Thesis Aim and Research Questions

The aim of this thesis was to investigate the FRED to assess it mechanistic effects within the field of motor control interventions for spinal stability in both astronaut and terrestrial populations. The following chapters of this thesis attempt to answer the following key questions: Do the underlying mechanisms of FRED exercise indicate that it may be a useful intervention to trial in the rehabilitation of lumbopelvic deconditioning resulting from microgravity exposure in astronauts and a sedentary lifestyle in the general population? What are the requirements for a standard and progressive training protocol using the FRED? What current

inventions are used to treat and rehabilitate lumbopelvic deconditioning and what are their effects? Chapter two systematically reviews the space research within the field of spinal stability. Chapter three assesses the activation of the LM and TrA muscles in all device settings to inform a training protocol. Chapter four compares sagittal plane kinematics during exercise on the FRED with walking in both a low back pain and asymptomatic population. Chapter five highlights the effects of using visual back during FRED exercise to inform the training protocol. Chapter six determines the time required to familiarise with the device. Chapter seven investigates the effect of using the handle bars during exercise to also inform the training protocol and chapter eight contains the concluding text. Chapter two deals with microgravity populations whereas all remaining chapters deal with LBP populations and results are discussed in a motor control context that is transferable between both of these populations, as discussed in section 1.8.3.

2. Chapter Two: Systematic Review of Countermeasures and Rehabilitation Interventions to Minimise Physiological Changes and Risk of Injury to the Lumbopelvic Area Following Long-Term Microgravity Exposure

2.1. Introduction

Human spaceflight results in exposure to an altered gravity state, mostly eliminating weight bearing and axial loads, resulting in physiological changes and potentially increased injury risk (Gernand 2004; di Prampero and Narici 2003; Buckey 2006). Buckey (2006) grouped changes into broad themes allowing them to be listed briefly as: bone loss, psychosocial, radiation biological, muscle loss, balance and postural control, cardiovascular and nutritional.

Gernand (2004) reported the implications of these physiological changes on subsequent safe functioning on return to a gravity loaded environment, highlighting the need for both countermeasure interventions during spaceflight and rapid and effective rehabilitation following spaceflight. For longer duration spaceflight of around six months, Gernand (2004) noted significant bone and muscle loss, as well as altered postural control, leaving the body susceptible to bone fracture, muscle injury and the potential to develop osteoporosis. Muscle atrophy and altered motor control have been specifically observed in the lumbopelvic region (Sayson and Hargens 2008).

A European Space Agency (ESA) report by Snijders et al. (2011) reported LBP in 12 out of 20 astronauts during spaceflight. The report highlighted the importance of maintaining spinal movements, as end range flexion and extension exercises were anecdotally noted as being employed to ease pain during spaceflight. A relationship was also highlighted between LBP and atrophy of deep spinal muscles, particularly LM, during bed-rest studies (Pool-Goudzwaard et al. 2015).

Wing et al. (1991) reported that 53-68% of astronauts experienced moderate to severe back pain when in space. On landing after a shuttle mission, a US astronaut reported severe LBP which was later linked with a herniated nucleus

pulposus at the L4-5 intervertebral (IV) disc and required surgical intervention (Johnston et al. 2010). Johnston et al. (2010) also reported that astronauts had a more than four-fold increased risk of herniated disc pulposus within the first year following spaceflight, compared with controls. Sayson and Hargens (2008) suggested that this back pain and disc injury could be caused by a range of factors linked to spinal lengthening and reduced loading. A review by Belavy et al. (2015) supported this, suggesting the increased lumbar IV disc herniation risk in the astronaut population was most likely caused by long term disc tissue deconditioning resulting from swelling of the discs due to unloading during spaceflight. However, the review only considered IV discs in isolation and does not refer to any potential predisposing factors such as spinal motor control.

Lumbopelvic adaptations to microgravity include adoption of a flexed posture (Figure 2-1) (Buckey 2006), spinal lengthening, increased intervertebral disc height and disc deconditioning, altered spinal curvatures (Sayson and Hargens 2008) and atrophy of the lumbopelvic musculature. A general pattern of selective extensor muscle atrophy over flexors has been seen throughout the body (Edgerton et al. 2001; Widrick et al. 2001). Spinal extensor volume decreases have been reported as greater than hip flexor (Psoas muscle) decline in astronauts (LeBlanc 1995). Anecdotal accounts also appear to show selective atrophy of trunk extensor muscles concomitant with improved flexor muscle performance immediately post mission (Evetts 2015). Hides et al. (2011) suggested that deep spinal muscle changes such as atrophy of LM and TrA muscles, along with selective hypertrophy of spinal flexors over extensors (Hides et al. 2007), may impact on the ability of the spine to distribute loads appropriately shortly after spaceflight simulation via bed-rest. Selective atrophy of spinal extensors without corresponding atrophy of the Psoas muscle was also seen in terrestrial individuals with LBP compared to no-LBP controls by Danneels et al.

(2000). Atrophy and motor control changes in the LM muscle have been linked with LBP (Hides et al. 1994; Hides et al. 2008) and development of poor intersegmental control of the lumbar spine (Bergmark 1989; Hodges 2004; Hodges and Cholewicki 2007; Hodges and Moseley 2003) which can potentially cause increased stress on spinal structures, resulting in pain (Panjabi 1992a; Panjabi 1992b; Panjabi 2003).

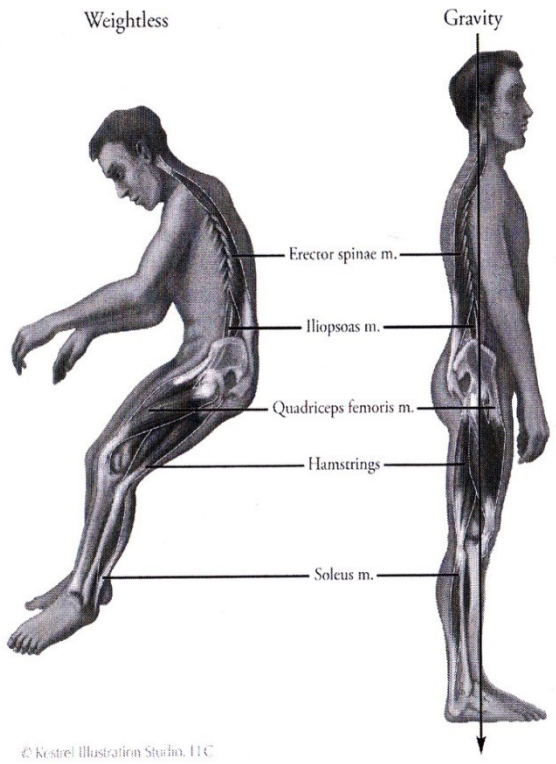


Figure 2-1 Postural adaptation to microgravity, showing loss of normal spinal curvature and increased flexion of the spinal column, reproduced from (Buckey 2006), with permission

Humans exposed to sustained microgravity develop a risk of significant spinal injury as a result of microgravity-induced poor intersegmental control of the lumbar spine combined with loaded activities such as, extra-vehicular activity, physically demanding medical procedures, landing and return to a g-loaded environment, which have the potential to be at least as demanding as those undertaken in normal Earth gravity (Gernand 2004). It is necessary, therefore, to know what physiological changes occur that could lead to increased injury risk, and which

interventions, both countermanding and rehabilitative, can be used to minimise and effectively rehabilitate physiological compromise. The current evidence also suggests that interventions to address lumbopelvic physiological adaptations are likely to be a required element of any rehabilitation programme following exposure to microgravity. While Evetts et al. (2014) indicated that European post-flight rehabilitation includes specific training for lumbopelvic posture and spinal muscles involved in intersegmental control of the lumbar spine, they highlighted a need to compare the effectiveness of interventions to advance the treatments given to astronauts. Such improvements are also likely to aid terrestrial healthcare with more effective interventions for people with LBP and post bed-rest rehabilitation (Evetts et al. 2014).

The aim of this systematic review was, therefore, to determine what interventions are effective at counteracting or rehabilitating changes, and reducing injury risks to the lumbopelvic region, following exposure to microgravity in humans. Specifically, this systematic review focussed on the lumbopelvic region due to its vital role in the maintenance of lumbar posture, intersegmental control of the lumbar spine and the link with LBP (Snijders et al. 2011; Hides et al. 2011; Panjabi 2003).

2.2. Methods

2.2.1. Scoping

An initial general search found no eligible studies conducted in spaceflight populations. Therefore, the scope of this review was expanded to allow inclusion of bed-rest study populations within studies designed to simulate axial unloading due to spaceflight. Due to the inherent difficulty in studying spaceflight populations (e.g. cost and small sample size) ground based simulations are often used. Several ground-based models exist, including bed-rest, limb immobilisation

and unilateral lower limb suspension. It has been reported that bed-rest is the most valid ground based model for simulating axial unloading caused by spaceflight, especially for studying postural and lower limb muscle changes (Adams, Caiozzo and Baldwin 2003; Pavy-Le Traon et al. 2007). However, bed-rest studies have limitations, as spaceflight nullifies both the Gz and Gx vectors, whereas bed-rest moves Gz into Gx, eliminating Gz, yet failing to cancel out Gx (Pavy-Le Traon et al. 2007).

2.2.2. Search strategy

A range of terms were used in various combinations to search the following databases: Pubmed, CINAHL, Web of Science, Science Direct, and The Cochrane Collaboration Library. The literature search was performed according to the search strategy shown in Table 2-1 during November 2014.

Table 2-1 Search term construction

Search number	Term	Key words in Boolean search format	Reason
1	Rehabilitation	rehabilitate OR rehabilitation OR recover* OR recovery	Locate studies which consider rehabilitation
2	Spaceflight /analogues	spaceflight OR space* OR space flight OR astronaut* OR microgravity OR micro gravity OR bed-rest OR bedrest OR weightless*	To find studies using spaceflight or simulating microgravity terrestrially using bed-rest.
3	Musculoskeletal	muscle* OR bone* OR skeletal OR musculoskeletal OR neuromusculoskeletal	Limiting search to musculoskeletal area
4	Intervention	intervention* OR treat OR treatment* OR physio OR physiotherapy OR physical therapy OR therapy OR exercise OR program* OR exercise program*	To find research which considered actual interventions
5	Lumbopelvic	lumb* OR pelv* OR low back OR lower back	Limiting search to interventions for the lumbopelvic region
6	Countermeasures	countermeasure* OR counter* OR protect* OR maintain OR prevent* OR train*	Locate studies which consider countermeasures
7	Combined rehab search	1 AND 2 AND 3 AND 4 AND 5	Search for musculoskeletal rehabilitation interventions for lumbopelvic region linked to spaceflight or bed-rest
8	Combined countermeasures search	2 AND 3 AND 4 AND 5 AND 6	Search for musculoskeletal countermeasure interventions for lumbopelvic region linked to spaceflight or bed bed-restrest
9		1 AND 2 AND 3	Less specific combination
10		4 AND 2 AND 3	Less specific combination
11		1 AND 2 AND 5	Less specific combination
12		4 AND 2 AND 5	Less specific combination
13		6 AND 2 AND 3	Less specific combination
14		6 AND 2 AND 5	Less specific combination
15		7 OR 8 OR 9 OR 10 OR 11 OR 12	Increased sensitivity search to check for any missed studies

2.2.3. Eligibility criteria and rationale

Inclusion criteria:

The following inclusion criteria (PICOS) were applied to studies for inclusion in the review:

- **P**opulation – Astronauts (during or post spaceflight) or bed-rest (spaceflight axial unloading simulation) study participants.

- **I**nterventions/**C**omparisons – Countermeasures or rehabilitation strategies tested against each other or against no intervention or placebo/sham intervention.

- **O**utcomes – Although it is preferable to have patient relevant outcomes (e.g. quality of life, ability to walk and function after space flight), studies in this field measure biomedical (surrogate) outcomes. Studies meeting the P, I and C were included but prioritised for surrogate measures relating to lumbopelvic health.

- **S**tudy designs: Randomised controlled trials (RCT), controlled clinical trials (CT), interrupted time series and before and after studies.

Exclusion criteria:

Any studies that did not meet the inclusion criteria e.g. all (non-human) animal research, were excluded. No restrictions on length of follow up, language, and publication date or status were applied.

2.2.4. Study selection & data extraction

Studies were screened by the lead author of this review (AW) using the Rayyan Software (http://rayyan.qcri.org/). Any uncertainty of study inclusion was discussed with two other co-authors (Dr Dorothee Debuse and Dr Nick Caplan, supervisors of this PhD). Initial screening was performed using abstracts and titles. Where an inclusion decision was unclear from initial screening, the full text was obtained. Studies that matched the inclusion criteria are listed in the results section. The numbers of studies excluded during full text screening are also reported in the results section, with reason for exclusion. An adapted version of The Cochrane Collaboration "Data collection form for intervention reviews: RCTs only" version 3, April 2014, (Cochrane 2015) was used to extract data from each paper. An additional author (Dr Mona Nasser, from The Cochrane Collaboration) advised and assisted with extraction of data from each study and disagreements were discussed to reach consensus.

2.2.5. Quality Assessment

Two quality assessment tools were used: the Physiotherapy Evidence Database scale (PEDro 1999) and The Cochrane Collaboration risk of bias analysis for randomised trials (Higgins, Altman and Sterne 2011). Two authors (Andrew Winnard and Dr Mona Nasser) independently assessed each study, and any disagreements were discussed to reach consensus. For quality assessment, if consensus was not possible, a third author (Dr Dorothee Debuse) was consulted. PEDro includes other quality items that are not risk of bias but it is a common tool used in systematic reviews of rehabilitation research.

2.2.6. Rating the level of indirectness of the simulated space studies (bed-rest studies)

There is limited high quality research in the form of randomised controlled trials in astronauts due to logistical limitations and small sample size. Bed-rest is commonly used to simulate axial unloading which occurs during spaceflight (Morey-Holton 2000) and can be designed with various and potentially differing elements which may affect its quality as a simulation (Mulder 2014). There are currently no tools for assessing bed-rest methodological quality. For this review, therefore, a methodological tool was developed to assess how the bed-rest studies compared to an "ideal design" study simulating unloading experienced in the space environment (Table 2-2). The key features of an ideal bed-rest study were based on literature review and consultation with experts (Pavy-Le Traon et al. 2007; Morey-Holton 2000; Adams, Caiozzo and Baldwin 2003). This included information on the aspects of ESA bed-rest protocols provided by the German Aerospace Centre (Mulder 2014). The use of this tool was piloted in the present study by two of the authors (Andrew Winnard and Dr Mona Nasser) for its readability, clarity and usefulness; however, no further empirical studies on its validity and reliability were performed at this stage. While this tool is useful to highlight which studies may have simulated a spaceflight environment with greater rigour, it is important to consider that the tool is not validated and is built on currently perceived knowledge of appropriate spaceflight simulation study characteristics. Evidence does not exist to assess assumptions of what constitutes appropriate bed-rest study methodology. The duration of bed-rest is required as simulation studies can only relate to spaceflight of similar duration and shorter bed-rest studies are unlikely to model longer-term space missions.

Two authors (Andrew Winnard and Dr Mona Nasser) independently rated studies with the bed-rest methodology tool and any disagreements were discussed to reach consensus. If consensus was not reached, a third author (Dr Dorothee Debuse) was consulted.

Table 2-2 Bed-rest methodological quality assessment

Point	Criteria
1	Was the bed-rest six degree head down tilt to simulate cephlad fluid shift?
2	Was diet individualised and controlled?
3	Was the daily routine fixed – with set wake – sleep times and same routines for all?
4	Are all phases of bed-rest standardised for all participants – same baseline data collection period, same bed-rest time and same recovery phase?
5	Was the bed-rest 'horizontal posture' maintained except for when the test condition required it? I.e. personal hygiene, bowel movements, urination should all occur in bed, no visitors should be allowed and knees should not be flexed?
6	Was sunlight exposure prohibited and participants supplemented with vitamin D?
7	Were all measurements scheduled the same for all participants and done at the same time of day?
8	Was the duration of bed-rest stated?

2.2.7. Data analysis

For the countermeasure studies, the raw change across all outcome measures in the inactive control groups from baseline to end of bed-rest was extracted. The effect size that existed between the changes seen in the intervention and control groups provided an indication of the effectiveness of each treatment. Data were pooled across the same outcomes within each intervention when they were tested at multiple spinal levels and had effects of similar size, with changes in the same direction.

All the studies identified used spaceflight related axial unloading simulation during bed-rest and measured surrogate outcomes. The assumption with the outcome measures in the included studies is that any change in the control group

is an “undesirable effect” and success is evaluated by the ability of an intervention to demonstrate changes in the opposite direction, creating a “desirable effect”. In the comparison between intervention and control group during bed-rest, four scenarios were defined and used to judge interventions as effective, neutral or ineffective based on both the size and direction of calculated effect:

1. Training effect: changes in “desirable” direction beyond baseline.
2. Full protective effect: changes reduced completely back to baseline.
3. Partially protective effect: changes in “desirable” direction but not reaching baseline.
4. Worsening effect: further changes in “undesirable direction”.

To quantify the amount by which the interventions altered the change relating to baseline, the intervention difference was expressed as a percentage of the change recorded in the inactive control groups.

$$Intervention\ ability\ to\ restore\ change\ to\ baseline\ (\%) = \frac{x_i}{x_c} \times 100$$

Where x_i is the difference in the intervention group between baseline and end of bed-rest/spaceflight and x_c is the same difference in the control group. For a rehabilitation study the differences for x_i and x_c were between pre bed-rest baseline and end of rehabilitation.

The percentages are reported as negative where the intervention partially prevented the change and by how much (% off baseline), and positive where the intervention caused a training effect. A negative percentage of more than 100% shows the intervention making the change worse than having no treatment.

Where data from a single study were pooled across vertebral levels a standard deviation is presented with this value.

For the rehabilitation study analysis, which did not have an inactive control group, specific motor control (SMC) was considered the test intervention and trunk and general strengthening (TFS) an active control. The effect size compares each intervention's change from baseline to the end of the rehabilitation period (90 days after bed-rest in the included study) and assumed a closer return to baseline was a more effective result. Therefore, the effects compare the two interventions for ability to restore changes back to baseline values rather than comparing to an inactive control.

2.2.7.1. Magnitude based inferences

All calculated effects were presented graphically with 90% confidence intervals, with indication of favouring intervention or control (Figures 3-8). To add further meaning to the effect sizes, a magnitude based inference approach was used to calculate the probability (%) of the true effect being positive or negative (Hopkins 2007). This was done in relation to a smallest worthwhile change of 0.2 (small change) and 0.6 (moderate change) effect size.

2.3. Results

A total of 3147 titles were identified in the full search results, which reduced to 2104 after duplicates were removed. All 2104 studies were screened on title and abstract for eligibility, resulting in 2094 further exclusions. The ten remaining titles were acquired in full text and two further exclusions made from the full text assessments (Figure 2-2). A total of eight papers were included in the final review. The reference lists of the eight studies included were then screened to identify further relevant studies, which may not have been found in the searches, but no further eligible papers were found.

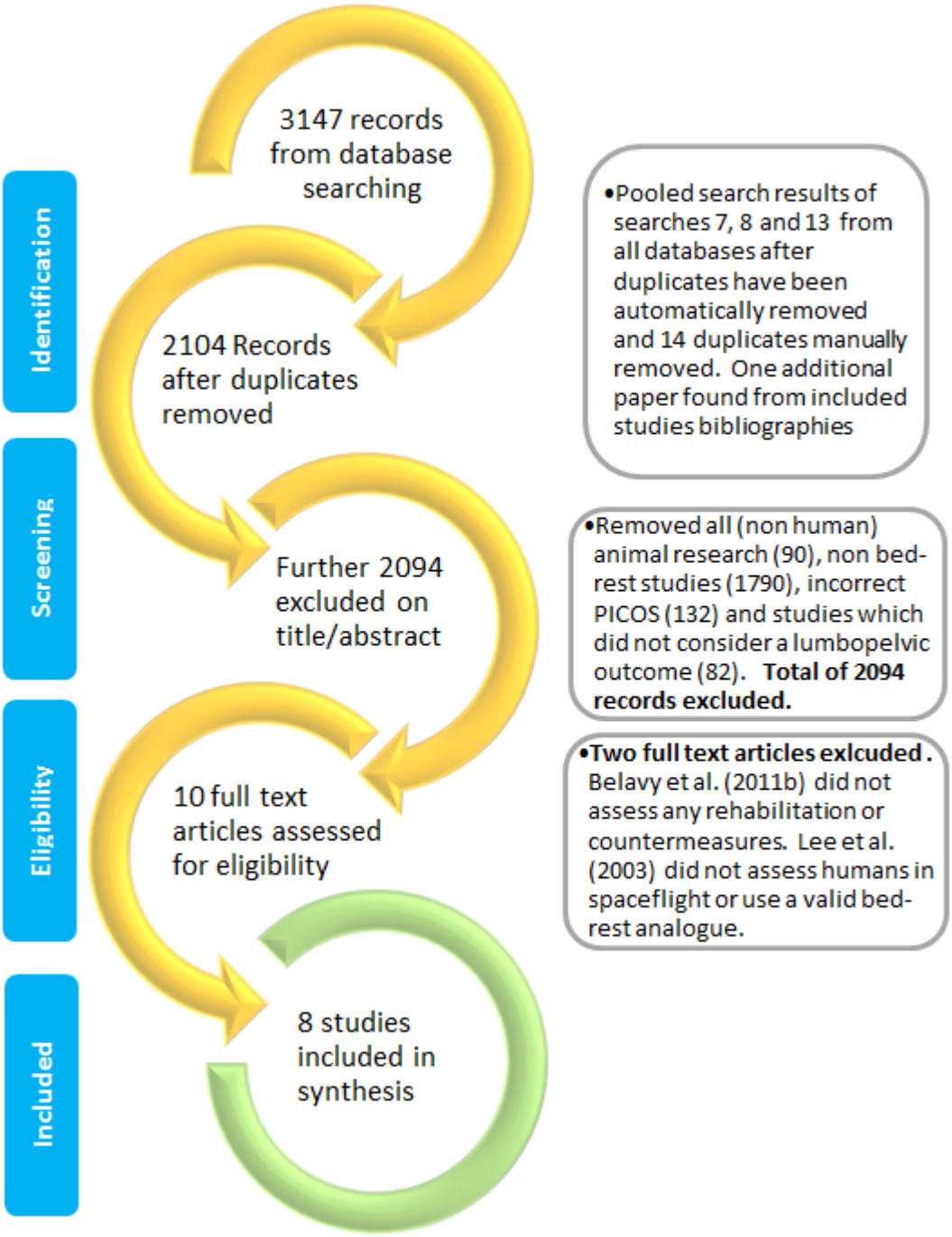


Figure 2-2 Search and screening results shown in PRISMA flow diagram standard

2.3.1. Characteristics of included studies

The characteristics of included studies are outlined in chronological order in Table 2-3. Seven of the eight included studies shared the RCT design. One study was a two-group intervention comparison and treated as an RCT, with one group being an active control, in this review. All eight quantitative studies, from which

required data could be extracted, were included in the quantitative synthesis. All studies used bed-rest as an analogue for axial unloading during spaceflight; no actual astronaut population studies were found by the search strategy. Interventions included resistance exercise (RE), vibration stimulation, lower body negative pressure (LBNP) treadmill exercise, and specific motor control (SMC) rehabilitation. Four studies shared two common samples meaning some of the samples reported in Table 2-3 are not independent. Belavy et al. (2010) and Hides et al. (2011) both utilised the second Berlin Bed-rest study population. Belavy et al. (2010) studied a countermeasure during bed-rest while Hides et al. (2011) was a post bed-rest rehabilitation analysis. Belavy et al. (2008) and Belavy et al. (2012) both used the first Berlin Bed-rest study population to assess the same countermeasure but with different outcome measures. Belavy et al. (2008) had one less participant than Belavy et al. (2012) due to one individual's MRI data being unavailable. Seven studies involved countermeasure interventions during the bed-rest period and had inactive control groups. One study (Hides et al. 2011) involved post-bed-rest rehabilitation and had an active control group. The number of participants for analysis is also shown in Table 2-3.

Table 2-3 – Characteristics of included studies

Study	Design	Population	Interventions	Control	Outcomes Measures
Cao et al. (2005)	Randomised controlled trial	Twelve sets of identical twins. One twin randomly assigned to control and other to the intervention group during 28 days of six degree head down tilt bed-rest.	Test group (n=12) exercising in a lower body negative pressure treadmill in a supine suspended position for 40mins 6 days per week. Loaded to one body weight. All % are of VO2 max (maximal Oxygen uptake): 7mins warm up at 40%, 3mins at 60%, 2mins at 40%, 3mins at 70%, 2mins at 50%, 3mins at 80%, 2mins at 60%, 3mins at 80%, 2mins at 50%, 3mins at 70%, 2mins at 40%, 3mins at 60% and 5mins cool down at 50%.	Control group (n=12); no intervention during bed-rest	MRI measures of: spinal length, lumbar disc heights, lumbar intervertebral angle, cross sectional area of Psoas and Erector Spinae muscles.
Marcias et al. (2007)	Randomised controlled trial	Fifteen sets of identical twins. One twin randomly assigned to control and the other to the intervention group. In six degree head down tilt bed-rest for 30 days.	Test group (n=15) exercise using a lower body negative pressure treadmill in a supine suspended position. 40min exercise period at 40-80% peak oxygen consumption 6 days a week for 30 days. Loaded to one body weight.	Control group (n=15);no intervention during bed-rest	MRI 1 day before bed-rest, on day 28 of bed-rest. MRI measures of: Spinal length, spinal compressibility, disc height. Lumbar strength pre and post bed-rest determined with lumbar extension dynamometer.

Study	Design	Population	Interventions	Control	Outcomes Measures
Belavy et al. (2008) BBR 1	Randomised controlled trial.	Nineteen healthy males during 56 days of head down tilt bed-rest. One test group and one control group.	Test group (n=9) Two RVE sessions daily, lasting 5-10 minutes each. RVE: Squat, heel raise and toe raise. In morning session also did explosive kick (full force knee extension). Resistance set greater than body weight. Whole body vibration set at 19-26Hz frequency and 3.5-4mm amplitude. Loaded to 1.2-1.9 times body weight.	Control group (n=10); no intervention during bed-rest.	MRI on day one of bed-rest and then at two week periods during bed-rest. Follow up scans at recovery days 4, 14, 28, 90 and 180. MRI measures of: Lumbar spine length, disc area, and height, intervertebral angles, cross sections of Lumbar Multifidus, Erector Spinae, Quadratus Lumborum, Psoas, Rectus Abdominis, External and Internal Oblique and Transversus Abdominialis muscles.
Holguin et al. (2009)	Randomised controlled trial	Twenty nine healthy volunteers during 90 days of supine bed-rest One test group and one control group.	Test group (n=18) low magnitude vibration exercise at 30Hz delivered at the feet while loaded to 60% of their body mass using a harness system for 10mins each day. Knees straight but not locked out during the stimulation.	Control group (n=11); no intervention during bed-rest	MRI at start of bed-rest, day 60 and 90 and 7 days post bed-rest at the S1-L1 area. MRI Disc volume and convexity and spinal length L1-S1. CT scan of intrinsic back muscle volume.

Study	Design	Population	Interventions	Control	Outcomes Measures
Belavy et al. (2010) BBR 2	Randomised controlled trial.	Twenty four healthy males during 60 days of six degrees head down tilt bed-rest. Two test groups and one control group.	Test group one (n=7) RE only. Test group two (n=8) RVE. Exercise performed three days per week. RE: Bilateral squat, single leg heel raise, double leg heel raise, back and toe raise. Resistance set greater than body weight. RVE: Same as RE with whole body vibration of 24Hz frequency and 3.5-4mm amplitude. Loaded to 1.3-1.5 times body weight	Control group (n=9); no intervention during bed-rest.	MRI pre bed-rest and on bed-rest days 27/28 and 55/56: Spine length L1-S1, disk volume, disk height, lumbar lordosis angle. MRI measures of: Cross sectional areas of Lumbar Multifidus, Erector Spinae, Quadratus Lumborum and Psoas muscles. LBP questionnaire pre bed-rest, every day during first two weeks, then weekly throughout remaining bed-rest period.
Belavy et al. (2011)	Randomised controlled trial.	Twenty five healthy males during 90 days of six degrees head down tilt bed-rest. Two test groups and one control group.	Test group one (n=8) fly wheel exercise sessions every third day during bed-rest. Supine squat and calf press. Test group two (n=7) spinal mobility exercises, by performing large amplitude low load slow trunk movements of the frontal, sagittal and longitudinal plane five times daily. Spinal mobility exercises were done as a self-mobilisation exercise.	Control group (n=9); no intervention during bed-rest.	MRI 17 days prior to bed-rest and on day 89 of bed-rest and either 13 or 90 days after bed-rest. MRI measures of: Disc heights, disc CSA, lumbar lordosis angle. Cross section of Multifidus, Erector Spinae, Quadratus, Psoas and Iliacus muscles.

Study	Design	Population	Interventions	Control	Outcomes Measures
Hides et al. (2011) Following BBR 2	Randomised two group comparison	Twenty one health males, following 60 days of six degree head down tilt bed-rest. Followed on from BBR2 and Belavy et al. (2010) with participants assigned to this post bed-rest rehabilitation study.	Test group (n=10) specific motor control exercise voluntarily contracting multifidus and deep abdominal muscles with ultrasound feedback followed by functional training in an upright position. Initially daily sessions, then two physiotherapy appointments and a home exercise plan (15 appointments over 90 days).	Comparison group (n=11); trunk and general strength exercise programme in supine position. Lifting the trunk and lower limbs off the floor, sit ups, diagonal sit ups, resistance created using Theraband. Progressed with more repetitions. Seen at same time intervals as intervention group.	MRI pre bed-rest, post bed-rest, recovery 14 and recovery 90. MRI measures of: Spinal length L1-S1, lordosis angle L1-S1, posterior and anterior disc height L1-S1, disc volume L1-S1, cross sectional area of Psoas, Lumbar Multfidus, Erector Spinae and Quadratus Lumborum muscles.
Belavy et al. (2012) BBR 1	Randomised controlled trial.	Twenty healthy males, aged 20-45 years, during 56 days of six degree head down tilt bed-rest. One test group and one control group.	Test group (n=10) RVE sessions daily, lasting 5-10 minutes each. Squat, heel raise, toe raise and explosive kicks (knee extension) with whole body vibration at 19-26Hz frequency and 4mm amplitude. Loaded to 1.2-1.9 times body weight.	Control group (n=10); no intervention during bed-rest	Electromyography of Erector Spinae, Internal and External Oblique, Gluteus Maximus and Lumbar Multifidus muscles. Specifically measured: lumbopelvic extensor-flexor co-contraction ratio, change in muscles tonic activity and extensor-flexor activity ratio.

Abbreviations: RVE; resistance vibration exercise, RE; resistance exercise, BBR; Berlin Bed-rest Study

2.3.2. Quality Scoring

A summary of the overall quality scores for all studies across all quality assessments is presented in Table 2-4.

2.3.3. PEDro Scores

All studies failed to conceal group allocations and blind participants and therapists. This made the highest score eight, which was attained by Belavy et al. (2010), Belavy et al. (2008) and Hides et al. (2011). Cao et al. (2005), Holguin et al. (2009) and Marcias et al. (2007) all failed to blind assessors, scoring seven. Belavy et al. (2011) failed to take measures from at least 85% of participants and did not perform intention to treat analysis, scoring six. Belavy et al. (2012) also failed to take measures from at least 85% of participants and did not perform intention to treat analysis, scoring five.

2.3.4. The Cochrane Collaboration Risk of Bias

All of the studies had at least one area where there was a high risk of bias and were classed as having a high overall risk of bias. The risks were mostly performance and measurement bias due to not concealing group allocation and failing to blind participants and assessors. No papers reported a clear randomisation method, despite saying that participants were randomised. The overall risks were similar across all the studies except for Holguin et al. (2009) which had high or unclear risks for all points except for selective reporting.

2.3.5. Bed-rest Methodological Quality

The study which satisfied most of the bed-rest methodology criteria was Belavy et al. (2010), which only failed to clearly state if sunlight exposure was prohibited. However, no studies clearly indicated fulfilling the sunlight criteria. All

the other studies scored between three and five except for Cao et al. (2005) which only scored two, although for most criteria it was unclear if elements had been met rather than definitely not met. While all studies indicated the days on which measures were taken, none specified that the measures were taken at the same time of day for all participants. While six-degree head down tilt bed-rest was satisfied in 6 of the 8 studies, the protocols did allow participants to raise the head on occasions, such as for eating. Two studies marked with asterisks in Table 2-4 specifically mentioned allowing participants to raise the head up to thirty degrees for “daytime activities”.

Table 2-4 Results of all quality control assessments performed across all included studies, ticks show condition was met, crosses show condition not met, up arrows show high risk of bias, down arrows show low risk of bias, question marks show unclear result.

	Belavy et al. (2010)	**Belavy et al. (2008)**	**Belavy et al.** (2011)	**Belavy et al** (2012)	**Cao et al.** (2005)	**Hides et al.** (2011)	**Holguin et al.** (2009)	**Marcias et al.** (2007)
PEDro criteria (short description)								
Eligibility criteria specified	✓	✓	✓	✓	✓	✓	✓	✓
Random allocation	✓	✓	✓	✓	✓	✓	✓	✓
Concealed allocation	×	×	×	×	×	×	×	×
Similar baseline groups	✓	✓	✓	✓	✓	✓	✓	✓
Blinding of participants	×	×	×	×	×	×	×	×
Blinding of therapists	×	×	×	×	×	×	×	×
Blinding of assessors	✓	✓	✓	×	×	✓	×	×
Measures obtained from 85% of participants	✓	✓	×	×	✓	✓	✓	✓
All participants received treatment or intention to treat analysis performed	✓	✓	×	×	✓	✓	✓	✓
Between groups statistics	✓	✓	✓	✓	✓	✓	✓	✓
Point and variability measures	✓	✓	✓	✓	✓	✓	✓	✓
Total score	**8**	**8**	**6**	**5**	**7**	**8**	**7**	**7**
Risk of bias criteria (short description)								
Random sequence generation	?	?	?	?	?	?	?	?
Allocation concealment	↑	↑	?	↑	↑	↑	↑	↑
Blinding of participants and assessors	↑	↑	↑	↑	↑	↑	↑	↑
Blinding of outcome assessment	↓	↓	↓	↑	↑	↓	↑	↑
Incomplete outcome data	↓	↓	?	?	↓	↓	↑	↓
Selective reporting	↓	↓	↓	↓	↓	↓	↓	↓
Total score	↑	↑	↑	↑	↑	↑	↑	↑
Bed-rest criteria (short description)								
Six degree head down tilt	✓	?*	✓	?*	✓	✓	✓	✓
Individualised and controlled diet	✓	✓	✓	✓	?	✓	✓	?
Set daily routine with fixed wake/seep time	✓	?	?	?	?	✓	?	?
Bed-rest phases standardised for all participants	✓	✓	✓	✓	?	✓	✓	✓
Uninterrupted bed-rest except for test condition	✓	?	?	?	✓	✓	?	?
Sunlight exposure prohibited	?	?	?	?	?	?	?	?
All measures taken same day and time	✓	✓	✓	✓	?	✓	✓	✓
Bed-rest duration (days)	60	56	90	60	28	60	90	28
Total points met	**6**	**4**	**3**	**5**	**2**	**5**	**3**	**2**

*Participants were allowed to raise trunk to 30 degrees tilt during day activities

2.3.6. Lumbopelvic Changes Observed when no intervention used

The lumbopelvic changes that have been observed across the studies when no intervention was used are listed in Table 2-5 for muscle changes and Table 2-6 for spinal morphology changes. This provides a reference for what can be expected to occur in the lumbopelvic region of individuals exposed to axial unloading simulation via bed-rest when countermeasure interventions are not undertaken.

Table 2-5 - Lumbopelvic muscle changes reported across all studies, method of measure and observed change in inactive control groups

Change Measured	Method of measure	Reference(s)	Change observed in controls
Multifdus muscle			
CSA at L1	MRI (% change)	Belavy et al. (2010)	Decrease 6%
CSA at L2	MRI (% change)	Belavy et al. (2010)	Decrease 4%
CSA at L3	MRI (% change)	Belavy et al. (2010)	Decrease 7%
CSA at L4	MRI (% change)	Belavy et al. (2010)	Decrease 7%
		Belavy et al. (2008)	Decrease 21%
CSA at L5	MRI (% change)	Belavy et al. (2010)	Decrease 12.2%
Volume at L1-S1	MRI (% change)	Belavy et al. (2011)	Decrease 10%
Erector Spinae muscle			
CSA at L1	MRI (% change)	Belavy et al. (2010)	Decrease 13.2%
CSA at L2	MRI (% change)	Belavy et al. (2010)	Decrease 11.3%
CSA at L3	MRI (% change)	Belavy et al. (2010)	Decrease 9.6%
CSA at L4	MRI (% change)	Belavy et al. (2010)	Decrease 8.8%
	MRI (mm^2 change)	Cao et al. (2005)	Decrease 468mm^2
CSA at L5	MRI (% change)	Belavy et al. (2010)	Decrease 8.4%
Volume at L1-S1	MRI (% change)	Belavy et al. (2011)	Decrease 10%
Max tonic activity change with lower limb movement. Lumbar region	EMG (%change)	Belavy et al. (2012)	Increase 15%*
Max tonic activity change with lower limb movement. Thoracic region	EMG (%change)	Belavy et al. (2012)	Increase 5%*
Psoas muscle			
CSA at L1	MRI (% change)	Belavy et al. (2010)	Increase 13%
CSA at L2	MRI (% change)	Belavy et al. (2010)	Increase 7.5%
CSA at L3	MRI (% change)	Belavy et al. (2010)	Increase 5%
CSA at L4	MRI (% change)	Belavy et al. (2010)	Increase 3%
		Belavy et al. (2008)	Increase 7%
CSA at L5	MRI (% change)	Belavy et al. (2010)	Increase 1.2%
Volume at L1-S1	MRI (% change)	Belavy et al. (2011)	Increase 2.5%*
Quadratus Lumborum muscle			
CSA at L1	MRI (% change)	Belavy et al. (2010)	Decrease 5%
CSA at L2	MRI (% change)	Belavy et al. (2010)	Decrease 6.3%
CSA at L3	MRI (% change)	Belavy et al. (2010)	Decrease 11.7%

Change Measured	Method of measure	Reference(s)	Change observed in controls
CSA at L4	MRI (% change)	Belavy et al. (2010)	Decease 8.9%
Volume at L1-S1	MRI (% change)	Belavy et al. (2011)	Decrease 3%*
EMG ratios			
Lumbopelvic extensor-flexor co-contraction	EMG (%change)	Belavy et al. (2012)	Decrease 2.5%*
Lumbopelvic extensor-flexor activity	EMG (%change)	Belavy et al. (2012)	Increase 3%*
Tonic activity			
Inferior Gluteus Maximus	EMG (%change)	Belavy et al. (2012)	Decrease 14%*
Internal Oblique	EMG (%change)	Belavy et al. (2012)	Increase 7.5%*
External Oblique	EMG (%change)	Belavy et al. (2012)	Decrease 3.5%*
Trunk strength			
Isokinetic extension	dynamometer (% change)	Belavy et al. (2012)	Decrease 34.9%
Isokinetic flexion	dynamometer (% change)	Belavy et al. (2012)	Decrease 9.6%
Lumbar strength at various flexion angles	Nm	Marcias et al. (2007)	Decrease 32Nm

* - values of change were estimated from figures as raw data were not available. CSA: cross sectional area

Table 2-6 - Lumbopelvic spinal morphology changes reported across all studies, method of measure and observed change in inactive control groups

Change Measured	Method of measure	Reference(s)	Change observed in controls
Lordosis angle			
L1-S1	MRI (% change)	Belavy et al. (2010) Belavy et al. (2011) Cao et al. (2005)	Decrease 2.5% Increase 5.2% Decrease 3.3%
with 50% body weight load L1-S1	MRI(degrees)	Marcias et al. (2007)	No change
Lumbar spine compressibility with 50% body weight load L1-S1	MRI (mm)	Marcias et al. (2007)	Decrease 1mm
Intervertebral disc			
Volume L1-S1 pooled	MRI (% change)	Belavy et al. (2011) Belavy et al. (2010)	Increase 5% Increase 6%
Anterior-posterior diameter L1-S1 pooled	MRI (% change)	Belavy et al. (2011)	Increase 0.2%
Transverse diameter L1-S1 pooled	MRI (% change)	Belavy et al. (2011)	Decrease 0.3%
Axial CSA L1-S1 pooled	MRI (% change)	Belavy et al. (2011)	Decrease 0.1%
Sagittal CSA L1-S1 pooled	MRI (% change) MRI (mm^2 change)	Belavy et al. (2011) Belavy et al. (2008)	Increase 2.4% Increase 22mm^2
Nuclei Pulposi volume L1L2	MRI (cm^3 change)	Holguin et al. (2009)	Increase 0.4 cm^3
Nuclei Pulposi volume L2L3	MRI (cm^3 change)	Holguin et al. (2009)	Increase 0.8 cm^3
Nuclei Pulposi volume L3L4	MRI (cm^3 change)	Holguin et al. (2009)	Increase 1.6 cm^3
Nuclei Pulposi volume L4L5	MRI (cm^3 change)	Holguin et al. (2009)	Increase 1 cm^3
Nuclei Pulposi volume L5S1	MRI (cm^3 change)	Holguin et al. (2009)	Increase 1.1 cm^3
Volume L1L2	MRI (cm^3 change)	Holguin et al. (2009)	Increase 1 cm^3
Volume L2L3	MRI (cm^3 change)	Holguin et al. (2009)	Increase 1.9 cm^3
Volume L3L4	MRI (cm^3 change)	Holguin et al. (2009)	Increase 2.1 cm^3
Volume L4L5	MRI (cm^3 change)	Holguin et al. (2009)	Increase 2.4 cm^3
Volume L5S1	MRI (cm^3 change)	Holguin et al. (2009)	Increase 2.2 cm^3
Convexity L1L2	MRI (10^{-1} change)	Holguin et al. (2009)	Decrease 1.4 10^{-1}
Convexity L2L3	MRI (10^{-1} change)	Holguin et al. (2009)	Decrease 1.2 10^{-1}
Convexity L3L4	MRI (10^{-1} change)	Holguin et al. (2009)	Decrease 0.8 10^{-1}

Change Measured	Method of measure	Reference(s)	Change observed in controls
Convexity L4L5	MRI (10^{-1} change)	Holguin et al. (2009)	Decrease 0.9 10^{-1}
Convexity L5S1	MRI (10^{-1} change)	Holguin et al. (2009)	Decrease 1.3 10^{-1}
Posterior height L1-S1 pooled	MRI (% change)	Belavy et al. (2010)	Increase 8.2%
		Belavy et al. (2011)	Increase 3%
Anterior height L1-S1 pooled	MRI (% change)	Belavy et al. (2010)	Increase 4.6%
		Belavy et al. (2011)	Increase 6.1%
Spinal length between L1-S1	MRI (% change)	Belavy et al. (2010)	Increase 2.8%
		Belavy et al. (2008)	Increase 2.6%*
		Belavy et al. (2011)	Increase 1.2%
		Holguin et al. (2009)	Increase 5%

2.3.7. Outcomes assessed

Table 2-7 shows which interventions were tested for each outcome. The table highlights the reason why decisions about which interventions were most effective is difficult to reach based on current research. Very few interventions have been consistently tested against the same outcomes. The only outcomes where good comparability existed were lordosis angle, disc volume and spinal length. Overall resistive vibration exercise (RVE) was the most frequently tested intervention, although spinal mobility exercises and flywheel exercise were tested against the most spinal morphology outcomes.

Table 2-7 Indication of which interventions were assessed against the various outcomes used across all studies

Outcomes	RVE	Flywheel	Spinal mobs	LBNP treadmill	LMMS	RE	SMC
Multifidus muscle CSA L1-L5 averaged	✓					✓	✓
Multifidus muscle CSA at L4	✓						
Multifidus muscle volume L1-S1		✓	✓				
Erector Spinae muscle CSA L1-L5 averaged	✓					✓	✓
Erector Spinae muscle CSA at L4				✓			
Erector Spinae muscle volume L1-S1		✓	✓				
Erector Spinae muscle lumbar tonic activity	✓						
Erector Spinae muscle thoracic tonic activity	✓						
Psoas muscle cross sectional area L1-L5 averaged	✓					✓	✓
Psoas muscle volume L1-S1		✓	✓				
Quadratus Lumborum muscle CSA L1-L4 averaged	✓					✓	✓
Quadratus Lumborum muscle volume L1-S1		✓	✓				
Lumbopelvic extensor-flexor co-contraction	✓						
Lumbopelvic extensor-flexor activity	✓						
Inferior Gluteus muscle Maximus tonic activity	✓						
External Oblique muscle tonic activity	✓						
Internal Oblique muscle tonic activity	✓						
Isokinetic strength trunk extension		✓	✓				
Isokinetic strength trunk flexion		✓	✓				
Lordosis angle L1-S1	✓	✓	✓	✓		✓	✓
Lordosis angle with 50% body weight				✓			
Lumbar spine compressibility with 50% body weight				✓			
Lumbar spine extension strength at various flexion angles				✓			
IV disc volume L1-S1	✓	✓	✓		✓	✓	✓
IV disc anterior-posterior diameter L1-S1		✓	✓				
IV disc transverse diameter L1-S1		✓	✓				
IV disc axial CSA L1-S1		✓	✓				
IV disc sagittal CSA L1-S1	✓	✓	✓				
IV disc nucleus pulposa volume L1-S1 averaged					✓		
IV disc convexity L1-S1 averaged					✓		
Posterior IV disc height	✓	✓	✓			✓	✓
Anterior IV disc height	✓	✓	✓			✓	✓
Spinal length L1-S1	✓	✓	✓	✓	✓	✓	✓

RVE: resistive vibration exercise, RE: resistive exercise, IV: intervertebral, CSA: cross sectional area, L# and S# refer to lumbar and sacral spinal regions, LMMS: low magnitude mechanical stimulation, SMC: specific motor control.

2.3.8. Interventions and outcomes with magnitude based inference results

There were six different countermeasures investigated during bed-rest in seven of the studies, including RVE, RE, flywheel exercise, spinal mobility exercises, LBNP treadmill and low magnitude mechanical signals (LMMS). Details of the interventions and the prescriptions are in section 2.3.1 Table 2-3.

Resistance vibration exercise involved supine lower limb, close-chain exercise with the feet placed on a suspended vibrating platform, with resistance generated by elastics between the vibrating platform and a pelvic belt and shoulder straps (Belavy et al. 2008; Belavy et al. 2012). Although initially developed as countermeasure against bone loss during spaceflight, vibration stimulation as used in both RVE and LMMS has been shown to improve lumbosacral proprioception (Fontana, Richardson and Stanton 2005) and promote a tonic vibration reflex in muscles subjected to the stimulation (Ribot-Cisca, Butler and Thomas 2003). The RE was the same as the RVE but without the vibrating platform (Belavy et al. 2010). Resistive loading between feet and shoulder straps in RVE and RE was expected to load the spine axially (Belavy et al. 2012) and may be part of the mechanism for preventing changes that occur during axial unloading.

Supine LBNP treadmill training resulted in cardiovascular demands, and produced ground reaction forces, similar to upright walking (Boda et al. 2000). One body weight ground reaction force is produced during the treadmill exercise by combination of the LBNP suction around an elastic waist seal and axial loading from shoulder straps attached to the waist seal (Cao et al. 2005). It was hypothesised that loading during the exercise may maintain spinal curvature and muscle strength (Marcias et al. 2007).

The flywheel exercise device was developed to provide resistance during lower limb, knee extension based exercises, in microgravity, using the inertia of a rotating flywheel (Alkner and Tesch 2004). Exercise on the flywheel device involves resting on a backrest attached with wheels to a fixed girder. Shoulders and hips are kept in place using pads, handles and a waist belt, while the feet are attached to a footplate. A band attaches the backrest to the flywheel which is located by the footplate. Inertia from the flywheel resists moving into knee extension while pushing down on the footplate, followed by the returning to a flexed knee position while resisting the inertia force pulling the backrest back to the start position (Alkner and Tesch 2004). While this is a lower limb global exercise device, it was hypothesised that this type of exercise would also produce axial loading and reduce spinal extensor muscle atrophy (Belavy et al. 2011).

Spinal mobility exercises involved low-load spinal movements intended to reduce LBP. The movements were initiated and controlled by the participants independently and involved active slow, large amplitude and low load spinal movements in the frontal, sagittal and longitudinal plane, five times daily (Belavy et al. 2011).

One study (Hides et al. 2011) examined the effects of post bed-rest rehabilitation on recovery, comparing two types of intervention: SMC rehabilitation and TFS rehabilitation. Specific motor control was designed to restore lumbar spine intersegmental control and normal lordotic posture, targeting LM, TrA and spinal extensor muscles, whereas TFS was a general strengthening programme for the superficial trunk muscles (Hides et al. 2011).

In Tables 2-8 and 2-9 the data source is included as a reference number to allow effects to be considered with the quality score of the corresponding paper.

The reference numbering system used is as follows: 1= Belavy et al. (2010), 2 = Belavy et al. (2008), 3 = Hides et al. (2011), 4= Belavy et al. (2011), 5= Cao et al. (2005). 6 = Belavy et al. (2012) 7= Marcias et al. (2007) and 8 = Holguin et al. (2009).

2.3.9. Effect of countermeasures on muscle changes

Table 2-8 shows the effects of all muscle related changes assessed across all eight studies.

Resistance vibration exercise had training effects for tonic activity in the lumbar Erector Spinae muscle, Lumbopelvic extensor-flexor co-contraction ratio, Lumbopelvic extensor-flexor activity ratio and External Oblique muscle tonic activity. The intervention was able to partially protect LM muscle CSA L1-L5, Erector Spinae muscle CSA L1-L5, Quadratus Lumborum muscle CSA L1-L4, Inferior Gluteus Maximus muscle tonic activity and Internal Oblique muscle tonic activity. The RVE programme worsened Erector Spinae muscle thoracic tonic activity and Psoas CSA L1-L5.

Flywheel exercise had no observed training effects, partially protected LM muscle volume L1-S1, Erector Spinae muscle volume L1-S1, Psoas muscle volume L1-S1 and Isokinetic trunk extension strength. The intervention worsened Quadratus Lumborum muscle volume L1-S1 and Isokinetic strength trunk flexion.

Spinal mobility exercises had no observed training effects. It partially protected LM muscle volume L1-S1, Psoas muscle volume L1-S1 (although it is unclear what the true effect is), isokinetic trunk extension strength and isokinetic trunk flexion strength. It worsened Erector Spinae muscle volume L1-S1 and Quadratus Lumborum muscle volume L1-S1.

Lower body negative pressure treadmill was only tested for one muscle change and was able to partially protect Erector Spinae muscle CSA at L4.

Resistance exercise had no observed training effects, partially protected Multifidus muscle CSA L1-S1, Erector Spinae muscle CSA L1-S1 and Quadratus Lumborum muscle CSA L1-L4, and worsened Psoas muscle CSA L1-L5.

Table 2-8 Effects of interventions on muscle changes showing direction of change with no interventions, intervention effect size, probability of true effect and the raw change in the intervention group expressed as a percentage of the control group indicating how far off baseline the intervention group was in relation to controls.

	n	Increase/ decrease in inactive controls	Effect size ±90% CI	Probability of true effect being mechanistically (±SD when pooled)		% recovered off baseline
				Small	Moderate	(±SD when pooled)
Resistance Vibration Exercise						
Multifidus muscle CSA L1-L5 pooled	16	↓	0.9±0.8 [1]	86.8±18.2%↑	80.3±15.8%↑	-36±30%
Multifidus muscle CSA at L4	19	↓	2.7±1.0 [2]	100%↑	100%↑	-30%
Erector Spinae muscle CSA L1-L5 pooled	16	↓	0.6±0.9 [1]	86±9.5 %↑	77.1±13.4%↑	-65±14%
Erector Spinae muscle lumbar tonic activity	20	↑	-2.9±1.1 [6]	100%↓	100%↓	+20% (training)
Erector Spinae muscle thoracic tonic activity	20	↑	0.6±0.8 [6]	89.2%↑	80.5%↑	-220%
Psoas muscle cross sectional area L1-L5 pooled	16	↑	0.7±0.9 [1]	89.5±19.3%↑	84.9±24.9%↑	-280±144%
Quadratus Lumborum muscle CSA L1-L4 pooled	16	↓	0.7±0.9 [1]	85.3±17.5%↑	78±23.9%↑	-31±21%
Lumbopelvic extensor-flexor co-contraction	20	↓	4.3±1.3 [6]	100%↑	100%↑	+80% (training)
Lumbopelvic extensor-flexor activity	20	↑	-3.0±1.0 [6]	100%↓	100%↓	+433% (training)
Inferior Gluteus Maximus muscle tonic activity	20	↓	2.6±1.0 [6]	100%↑	100%↑	-3.60%
External Oblique muscle tonic activity	20	↓	2.7±1.0 [6]	100%↑	100%↑	+200% (training)
Internal Oblique muscle tonic activity	20	↑	-1.1±0.8 [6]	98.7%↓	97.1%↓	-13%
Flywheel Exercise						
Multifidus muscle volume L1-S1	17	↓	0.3±0.8 [4]	68.1%↑	52.8%↑	-80%
Erector Spinae muscle volume L1-S1	17	↓	0.4±0.8 [4]	71.2%↑	56.7%↑	-70%
Psoas muscle volume L1-S1	17	↑	-0.3±0.8 [4]	68.2%↓	53.1%↓	-40%
Quadratus Lumborum volume L1-S1	17	↑	-0.2±0.8 [4]	61.3%↓	46.5%↓	-183%
Isokinetic strength trunk extension	17	↓	0.2±0.8 [4]	58.1%↑	42.9%↑	-80%

Isokinetic strength trunk flexion	17	↓	-1.0±0.8 [4]	96%↓	92%↓	-184%
Spinal mobility exercises						
Multifidus muscle volume L1-S1	16	↓	0.3±0.8 [4]	67.1%↑	52.5%↑	-85%
Erector Spinae muscle volume L1-S1	16	↓	-0.1±0.8 [4]	48.3%↓	32.1%↓	-110%
Psoas muscle volume L1-S1	16		0.0±0.8 [4]	Unclear	Unclear	-96%
Quadratus Lumborum muscle volume L1-S1	16	↓	-0.4±0.8 [4]	72.4%↓	59.4%↓	-250%
Isokinetic strength trunk extension	16	↓	0.4±0.8 [4]	70.3%↑	56.5%↑	-60%
Isokinetic strength trunk flexion	16	↓	1.1±0.9 [4]	97%↑	94%↑	-14%
Lower Body Negative Pressure Treadmill						
Erector Spinae muscle CSA at L4	24	↓	1.0±0.8 [5]	97.5%↑	94.7%↑	-79.49±14%
Resistance Exercise						
Multifidus muscle CSA L1-L5 pooled	16	↓	0.6±0.8 [1]	80.3±15.8%↑	70.3±21.8%↑	-56±15%
Erector Spinae muscle CSA L1-L5 pooled	16	↓	1.3±0.9 [1]	98.2±1.3%↑	96.2±2.6%↑	-33±16%
Psoas muscle cross sectional area L1-L5 pooled	16	↑	0.5±0.8 [1]	84±33.3%↑	81.2±37.3%↑	-257±172%
Quadratus Lumborum muscle CSA L1-L4 pooled	16	↓	1.0±0.8 [1]	93±9%↑	88.1±14%↑	-6±6%

Figures 2-3 and 2-4 show the effect size and 90% confidence interval for the interventions assessed with muscle related outcomes. Where two interventions were assessed against the same outcome, the effect sizes are plotted adjacent to allow comparison. Minimal mechanistic worthwhile change ranges of 0.2 and 0.6 for at least small and moderate sized effects respectively are shown.

Resistance vibration exercise had a larger effect than RE for protecting LM and Psoas muscle CSA. However, RE had a larger effect than RVE for lumbar Erector Spinae and Quadratus Lumborum muscle CSA. Resistance vibration exercise also had large effect sizes for protecting against changes in LM muscle CSA at L4, lumbopelvic extensor-flexor co-contraction and activity ratio, inferior Gluteus Maximus, internal and External Oblique and lumbar Erector Spinae muscle tonic activities, but no data exists to compare these effects with other interventions. Flywheel and spinal mobility exercises showed very similar effects which were either small or unclear, except for spinal mobility exercises which was more effective and had moderate effect size for protecting isokinetic trunk flexion strength. Resistance vibration exercise and RE both worsened Psoas muscle CSA changes in the lumbar region and there was little difference between them in the size of this effect. Lower body negative pressure treadmill training had a similar sized effect for protecting Erector Spinae muscle CSA at L4 as RVE and RE did between L1 and S1.

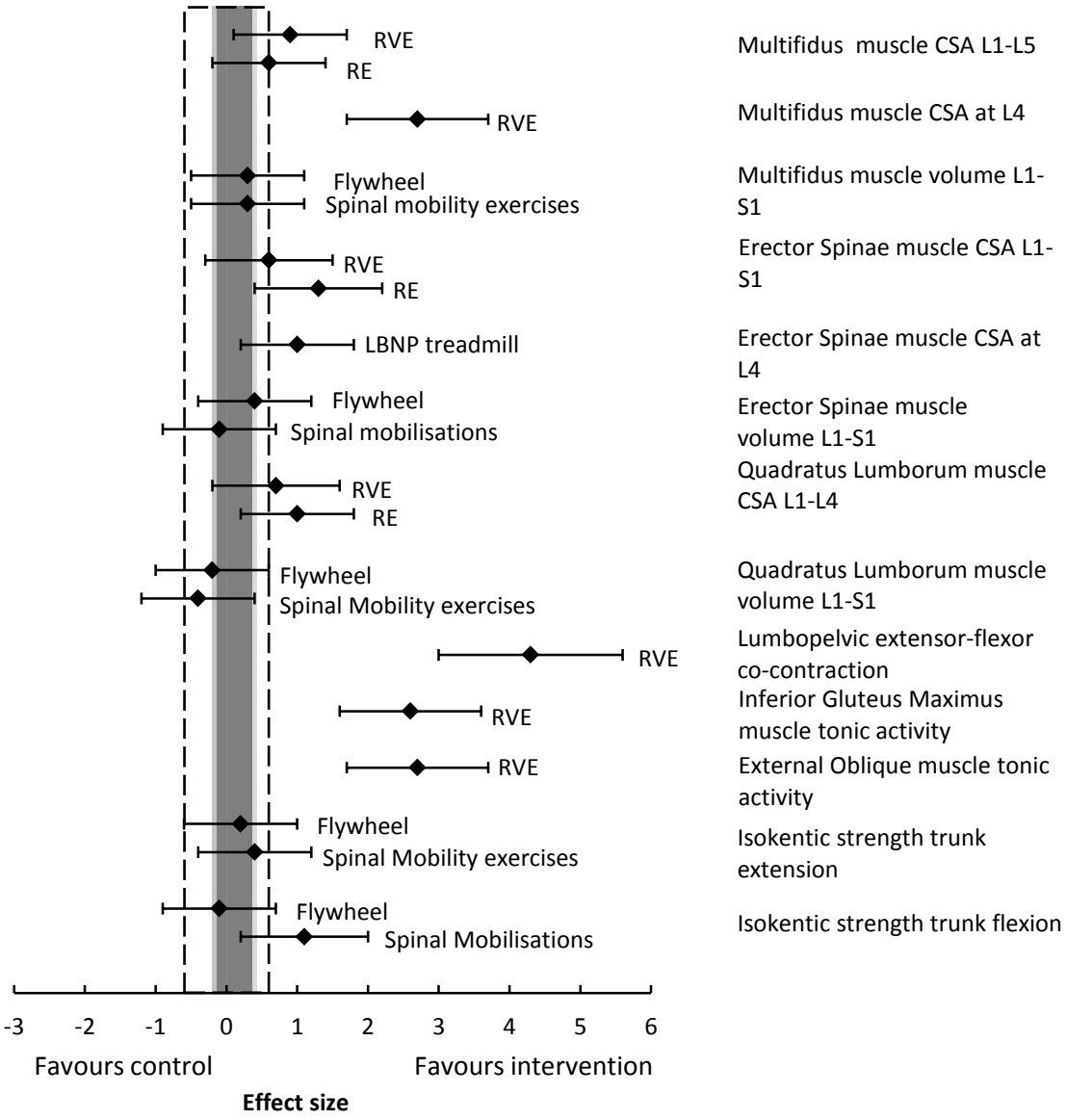


Figure 2-3 Muscle changes where positive effects favour interventions – as occurs in cases where no intervention causes a decrease in the outcome measures Shaded area represents 0.2 effect size (at least small), dashed line represents 0.6 effect size (at least moderate). Tails are 90% confidence interval.

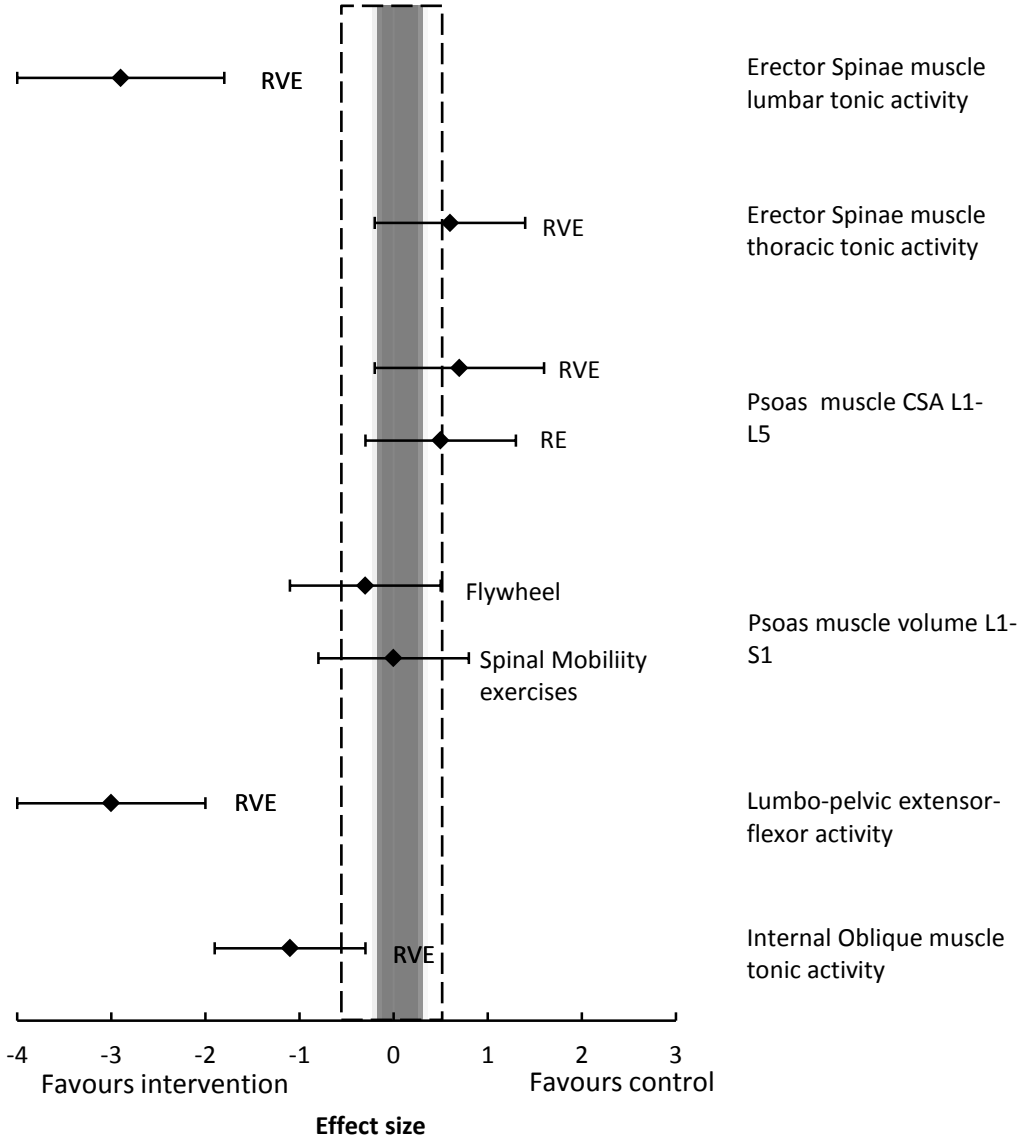


Figure 2-4 Muscle changes where negative effect favours intervention – as occurs in cases where no intervention causes an increase in the outcome measures. Shaded area represents 0.2 effect size (at least small), dashed line represents 0.6 effect size (at least moderate). Tails are 90% confidence interval.

2.3.10. Effect of countermeasures on spinal morphology changes

Table 2-9 shows the effects of interventions on spinal morphology changes across all studies. For spinal morphology the word intervertebral is abbreviated to IV.

Resistance vibration exercise did not have any training effect. It partially protected IV disc volume L1-S1, IV disc sagittal CSA L1-S1, Posterior IV disc height L1-S1 and Spinal length L1-S1. It failed to prevent, and worsened, Lordosis angle L1-S1 and Anterior IV disc height L1-S1.

Flywheel exercise had training effects for IV disc anterior-posterior diameter L1-S1 and IV disc sagittal CSA L1-S1. It partially protected anterior IV disc height L1-S1 and lordosis angle and worsened IV disc transverse diameter L1-S1, IV disc axial CSA L1-S1, Posterior IV disc height L1-S1 and Spinal length L1-S1.

Spinal mobility exercises had training effects for IV disc anterior-posterior diameter L1-S1 and IV disc sagittal CSA L1-S1. The intervention partially protected IV disc volume L1-S1 and Anterior IV disc height L1-S1, and worsened lordosis angle L1-S1, IV disc transverse diameter L1-S1, IV disc axial CSA L1-S1, Posterior IV disc height L1-S1 and Spinal Length L1-S1.

Lower body negative pressure treadmill had training effects for lumbar spine compressibility with 50% body weight and partially protected lordosis angle L1-S1, lumbar spine extension strength at various flexion angles and spinal length L1-S1.

Low magnitude mechanical signals had no observed training effects and partially protected IV disc volume L1-S1, IV disc nuclei pulposi volume L1-S1, IV disc convexity L1-S1 and spinal length L1-S1.

Resistance exercise had no observed training effects. The intervention was able to partially protect lordosis angle L1-S1, posterior IV disc height L1-S1, anterior IV disc height L1-S1 and spinal length L1-S1, and worsened IV disc volume L1-S1.

Table 2-9 Effects of interventions on spinal morphology change

	n	Increase/ decrease in inactive controls	Effect size ±90% CI	Probability of true effect being mechanistically		% recovery off baseline
				Small	Moderate	
Resistance Vibration Exercise						
Lordosis angle L1-S1	16	↓	-0.1±0.8 [1]	52.7%↓	37.5%↓	-124%
IV disc volume L1-S1	16	↑	-0.36±0.8 [1]	71%↓	56.6%↓	-73%
IV disc sagittal CSA L1-S1	19	↑	-2.9±1.1 [2]	100%↓	100%↓	-9%
Posterior IV disc height L1-S1	16	↑	-0.1±0.8 [1]	52.1%↓	37.1%↓	95%
Anterior IV disc height L1-S1	16	↑	0.4±0.8 [1]	75.2%↑	61.5%↑	-126%
Spinal length L1-S1	16	↑	-1.1±0.9[1]	81.5±26.1%↓	73.8±37%↓	-60±41%
Flywheel Exercise						
Lordosis angle L1-S1	17	↑	-0.2±0.8 [4]	57.3%↓	41.8%↓	-62%
IV disc volume L1-S1	17	↑	-0.5±0.8 [4]	79.2%↓	66.4%↓	-56.%
IV disc anterior-posterior diameter L1-S1	17	↑	-1.4±0.9 [4]	99.2%↓	85.5%↓	+550% (training)
IV disc transverse diameter L1-S1	17	↓	-1.8±0.9 [4]	99.9%↓	99.8%↓	-600%
IV disc axial CSA L1-S1	17	↓	-1.9±1.0 [4]	99.9%↓	93.9%↓	-2900%
IV disc sagittal CSA L1-S1	17	↑	-1.0±0.9 [4]	95.8%↓	91.6%↓	+117% (training)
Posterior IV disc height L1-S1	17	↑	0.7±0.8 [4]	88.5%↑	79.6%↑	-260%
Anterior IV disc height L1-S1	17	↑	-0.2±0.8 [4]	56.2%↓	40.6%↓	-87%
Spinal length L1-S1	17	↑	0.1±0.8 [4]	51%↑	36%↑	-108%
Spinal mobility exercises						
Lordosis angle L1-S1	16	↑	0.4±0.8 [4]	71.2%↑	57%↑	-171%
IV disc volume L1-S1	16	↑	-0.1±0.8 [4]	51.1%↓	36.1%↓	-92%
IV disc anterior-posterior diameter L1-S1	16	↑	-0.6±0.9 [4]	98.3%↓	75.5%↓	+200% (training)
IV disc transverse diameter L1-S1	16	↓	-1.8±1.0 [4]	99.7%↓	99.6%↓	-600%
IV disc axial CSA L1-S1	16	↓	-0.9±0.9 [4]	99.8%↓	88.2%↓	-1400%

IV disc sagittal CSA L1-S1	16	↑	-0.7±0.9 [4]	87%↓	78.1%↓	+33% (training)
Posterior IV disc height L1-S1	16	↑	0.9±0.9 [4]	93.6%↑	88.1%↑	-283%
Anterior IV disc height L1-S1	16	↑	-0.2±0.8 [4]	60.6%↓	46.1%↓	-85%
Spinal length L1-S1	16	↑	0.2±0.8 [4]	53.9%↑	37.8%↑	-117%
Lower Body Negative Pressure Treadmill						
Lordosis angle L1-S1	24	↓	1.2±0.7 [5]	99.4%↑	98.7%↑	-58%
Lordosis angle with 50% body weight	30	-	-0.7±0.7 [7]	95.1%↓	90%↓	No change in inactive bed-rest to compare
Lumbar spine compressibility with 50% body weight	30	↓	3.2±0.9 [7]	100%↑	100%↑	+20% (training)
Lumbar spine extension strength at various flexion angles	30	↓	1.4±0.7 [7]	99.9%↑	99.8%↑	-28%
Spinal length L1-S1	24	↑	-2.7±0.9[5]	100%↓	100%↓	-65%
Low Magnitude Mechanical Signals						
IV disc volume L1-S1	24	↑	-0.1±0.7 [8]	51±8.21%↓	34.6±6.2%↓	- 82.1±18.4%
IV disc nucleusi pulposi volume L1-S1 pooled	24	↑	At L1, 2, 4 0.1±0.7 [8] At L3, 5 -0.3±0.7 [8]	At L1, 2, 4 47.5±5%↑ At L3, 5 66.9±12%↓	At L1, 2, 4 32.1±6%↑ At L3, 5 49.5±11%↓	-90±54%
IV disc convexity L1-S1 pooled	24	↓	1.2±0.8 [8]	96.8±3.5%↑	92.8±7.2%↑	-10±25%
Spinal length L1-S1	24	↑	-0.3±0.7[8]	66.5%↓	48.9%↓	-58%
Resistance Exercise						
Lordosis angle L1-S1	16	↓	0.1±0.8 [1]	50.9%↑	35.3%↑	-76%
IV disc volume L1-S1	16	↑	0.1±0.8 [1]	47.5%↑	32.1%↑	-104%
Posterior IV disc height L1-S1	16	↑	-0.1±0.8 [1]	52.1%↓	36.8%↓	-95%
Anterior IV disc height L1-S1	16	↑	-0.1±0.8 [1]	54.8%↓	39.3%↓	-91%
Spinal length L1-S1	24	↑	-0.6±0.8	85.7%↓	75.5%↓	-75%

Figures 2-5 and 2-6 show the effect size and 90% confidence interval for the interventions tested against spinal morphology related outcomes. As with muscle changes, where two interventions were assessed against the same outcome, the effect sizes are plotted adjacent to allow comparison. Minimal mechanistic worthwhile change thresholds of 0.2 and 0.6 for at least small and moderate sized effects, respectively, are shown.

Resistance vibration exercise, flywheel, spinal mobility exercises, LMMS and RE were all assessed for protecting lumbar IV disc volume in the lumbar spine. Only RVE and Flywheel had clear, but small, effects for protecting this (Figure 2-5). Flywheel had a larger effect than spinal mobility exercises protecting lumbar IV disc anterior-posterior diameter. Resistance vibration exercise was clearly more effective than either flywheel or spinal mobility exercises for protecting lumbar IV disc sagittal CSA. The effect of RVE and RE in protecting lumbar IV disc posterior height was unclear, however, flywheel and spinal mobility exercises had small worsening effects. Flywheel, spinal mobility exercises and RE had no clear effect on lumbar IV disc anterior height, whereas RVE had a small worsening effect (Figure 6). Lower body negative pressure treadmill had a large effect preventing spinal length increase in the lumbar spine and was clearly more effective than RVE, flywheel, spinal mobility exercises, LMMS and RE. Resistance vibration exercise, LMMS and RE had small effects for preventing spinal length with RVE being slightly more effective than RE, and LMMS. Flywheel and spinal mobility exercises had no clear effect for preventing lumbar spinal length increase. Flywheel and spinal mobility exercises both made lumbar IV disc transverse diameter and axial CSA worse.

Lordosis angle appears on both figures showing both positive and negative effect sizes as favouring the interventions. This is due to a conflicting finding from

Belavy at al. (2011) of lordosis angle increasing in bed-rest, whereas all other studies found it to decrease.

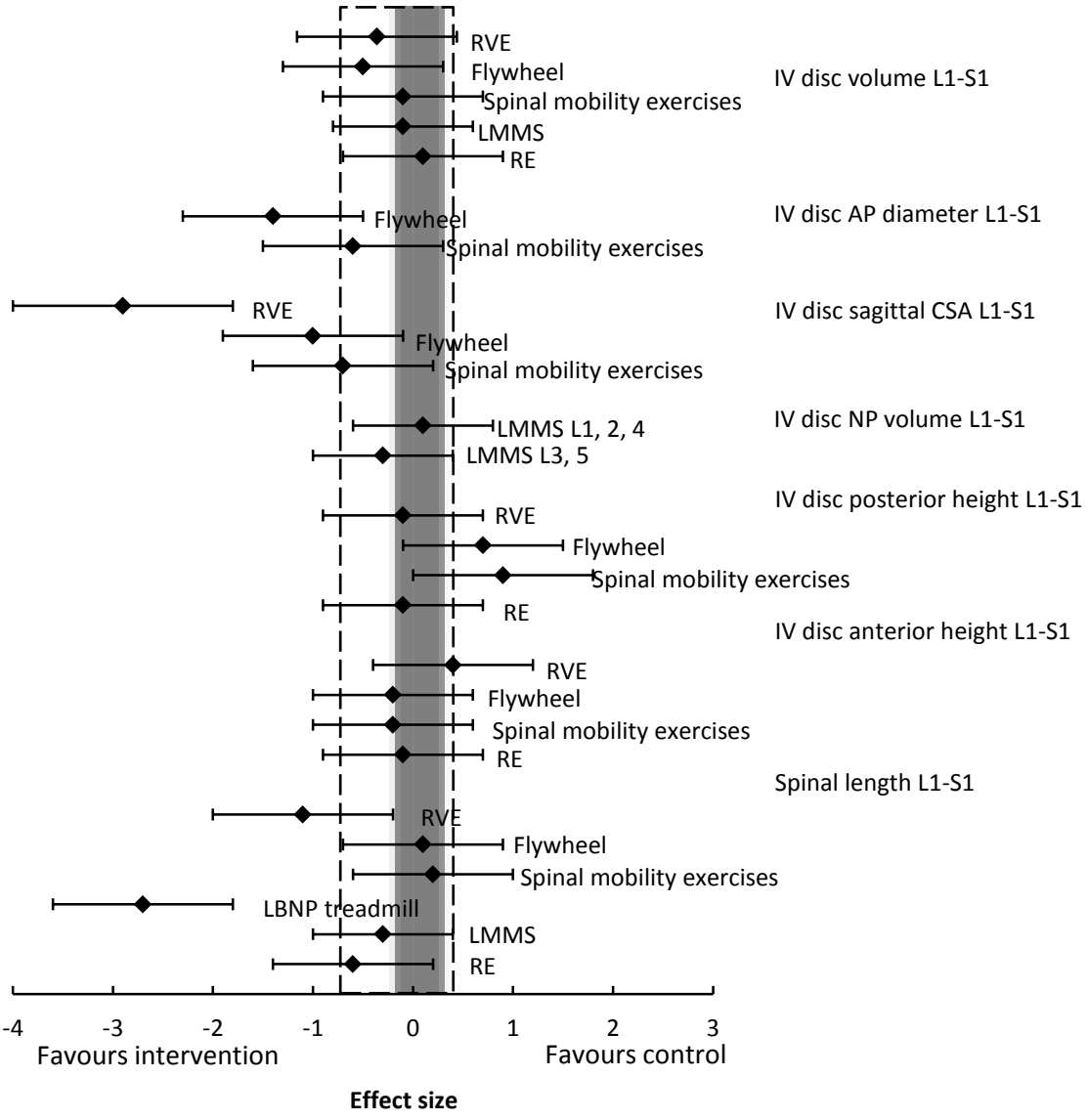


Figure 2-5 Spinal morphology changes where negative effects favour interventions – as occurs in cases where no intervention causes a increase in the outcome measures. Shaded area represents 0.2 effect size (at least small), dashed line represents 0.6 effect size (at least moderate). Tails are 90% confidence interval

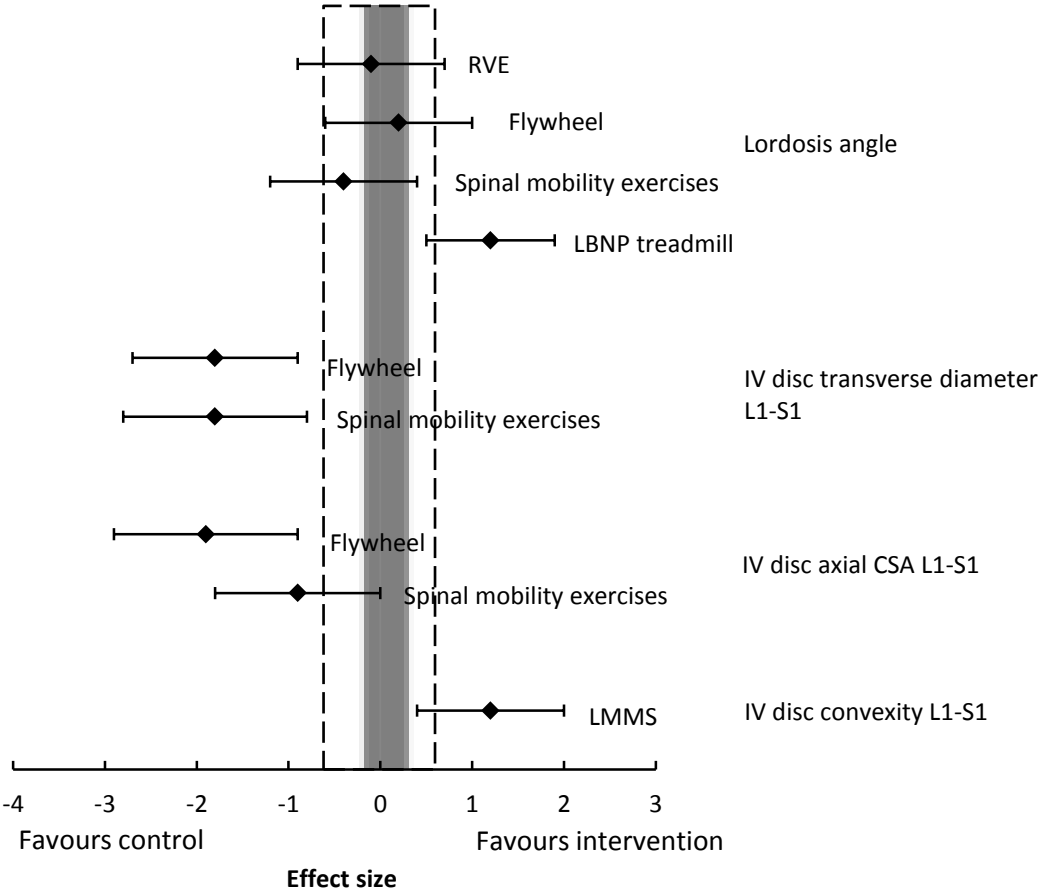


Figure 2-6 Spinal morphology changes where positive effects favour interventions – as occurs in cases where no intervention causes a decrease in the outcome measures. Shaded area represents 0.2 effect size (at least small), dashed line represents 0.6 effect size (at least moderate). Tails are 90% confidence interval

2.3.11. Effect of rehabilitation on muscle and spinal morphology changes

Table 2-10 shows the effects of the rehabilitation interventions on muscle and spinal morphology changes in the one included rehabilitation study. Specific motor control exercise was compared with TFS as a control group for calculating effect sizes.

Specific motor control had a training effect for Erector Spinae muscle CSA at L5 only, was able to partially protect against changes in LM muscle CSA L1-L5, Erector Spinae muscle CSA L1-L4, Psoas muscle CSA L1-L5, lordosis angle L1-S1, Posterior IV height L1-S1 and spinal length L1-S1. It caused no change in anterior IV disc height L1-S1. It had a worsening effect on change in Quadratus Lumborum muscle CSA L1-L4.

Trunk and general strengthening had a training effect for LM muscle CSA L1-L5 and Erector Spinae muscle CSA L1-L5 and fully protected lordosis angle L1-S1. It was able to partially protect against changes in Psoas muscle CSA L1-L5, Quadratus Lumborum muscle CSA L1-L4, IV disc volume L1-S1, posterior IV disc height L1-S1, anterior disc height L1-S1 and spinal length L1-S1.

Table 2-10 – Effects of rehabilitation interventions on muscle and spinal morphology changes

	n	Direction of change in bed-rest	Effect size of SMC vs TFS ±90% CI	Probability of true effect being mechanistically Small	Moderate	% recovery off baseline SMC	TFS
Multifidus muscle CSA L1-L5 pooled	21	↓	-1.4±0.8 [3]	52.7%↓	37.5%↓	-6±17%	+70% (training)
Erector Spinae muscle CSA L1-L5 pooled	21	↓	**L1-L4 pooled** -0.2±0.7 [3] **L5:** 0.1±0.7 [3]	**L1-L4 pooled** 74.6±25%↓ **L5:** 55.2%↑	**L1-L4 pooled** 64.8±33%↓ **L5:** 39.7%↑	L1-L4: -19±6% L5: +59% (training)	L1-L4: +7±11% (training) L5: +29% (training)
Psoas muscle CSA L1-L5 pooled	21	↑	**L1-L2:** -0.5±0.7 [3] **L3-L5:** 0.5±0.7 [3]	**L1-L2:** 80±17.2%↓ **L3-L5:** 86.4±3.7%↑	**L1-L2:** 85.2±22.8%↓ **L3-L5:** 76.1±5.5%↑	**L1-L2:** 0±1% **L3-L5** -32±4%	**L1-L2:** -55±55% **L3-L5** -1±26%
Quadratus Lumborum muscle CSA L1-L4 pooled	21	↓	-0.5±0.7 [3]	74.5±21.8%↓	63.5±26.5%↓	-110±40%	-10±134%
Lordosis angle L1-S1	21	↓	-0.3±0.7 [3]	68.6%↓	53.4%↓	-28%	+0% (fully protected)
IV disc volume L1-S1	21	↑	0.7±0.7 [3]	90.4%↑	82.7%↑	-100%	-67%
Posterior IV disc height L1-S1	21	↑	0.8±0.7 [3]	93.5%↓	87.5%↓	-40%	-67%
Anterior IV disc height L1-S1	21	↑	0.0±0.7 [3]	50%↓↑	50%↓↑	-100%	-57%
Spinal length L1-S1	21	↑	-0.1±0.7 [3]	50.5%↓	35%↓	-43%	-44%

The effect sizes show SMC exercises were more effective at rehabilitating changes in Erector Spinae muscle CSA but only at the L5 level, Psoas muscle CSA at the L3, L4 and L5 levels and Posterior IV disc height L1-S1. TFS was more effective for rehabilitating changes in LM muscle CSA L1-L5, Erector Spinae muscle CSA at the L1-L4 levels, Psoas muscle CSA at the L1 and L2 levels, Quadratus Lumborum muscle CSA L1-L4, Lordosis angle L1-S1 and IV disc volume L1-S1. It was unclear which intervention was more effective at preventing anterior IV disc height and spinal length increases from the effect sizes; both interventions partially protected spinal length to a similar percentage of baseline, however SMC left anterior disc height unchanged whereas TFS took it back to around 57% off the pre bed-rest baseline. Figures 2-7 and 2-8 show these effect sizes graphically.

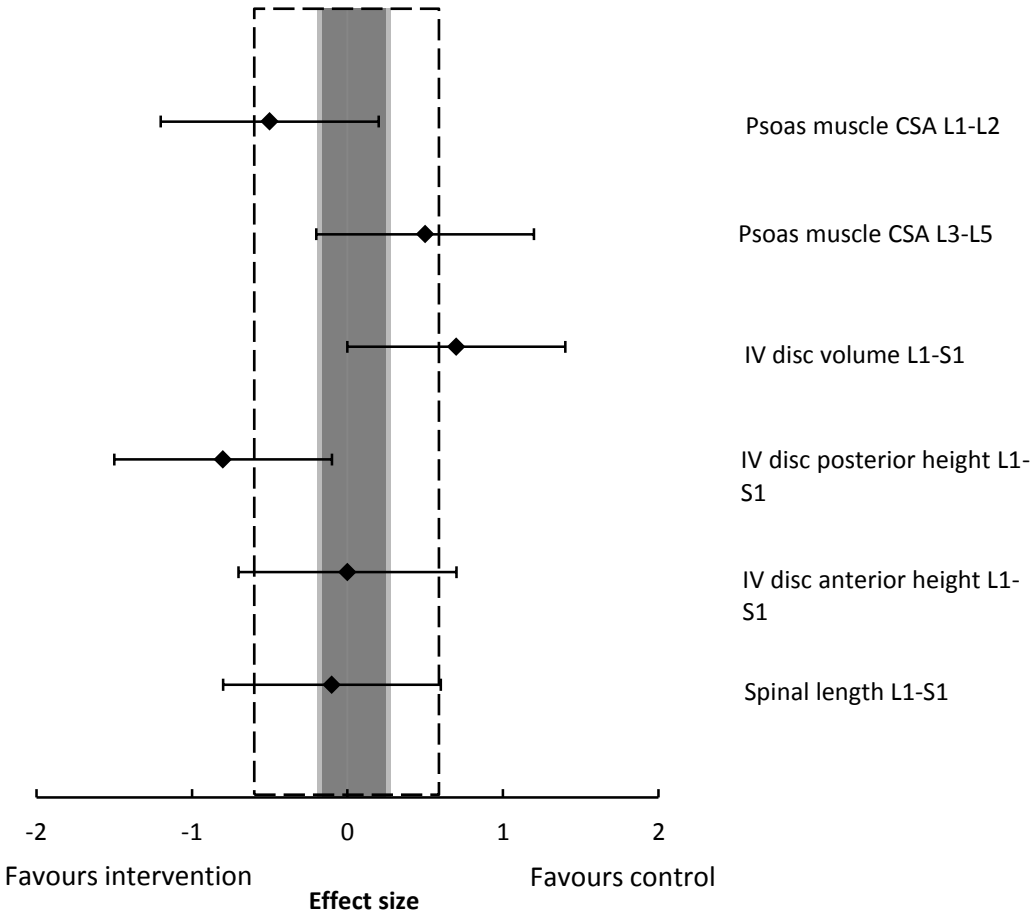


Figure 2-7 Specific motor control rehab vs trunk and general strengthening (control). Shaded area represents 0.2 effect size (at least small), dashed line represents 0.6 effect size (at least moderate). Tails are 90% confidence interval

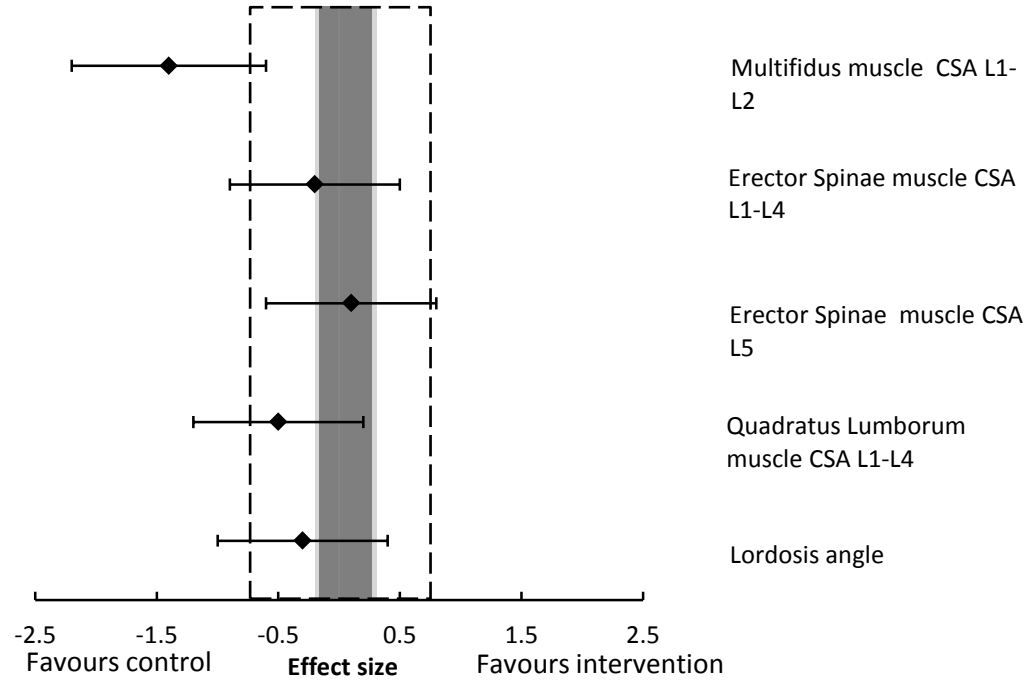


Figure 2-8 Specific motor control rehab vs trunk and general strengthening (control). Shaded area represents 0.2 effect size (at least small), dashed line represents 0.6 effect size (at least moderate). Tails are 90% confidence interval

2.4. Discussion

Only bed-rest spaceflight analogue studies were found for inclusion. Of the eight included studies, seven considered during bed-rest countermeasures and one studied post bed-rest rehabilitation.

2.4.1. Lumbopelvic changes expected with no treatment

The lumbopelvic changes occurring in response to spaceflight simulation via bed-rest without countermeasures, across the included studies, are reported. Lumbar Multifidus, Erector Spinae and Quadratus Lumborum muscles all reduce in size, while the Psoas muscle increases. Inferior Gluteus Maximus and External Oblique muscle activity decreases while Internal Oblique activity increases. Trunk isokinetic strength decreases in flexion and extension movements. Trunk extensor activity and extensor-flexor co-contraction ratio both decrease. Postural changes include reduced lumbar lordosis angle (one study, (Belavy et al. 2011) conflicts with this finding) and increased spinal length. The IV discs are affected, increasing in volume, height and sagittal CSA while losing convexity, axial CSA and transverse diameter. These findings agree with those reported previously by Sayson and Hargens (2008), Gernand (2004) and Buckey (2006). The full list of quantified changes reported in this study may be used by future clinical trials, assessing the same outcomes, for comparison of treatment group results.

2.4.2. Interventions and effectiveness

The full list of interventions and details is available in Table 2-3. No countermeasure was able to prevent all lumbopelvic changes.

2.4.3. Countermeasures – muscle changes

The most effective countermeasure appeared to be RVE, being the only one to have training effects, increasing External Oblique and Lumbar Erector Spinae

muscle tonic activity during lower limb movements. Resistance vibration exercise also had larger effect sizes compared with RE for protecting against decreases in the size of the LM muscle. Resistance exercse alone had slightly larger effects than RVE for preventing decreases in Quadratus Lumborum and Lumbar Erector Spinae muscle CSA. However, preventing LM muscle atrophy may be considered more important for mitigating spinal pain and damage risk as this muscle has been linked to LBP and injury (Hides et al. 1994; Hides et al. 2008; Bergmark 1989; Panjabi 2003). Flywheel and spinal mobility exercises had small or unclear effect sizes for protecting against all muscle changes for which they were assessed, except for spinal mobility exercises partially preventing trunk flexion strength loss. Spinal mobilisation's effect on trunk strength may have been a result of the nature in which the spinal mobility exercises were performed, being large amplitude active spinal movements in three planes (Belavy et al. 2011). Lower body negative pressure treadmill was only trialled for preventing decreases in Erector Spinae muscle CSA at L4, for which it had a moderate effect. However, as stated, Erector Spinae muscle CSA may not be as relevant to lumbopelvic injury and pain prevention as LM muscle atrophy. While RVE appears to be the most effective countermeasure for protecting against muscle changes, both RVE and RE can, however, cause further increases in Psoas muscle CSA, and RVE can cause additional increases in thoracic Erector Spinae muscle activity, all above the magnitude of change seen with no treatment. Psoas muscle hypertrophy may increase imbalances in the trunk flexion-extension strength ratio with greater flexion bias. Hypertrophy of the lumbopelvic flexors coupled with atrophy of the lumbopelvic extensors has been reported during inactive axial unloading simulation via bed-rest (Belavy, et al., 2008), and such an imbalance has been linked as a risk factor in LBP terrestrially (Lee et al. 1999).

Resistance vibration exercise was assessed against 12 out of 19 muscle outcomes compared with four for spinal mobility exercises and flywheel and only one for LBNP treadmill. Lack of direct intervention comparability limits the quality of comparison conclusions.

2.4.3.1. Countermeasures - spinal morphology changes

Lower body negative pressure treadmill exercise appeared to be most successful in protecting against spinal morphology changes as it was the only intervention able to fully prevent loss of lumbar lordosis and increased spinal length. Chronic and maintained increased spinal length may be particularly relevant to injury and pain risk, having been linked to disc degeneration through interruption of the diurnal cycle of disc compression and expansion (Sayson and Hargens 2008). A diurnal disc cycle is needed for normal fluid and nutrition turnover observed during typical terrestrial sleep-wake/loading-unloading cycles, which become disrupted in bed-rest and spaceflight (Sayson and Hargens 2008; Johnston et al. 2010; Belavy et al. 2015). Decreased lordosis angle may also be a key outcome, as prolonged periods of flexed lumbar posture have been linked to tissue creep in discs and posterior spinal ligaments and disc prolapse on subsequent axial loading (Adams and Hutton 1982). However, LBNP treadmill has not been assessed for preventing any intervertebral disc changes specifically. Prolonged increases in disc volume due to lack of axially loaded compression periods are also considered to be a key risk factor for disc degeneration (Sayson and Hargens 2008). Moreover, Adams and Hutton (1982) have suggested that the differences in anterior and posterior disc heights may be relevant to both lack of compression periods and prolonged flexion postures causing tissue creep. Assessing LBNP treadmill against these outcomes would be useful to further assess its effectiveness.

Resistance vibration exercise was found to be partially effective for preventing increases in lumbar disc volume and spinal length. While it further increased the loss of lumbar lordosis, it simultaneously further increased anterior disc height, over the amount of change seen with no intervention. While increasing anterior disc height may be useful for reducing the posterior tissue creep caused by prolonged flexed posture, increased loss of lumbar lordosis could be an aggravating factor for posterior tissue creep, therefore maintaining stress on the IV discs. Consequently, these conflicting results leave the effectiveness of resistance vibration exercise on spinal morphology unclear and potentially questionable. Low magnitude mechanical signals, partially protected lordosis angle, spinal length and disc volume. However, the LMMS effect sizes were very small and sometimes unclear, resulting in low effectiveness compared with RE and RVE. Resistance exercise partially protected lordosis angle, spinal length and anterior and posterior disc heights, however it worsened disc volume and its protective effects were all small, being potentially mechanistically *trivial*, and less than RVE for protecting spinal length.

Exercise on the flywheel apparatus and spinal mobility exercises were able to fully prevent some of the disc area and diameter changes. They both resulted in increased spinal length and posterior disc height compared to controls, which could increase risks of disc damage. Flywheel exercise was able to reduce anterior disc height, however, it increased posterior disc height, possibly due to the flexed posture adopted in the exercise. Considering that flexed postures have been linked to tissue creep and disc prolapse (Adams and Hutton 1982), this would appear to make flywheel an inappropriate countermeasure for the lumbopelvic region.

2.4.3.2. Countermeasures – overview

Use of the lower body negative pressure treadmill appeared to be the most effective overall countermeasure, with RVE the most effective for muscle changes but appearing to have a risk of worsening some changes in spinal morphology compared to controls. The treadmill exercise should be trialled using intervertebral disc height and volume and LM muscle size outcomes to further assess its effectiveness for spinal pain and injury risk prevention. It is not clear whether the treadmill or low pressure element both contribute to the effect and these aspects could be trialled individually. Due to the potential value of RVE for protecting muscle changes, it may be worth investigating if it could be performed in a way that maintains the muscle effects while eliminating the changes it currently causes to spinal morphology. Repetitive axially loaded flexion and extension has been linked to increased risk of intervertebral disc herniation (Callaghan and McGill 2001). Axially loaded squat exercise, as used in the RE and RVE programmes, were found to be commonly performed incorrectly by Durral and Manske (2005), most often due to inclusion of lumbar flexion. It was recommended that axially loaded squats be performed in a neutral spinal position, requiring pre-exercise teaching and peri-exercise visual assessment to train and verify adequate performance (Durral and Manske 2005). Additionally, it was suggested that pre-assessment of intersegmental control of the lumbar spine and pre-training of any deficiencies, such as poor LM muscle activity, may help mitigate spinal damage risk during RE (Durral and Manske 2005). Posture training, pre-assessment of intersegmental control of the lumbar spine and visual assessment of lumbar spine posture ensuring lordosis during exercise were not reported in the RVE or RE programmes. Such elements could be included and assessed for potential reduction of negative spinal morphology outcomes in future RE and RVE studies.

2.4.4. Rehabilitation

It is unclear which rehabilitation intervention was more effective based on effect size results alone. Results favoured SMC for restoring spinal length and posterior disc height, suggesting it may reduce the risk of prolapse or disc damage during rehabilitation. However, TFS was favoured for training LM muscle and restoring lordosis angle and overall disc volume. The authors of the rehabilitation study suggested that SMC is favourable over TFS. The reason for this is that SMC is expected to place less force on the discs and is associated with the lower rate of disc volume and anterior height changes (Hides et al. 2011). Lower forces on the discs during rehabilitation, at a time when the discs may be deconditioned and vulnerable to injury, may help restore posture and motor control with reduced risk of damage to the discs during the process. Therefore, a training programme starting with SMC when disc injury risk is high, then progressing to general trunk strengthening once lumbar postural control is restored may be indicated. Other rehabilitation methods which train the LM muscle and maintain lordosis angle, without high axial loading, would also be worth investigating.

Debate exists within terrestrial based rehabilitation literature comparing effectiveness of SMC exercises to other interventions for treating LBP and spinal injury. A recent systematic review found SMC was more effective than general exercise, manual therapy and minimal interventions for disability and pain outcomes at short and long term (Bystrom, Rasmussen-Barr and Grooten 2013). However spinal mobility exercises were found more effective than motor control, general exercise, manual therapy and minimal intervention for pain outcomes (Bystrom, Rasmussen-Barr and Grooten 2013). An earlier review by Macedo et al. (2009) found SMC effective only when compared with minimal interventions, but not general exercise. However Bystrom, Rassmuss-Bar and Grooten (2013)

utilised more recent research, and different review methodology, specifically isolating effects of SMC compared with other treatments, even when used in multiple intervention approaches. A systematic review by Wong et al. (2014) reported temporal changes in TrA muscle thickness during contraction was unrelated to temporal changes in patient reported LBP or disability scores. The same review found conflicting evidence for the same relationship but with the LM muscle rather than TrA muscle. Another systematic review by Laird et al. (2012) reported that interventions aiming to restore normal lumbopelvic movements were infrequently able to change observable movements, or improve pain, or activity limitation, outcome measures. Wong et al. (2014) suggested common clinical outcomes such as ultrasound imaging to assess the muscle activity, may have poor validity and reliability for research, resulting in variation and correlation attenuation. Wong et al. (2014), therefore, recommended relying more on electromyographic studies in the future. Another systematic review of specific spinal stabilisation exercises for LBP by Hauggaard and Persson (2007) agreed with Bystrom, Rassmuss-Bar and Grooten (2013) on the existence of evidence supporting the effectiveness of SMC for LBP, however, heterogeneity of outcomes across studies limited intervention comparability, adding to calls for standardisation of outcome measures.

European guidelines show chronic LBP and increased risk of spinal injury have several varied potential causes (Airaksinen et al. 2004). Therefore selection of outcomes and determination of clinically worthwhile variation within them is difficult. Attempting to find a single approach in a phenomenon with multi-dimensional causes may be self-limiting and a potential cause of conflicting results. O'Sullivan (2005) advocated sub-grouping spinal problems based on signs and symptoms, each with specific clinical definitions to resolve definition and diagnosis difficulties. Based on the subgroups, bed-rest induced changes in

spinal posture, atrophy and reduced activity in LM and TrA muscles fit into the motor control subgroup, whereas superficial muscle loss is attributable to the signs and symptoms domain. Therefore, an approach beginning with SMC to correct the spinal positioning and deep muscle control, progressing to functional positions and then rehabilitating the superficial muscles to support larger scale and demanding movements may be justified. This argument is supported by another systematic review which found multiple intervention approaches the most effective for LBP outcomes (Ferreira et al. 2006). A multiple countermeasure approach including LBNP treadmill and RVE (provided RVE associated spinal morphology risks can be mitigated) may have the best chance of being effective. Research into new interventions combining elements required to prevent or rehabilitate lumbopelvic changes, caused by axial unloading, may also be useful. For example, deep muscle training with functional movements, and promotion of a normal upright spinal posture, based on the work of Debuse et al. (2013), Gibbon et al. (2013) and Caplan et al. (2014) may be worth trialling following actual spaceflight or simulation via bed-rest.

2.4.5. Human Space Flight

Current in-flight countermeasures include combination prescriptions of RE, treadmill training with axial loading via a harness and cycle ergometer exercise (Ploutz-Snyder 2013; Loerch 2010). The RE and treadmill training do not prevent all expected lumbopelvic changes. Addition of vibration to the RE component may improve its effect on muscle changes but risk worsening spinal morphology changes. The power demand and potential for vibration to impact space vehicle structure would need to be considered. However the current International Space Station treadmill and resistance exercise device are vibration isolated from the main structure (Loerch 2010) so it may be feasible to also isolate a vibration platform. As the effect of treadmill training without LBNP in bed-rest is unknown,

it is not clear whether LBNP adds effectiveness to treadmill training. LBNP devices may also be limited by potential difficulties in donning and doffing the required equipment in microgravity and potential participant discomfort during use (Barry 2015). This is an area that requires further research. Cycle ergometer exercise has not been trialled for preventing lumbopelvic changes; therefore its effects are unknown in this context.

Due to current countermeasures failing to protect against all changes, post flight rehabilitation is very likely to be required. The European model for post spaceflight rehabilitation already focuses on correcting lumbopelvic muscle imbalance and reversing atrophy of LM and TrA muscles using the SMC approach (Evetts et al. 2014). Astronauts are trained to voluntarily contract LM and TrA muscles using live ultrasound imaging feedback. Following this, functional and weight bearing positions are used targeting the LM muscle activity over Psoas muscle to address any muscle imbalances (Evetts et al. 2014). The programme then integrates strength training, endurance and proprioceptive retraining programme tailored to individual's needs (Lambrecht 2015). A rehabilitation programme, like the European model of SMC followed by general trunk strengthening may be the advocated method based on this review. However, this is based on a single bed-rest rehabilitation paper and systematic review of previous terrestrial LBP research. Further studies in relevant populations and ideally an astronaut study, including population relevant and reported outcome measures rather than relying solely on surrogate measures, would be required to generate evidence determining if the SMC followed by TFS approach is effective for post spaceflight use. It would also be useful to establish minimal worthwhile changes in the relevant population reported outcome measures, in order to show interventions are effective at producing beneficial and patient centred outcomes.

A trial comparing the current in flight countermeasure programme with a LBNP treadmill element, possibly including vibration within the resistance element, on prevention of lumbopelvic changes may be useful. Such a trial could assess each intervention for the sub groups of lumbopelvic problems they specifically address, along with overall treatment programme effectiveness. Including elements such as pre-assessment and training of intersegmental control of the lumbar spine, alongside ensuring RE/RVE is performed in a neutral lumbopelvic position, could also be assessed for ability to mitigate spinal morphology related injury risks associated with axially loaded RE. A similar approach could be taken for a combined rehabilitation programme of SMC followed by general trunk strengthening. This would provide valuable information as to what specific domains are effectively dealt with and guide research to additional or new treatment elements. Further systematic review at that point could inform updated overall treatment programme recommendations and monitor progress in treating lumbopelvic changes caused by axial unloading.

Interventions for the lumbopelvic region should not negatively impact the wider physiological changes caused by spaceflight or bed-rest simulation. Treatment effectiveness data could be combined from further systematic reviews, similar to this one, conducted across all physiological areas affected by unloading due to spaceflight or bed-rest. Resistance exercise, for example, may be required for maintenance of global lower limb muscles (Pavy-Le Traon et al. 2007; Ferrando et al. 1997). Therefore, suggesting ways to modify axially loaded RE to reduce any increased risk of causing lumbopelvic damage, while still being effective outside the lumbopelvic region, may be preferable. An overall appraisal may be required to deal with conflicting recommendations from individual studies should differing effects be reported at various physiological regions in isolation. Guidance could also be provided for future research, by highlighting treatment programme

sections with poor effectiveness or conflicts between interventions. Large numbers of participants are needed for RCTs, so these will not be feasible for inflight studies and other study designs will need to be considered to provide sufficient evidence and validated against spaceflight populations.

2.4.6. Current intervention evidence base

Six countermeasure interventions and two rehabilitation interventions for the lumbopelvic region have been trialled across eight published bed-rest studies. Two studies utilised the First Berlin Bed-rest Study, while another two used the second Berlin Bed-rest Study, resulting in six distinct trial populations. Comparability between interventions is limited due to outcome heterogeneity across the studies. The rehabilitation interventions were assessed in a single study, without an inactive control group, due to ethical reasons (Hides 2015). Consequently, the quality of intervention recommendations for clinical use is restricted. Further research is advocated in this area, especially in rehabilitation, as countermeasure interventions have been shown unable to fully protect against many of the changes. Standardisation of outcome measures in the research community is recommended. None of the studies attempted to blind participants, resulting in performance bias. While blinding participants in exercise intervention trials is acknowledged as being difficult due to potentially obvious sham interventions, potential methods to counter this, within back pain exercise therapy trials, have been suggested (Helmhout et al. 2008).

No population reported outcome measures were used in the included studies. There is a risk of mismatch between clinician reported outcomes and population reported outcomes regarding how effectively interventions meet the population's needs and preferences (Nelson et al. 2015). Additionally, there are no reported minimal worthwhile changes for lumbopelvic outcome measures. Missing patient

reported outcomes and known minimal clinically significant changes make it difficult to establish the clinical and patient relevant effectiveness of interventions. In effect, the research performed in this area to date, has only shown that mechanistic and statistically relevant changes can be achieved through use of the tested interventions. However, it remains unknown if the reported changes in surrogate outcome measures are ones which astronauts consider relevant to their quality of life or if the intervention effects are clinically meaningful. It is recommended that future research attempt to establish clinically meaningful differences in lumbopelvic outcome measures and make use of population reported outcome measures such as quality of life, activity scores and return to normal activity measures.

2.4.7. Conclusions

The results of this systematic review suggest that LBNP treadmill exercise is the most effective countermeasure against lumbopelvic changes caused by spaceflight simulation via bed-rest, with RVE effective for preventing muscle changes but having an increased chance of worsening spinal morphology related injury risks. Suggestions were made for potential injury risk mitigation steps which could be tested in RVE.

Current countermeasures are unlikely to fully protect against all lumbopelvic changes occurring due to microgravity exposure, creating a rehabilitation requirement. Specific motor control followed by general trunk strengthening (once posture and deep lumbopelvic muscles are restored) was be the most effective rehabilitation approach found in the available literature. This suggestion should be treated with caution as it is based on only one rehabilitation study performed to date and the general trunk strengthening was treated as a control. More research

is required into interventions which may further improve overall effectiveness, preferably with standardised outcome measures.

2.4.8. Limitations of the systematic review

The small evidence base and heterogeneity of outcomes across the studies limits conclusions; more research is required, especially in rehabilitation. No true spaceflight population trials have been conducted, meaning conclusions are all based on simulation via bed-rest. Clear data to determine if mechanisms of back pain and spinal injury are the same between bed-rest and spaceflight populations do not yet exist. Without data to compare bed-rest and astronaut populations, with large enough representative populations, it is unknown if the effectiveness seen in analogue research will be the same in astronauts. Included studies utilised only surrogate and clinician reported outcome measures. Gaining access to patient views and the use of patient reported outcome measures relating to quality of life, and ability to perform population relevant functions post spaceflight, may also help drive intervention recommendations which are more clearly relevant to patient preferences and needs (Nelson et al. 2015).

The duration of bed-rest across the included studies varied, two used 28 days, one used 56 days, three used 60 days and two used 90 days. The variation in the lengths impacts the comparability between studies. Additionally, the results reported from the bed-rest studies can be assumed as valid only for space flight of similar duration (Mulder 2014). Therefore the LBNP treadmill exercise results may only relate well to shorter duration spaceflight missions of around 28days. RE, RVE, LMMS, flywheel and spinal mobility exercises may relate more to longer duration spaceflight missions of 60-90 days.

3. Chapter Three: Investigation of Recruitment of Lumbar Multifidus and Transversus Abdominis, Control of Movement Variability and Participant Perceived Comfort While Exercising in Various Settings Using the Functional Readaptive Exercise Device

3.1. Introduction

Management of poor lumbopelvic motor control and lumbar segmental instability, using motor control exercises, aimed at normalising the recruitment patterns of LM and TrA, was summarised in the thesis introduction using an overview by O'Sullivan (2000). Traditional LM and TrA training interventions recommend a progressive training protocol of, isolating muscle activation through biofeedback (Hides et al. 2008), training control of muscle activation, developing activation in functional activities and finally, building endurance of LM and TrA (O'Sullivan 2000; Hides et al. 2008). It has already been shown that the FRED, which is being assessed for potential use as an intervention in this field, recruits the LM and TrA without need for conscious muscle activation (Debuse et al. 2013). Therefore, FRED exercise is likely to be of use from the initial training stage of isolating contraction. However, it is not yet clear how a FRED intervention could be developed as part of a progressive training protocol.

The third prototype of the device, which was in use at the time of this study, incorporates easily adjustable crank and footplate positions. This allows use of five crank amplitudes (Figure 3-1) and five footplate positions (Figure 3-2), which combine to produce a total of 15 different exercise conditions (Table 3-1). The crank positions alter the amplitude of the movement, with 1 being the largest amplitude and 5 the smallest, while the footplate positions adjust the position of the device user forwards and backwards.

Figure 3-1The FRED with the adjustable crank highlighted by white arrows the footplates shown in the blue circle

Figure 3-2 A close up view of the adjustable footplate (image from FRED operating instructions)

Table 3-1 Possible Exercise settings – Ticks Indicate Possible Combinations, Crosses Indicate Unusable Combinations Which Would Damage the Device

		Foot Plate Positions				
Crank Amplitude		5	4	3	2	1
5	0.2m	✓	✓	✓	✓	✓
4	0.28m	×	✓	✓	✓	✓
3	0.36m	×	×	✓	✓	✓
2	0.425m	×	×	×	✓	✓
1	0.5m	×	×	×	×	✓

It was expected that resultant different foot paths during exercise on the device may have a differing effect on relevant motor control outcomes. This gives potential for a graduated training protocol to be developed which progressively challenges users of the device. Understanding the effects of footplate position and amplitude may allow formulation of a progressive training protocol, to allow greater use of the device as a rehabilitation intervention, and inform settings for use in future research studies.

A computer model of the device was used to visually illustrate the likely effect of the various amplitude and footplate positions on the movement pattern at the feet (Lindenroth 2013) (Figure 3-3).

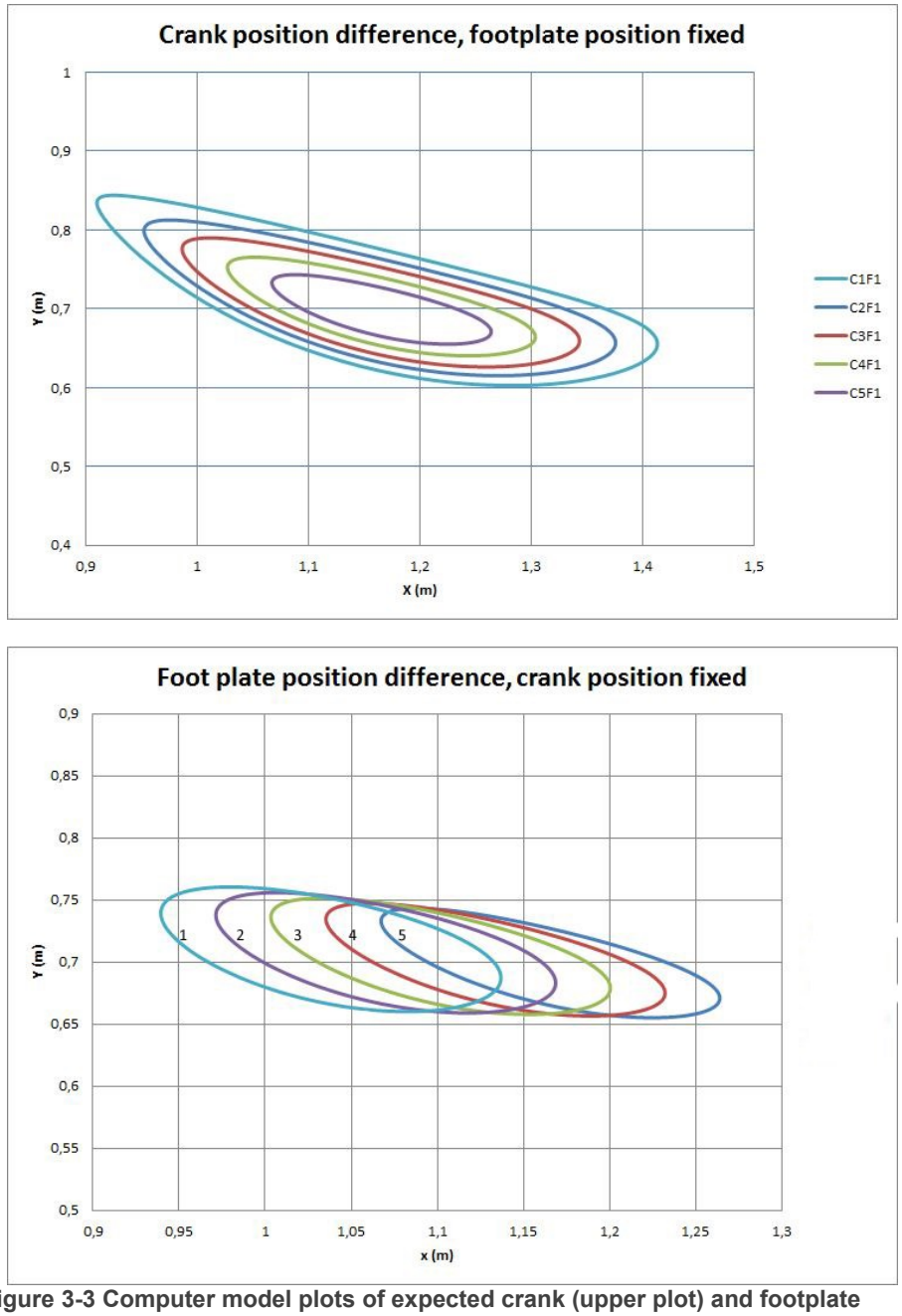


Figure 3-3 Computer model plots of expected crank (upper plot) and footplate (lower plot) position effect on exercise movement (Lindenroth 2013)

The computer model plots show the predicted movement pathways of the feet during exercise in each amplitude (labelled crank in the figure) and footplate position. It can be seen that as the amplitude increases the movement pathway increases both vertically and horizontally. Adjusting the footplate position is likely to move the user forwards and backwards during exercise, but does not appear to alter the shape of the movement pathway. This suggests that amplitude may be the more important element in modulating the challenge of FRED exercise. The hypothesis for this being that a larger foot movement may be more difficult to

control. Whereas moving forwards and backwards with the same size and shape movement pattern is not expected to vary movement control demands.

In order to develop the FRED as an intervention, beyond proof-of-concept investigations, this chapter intended to determine the influence of the various FRED settings on deep spinal muscle activity and movement control to inform the development of a progressive rehabilitation programme.

3.1.1. Aim and Objectives

The aim of this study was to develop a feasible and effective progressive exercise protocol using the new prototype device. The objectives were:

1. To investigate the differences between the various exercise settings across several relevant outcome measures of motor control and participant perceived comfort.
2. To develop understanding and evidence of differences between the exercise settings.
3. To use the data gathered to recommend a graduated and progressively demanding training protocol using the various device settings.

3.2. Methods

A random order within participant design was used to investigate the full range of device settings. The study received ethics approval from the Faculty of Health and Life Sciences Ethics Committee at Northumbria University (see appendix J).

3.2.1. Recruitment

Eight male participants with no-LBP were recruited using convenience sampling from within Northumbria University students and staff and were provided with study details (appendix A), enabling them to provide written informed consent (appendix B) prior to testing. Participants were screened for exclusion criteria based on previous studies using similar methodology (Kiesel et al. 2007). This included those aged under 18 and over 55 years, having history of neuromusculoskeletal problems or injuries affecting the ability to move (including LBP in past six months), heart disease, abdominal or spinal surgery in last three years and epilepsy.

Additionally, participants were required to complete and pass the Physical Activity Readiness and General Practice Physical Activity Questionnaires prior to testing. The Physical Activity Readiness Questionnaire identifies any persons for whom increased physical activity is contraindicated for medical reasons and evidence shows is at least 100% sensitive and 80% specific across all versions (Cardinal, Esters and Cardinal 1996). No persons assessed in this study showed contraindications to increasing physical activity. The General Practice Physical Activity Questionnaire is a validated and rapid measure of a person's current weekly physical activity levels, which maps to a Physical Activity Index categorising them as inactive, moderately inactive, moderately active or active. The scale was found to have good face validity and reliability in an NHS report (NHS 2006). Participants completed the questionnaire prior to testing to establish base line activity levels and assess for any variations which may have had a confounding impact on results. Demographics of all included participants are presented in Table 3-2.

Table 3-2 Participant Demographics (GPPAQ is General Practice Physical Activity Questionnaire)

Participant	Gender	Age (yrs)	Mass (kg)	Stature (m)	BMI	GPPAQ
001	Male	31	85	1.87	24	Active
002	Male	19	63.8	1.71	22	Active
003	Male	20	71.1	1.86	21	Active
004	Male	19	79.2	1.75	26	Active
005	Male	18	73.5	1.80	23	Active
006	Male	22	72.0	1.71	25	Active
007	Male	33	81.6	1.80	25	Moderately Active
008	Male	19	81.3	1.85	24	Active
Mean	-	23	75.9	1.79	24	-
Standard Deviation	-	5.9	7.0	0.07	1.8	-

3.2.2. Experimental Protocol and Data Collection

The FRED prototype version three was used throughout this study. The 15 possible combinations of footplate and amplitude settings were allocated numbered exercise conditions as per Table 3-3.

Table 3-3 Exercise Conditions – crank position 1 being the largest amplitude and footplate position 1 being the furthest forwards

Exercise condition	Crank Position	Footplate position
1	1	1
2	2	1
3	2	2
4	3	1
5	3	2
6	3	3
7	4	1
8	4	2
9	4	3
10	4	4
11	5	1
12	5	2
13	5	3
14	5	4
15	5	5

Participants exercised in all conditions except for condition one (largest crank and feet furthest forward) which was removed for safety reasons, due to it being considered too hard to control for first-time device users during pilot studies. The order of exercise conditions was randomised for each participant using a Latin Square random sequence grid generator (hamsterandwheel.com). Testing was split across two sessions over two consecutive days, with half the conditions tested on each day to prevent any training or loss of technique effects confounding results. Rest, ground standing and control conditions were also assessed for comparison.

Rest was defined as participants lying, fully supported on a plinth in a relaxed state. For LM measures this was prone, with a pillow placed under the abdomen, if needed, to reduce excessive lumbar lordosis. For TrA measures this was supine crook lying with the knees visually observed to be in 90 degrees flexion. Control was defined as standing in an upright static posture on the device with the footplate and crank set to the mid positions (3 and 3), holding the footplates so the dominant foot was in the furthest forward position, with both footplates held in

horizontal alignment. Ground standing involved standing in a static upright posture on stable and even ground (the lab floor).

In all vertical conditions participants were instructed to maintain an upright neutral posture, looking forwards with arms relaxed by their sides. Rest and control were assessed at the start of the initial participant test session, followed by seven random exercise conditions, while ground standing was assessed at the start of the second visit followed by the remaining seven randomised exercise conditions. At the initial testing visit, participants were given a five-minute familiarisation period exercising on the device. Explanation was given of the feedback which the device provides to help users maintain a steady speed and even movement. When FRED settings were altered, participants undertook an additional one-minute re-familiarisation period for the new movement setting. Testing was performed in a temperature and humidity controlled laboratory with a constant temperature of 23 degrees throughout.

3.2.3. Outcome Measures

The outcome measures assessed included several measures of motor control and participant's perceived comfort of each exercise setting. The motor control outcomes included LM and TrA muscle recruitment, variability of LM and TrA muscle recruitment per foot cycle and movement variability at the feet. Comfort was assessed using a tailor made comfort scale.

3.2.4. Muscle Recruitment

The exercise conditions which showed the highest recruitment of LM and TrA may be considered best for a potential training programme. Muscle thickness change was measured using ultrasound imaging (USI) to assess recruitment. This is as a common and validated outcome measure for assessment of low

levels of muscle activation associated with postural control (Koppenhaver et al. 2009).

All USI data were collected in B mode using a digital ultrasound imager with 2-7MHz curvilinear transducer (Technos, Esaote, Genoa, Italy). Frequency, gain, brightness and focus were set to ensure optimum visualisation of the muscles during acquisition for each participant. All USI measurements were taken on participants' dominant side.

Thickness of LM was assessed with the transducer placed longitudinally along the spine with the image midpoint at the facet joint level of interest. Thickness was taken as the distance from the echogenic tip of the facet joint to the subcutaneous fascia based on methods from Kiesel et al. (2007). Imaging was performed at the L5/S1 facet joint. This imaging location was chosen as it produced the best quality USI video for automatic measurement using edge detection during pilot studies. Imaging further up the spine resulted in artefacts appearing in the muscle, which the automatic edge detection was unable to resolve, and reduced ability to visualise all required structures throughout the FRED cycle. Therefore, L5/S1 had the highest data rate for analysis.

Thickness of TrA was measured with the transducer placed transversely against the anterolateral abdominal wall in line with the navel and the muscle belly positioned centrally on the image. Thickness was taken as the distance between the upper and lower muscle fascia at a point at least 0.5 mm lateral from where the muscle tip joined the abdominal aponeurosis, based on methods described by Koppenhaver et al. (2009).

Periods of ultrasound data were captured at 25 frames per second using a Lenovo, Windows 8 PC connected to the ultrasound imager using a PC-to-TV splitter (SA235, Kworld, California, USA) and Terratec G5 converted to digital PC

input (G5, Terratec, Alsdorf, Germany). Video editing software (MAGIX Video Easy version 3.0.1.5, Terratec, Alsdorf, Germany) recorded the USI video data in 720x480 pixels at 25 frames per second. For all exercise conditions, a minimum of six complete FRED cycles of data were recorded and for all static control conditions five seconds worth of data were recorded. All USI video data were converted from mpg to mov format using transcode software (DLR, Germany). Muscle thickness data were then measured using automatic edge detection software (Vasculometer 1.2, DLR, Germany) designed for analysing distances between parallel edges in USI (Bremser et al. 2012). The following edge detection software settings were used: horizontal smoothing 3.5 and vertical smoothing 10, near and far wall settings were adjusted to select the facet joint tip and subcutaneous fascia for LM (Figure 3-4) and the near and far muscle fascia for TrA (Figure 3-5). The smoothing settings refer to a system of reducing noise to create a clear image and with defined structure edges for automatic detection and measurement. Smoothing overlays frames and calculates a mean from the overlay to create a single clearer image. Higher smoothing results in more reliable edge detection, but reduces accuracy due to averaging across more frames. Therefore the setting chosen was the highest required for edge detection but at the lowest necessary for that. The settings were kept the same throughout all data collection to prevent changes from potentially confounding results. Any sections of video which did not allow adequate visualisation of the muscles were masked and therefore discarded from analysis.

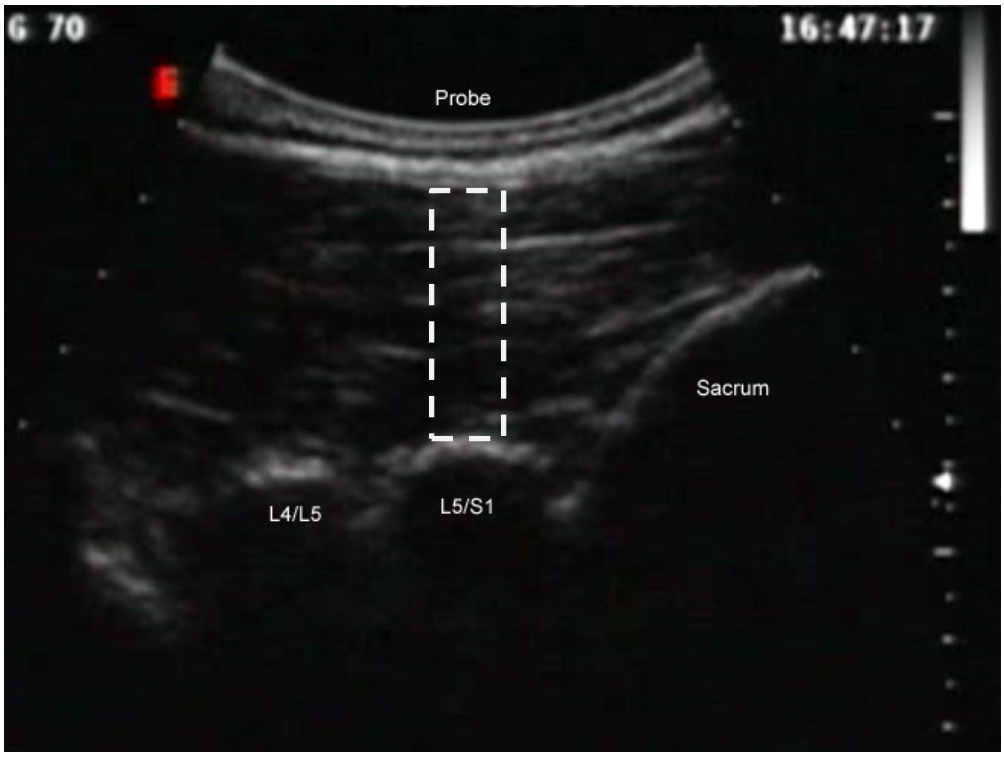


Figure 3-4 Shows a screen shot from a typical LM USI video; the probe, Sacrum, L5/S1 and L4/L5 facet joints are labelled. The white rectangle shows the location where the area of interest was positioned for automatic edge detection.

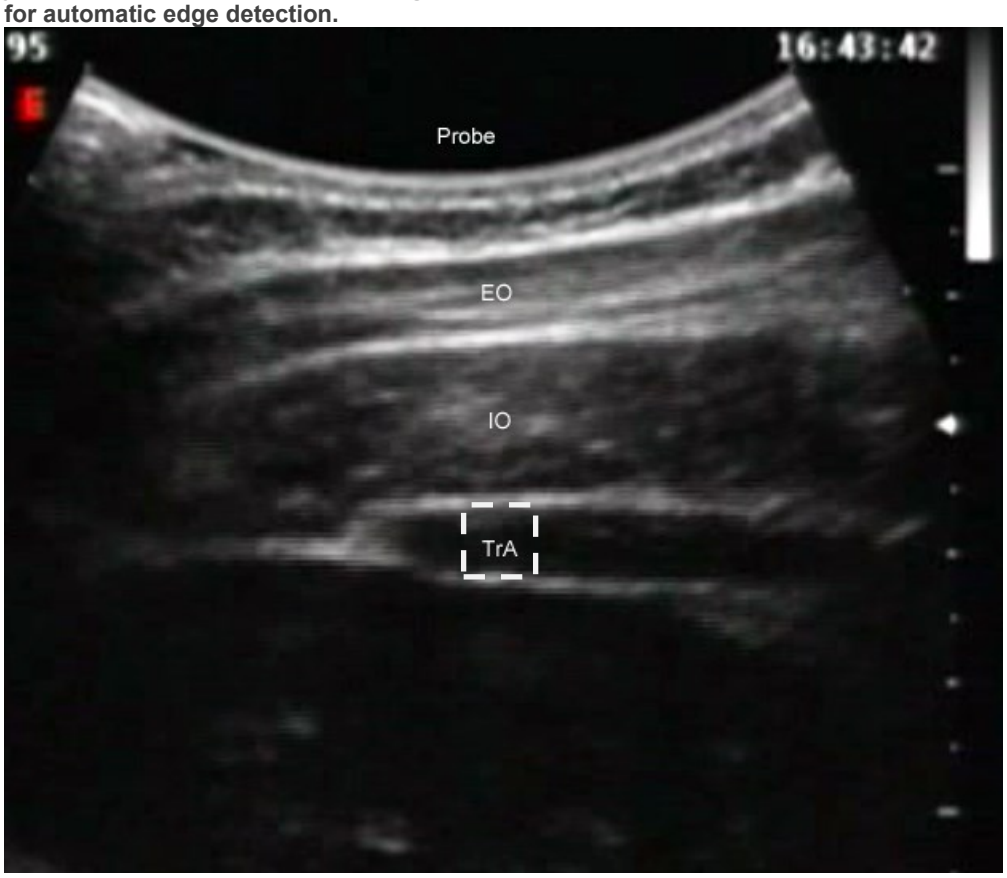


Figure 3-5 Shows a screen shot from a typical TrA USI video; the probe, TrA, internal oblique (IO) and external oblique (EO) muscles are labelled. The white rectangle shows the location where the area of interest was positioned for automatic edge detection.

During pilot studies it was found difficult to keep a steady video image of LM as the ultrasound transducer did not move with participants' exercise movements when imaging during exercise. To resolve this, an ultrasound transducer holder (Figure 3-7) was developed to steady the transducer and enabling generation of stable LM USI video data. The holder consisted of a foam block with a rectangular slit into which the transducer fitted, fixed onto the participants using two adjustable material straps. This allowed the transducer to move with participants' natural movements. Two larger holes either side of the rectangular one allowed additional ultrasound gel to be inserted without needing to remove the holder or transducer.

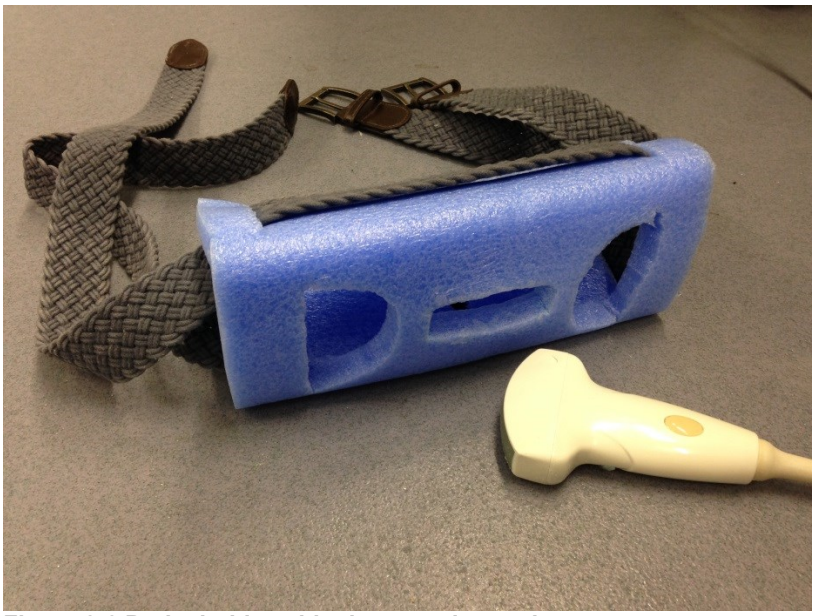


Figure 3-6 Probe holder with ultrasound transducer

For LM, thickness was measured automatically in the edge detection software as the area of interest for analysis was stable throughout the video. In TrA analysis, the normal lateral movement of the muscle during its activation prevented automatic analysis as the software was unable to laterally track the area of interest. To compensate for this, TrA thickness was measured manually every five frames throughout all video data. All muscle thickness data were then imported into Microsoft Excel 2010 for analysis.

A research assistant operated the ultrasound video capture and exercise device software. The second individual observed the number of FRED cycles recorded and made a mark on the USI data to show when each cycle occurred. Marks were generated by pressing the menu button on the ultrasound device which left a visual mark on the lower portion of the videos, while having no effect on the USI itself. The points were visually estimated to be the point at which participant's left feet were in the highest point of the exercise cycle.

3.2.5. Muscle Recruitment Variation

During initial analysis it was observed that in some participants there was increased variation in muscle thickness. It was hypothesised that an individual with good motor control, exercising on the device would have a relatively tonic muscle contraction of LM and TrA with low variability in muscle recruitment. Therefore a consistently high muscle recruitment variation during exercise may be an indicator of poor motor control or a more challenging device setting for consideration in a progressive training programme. Similarly, an increased variability in certain device settings could be indicative of ones that challenged the participant's motor control more.

To assess this, the difference in muscle recruitment variation (maximum change in muscle thickness during each cycle, ΔLM_{max} or ΔTrA_{max}) per FRED cycle was calculated from the muscle recruitment data and the average of cycles reported as the ΔLM_{max} or ΔTrA_{max} in each device setting.

3.2.6. Movement Variability at the Feet

It was hypothesised that an individual with good motor control, exercising on the device would produce an even movement throughout. Conversely, an individual with poor motor control would likely produce uneven movements with

rapidly varying movement velocities. The current device prototype was the first one designed to record data on movement variability. The angular velocity of the FRED crank wheel was measured using a integral rotary encoder (RP6010, ifm Electronic GmbH, Essen, Germany). The data output was analysed live using a PC connected to the FRED within bespoke software (Mazur Automation, Munich, Germany). Movement variability was quantified as the difference (%) between the live speed of exercise movement and the average speed over the previous second. This was recorded as a negative change if the live speed was slowing and positive if it was increasing. Movement variability data were then converted to an absolute number for analysis. Therefore, a high movement variability result was indicative of an uneven movement while a movement variability of zero represented a perfectly even movement. A high movement variability result may be an indicator of poor motor control or a more challenging device setting for consideration in a progressive training protocol. The movement variability data were recorded live from the device on a second Lenovo, Windows 8 PC running custom created FRED software (Mazur Automation, Germany) which was connected directly to the exercise device. The data were then imported into Microsoft Excel 2010 for analysis.

3.2.7. Comfort

It was felt that participants' individual feeling of comfort during exercise in each condition would also impact where it should be placed in a training protocol. If a particular condition was reported to be extremely uncomfortable during first-time exercise on the device, then it was considered inappropriate to recommend it as an initial training point. Participants' perceived comfort during exercise in each exercise condition was, therefore, assessed using a custom made scale designed specifically for FRED studies: the Newcastle Comfort Scale (Table 3-4). The scale asked participants to score their comfort on a numerical scale from zero to

five. Participants were shown the comfort scale prior to each day's testing period and had the statements read and shown to them at each testing point. The comfort rating was recording during and immediately after each individual test condition and 24 hours after each visit to the laboratory. The 24 hour post exercise measurement was to ascertain if any delayed onset muscle aches or discomfort was reported.

Table 3-4 Newcastle Comfort Scale

Are you:	
0	Aware of exercising but not aching at all
1	Aching a little
2	Aching
3	Aching a lot
4	Aching so much you want a break
5	Aching so much you want to stop exercising altogether

3.2.8. Reliability and Validity of Outcome Measures

3.2.8.1. Muscle Recruitment

The use of USI for measuring the thickness change of LM and TrA in order to estimate recruitment has previously been assessed for reliability and validity.

Ultrasound imaging measurements of LM recruitment were validated by Kiesel et al. (2007) against fine wire electromyography, which is a recognised method of assessing muscle activity (Koppenhaver et al. 2009; McMeeken et al. 2004) but is an invasive technique compared to USI. The study assessed the relationship between measured thickness changes using USI and muscle activity determined by electromyography during 19-34% maximal voluntary contractions. Although only done in a small population of five participants, the linear correlation between LM muscle activation measured using fine wire electromyography and thickness measures using USI was high ($r=0.79$, $P<0.001$).

A similar study was performed on TrA in thirteen mixed gender volunteers by McMeeken et al. (2004). The study compared fine wire EMG change in activation with thickness change measured using USI. A linear correlation was again found up to 80% maximal voluntary contraction ($r=0.87$, $p<0.001$). A study by Hodges et al. (2003), also comparing fine wire electromyography with TrA thickness change on USI suggested that correlations weaken beyond low level contractions in the range of up ~23% of maximal voluntary contraction. Therefore, validity of USI thickness measures may be questionable when used to assess exercises or movements which produce strong contractions of the muscles. Many of the movements used to set the 100% maximal voluntary contraction reference in the electromyography studies include prone spinal extension with maximally loaded upper limbs (Kiesel et al. 2007), the Valsalva manoeuvre and maximal abdominal hollowing (McMeeken et al. 2004). The postures and exercises in this study are

all aimed at recruiting the muscles within their normal functional range, without the addition of loading or resistance. Therefore, the level of recruitment is likely to remain within the range commonly validated for using USI.

Between and within day reliability of contracted LM USI thickness measurements have previously been shown to be good, with an intraclass correlation of 0.97 and 0.99, respectively (Koppenhaver et al. 2009). Between and within-day reliability of contracted TrA USI thickness measures were also shown to be good with intraclass correlations of 0.87 and 0.97, respectively (Koppenhaver et al. 2009). To ensure reliability in this study, all ultrasound images were taken by the same individual to maintain consistency between participants and test days. The imager had previous experience of USI studies of LM and TrA and underwent training in USI generation. The training included basic fundamentals of USI generation and lessons in specifically imaging LM and TrA. Additionally, a single rater, repeat measures, consecutive day reliability analysis was undertaken using typical error analysis (details in section 3.2.10). Two participants had repeat single measures taken in exercise conditions two and eleven on each day. These two conditions provided the extremes of crank amplitude. The results of the reliability study are reported in section 3.3.2 with discussion in section 3.4.4.

The edge detection software is a recently developed method, designed and validated by the German Aerospace Agency (DLR) for measuring diameters of blood vessels with USI (Bremser et al. 2012). A region of interest in the USI data must be defined by the operator, using knowledge and experience of the structures for analysis, to give best results. Images are then analysed frame by frame. A first derivative Gaussian filter was applied to filter and reduce noise in the image by averaging regions of pixel brightness. The images were then skeletonised, so edges appear as lines with thinner edge sections excluded from

analysis. Horizontal lines were computed and a classification step selected the most likely edges of the structure based on length, edge strength, linear regression coefficient and distance to the centre of the region of interest. Both the region of interest and the distance to the centre of it were defined by the operator to assist in the selection of the correct horizontal lines for analysis. The distance between the two edges was then calculated by counting and averaging the vertical lines of pixels between the two horizontal edges. As this is new technology and the first time it has been used in this type of analysis, some limitation existed in applying this method to muscle thickness of TrA and LM. The TrA muscle tends to translate laterally across the USI during contraction; the region of interest in the software is unable to track this and, therefore, had to be set manually, frame by frame, for TrA images. Additionally TrA is not always able to be positioned horizontally on USI and the software assumes horizontal lines should not be tilted more than 5 degrees. For both LM and TrA there can also be echogenic muscle fascia or other horizontal line artefacts on the image that can affect the edge detection process. Frames where such artefacts prevented correct measurement were masked and removed from the analysis to prevent interference in results. Bremser et al. (2012) found this method valid for measuring diameter of blood vessels, but no studies using this type of analysis were found measuring muscle thickness.

To validate this system several frames of USI video data were also measured using ImageJ (v1.44) image analysis software and comparison made between the measurements of both results were found to be in agreement. ImageJ analysis is consistent with thickness measure methods used in FRED studies (Debuse et al. 2013).

3.2.8.2. Movement Variability

Movement variability was a novel outcome measure specific to the FRED. Therefore, no previous evidence of its validity and reliability as an outcome measure of motor control existed. As the device records movement variability automatically and mechanically itself it was expected to have high validity and reliability to measure speed fluctuations during movement. No human error component existed and the device sensors were considered fit for purpose. However, as with the muscle thickness measurements, a single rater, repeat measures, consecutive day reliability analysis was undertaken using typical error (details in section 3.2.10). Two participants had repeat single measures taken in exercise conditions two and eleven on each day for this purpose.

3.2.8.3. Comfort

The Newcastle Comfort Scale is also a novel outcome measure specific to this study. No evidence currently exists to comment on its validity or reliability, however, it was designed by the creator of the exercise device based on long term experience of work and previous studies with the FRED.

3.2.9. Ethics

The study recruited human participants and their dignity, wellbeing and rights were protected at all times. A risk analysis was performed prior to any testing and steps to ensure health and safety were implemented. No lasting effects of the exercise were expected for any participants. Informed consent was provided in writing by all participants and they were informed they could withdraw from the study and remove their data at any time. No incentives or money for travel costs were provided to participants. The testing environment was made private as participants had to partially undress to expose the lower back and

anterolateral abdominal region for the USI images to be taken. Ultrasound gel was applied to participants, which can be uncomfortable due to being cold on initial skin contact, participants were informed of this and warned again at each application. The ultrasound gel was removed as soon it was no longer required. Participant data were stored in a secure location in a site folder at all times and will be destroyed after a maximum of three years following study completion.

3.2.10. Data Analysis

Magnitude based inference (MBI) statistics were used to run multiple-pairwise comparisons between the various combinations of exercise and control conditions. These statistics provide the probability for each comparison that the true (population) change is *positive*, *negative* or *trivial* with reference to a pre-determined minimal worthwhile change. This method allows an inference on how meaningful any population difference is (Batterham and Hopkins 2006). It is useful to have a previously reported and validated minimal clinically meaningful change on which to base inferences. However, clinically relevant differences have yet to be determined for the outcomes assessed in this study. This was in part due to the current prototype being a recent development and the use of several novel outcome measures. Therefore, the test-retest typical error of measurement in each outcome was set as the worthwhile change on which to base inferences. This allowed comparisons to be assessed and commented on based on the probability of a true measurable change occurring which was equal to, or more than, the typical error of measurement.

Magnitude based inference was chosen instead of using traditional null hypothesis testing for several reasons. In this case, a null hypothesis would have stated that no difference existed between comparisons. The probability of the observed data occurring if the null were true would then be calculated and a

decision would be made to retain or reject the null using a common, yet arbitrary, cut off of ≤5% chance that any observed difference was due to random sampling error. This would not have provided information on the direction or magnitude of the changes and would not have compared the change to an actual minimal worthwhile change (Sterne and Smith 2001). It would also have resulted in a high risk of type one errors occurring due to the large numbers of comparisons planned, or would have necessitated a much larger sample of the population to allow for correcting of the significance testing cut off point to compensate for the high number of comparisons.

The typical error of measurement for all outcomes was calculated by recording data from two identical exercise conditions in the same participants on two consecutive days. The conditions chosen to be tested for typical error were two (crank 2, footplate 1) and eleven (crank 5, footplate 1), which keep the footplate in the same position but give a range of all crank positions tested. The difference scores between measurements in each condition were calculated by subtracting the first day's measurements from the second.

$$Typical\ Error = \frac{SD\ (Difference\ Scores)}{\sqrt{2}}$$

Differences greater than this error were taken as the minimal worthwhile change. The mean change, 90% confidence intervals and probabilities (%) that the true values were mechanistically positive, trivial or negative were then reported and qualitatively defined by the following scale defined by Hopkins et al. (2008), where <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*".

The following comparisons were made using Magnitude Based Inferences:

- All device settings compared to rest, ground standing and control for muscle recruitment.

- Device settings grouped by crank and footplate position compared to each other for muscle recruitment, muscle recruitment variation and movement variability.

Trends in the Newcastle Comfort Scale were assessed in the raw data and graphically. Absolute muscle thickness values were also normalised to resting using the following equation:

$$Thickness\ Change\ (\%) = \frac{Thickness(ex) - Thickness(rest)}{Thickness(rest)} x100$$

By grouping settings together by crank and footplate, the overall number of comparisons being analysed was reduced and trends specific to the crank and footplate position exercise conditions could be isolated without the other confounding them. Only footplate data collected in crank amplitude position 5 was used to compare the effect of different footplate positions and only data collected in footplate positions 1 was used to compare all crank positions.

During analysis, small trends were found in the raw results between amplitude positions and weakly supported by the typical error based MBI statistics. Using the typical error as the threshold for MBI was considered conservative as it used the highest level of variation found in all the tested FRED conditions. While a conservative statistic makes the comparisons more rigorous and is useful for comparing all settings with the rest, control and ground standing conditions, it may miss small, yet worthwhile effects existing between settings such as between the various amplitudes. Therefore, the weak trends between the amplitude settings were also assessed using the effect size (Cohen's d), which was calculated between each amplitude setting.

$$d = \frac{sample\ mean1 + smaple\ mean2}{pooled\ standard\ deviation\ of\ sample\ 1\ and\ 2}$$

A effect size of 0.2 (at least a small effect) was set as the minimal worthwhile change on which to base inferences as showing at least a small effect size existed (Hopkins et al. 2008). In comparisons where participant variation made small effects unclear, the minimal worthwhile change threshold was increased to the lowest level which produced a clear result, of either 0.6 or 1.2, which show at least moderate and large effects, respectively (Hopkins et al. 2008). Any worthwhile change threshold variations were highlighted in the results. The effect size and MBI statistics were then presented with 90% confidence intervals and probabilities (%) that the true change was mechanistically positive, trivial or negative, as before, using the same methods from Hopkins et al. (2008).

3.3. Results

3.3.1. Demographics

Eight participants, all male, participated in the study and their demographics were presented in Table 3-2 in section 3.2.1. The average age was 23±5.9 years and the average BMI was 24±1.8. All participants were classed as either moderately active or active in the week prior to testing with the General Practice Physical Activity Questionnaire. No outlier values were recorded in the demographics. No dropouts occurred and all planned measurements were taken for all participants.

3.3.2. Reliability Results and Typical Error Calculation

Table 3-5 illustrates the typical error of measurement for all variables. The condition with the highest variability in difference scores was used to determine

the typical error for use as the inference threshold in MBI. The typical errors were calculated as, 1.1 mm for absolute LM thickness, 1.04 mm for absolute TrA thickness, 0.82 mm for ΔLM_{max}, 0.48 mm for ΔTrA_{max} and 0.46% for movement variability.

Table 3-5 Typical Error results

condition	participant	average day 1	average day2	difference Scores
Absolute LM thickness (mm)				
2	8	44.28	44.53	0.25
	7	33.15	33.15	0.00
11	8	44.95	43.66	1.29
	7	33.57	34.50	0.93
Absolute TrA thickness (mm)				
2	8	4.07	3.98	0.09
	7	3.65	3.62	0.02
11	8	3.63	4.25	-0.61
	7	4.46	2.99	1.47
ΔLM_{max} (mm)				
2	8	2.98	1.66	1.32
	7	1.66	1.97	-0.32
11	8	1.44	0.95	0.49
	7	1.04	0.83	0.21
ΔTrA_{max} (mm)				
2	8	1.28	1.24	0.04
	7	2.44	1.43	1.01
11	8	0.58	1.10	0.52
	7	1.12	0.78	0.34
Movement variability (%) per cycle				
2	8	8.25	7.66	0.59
	7	9.27	7.76	1.52
11	8	6.72	6.64	0.08
	7	5.29	4.14	1.15

3.3.3. Raw Data for all Conditions

Table 3-6 presents a summary of all the raw data for all the test conditions across six cycles of FRED exercise for both LM, TrA and movement variability. Table 3-7 shows the results of the Newcastle Comfort Scale during and after exercise across all exercise conditions.

Table 3-6 Summary of Raw Data For all Test Conditions

	Exercise conditions 2-15, Ground Standing (GS), Control (Cntl) and Rest																
	2	3	4	5	6	7	8	9	10	11	12	13	14	15	GS	Cntl	Rest
LM																	
Thickness (mm)	31.3	31.6	31.1	31.0	31.3	30.9	31.1	31.7	31.5	31.2	31.3	31.6	31.7	31.1	32.4	31.3	26.2
SD	7.1	6.6	6.8	7.2	6.9	7.3	7.1	7.0	7.3	7.6	7.1	7.1	6.7	7.2	6.5	7.2	7.1
Normalised thickness to rest (%)	20.8	22.4	20.2	19.0	21.1	19.2	19.9	22.4	21.2	19.8	20.8	21.8	22.5	19.9	25.3	20.2	0.0
SD	12.2	10.7	10.2	6.6	10.7	10.7	10.4	9.3	8.6	8.1	11.7	8.7	10.1	9.8	10.1	9.8	0.0
ΔLM_{max} (mm)	2.4	1.7	1.7	2.0	1.6	1.8	1.4	1.2	1.6	1.1	1.5	1.4	1.0	1.3	0.9	1.3	0.7
SD	2.1	0.4	0.6	1.2	0.9	0.9	0.4	0.2	0.6	0.4	0.5	1.0	0.5	0.4	0.3	0.7	0.4
TrA																	
Thickness (mm)	4.8	4.3	4.7	4.6	4.2	4.3	4.2	4.0	4.4	4.1	4.3	4.3	4.1	4.4	4.0	4.0	3.0
SD	1.7	1.4	1.2	1.2	1.3	1.1	1.0	1.0	1.3	1.0	1.0	1.3	1.1	1.1	1.2	1.8	1.0
Normalised thickness to rest (%)	48.4	34.5	48.6	45.0	29.8	34.3	33.2	25.9	36.1	29.1	34.0	33.0	29.1	38.6	22.6	20.9	0.0
SD	40.3	19.8	20.8	20.9	20.3	14.7	16.3	15.8	19.9	14.7	15.3	15.2	13.2	16.3	9.8	10.6	6.5
ΔTrA_{max} (mm)	1.9	1.6	1.6	1.8	1.7	1.3	1.2	1.3	1.6	1.0	1.1	1.2	0.9	1.2	0.9	1.4	0.7
SD	0.6	0.4	0.5	0.3	0.5	0.2	0.3	0.3	0.4	0.3	0.3	0.2	0.3	0.2	0.2	0.7	0.5
Movement variability																	
mean	8.7	8.8	9.2	7.5	7.2	6.4	5.2	4.8	6.3	5.2	5.9	4.6	5.0	4.4			
SD	1.9	1.3	3.0	2.6	2.3	1.6	1.1	1.6	1.9	0.9	2.7	1.0	0.9	1.7			

Table 3-7 Results of Newcastle Comfort Score Averaging for All Participants During and After Exercise

Condition	2	3	4	5	6	7	8	9	10	11	12	13	14	15	24 hours after visit:	
During exercise:																
mean	0.5	0.1	0.9	0.4	0.5	0.1	0.8	0.3	1.0	0.0	0.0	0.0	0.0	0.0		
SD	0.5	0.4	1.1	0.7	0.5	0.4	0.7	0.5	0.7	0.4	0.5	0.4	0.7	0.4		
After exercise:															**1**	**2**
mean	0.1	0.9	0.4	0.5	0.1	0.8	0.3	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD	0.4	1.1	0.7	0.5	0.4	0.7	0.5	0.7	0.4	0.5	0.4	0.7	0.4	0.5	0.4	0.7

The raw results from Tables 3-6 and 3-7 are presented graphically in Figures 3-8 to 3-10. It appeared from the figures that LM and TrA absolute thickness increased from rest in all conditions but did not appear to change from the control and ground standing positions. However, ΔLM_{max}, ΔTrA_{max} and movement variability appeared to be higher in larger amplitude settings. No trends in NCS were evident.

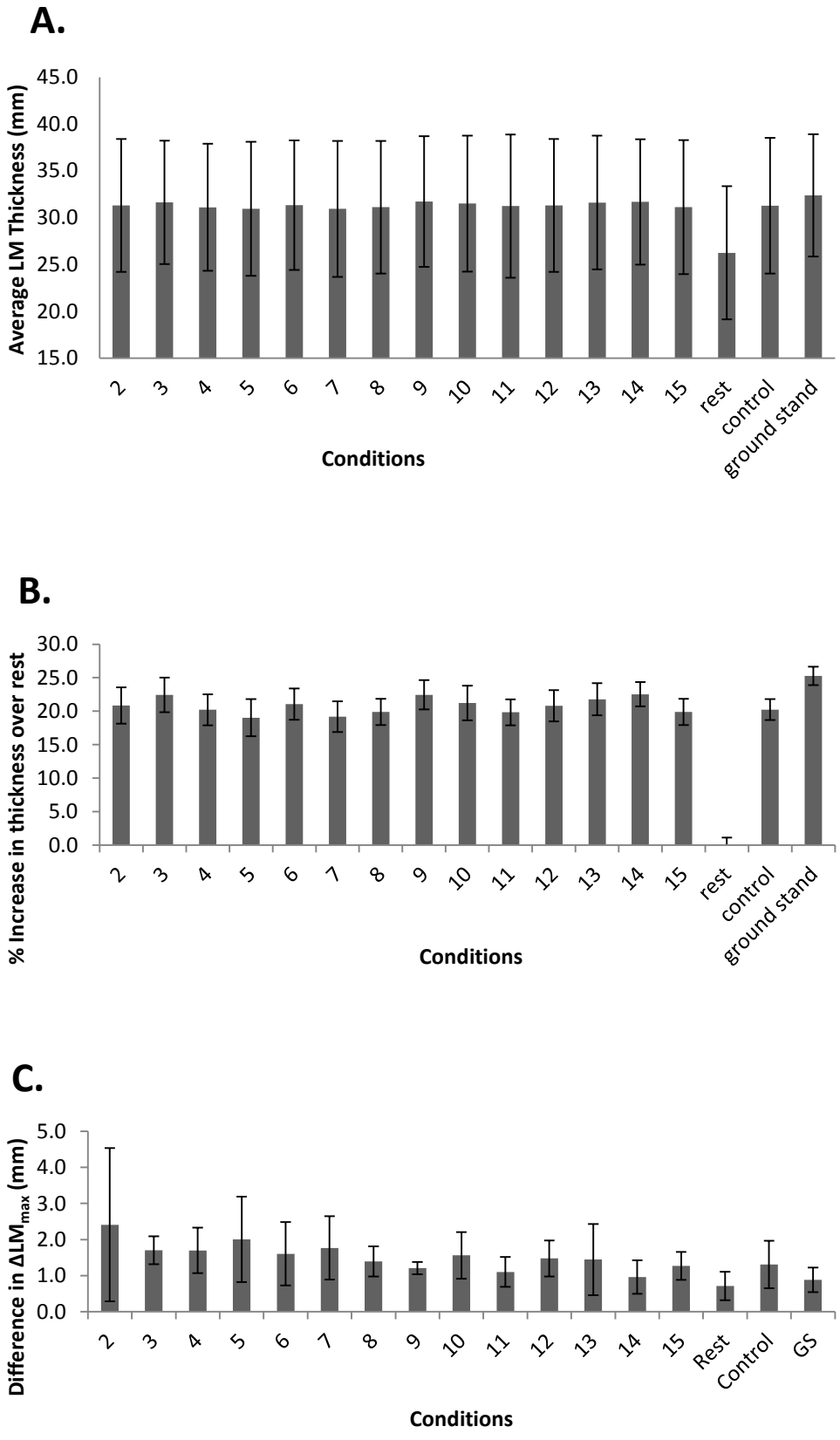


Figure 3-7 Muscle thickness for LM in each exercise condition as A. absolute thickness, B. mean normalised thickness and C. ΔLM_{max} difference per FRED cycle

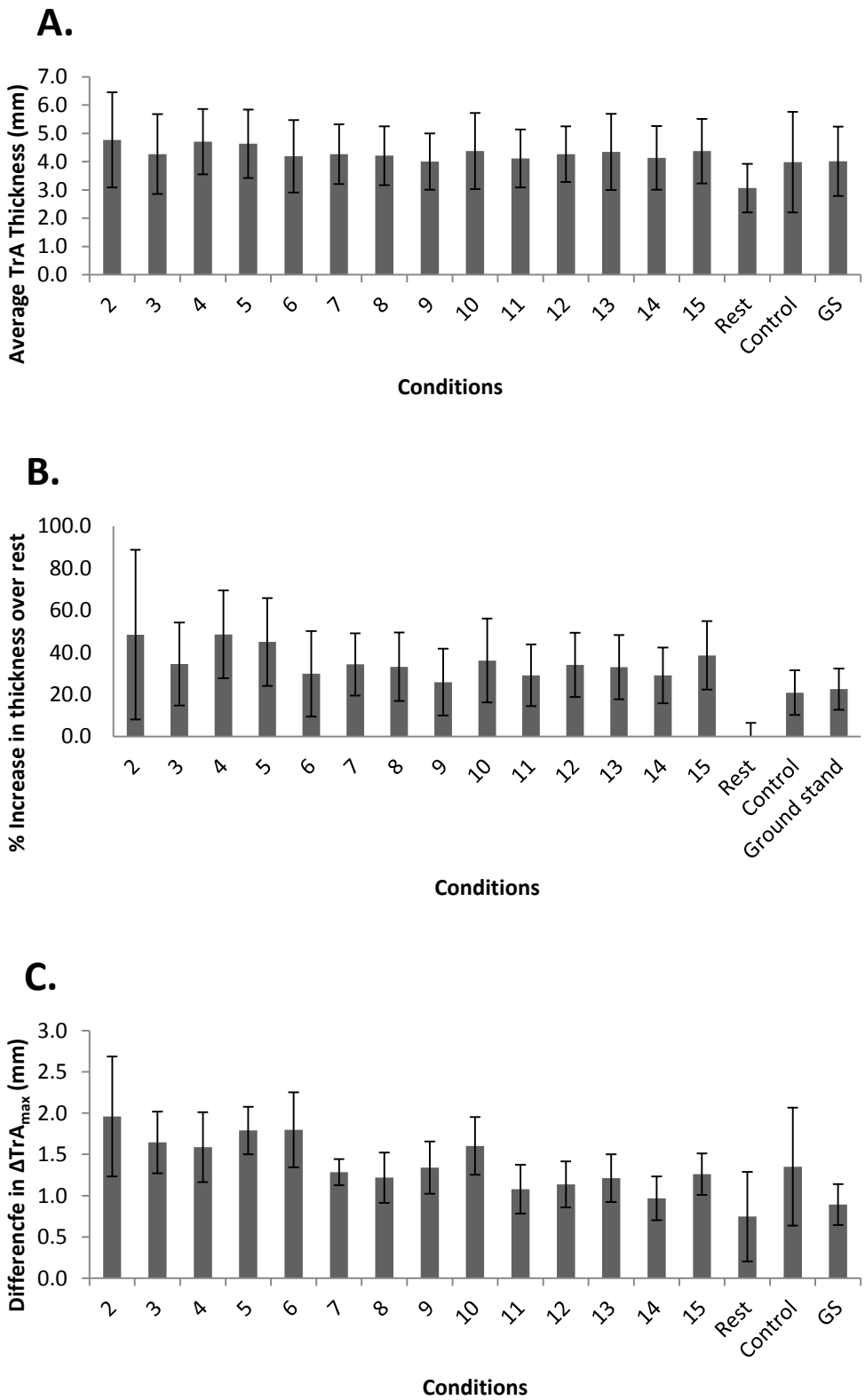


Figure 3-8 Muscle thickness for TrA in each exercise condition as A. absolute thickness, B. mean normalised thickness and C. ΔTrA_{max} difference per FRED cycle

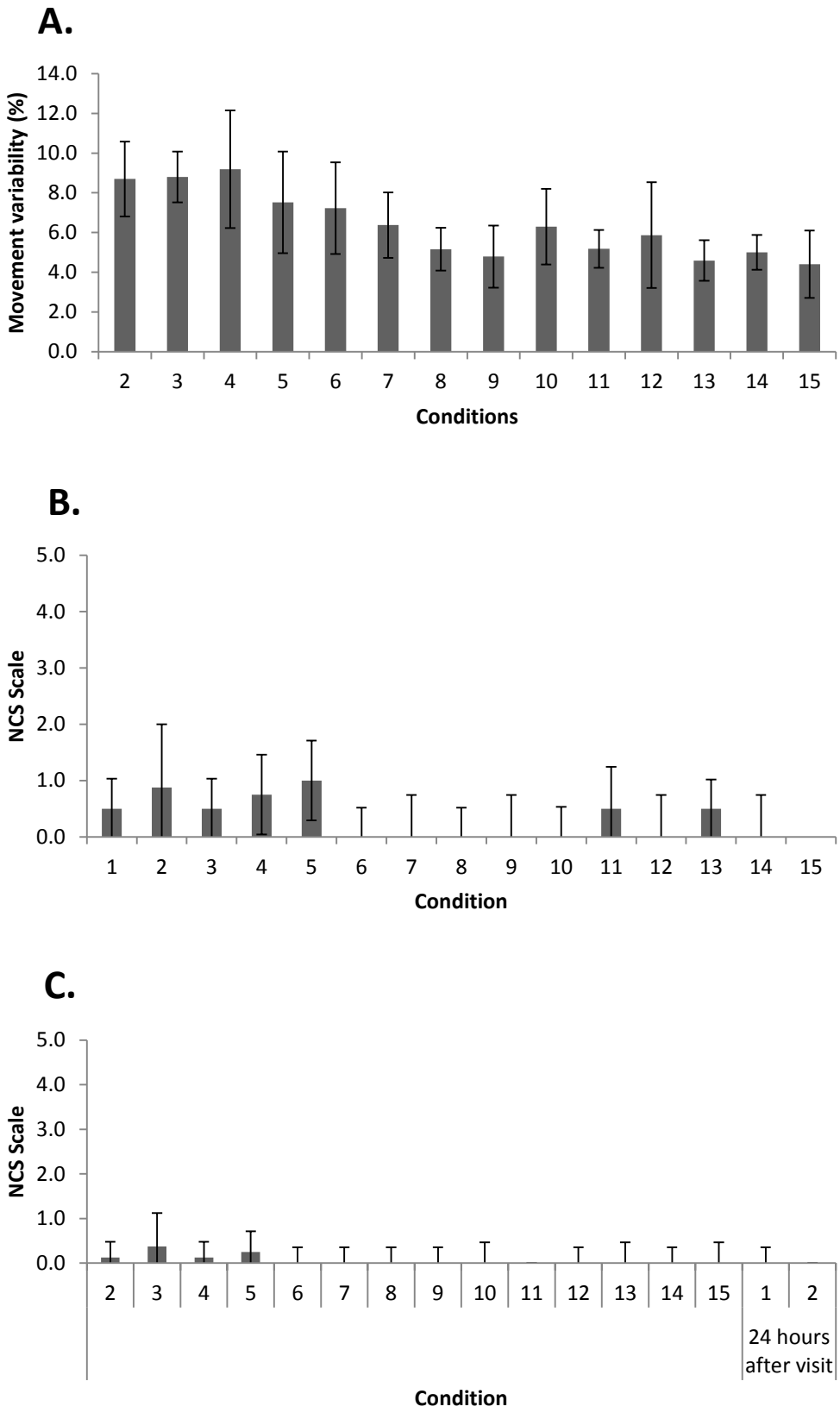


Figure 3-9 A. Mean movement variability across all exercise conditions, B. Mean NCS rating across all exercise conditions and C. Mean NCS rating after all exercise conditions

3.3.4. Magnitude Based Inference Comparisons

Table 3-8 presents the results of MBI comparisons made between each exercise condition and rest, control and ground standing for LM thickness. Figure 3-11 presents these results graphically. It was *most likely* that all exercise conditions recruited LM more than rest. The thickness change increase observed in this study was 4.7±1.4 mm to 5.5±1.7 mm. It was *possible* that all exercise conditions recruit LM less than ground standing. The thickness change decrease observed in this study was between 0.7±1 mm and 1.4±1.1 mm. Table 3-9 presents the results of MBI comparisons made between each exercise condition and rest, control and ground standing for TrA thickness. Figure 3-12 presents these results graphically. It was at least *possible* that all exercise conditions recruited TrA more than rest. The thickness change increase was between 0.9±0.5 mm and 1.7±0.9 mm. It was *very likely* that all exercise conditions did not recruit TrA more or less than ground standing except for an *unlikely* decrease in recruitment in conditions 2 (crank 2, footplate1), 4 (crank 3, footplate 1) and 5 (crank 3, footplate 2). It was *unlikely* that any exercise conditions recruit LM or TrA more or less than the control condition. There were no obvious trends or differences in NCS score between conditions.

Table 3-8 Difference in LM muscle thickness (mm) in each exercise condition compared with the rest, control and ground standing. Threshold for inferences set at typical error for LM thickness of 1.1mm.

Condition	Mean change	90%Confidence limits		Mechanistic inference
Compared to rest				
2 (crank 2 footplate 1)	5.1	3.4	6.7	most likely +ive
3(crank 2 footplate 2)	5.4	4.2	6.6	most likely +ive
4(crank 3 footplate 1)	4.9	3.7	6.0	most likely +ive
5(crank 3 footplate 2)	4.7	3.9	5.5	most likely +ive
6(crank 3 footplate 3)	5.1	3.9	6.3	most likely +ive
7(crank 4 footplate 1)	4.7	3.3	6.1	most likely +ive
8(crank 4 footplate 2)	4.9	3.5	6.2	most likely +ive
9(crank 4 footplate 3)	5.5	4.5	6.5	most likely +ive
10(crank 4 footplate 4)	5.3	4.2	6.3	most likely +ive
11(crank 5 footplate 1)	5.0	3.8	6.1	most likely +ive
12(crank 5 footplate 2)	5.1	3.6	6.6	most likely +ive
13(crank 5 footplate 3)	5.4	4.2	6.5	most likely +ive
14(crank 5 footplate 4)	5.4	4.4	6.5	most likely +ive
15(crank 5 footplate 5)	4.9	3.7	6.1	most likely +ive
Compared to control				
2 (crank 2 footplate 1)	0.0	-1.1	1.2	Unclear
3(crank 2 footplate 2)	0.4	-0.8	1.5	unlikely +ive
4(crank 3 footplate 1)	-0.2	-1.5	1.1	unclear
5(crank 3 footplate 2)	-0.3	-1.3	0.6	unlikely –ive
6(crank 3 footplate 3)	0.1	-1.0	1.1	unlikely +ive
7(crank 4 footplate 1)	-0.3	-1.7	1.0	unlikely –ive
8(crank 4 footplate 2)	-0.2	-0.8	0.4	very likely trivial
9(crank 4 footplate 3)	0.4	-0.7	1.5	unlikely +ive
10(crank 4 footplate 4)	0.2	-0.7	1.1	unlikely +ive
11(crank 5 footplate 1)	0.0	-0.8	0.7	very likely trivial
12(crank 5 footplate 2)	0.0	-1.1	1.2	unclear
13(crank 5 footplate 3)	0.3	-0.3	1.0	very likely trivial
14(crank 5 footplate 4)	0.4	-0.6	1.5	unlikely +ive
15(crank 5 footplate 5)	-0.2	-1.4	1.1	unlikely –ive
Compared to ground standing				
2 (crank 2 footplate 1)	-1.1	-0.7	-1.3	possibly –ive
3(crank 2 footplate 2)	-2.6	-1.7	-2.4	possibly –ive
4(crank 3 footplate 1)	0.5	0.2	-0.2	possibly –ive
5(crank 3 footplate 2)	-1.1	-0.7	-1.3	possibly –ive
6(crank 3 footplate 3)	-2.6	-1.7	-2.4	possibly –ive
7(crank 4 footplate 1)	0.5	0.2	-0.2	possibly –ive
8(crank 4 footplate 2)	-1.1	-0.7	-1.3	possibly –ive
9(crank 4 footplate 3)	-2.6	-1.7	-2.4	unlikely –ive
10(crank 4 footplate 4)	0.5	0.2	-0.2	possibly –ive
11(crank 5 footplate 1)	-1.1	-0.7	-1.3	possibly –ive
12(crank 5 footplate 2)	-2.6	-1.7	-2.4	possibly –ive
13(crank 5 footplate 3)	0.5	0.2	-0.2	possibly –ive
14(crank 5 footplate 4)	-1.1	-0.7	-1.3	unlikely –ive
15(crank 5 footplate 5)	-2.6	-1.7	-2.4	possibly –ive

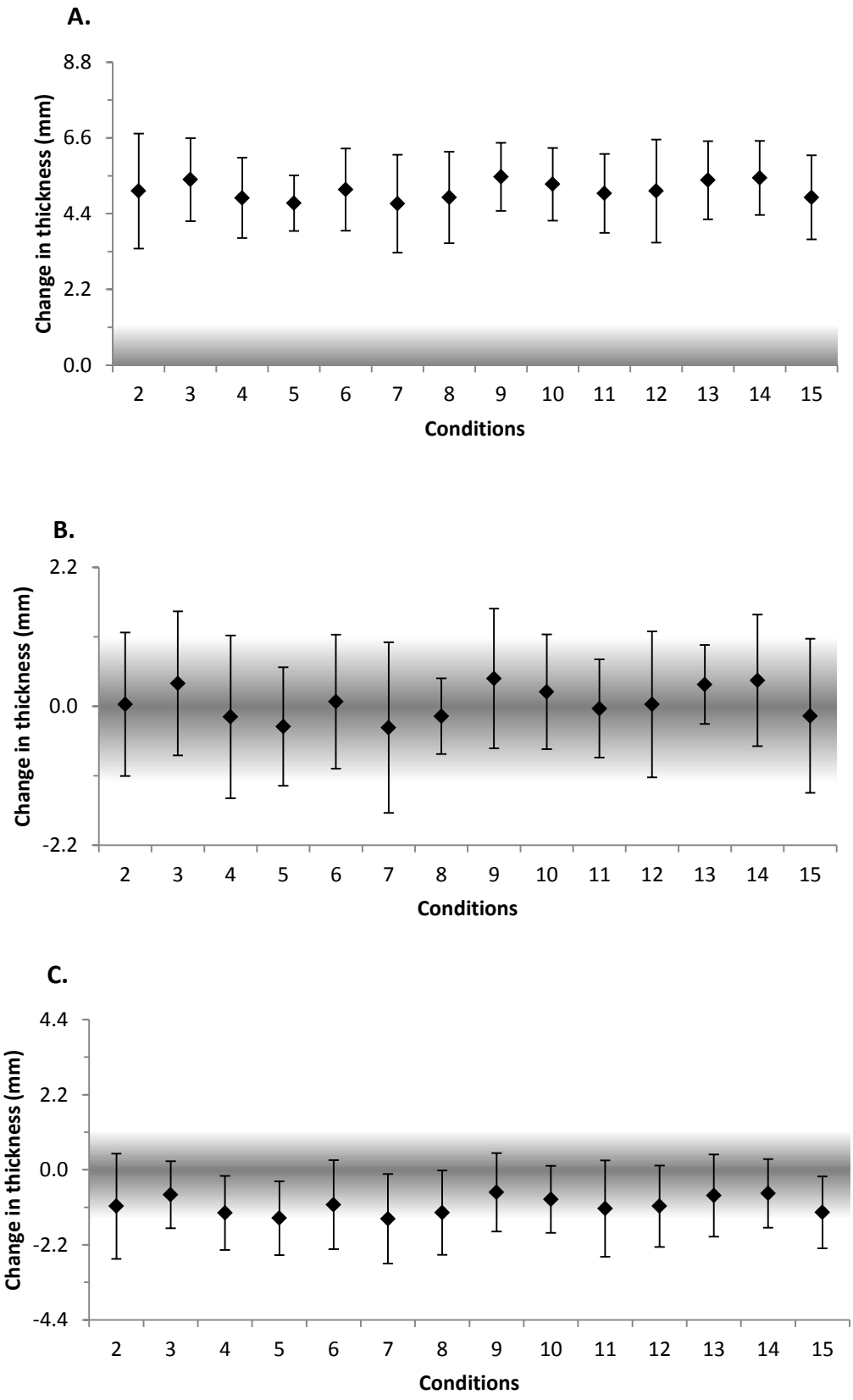


Figure 3-10 Results of MBI comparisons for mean change in LM thickness compared with A. rest, B. control and C. ground standing . The tails show 90% confidence intervals and the shaded area represents the inference threshold of 1.1mm

Table 3-9 Difference in TrA muscle thickness (mm) in each Exercise Condition compared with the rest control and ground standing. Calculated with a threshold for inferences set at typical error for TrA thickness of 1.04mm.

Condition	Mean change	90%Confidence limits		Mechanistic inference
Compared to rest				
2 (crank 2 footplate 1)	1.7	0.8	2.6	likely +ive
3(crank 2 footplate 2)	1.2	0.4	2.0	possibly +ive
4(crank 3 footplate 1)	1.6	0.9	2.4	likely +ive
5(crank 3 footplate 2)	1.6	0.9	2.2	likely +ive
6(crank 3 footplate 3)	1.1	0.4	1.8	possibly +ive
7(crank 4 footplate 1)	1.2	0.6	1.8	possibly +ive
8(crank 4 footplate 2)	1.1	0.5	1.8	possibly +ive
9(crank 4 footplate 3)	0.9	0.4	1.5	possibly +ive
10(crank 4 footplate 4)	1.3	0.6	2.0	likely +ive
11(crank 5 footplate 1)	1.0	0.5	1.6	possibly +ive
12(crank 5 footplate 2)	1.2	0.6	1.8	possibly +ive
13(crank 5 footplate 3)	1.3	0.8	1.8	likely +ive
14(crank 5 footplate 4)	1.1	0.5	1.7	possibly +ive
15(crank 5 footplate 5)	1.3	0.6	2.0	possibly +ive
Compared to control				
2 (crank 2 footplate 1)	0.8	0.2	1.3	unlikely +ive
3(crank 2 footplate 2)	0.3	-0.6	1.1	unlikely +ive
4(crank 3 footplate 1)	0.7	0.2	1.3	unlikely +ive
5(crank 3 footplate 2)	0.6	0.0	1.3	unlikely +ive
6(crank 3 footplate 3)	0.2	-0.7	1.1	unlikely +ive
7(crank 4 footplate 1)	0.3	-0.6	1.1	unlikely +ive
8(crank 4 footplate 2)	0.2	-0.7	1.2	unlikely +ive
9(crank 4 footplate 3)	0.0	-0.8	0.8	very likely trivial
10(crank 4 footplate 4)	0.4	-0.1	0.9	very likely trivial
11(crank 5 footplate 1)	0.1	-0.6	0.9	very likely trivial
12(crank 5 footplate 2)	0.3	-0.5	1.1	unlikely +ive
13(crank 5 footplate 3)	0.4	-0.2	0.9	very likely trivial
14(crank 5 footplate 4)	0.2	-0.4	0.7	very likely trivial
15(crank 5 footplate 5)	0.4	-0.5	1.3	unlikely +ive
Compared to ground standing				
2 (crank 2 footplate 1)	-1.1	-2.6	0.5	unlikely +ive
3(crank 2 footplate 2)	-0.7	-1.7	0.2	very likely trivial
4(crank 3 footplate 1)	-1.3	-2.4	-0.2	unlikely +ive
5(crank 3 footplate 2)	-1.4	-2.5	-0.3	unlikely +ive
6(crank 3 footplate 3)	-1.0	-2.3	0.3	very likely trivial
7(crank 4 footplate 1)	-1.4	-2.7	-0.1	very likely trivial
8(crank 4 footplate 2)	-1.3	-2.5	0.0	very likely trivial
9(crank 4 footplate 3)	-0.7	-1.8	0.5	most likely trivial
10(crank 4 footplate 4)	-0.9	-1.9	0.1	very likely trivial
11(crank 5 footplate 1)	-1.1	-2.5	0.3	most likely trivial
12(crank 5 footplate 2)	-1.1	-2.3	0.1	most likely trivial
13(crank 5 footplate 3)	-0.8	-2.0	0.5	most likely trivial
14(crank 5 footplate 4)	-0.7	-1.7	0.3	most likely trivial
15(crank 5 footplate 5)	-1.3	-2.3	-0.2	very likely trivial

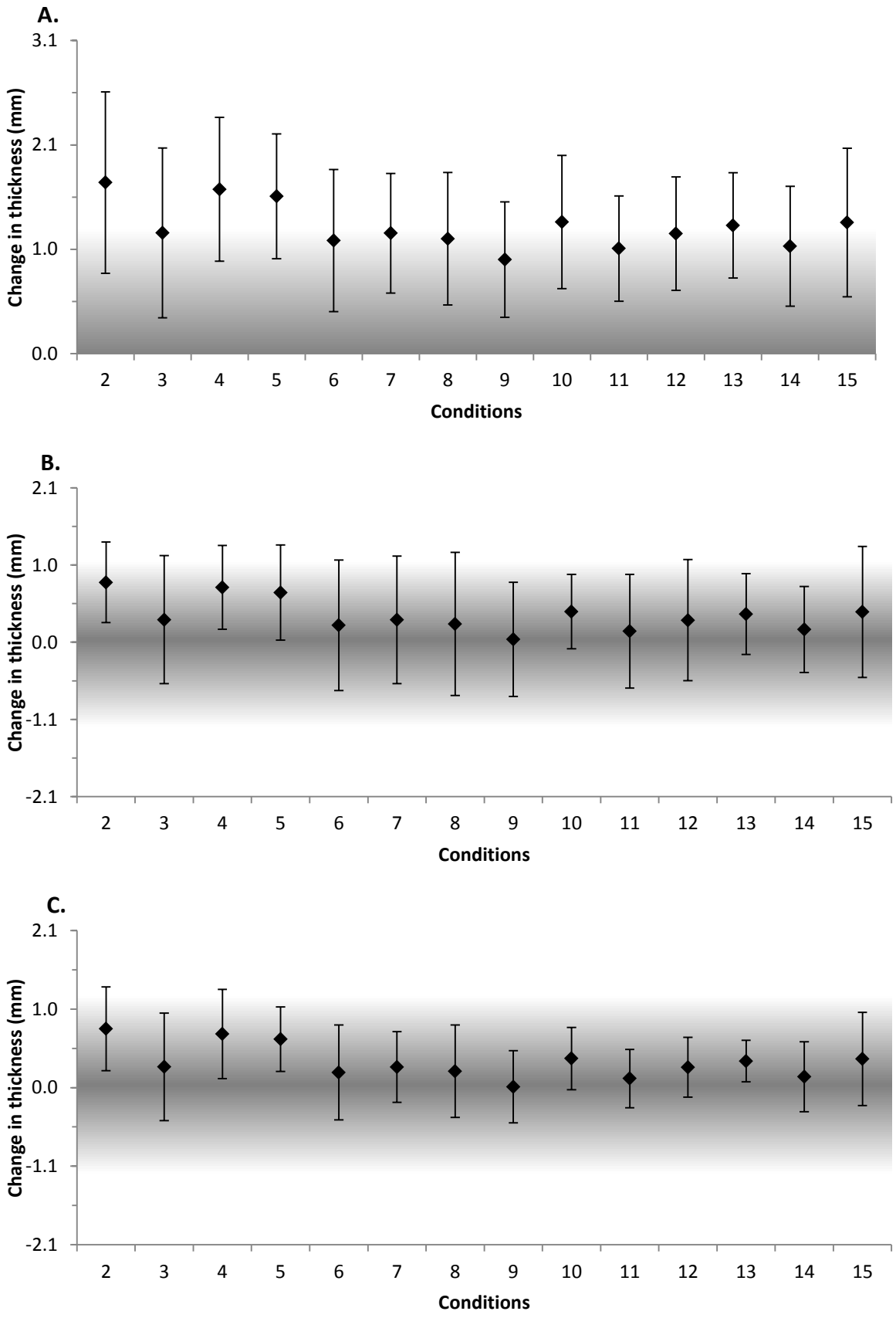


Figure 3-11 Results of MBI comparisons for mean change in TrA thickness compared with A. rest, B. control and C. ground standing . The tails show 90% confidence intervals and the shaded area represents the inference threshold of 1.04mm

To test for differences between the various crank amplitude and footplate positions, the exercise conditions were grouped by each amplitude and footplate setting. The groupings of exercise conditions to device settings are illustrated in Table 3-10.

Table 3-10 Groupings of FRED conditions by Crank and Footplate Positions

	Crank Positions				
	1	2	3	4	5
FRED Conditions	-	2	4	7	11
		3	5	8	12
			6	9	13
				10	14
					15

	Footplate Positions				
	1	2	3	4	5
FRED Conditions	2	3	6	10	15
	4	5	9	14	
	7	8	13		
	11	12			

Table 3-11 presents the MBI comparisons between crank amplitudes using the typical error inference thresholds for all variables. The table shows at best, only *trivial* differences between the amplitudes on LM absolute muscle thickness, either *trivial* or an *unlikely* reduction in TrA muscle thickness in smaller amplitudes, an *unlikely* reduction in ΔLM_{max} muscle thickness in smaller amplitudes (however, this trend was not always clear), a *possible* reduction in ΔTrA_{max} muscle thickness in the smallest compared to largest crank amplitude and a *most likely* reduction in movement variability in the smallest compared to largest crank amplitude. The movement variability trend continues to be at least *very likely* between every larger and smaller crank amplitude comparison except for between crank amplitude positions 3 and 2 where it becomes unclear.

Table 3-11 Difference in muscle recruitment and motor control outcomes in each crank Position, all in footplate position one. Calculated with threshold for inferences set at typical error for LM thickness of 1.1mm, for ΔLM_{MAX} thickness of 0.8mm, for movement variability of 0.46%, for TrA thickness of 1.04mm and for ΔTrA_{max} thickness of 0.48mm

Crank Positions	Mean change	90%Confidence limits		Mechanistic inference
Difference in LM thickness between crank positions (mm)				
3-2	-0.4	-1.3	0.5	unlikely –ive
4-2	-0.4	-1.1	0.4	unlikely –ive
5-2	-0.1	-1.0	0.9	likely trivial
4-3	0.1	-0.3	0.6	very likely trivial
5-3	0.1	-0.9	1.2	unlikely +ive
5-4	0.1	-0.9	1.1	unlikely +ive
Difference in ΔLM_{max} thickness change per cycle between crank positions (mm)				
3-2	-0.2	-1.2	0.8	unclear
4-2	-0.4	-1.1	0.4	unlikely –ive
5-2	-0.1	-1.0	0.9	unclear
4-3	-0.2	-1.0	0.6	unlikely –ive
5-3	0.1	-0.9	1.2	unclear
5-4	0.3	-0.8	1.4	unlikely +ive
Difference in TrA thickness between crank positions (mm)				
3-2	-0.1	-0.7	0.5	very likely trivial
4-2	-0.5	-1.1	0.1	unlikely –ive
5-2	-0.7	-1.3	0.0	unlikely –ive
4-3	-0.4	-1.0	0.1	very likely trivial
5-3	-0.6	-1.2	0.0	unlikely –ive
5-4	-0.2	-0.6	0.3	most likely trivial
Difference in ΔTrA_{max} thickness change per cycle between crank positions (mm)				
3-2	-0.2	-0.7	0.2	very likely trivial
4-2	-0.6	-1.0	-0.1	very likely trivial
5-2	-0.9	-1.3	-0.5	possibly –ive
4-3	-0.3	-0.7	0.0	most likely trivial
5-3	-0.6	-1.0	-0.3	very likely trivial
5-4	-0.2	-0.4	0.0	most likely trivial
Difference in movement variability between crank positions (from minimum seven cycles)				
3-2	-0.8	-2.3	0.7	unclear
4-2	-3.1	-4.4	-1.8	very likely –ive
5-2	-3.7	-4.9	-2.6	most likely –ive
4-3	-2.3	-3.9	-0.8	very likely –ive
5-3	-3.0	-4.7	-1.3	very likely –ive
5-4	-0.6	-1.5	0.2	possibly –ive

Figure 3-13 presents the results of comparisons between crank comparisons for LM outcomes. Figure 3-14 presents the results of the same comparisons for TrA outcomes and Figure 3-15 for movement variability outcomes.

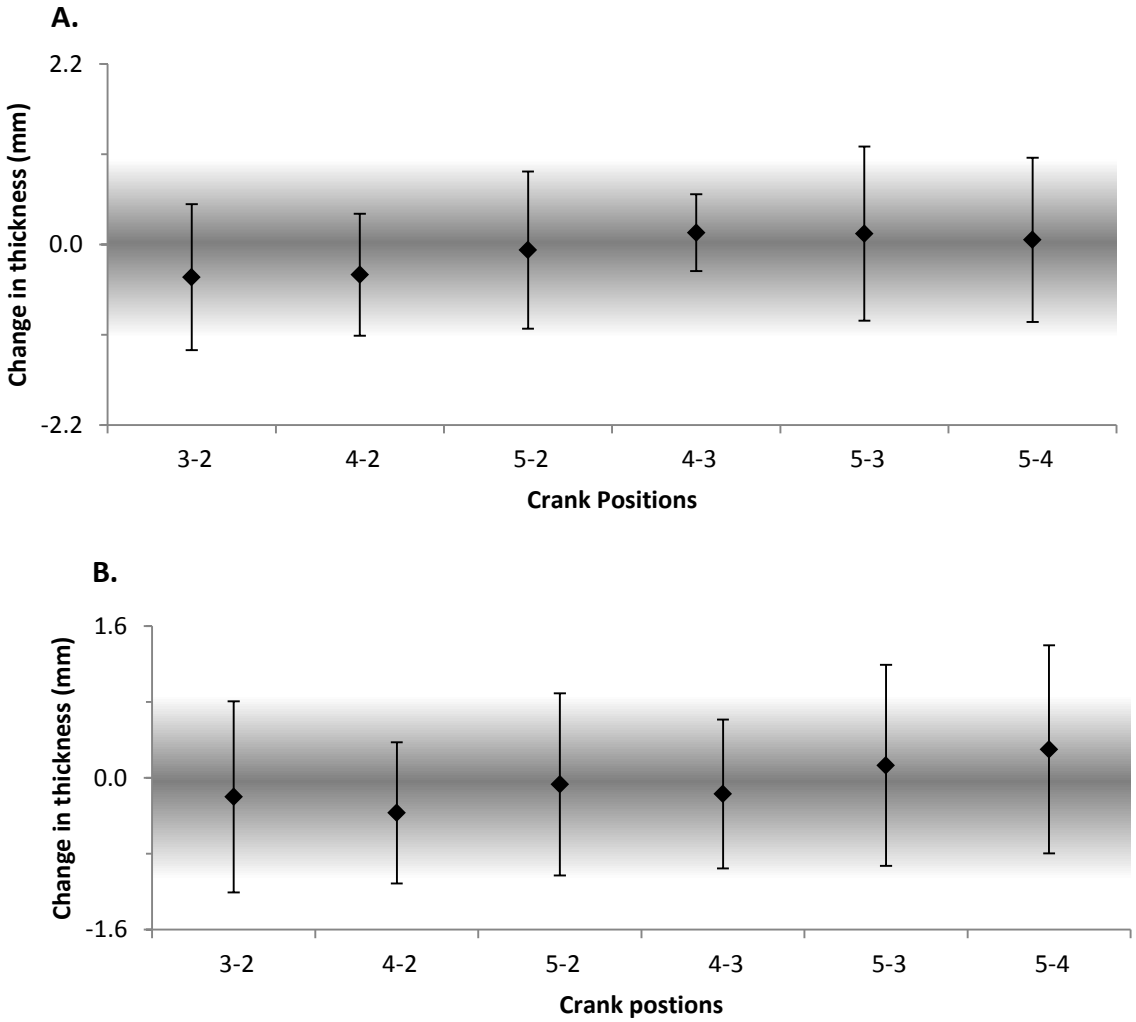


Figure 3-12 Results of MBI comparisons for mean change in LM outcomes between each crank position for A. LM thickness with shaded area representing the inference threshold of 1.1mm and B. ΔLM_{max} with shaded area showing inference threshold of 0.8mm. All tails show 90% confidence intervals. All comparisons were in footplate position one.

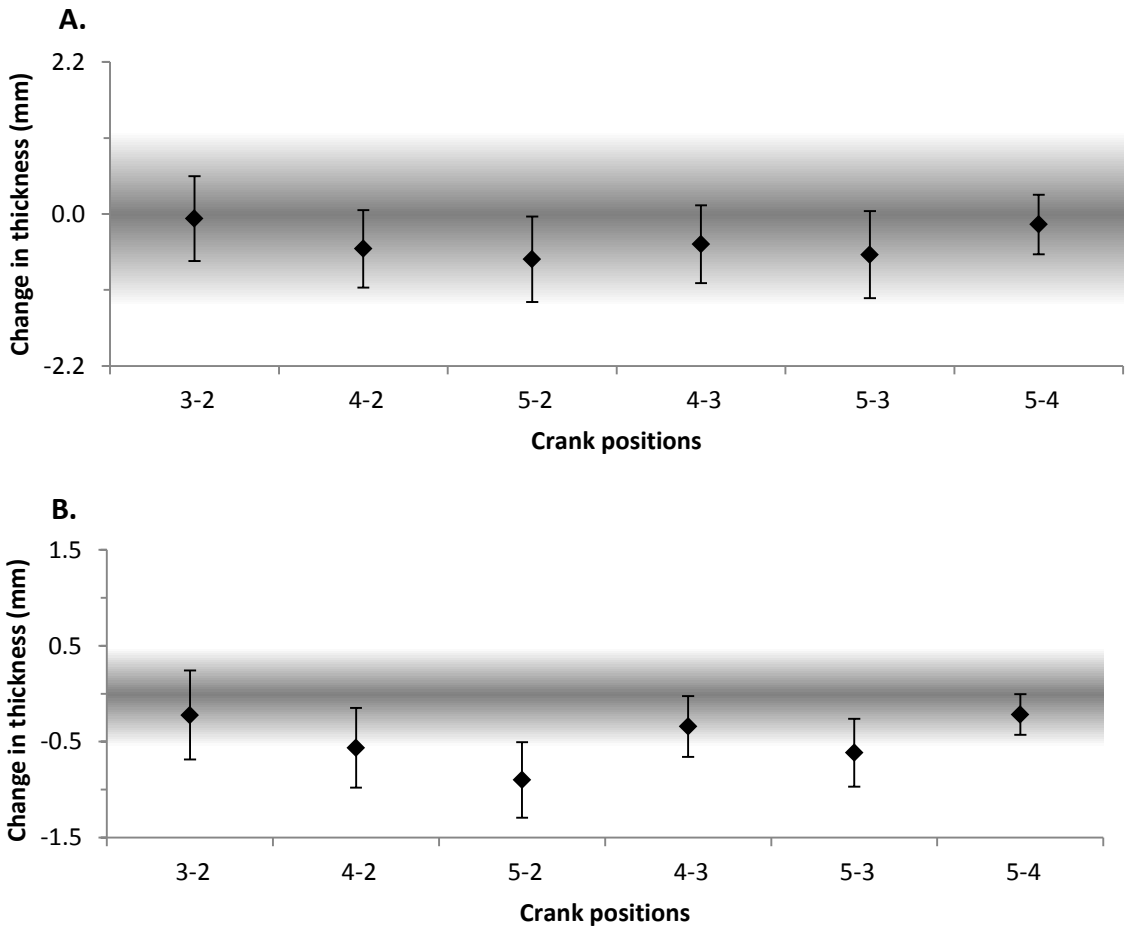


Figure 3-13 Results of MBI comparisons for mean change in TrA outcomes between each crank position for A. TrA thickness with shaded area representing the inference threshold of 1.04mm and B. ΔTrA_{max} with shaded area showing inference threshold of 0.48mm. All tails show 90% confidence intervals. All comparisons were in footplate position one.

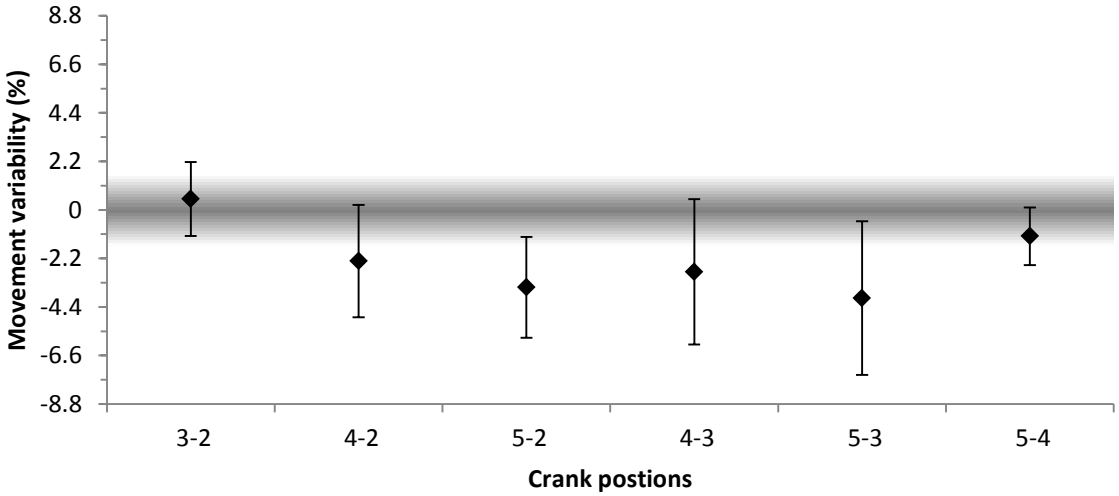


Figure 3-14 Results of MBI comparisons for mean change in Movement variability between each crank position with shaded area showing inference threshold of 0.46%. All tails show 90% confidence intervals. All comparisons were in footplate position one.

Table 3-12 illustrates the results of comparisons between each footplate position for muscle recruitment measures. Table 3-13 presents the same results for the movement variability. The results show that it was *unlikely* that any difference in muscle recruitment, muscle recruitment variability or movement variability was found between any footplate positions. Therefore, the results would appear to show that footplate position did not affect muscle recruitment or motor control.

Table 3-12 Difference in muscle recruitment between each footplate position, all in crank position five. Calculated with threshold for inferences set at typical error for LM thickness of1.1mm, for ΔLM_{max} thickness of 0.8mm, for TrA thickness 1.04mm and for ΔTrA_{max} thickness of 0.48mm

Footplate Positions	Mean change	90%Confidence limits		Mechanistic inference
Difference in LM thickness between footplate positions (mm)				
2-1	0.1	-1.1	1.2	unclear; get more data
3-1	0.4	-0.1	0.9	very likely trivial
4-1	0.4	-0.5	1.4	unlikely +ive
5-1	-0.1	-1.2	1.0	unlikely –ive
3-2	0.3	-0.9	1.6	unlikely +ive
4-2	0.4	-0.2	1.0	very likely trivial
5-2	-0.2	-0.8	0.4	very likely trivial
4-3	0.1	-0.9	1.0	likely trivial
5-3	-0.5	-1.7	0.7	unlikely –ive
5-4	-0.6	-1.1	0.0	unlikely –ive
Difference in ΔLM_{max} thickness change per cycle between footplate positions (mm)				
2-1	0.3	-0.1	0.7	very likely trivial
3-1	0.3	-0.3	0.9	unlikely +ive
4-1	0.0	-0.2	0.2	most likely trivial
5-1	0.1	-0.2	0.4	most likely trivial
3-2	0.1	-0.7	0.8	unlikely +ive
4-2	-0.5	-1.0	0.0	unlikely –ive
5-2	-0.2	-0.6	0.2	very likely trivial
4-3	-0.4	-0.9	0.2	unlikely –ive
5-3	-0.2	-1.0	0.6	unlikely –ive
5-4	0.3	-0.1	0.7	very likely trivial
Difference in TrA thickness between footplate positions (mm)				
2-1	0.1	-0.3	0.6	most likely trivial
3-1	0.2	-0.2	0.7	very likely trivial
4-1	0.0	-0.5	0.6	very likely trivial
5-1	0.3	-0.4	0.9	very likely trivial
3-2	0.1	-0.4	0.6	very likely trivial
4-2	-0.1	-0.5	0.3	most likely trivial
5-2	0.1	-0.3	0.5	most likely trivial
4-3	-0.2	-0.7	0.3	very likely trivial
5-3	0.0	-0.7	0.8	very likely trivial
5-4	0.1	-0.3	0.5	most likely trivial
Difference in ΔTrA_{max} thickness change per cycle between footplate positions (mm)				
2-1	0.0	-0.2	0.3	very likely trivial
3-1	0.1	-0.1	0.3	very likely trivial
4-1	-0.1	-0.3	0.2	very likely trivial
5-1	0.2	-0.1	0.4	very likely trivial
3-2	0.1	0.0	0.2	most likely trivial
4-2	-0.2	-0.4	0.1	very likely trivial
5-2	0.1	-0.1	0.3	very likely trivial
4-3	-0.2	-0.4	0.0	very likely trivial
5-3	0.1	-0.2	0.3	very likely trivial
5-4	0.3	0.1	0.5	unlikely +ive

Table 3-13 Difference in movement variability between each footplate position, all in crank position five. Calculated with threshold for inferences set at typical error for movement variability of 0.46%.

Footplate Postisions	Mean change	90%Confidence limits		Mechanistic inference
Difference in movement variability between footplate positions (from min seven cycles)				
2-1	0.9	-1.8	3.7	Unclear
3-1	-0.6	-1.6	0.4	possibly –ive
4-1	-0.2	-0.6	0.3	unlikely –ive
5-1	-0.8	-2.9	1.3	Unclear
3-2	-1.2	-3.5	1.1	Unclear
4-2	-0.9	-3.4	1.6	Unclear
5-2	-1.5	-4.3	1.4	Unclear
4-3	0.2	-0.6	1.0	Unclear
5-3	-0.2	-2.4	2.1	Unclear
5-4	-0.5	-2.3	1.4	Unclear

Figure 3-16 presents the results of comparisons between footplate comparisons for LM outcomes. Figure 3-17 presents the results of the same comparisons for TrA outcomes and Figure 3-18 for movement variability outcomes.

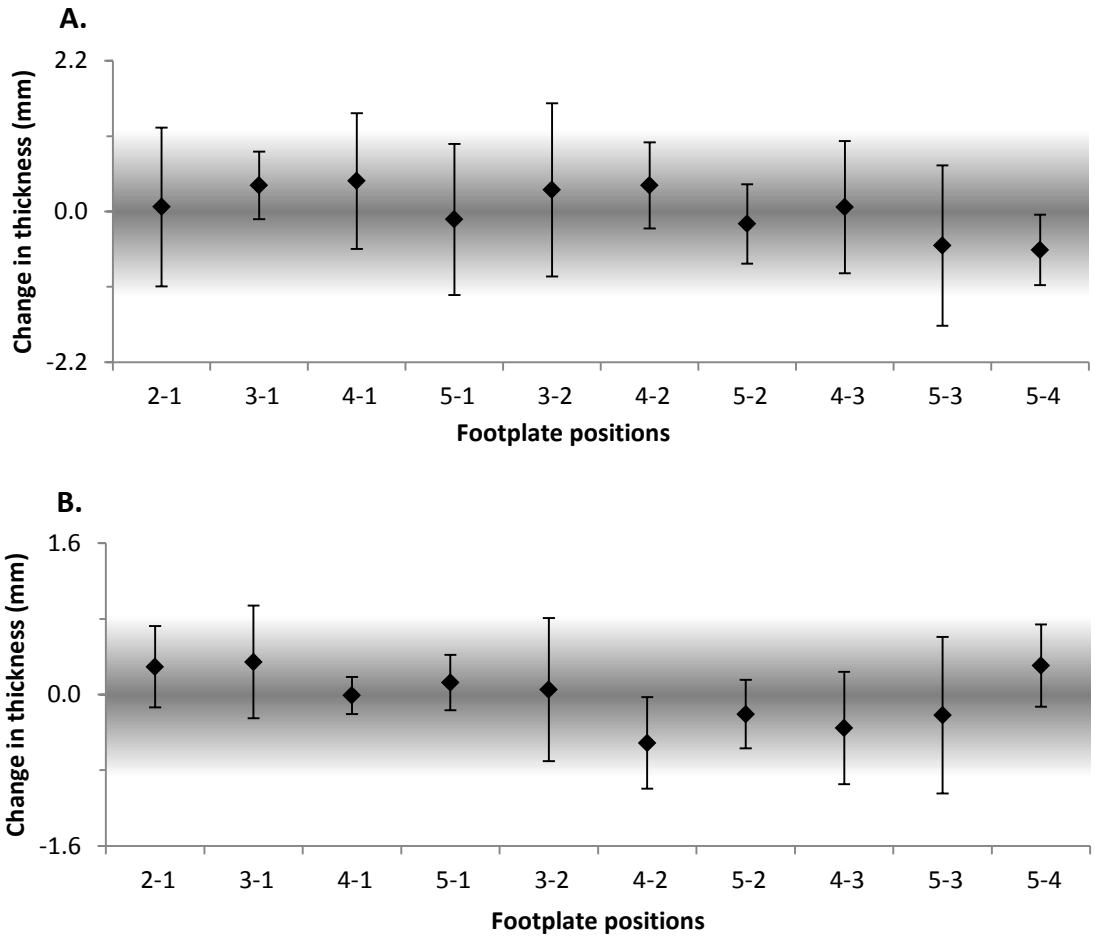


Figure 3-15 Results of MBI comparisons for mean change in LM outcomes between each footplate position for A. LM thickness with shaded area representing the inference threshold of 1.1mm and B. ΔLM_{max} with shaded area showing inference threshold of 0.8mm. All tails show 90% confidence intervals. All comparisons were in crank position five.

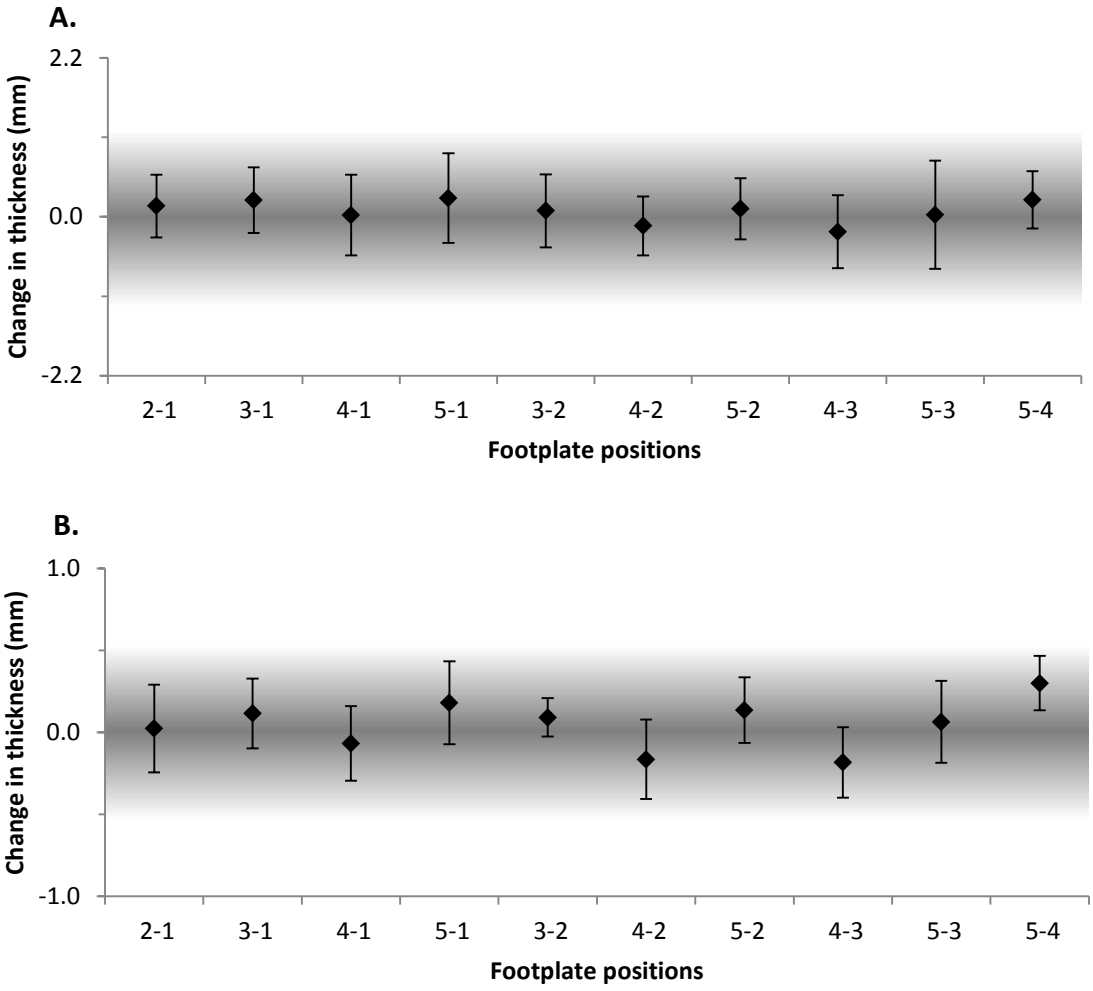


Figure 3-16 Results of MBI comparisons for mean change in TrA outcomes between each footplate position for A. TrA thickness with shaded area representing the inference threshold of 1.04mm and B. ΔTrA_{max} with shaded area showing inference threshold of 0.48mm. All tails show 90% confidence intervals. All comparisons were in crank position five.

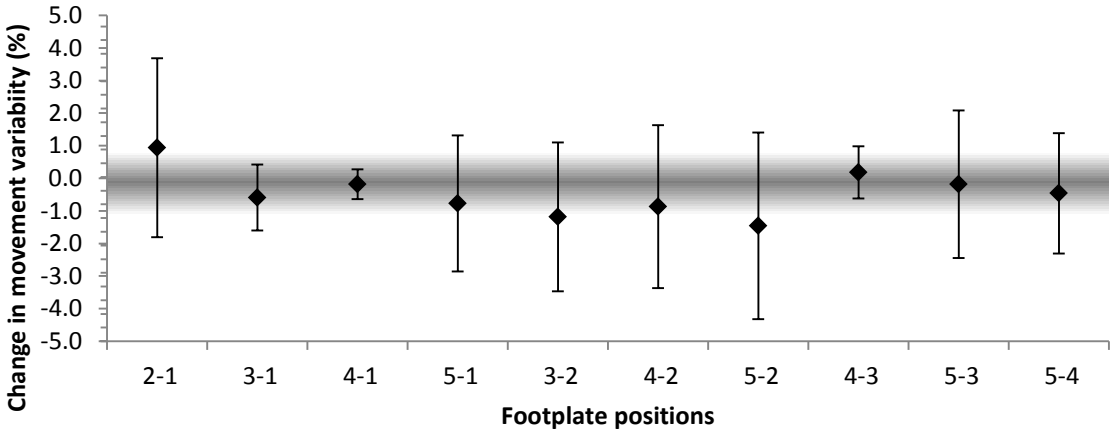


Figure 3-17 Results of MBI comparisons for mean change in movement variability between each footplate position with shaded area showing inference threshold of 0.46%. All tails show 90% confidence intervals. All comparisons were in crank position five.

3.3.1. Effect size analysis between crank amplitudes

Some weak trends were apparent between the crank amplitudes for absolute TrA thickness, ΔLM_{max}, ΔTrA_{max} and movement variability. Therefore, effect size analysis was performed on these variables to assess for any worthwhile effects which may have been missed by the deliberately conservative typical error statistics. Figures 3-19 to 3-23 illustrate the raw change between each crank amplitude across these variables. Tables 3-14 to 3-17 present the corresponding effect size comparisons with MBI statistics. For this analysis the amplitudes were labelled as distance of the foot plate arm attachment away from the crank axle. Therefore, labels were 0.2 m (setting 5) 0.28 m (setting 4), 0.36 m (setting 3) and 0.425 m (setting 2). This labelling better illustrates the effect size in relation to amplitude change in meters.

Transversus abdominis muscle thickness

In the smallest amplitude, TrA thickness was 4.1±1.0 mm, and increased to 4.8±1.7 mm in the largest amplitude. Figure 3-19 appears to show a trend of increased TrA thickness as the amplitude increased in size. Table 3-14 shows that increasing the amplitude was *likely* to increase TrA thickness between the two largest and the smallest amplitudes. However the trend is only *possible* between the other amplitudes and becomes *very likely trivial* between both the two largest and two smallest amplitudes.

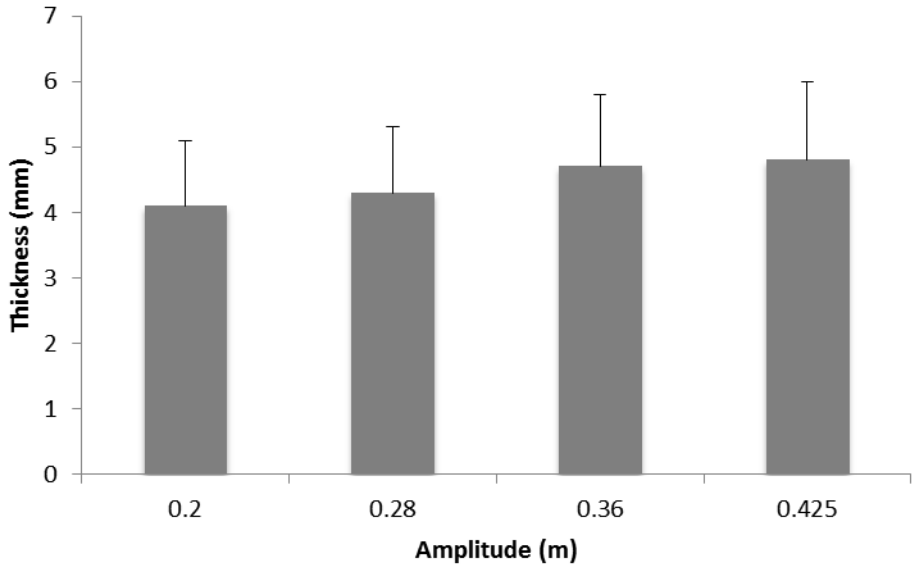


Figure 3-18 TrA muscle thickness as a function of amplitude and at rest.

Table 3-14 Difference in TrA muscle thickness between each crank position, and each position compared to rest, calculated with threshold for inference of effect size at least 0.2, [1] indicates inference threshold of 0.6.

Crank amplitude (m)	effect size	90% Confidence limits		Mechanistic inference
0.425-0.36	0.0	-0.2	0.4	Very likely trivial [1]
0.425-0.28	0.3	0.0	0.6	Possibly +ve
0.425-0.2	0.4	0.0	0.8	Likely +ve
0.36-0.28	0.4	-0.1	0.8	Possibly +ve
0.36-0.2	0.5	0.0	1.0	Likely +ve
0.28-0.2	0.1	-0.2	0.5	Very likely trivial [1]

Lumbar multifidus muscle thickness variability

In the smallest amplitude, ΔLM_{max} was 1.1±0.4 mm, and increased to 2.5±2.1 mm in the largest amplitude (Figure 3-20). Table 3-15 shows high levels of variation across participants resulting in few clear inferences at the 0.2 effect size level. Larger amplitudes were at least *likely* to result in increased ΔLM_{max} compared to the smallest. However, this trend was only *possible* between the

other amplitudes, and was *trivial*, between 0.36 m and 0.28 m

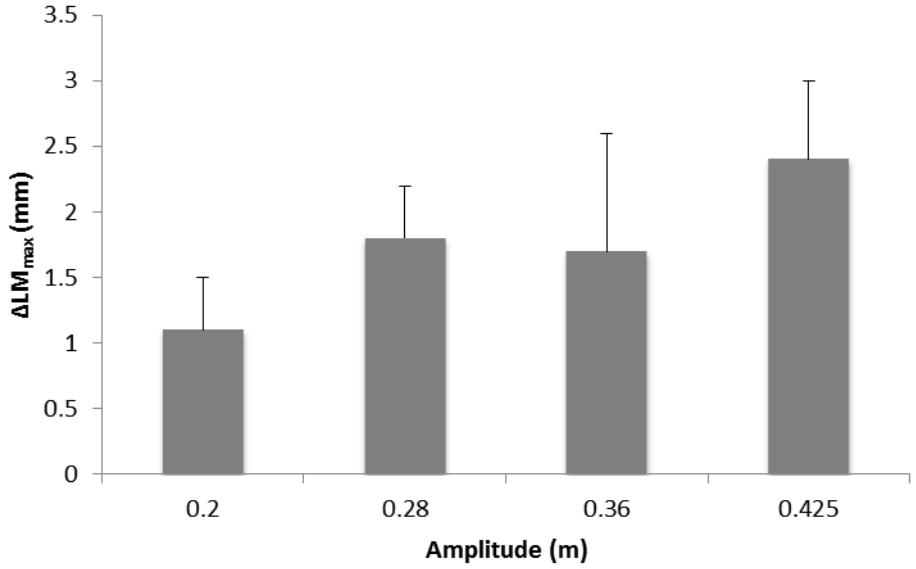


Figure 3-19 ΔLM_{max} as a function of amplitude.

Table 3-15 Difference in max-min LM muscle thickness between each crank position, calculated with threshold for inference of at least effect size 0.2, [1] indicates inference threshold of 0.6 and [2] of 1.2

Crank positions	Effect size	90% Confidence limits		Mechanistic inference
0.425-0.36	0.4	-0.5	1.3	Possibly positive [1]
0.425-0.28	0.4	-0.3	1.0	Possibly positive [1]
0.425-0.2	0.4	-0.1	0.8	Likely positive
0.36-0.28	-0.1	-0.9	0.7	Very likely trivial [2]
0.36-0.2	1.0	0.3	1.7	Very likely positive
0.28-0.2	0.8	0.0	1.6	Likely positive

Transversus abdominis muscle thickness variability

In the smallest amplitude, ΔTrA_{max} was 1.0±0.3 mm, and increased to 1.9±0.6 mm in the largest amplitude condition (Figure 3-21). Table 3-16 shows that it was at least *likely* that larger amplitudes resulted in increased ΔTrA_{max} except for between the two largest amplitudes where the trend was only *possible*.

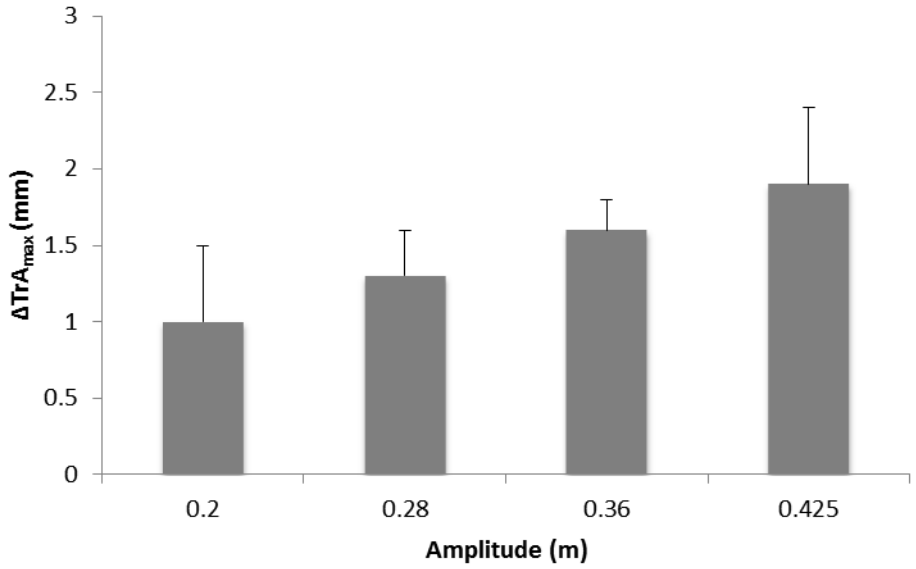


Figure 3-20 ΔTrA_{max} as a function of amplitude.

Table 3-16 Difference in ΔTrA_{max} between each crank position, calculated with threshold for inference of at least effect size 0.2, [1] indicates inference threshold of 0.6

Crank positions	Effect size	90% Confidence limits		Mechanistic inference
0.425-0.36	0.5	-0.4	1.3	Possibly positive 1
0.425-0.28	1.3	0.5	2.1	Very likely positive
0.425-0.2	1.6	0.9	2.3	Most likely positive
0.36-0.28	0.9	0.1	1.7	Likely positive
0.36-0.2	1.4	0.6	2.3	Very likely positive
0.28-0.2	0.8	0.0	1.6	Likely positive

Movement variability

In the smallest amplitude, movement variability was 5.2±0.9%, and increased in all amplitudes to 9.2±3% at 0.36 m, dropping to 8.7± 1.9% at 0.425 m (Figure 3-22). Table 3-17 shows that it was at least *likely* that larger amplitudes caused increased movement variability. However, the change was *unlikely* between the largest two amplitudes.

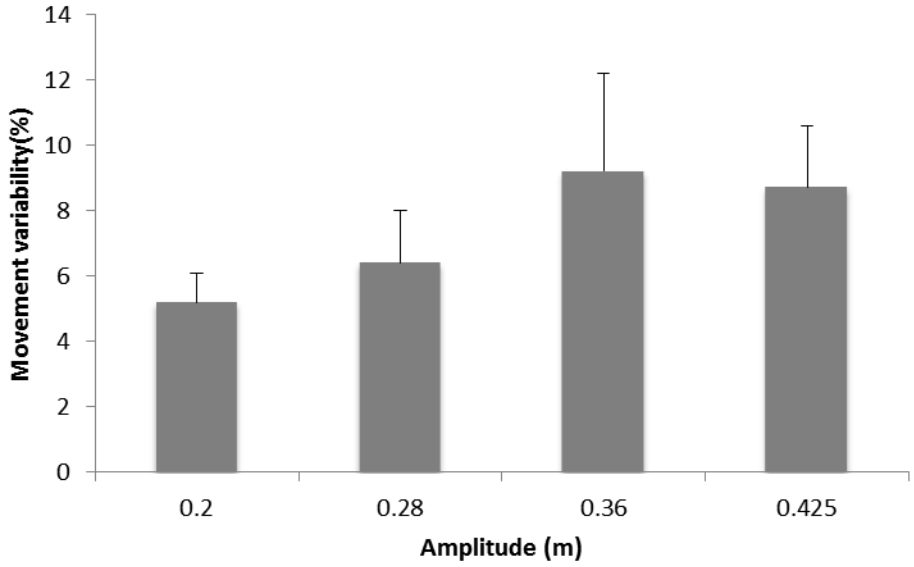


Figure 3-21 Movement variability as a function of amplitude

Table 3-17 Difference in movement variability between each crank position, calculated with threshold for inference of at least effect size 0.2, [1] indicates inference threshold of 0.6

Crank positions	Effect size	90% Confidence limits		Mechanistic inference
0.425-0.36	-0.2	-0.7	0.4	Unlikely -ve [1]
0.425-0.28	1.1	-0.1	2.2	Likely +ve
0.425-0.2	1.9	0.7	3.1	Very likely +ve
0.36-0.28	0.9	-0.2	2.0	Likely +ve
0.36-0.2	1.5	0.2	2.7	likely +ve
0.28-0.2	0.7	-0.1	1.5	Likely +ve

3.4. Discussion

The main finding of this chapter was that all FRED settings increased muscle thickness of LM and TrA compared to rest, which validates previous findings of Debuse et al. (2013) that FRED exercise appears to recruit both muscles automatically, and demonstrates that all settings are useful for training. It was also found that increasing the amplitude of foot movement while exercising on the FRED elicited increased movement variability at the feet, which was linked to trends in increased ΔTrA_{max}, ΔLM_{max} and TrA muscle recruitment. This suggests larger amplitudes increase the challenge placed on the motor control system.

3.4.1. Comparison of Individual Exercise Conditions

It is clear from the results that all exercise conditions increase recruitment of both LM and TrA compared to rest. This adds to the evidence that exercise on the device recruits these muscles without conscious need to trigger that activation as reported in previous studies on the device (Debuse et al. 2013). Debuse et al. (2013) reported mean thickness changes between rest and exercise of 7 mm for LM and 2.5 mm for TrA, which were larger differences than seen in this study. Debuse et al. (2013) measured thickness change at a single point of the device cycle, estimated to be where thickness was highest, therefore reporting the maximal difference that could be expected in muscle thickness between exercise and rest. This study is more representative of the true mean difference throughout a full cycle of FRED exercise averaged over six complete cycles compared to rest. Therefore, the recruitment reported here takes into account potential variations in muscle thickness, evident in the ΔTrA_{max} and ΔLM_{max} results, throughout a period of training and provides a more representative estimate of mean muscle recruitment of the full FRED cycle. There may also be a very small risk that subtle differences between the prototypes impacted on muscle recruitment, however, this is unlikely due to similarities in their design.

No measurable difference was recorded between the exercise conditions and standing still on the device. This may indicate that muscle recruitment is not due to the movement during exercise and so may instead be a result of one of the other device mechanisms, such as standing on and controlling the movement of the unstable footplates or the posture adapted on the device. However, the importance of using a functional movement in the rehabilitation of LM and TrA has been highlighted previously (O'Sullivan 2000), and FRED exercise facilitates dynamic movement of the legs over a stationary trunk (Debuse et al. 2013; Gibbon, Debuse and Caplan 2013; Caplan et al. 2014)

It was also *most likely* that there was no difference in LM and TrA recruitment between ground standing and all FRED conditions. This would suggest that upright posture was the main mechanism resulting in muscle recruitment. There is a low probability that LM activity was slightly less on the FRED than in ground standing by up to 2.1 mm. This may be due to variations in muscle recruitment when exercising or standing on the FRED with an increased challenge to motor control, rather than potentially more constant and tonic recruitment in static ground standing.

The lack of observed change between all the conditions involving upright posture may also be a result of the population tested. It is possible that in healthy, young populations without LBP, the muscles automatically recruit in response to upright postures which can be considered a normal response to control the upright sagittal spinal and pelvic posture against gravity (Claus et al. 2009; O'Sullivan et al. 2006). Therefore, very little difference between standing and walking on a stable surface, and exercising on the device may be expected in no-LBP populations. The difference may then become larger when tested in a clinical population, if the device is effective as a clinical intervention for deep lumbopelvic muscle recruitment. The device has yet to be shown as being able to automatically activate LM and TrA in a population with proven prior impairment in recruitment. The evidence generated thus far strongly shows the device is able to recruit the muscles and should be used to justify future trials in clinical populations to test its effectiveness as a clinical intervention.

3.4.2. Comparison of Crank and Footplate Positions

The results of the typical error analysis showed weak trends that increasing crank amplitude resulted in increased TrA muscle activation, ΔTrA_{max}, ΔLM_{max} and movement variability. There were no trends found between the various footplate

positions. This agreed with the computer model illustrated in Figure 3-3 and further illustrates that it is the crank amplitude position which changes the exercise movement and impacts on motor control outcomes rather than the footplate positions. Overall, this suggests that larger crank amplitudes present more of a challenge and may result in slightly increased muscle recruitment and less even movements.

The trends seen in the typical error analysis between crank amplitudes were confirmed by the effect size analysis comparing amplitudes. Effects were found showing that increasing the amplitude of foot movement while exercising on the FRED elicited an increased movement variability at the feet which was linked to increased ΔTrA_{max}, ΔLM_{max} and TrA muscle recruitment. When combined with the typical error analysis and computer plots showing the differences between the amplitudes, this strongly suggests larger crank amplitudes increase the challenge placed on the motor control of the spine. This trend may be caused by larger amplitude cranks resulting in an increased vertical distance throughout which the front foot drop must be controlled. This has the effect of increasing both the height and the time during which the front foot drop occurs, both of which may be factors in increasing the demands on the deep spinal muscles and general motor control of the entire movement. This may be similar to the mechanisms were increased stride length in walking and running have previously been shown to lead to increased leg muscle activity (Patla, Armstrong and Silveira 1989).

3.4.3. Development of a Training Protocol

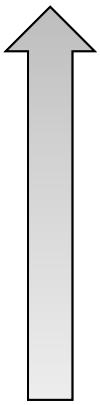
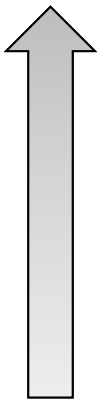
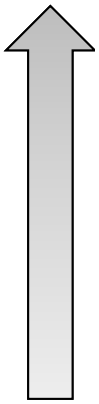
Traditional LM and TrA training interventions recommend progressive training, starting by isolating muscle recruitment, to recruitment during upright functional positions while maintaining lumbar lordosis and thoracic kyphosis and then gaining endurance of the LM and TrA muscles (Hides et al. 2008; O'Sullivan

2000). Previous evidence (Debuse et al. 2013) and the rest comparisons suggest recruitment of LM and TrA occurs automatically during FRED exercise. The same evidence and rest comparisons also demonstrate the exercise can be performed correctly in an upright functional position from first use, in healthy first-time FRED users. This agrees with other research investigating the learning of challenging balance exercises in upright posture that demonstrated healthy individuals could perform stilt walking safely on first attempt, but that technique refinement then occurs over time, with multiple practice sessions (Akram and Frank 2011). Therefore, a progressive training protocol using the FRED is likely to begin with recruiting the muscles while maintaining lumbar lordosis and thoracic kyphosis during upright functional movements and advance to muscle endurance.

As the results showed crank amplitude was the main element of the FRED settings which affects recruitment and motor control outcomes while the footplate had very small, if any, effect, it is recommended to use FRED conditions 2, 4, 7 and 11. These four conditions use all crank amplitude positions (two to five respectively) without needing to alter the footplate position, which remains in position one throughout. In addition, this footplate setting places device users in the forward most position possible and closest to the handle bars of the device should they be required during exercise for safety reasons. Traditional LM and TrA training progresses the functional movement stage by reducing base of support, increasing movement size or using physical loads such as holding weights in the upper limbs (O'Sullivan 2000; Hides et al. 2008). As the results of this study show that increasing crank amplitude settings resulted in reduced ability to maintain smooth movements and increased ΔLM_{max} and ΔTrA_{max}, it appears that FRED progression can be based on increasing amplitude size to increase the motor control demand. It is, therefore, suggested that users begin in the lowest

amplitude setting and increase by one setting once they can consistently minimise movement variability. Over a period of training, the exercise can be progressed and the user is able to control a larger amplitude setting with an increased motor control challenge. The progression and expected differences in outcomes between them based on the evidence of this study are presented in Table 3-18.

Table 3-18 FRED training Progression and Effect on Outcomes

Progression	FRED condition	Muscle recruitment (thickness)	Movement and muscle recruitment variability
	**2** (crank 2 footplate 1) **4** (crank 3 footplate 1) **7** (crank4 footplate 1) **11** (crank 5 footplate 1)	 Increases in LM and TrA thickness. Potential thickness increase of 0.5±0.6mm to 0.7±0.6mm All are expected to recruit LM and TrA more than rest. Potential thickness increase over rest of 4.7±1.4mm to 5.5±1.7mm for LM and 0.9±0.5mm and 1.7±0.9mm for TrA	 Increased movement variability, ΔLM_{max}, and ΔTrA_{max}.

3.4.4. Reliability

The typical error analysis provided conservative estimates of intra-rater between day measurable changes that can be detected using this type of methodology. For contracted lumbopelvic muscle thickness, a change of 1.1 mm could be measured in LM and 1.04 mm in TrA. These are comparable to the standard error of measurement results previously reported by Koppenhaver et al. (2009) of 1.1 mm for LM, but higher than the 0.5 mm reported for TrA. This suggests the methodology used in this study has similar reliability for LM but lower reliability for TrA. This may be due to the small amount of data used in the typical error calculations in this study and that the highest varying participant and condition was used to ensure a conservative typical error estimate. The typical

errors reported here are smaller than minimal detectable changes reported by Koppenhaver et al. (2009), of 3.1 mm for contracted LM and 1.3 mm for contracted TrA for intra-rater between-day measures. However, the minimal detectable change shows the difference that must occur to be 95% confident of a true change. This is more conservative than what is needed for the MBI approach used in this study and risks masking smaller but still potentially useful changes, especially in small sample studies such as this (Shakespear 2001).

Conservative examples of intra-rater between-day measurable changes for the novel outcome measures used in this study were a variation of 0.82 mm for LM recruitment, 0.48 mm for TrA and 0.46% for movement variability. As these outcomes are novel and specific to the FRED, there was no previous literature to compare to. However, the good between-day reliability results found in the muscle thickness measures suggest measures were assessed rigorously throughout the study. The reliability estimates reported for the novel outcomes here may also act as a benchmark to compare to for future studies which use these outcome measures. As studies of the device develop towards clinical trials, it may be useful to establish the validity and reliability of the common outcome measures used in these studies and evidence of clinically relevant, minimal worthwhile changes in relevant populations.

3.4.5. Limitations

Only the ultrasound outcome measure had previous evidence showing it to be valid and reliable with previous data to compare to. Outcomes of ΔLM_{max}, ΔTrA_{max} movement variability and comfort were novel. Their validity and reliability may, therefore, be questioned. ΔLM_{max}, ΔTrA_{max} and movement recruitment variability did show measurable changes suggesting they may be valid if tested and conservative estimates were provided for their reliability from this study,

although calculated from a very small population and, therefore, should be treated with some caution. The Newcastle Comfort Scale was unable to detect any changes between any of the conditions it was used in and so consequently was not tested for reliability or used in any MBI statistics. This may suggest that all settings were equally comfortable or it may be the scale is not valid or sensitive to the changes in comfort caused by the FRED. Future studies should either validate the scale before its use or implement an alternative outcome measure that has already been shown to be both a valid and reliable outcome measure for the purpose.

The results of this study were only able to show mechanistic changes reported in all the outcome measures. They do not show if these changes are meaningful to clinical populations, or if they are of sufficient magnitude to be effective as a LBP intervention. Minimal clinically worthwhile changes in populations where the device could be used as an intervention need to be established in order to make inferences and conclusions about the clinical relevance of the device. Correlating validated clinical, and device relevant, outcomes or constructs (potentially pain or disability outcomes would be appropriate), to changes in muscle thickness, recruitment variation and movement variability could be a way in which to establish such minimal clinically worthwhile changes. Once established they could be used to set the thresholds for MBI to produce meaningful insights into the ability of the device to generate clinically worthwhile changes in the relevant outcomes. This would be useful in studies wanting to test whether the device is effective in a clinical population.

A study into TrA and internal and external oblique thickness changes linking them to clinical outcomes of pain and Roland Morris disability questionnaire showed thickness change was a poor indicator of clinical outcomes (Mannion et al. 2012). However, the study only considered baseline and end of

nine-weeks therapy, so a ceiling effect may have been reached earlier on and been unnoticed. It also only considered TrA and internal and external oblique muscles, without giving consideration to LM. Additionally they used M mode USI with Doppler imaging which is different approach to assessing recruitment with USI, and so their conclusions may not be transferable to this context. A fine wire electromyography study comparing activation of LM and TrA to clinical outcomes could be used to establish minimal clinically relevant changes in the muscle recruitment outcome.

For LM, a study was done measuring cross sectional area and back pain in elite cricketers over a 13 week training camp, where the cross sectional area was seen to increase with a decrease in pain (Hides et al. 2008). This shows LM cross sectional area may be a more suitable outcome to use during a clinical trial over a period of time and a minimally clinically worthwhile change may be determined linking with outcomes such as pain.

The ground standing measures were taken at the beginning of the second day of testing. It is possible they were influenced by training effects from exercising on the device 24 hours earlier. Although a training effect of FRED exercise has not been documented to date, other training protocols for LM and TrA recruitment have been shown to increase the muscle sizes over time (Hides et al. 2008).

3.4.6. Conclusion

The exercise device clearly recruits TrA and LM more than rest. However, in this study, the recruitment was not observed to be more than standing on stable or unstable ground in a small healthy population with no-LBP. It was most probable that the footplate positions did not change any of the measured outcomes. The larger crank positions resulted in a greater challenge to

movement and muscle recruitment variability for both LM and TrA muscles as well as increased TrA recruitment. Based on this, it is recommended to train in the foremost footplate position, labelled as number one. The crank position should then be set to the largest amplitude in which the user can maintain an even movement based on assessment by a certified FRED operator. Exercise can be done in lower amplitudes to regress the exercise to the position where the user demonstrates adequate motor control to exercise with low movement variability.

The evidence that the device recruits muscles and affects motor control outcomes can be used to justify trialling the device in clinical populations. However, it would be useful to establish minimally clinically worthwhile changes in outcome measures used in such a trial. Additionally, the biomechanical mechanisms of the device within the lumbopelvic region should be investigated to assess the posture promoted by the device, based on the finding that muscle recruitment may be caused more by the posture adopted during exercise, than the movement.

4. Chapter Four: Investigation of Lumbopelvic Kinematics and FRED Measured Outcomes in a Large Population Including Participants With Back Pain.

4.1. Introduction

Chapters one and three established the background and justification for investigating the mechanisms of FRED exercise as a potential rehabilitation intervention for the LM and TrA muscles. The same chapters also explained that this type of rehabilitation involves training the recruitment and endurance of the LM and TrA muscles. Chapter three went on to conclude that the posture promoted during FRED exercise may be a possible mechanism resulting in the LM and TrA activity found during exercise on the FRED. While non-specific LBP has no specific causative factor, altered spinal mechanics have been reported as a common element (Panjabi 2006) and previously linked to atrophy (Hides et al. 2008; Danneels et al. 2000; Hodges et al. 2006; Hodges and Richardson 1996; Ferreira, and Hodges 2004) and altered motor control (Hodges and Richardson 1996) of the LM and TrA muscle. Changes and loading, specifically in sagittal plane spinal positions have already been linked with LBP (Videman, Nurminen and Troup 1990; McGill 1997; Wormersley and May 2006) and were therefore, investigated.

4.1.1. Sagittal lumbar posture and LBP

Videman, Nurminen and Troup (1990) assessed the epidemiology of LBP in relation to occupation, spinal loading and lumbar spine pathology within cadaveric studies of 149 males. Degenerative lumbar changes were compared with reports of back pain in the years preceding death and the type of work and spinal loading performed over the years prior. It was found that work involving heavy lifting or driving correlated to higher levels of reported LBP and post mortem lumbar degenerative changes, followed by sedentary deskwork. Conversely, occupations involving a mix of tasks and postures resulted in reduced back pain incidence and the lowest reported levels of lumbar degenerative

changes (Videman, Nurminen and Troup 1990). This evidence suggested a link between heavy lifting, or prolonged, flexed spinal sitting postures, and higher incidence of back pain and lumbar spine degenerative changes. McGill (1997) also found that it was more common for spinal injuries to be the result of cumulative effects of several repeated, or sustained, low level tissue failures, or long term poor sagittal spinal postures, over time. A study by Wormersley and May (2006) also observed increased incidence of sagittal spinal flexion in a group of young volunteers complaining of backache compared to a second group who spent less time with a flexed spine in the sagittal plane. Maintaining a normal lumbar lordosis and minimising spinal flexion during lifting postures has also been found to greatly decrease the risk of injury to the spine and LBP (McGill 1997).

4.1.2. Link between LM, TrA and sagittal spinal posture

In the lumbar spine, the Multifidus muscle originates from mammillary processes of the vertebrae, inserting onto the spinous processes of vertebrae 2-4 segment levels superior (Musculino 2005). It also originates from the posterior sacrum, posterior superior iliac spine and posterior sacroiliac ligament (Musculino 2005). A detailed analysis of LM anatomy was performed by Macintosh et al. (1986), who observed that the superficial LM fibres extend for longer distances and tend to attach to the sacrum and ilia (Figure 4-1). The deeper LM fibres tend to run shorter distances, staying between the vertebral segments. It was suggested, therefore, that superficial LM fibres have a role in controlling lumbar spine lordosis (Macintosh et al. 1986). A fine wire EMG study of both superficial and deep fibres in eight participants by Mosely, Hodges and Gandevia (2002) validated the finding that superficial fibres control lumbar orientation while activation of deep fibres contribute to control and reduction of inter-segmental movements. Deep fibres were recruited in anticipation of any direction of single arm movements, whereas superficial fibres were only recruited in anticipation of

shoulder flexion. It was theorised that shoulder flexion produced larger vertebral reaction forces in a sagittal plane requiring control of the lordosis and therefore activating superficial fibres (Moseley, Hodges and Gandevia 2002). The orientation of and forces produced by the LM also suggest it is the strongest stabiliser of the lumbar spine (Kim et al. 2007)

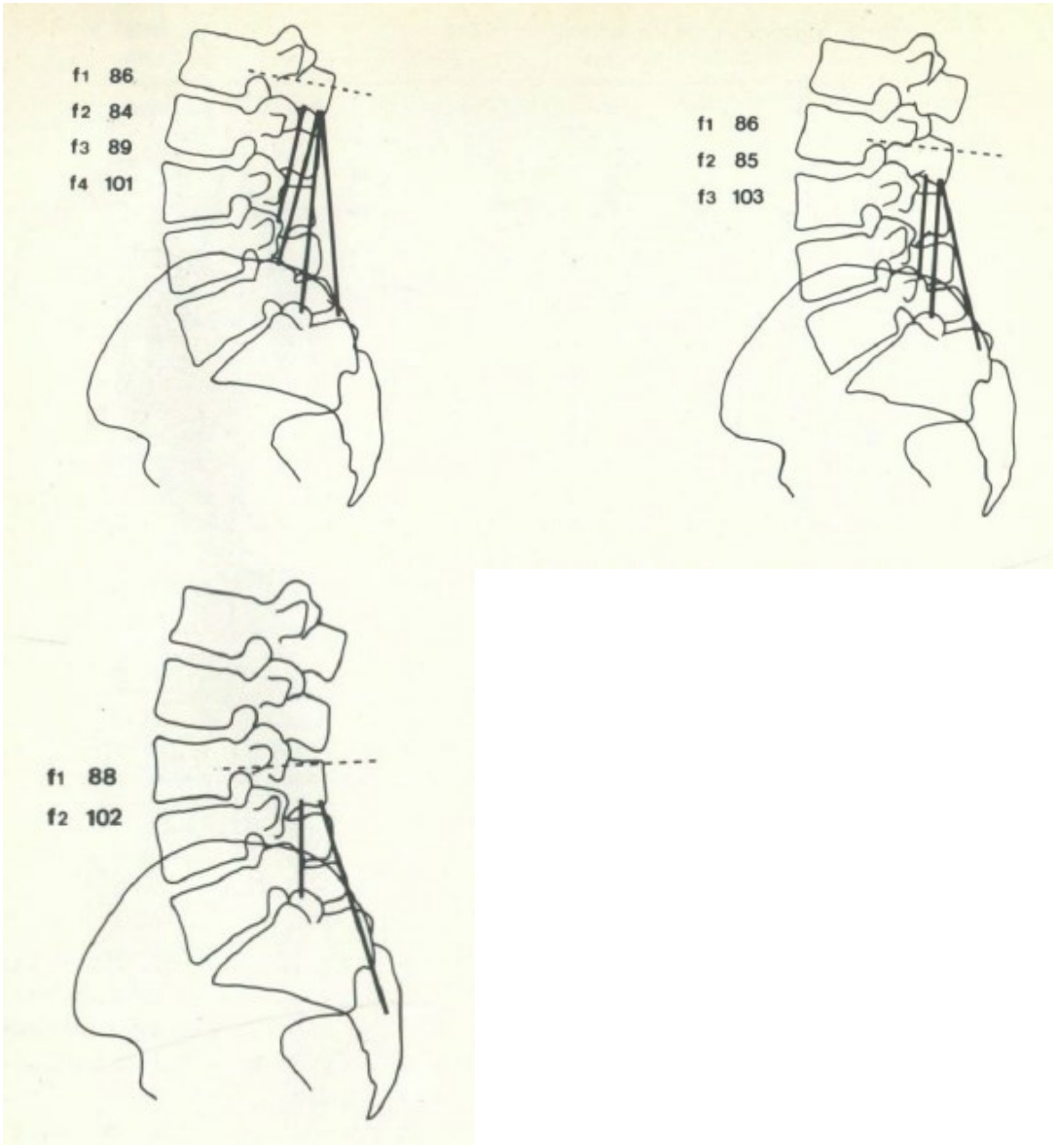


Figure 4-1 Diagram of LM fibres in the sagittal plane from Macintosh (1986), illustrating how some fibres are likely to have a role in maintaining lumbar lordosis

Additionally, O'Sullivan (2000) observed loss of lordosis control in clinical patients with LBP, within which he also observed symptoms of lumbar segmental instability. Loss of lordosis control occurred in these patients in one of three

patterns: a flexion pattern with hypolordotic lumbar spine and posteriorly rotated pelvis, (Figure 4-2). An extension pattern with hyperlordotic lumbar spine and hyper-active erector spinae, compensating for reduced ability to isolate deep muscle contraction, (Figure 4-3), and in unilateral back pain, a lateral pattern was observed with shift of the lumbar spine in the coronal plane.

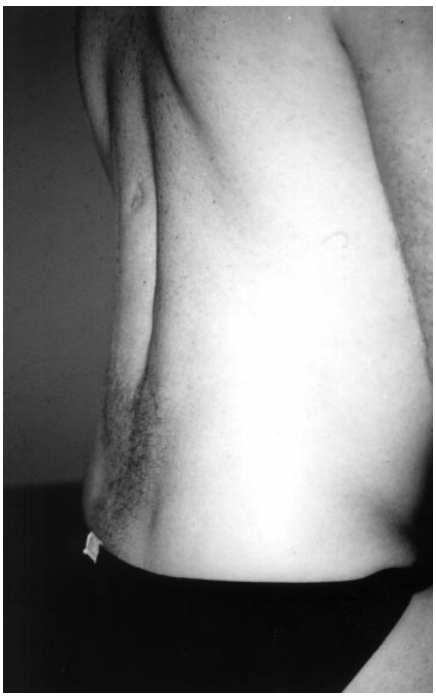


Figure 4-2 Photograph of lumbar segmental instability patient from O'Sullivan 2000, demonstrating lumbar posture typical of a flexion pattern

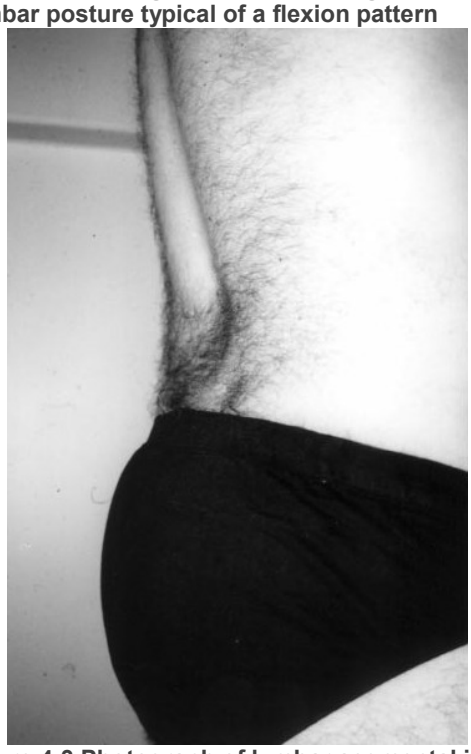


Figure 4-3 Photograph of lumbar segmental instability patient from O'Sullivan 2000, demonstrating lumbar posture typical of an extension pattern

O'Sullivan et al. (2006) examined the activation of LM and erector spinae in various postures and found most activity in a posture termed 'lumbopelvic' compared to 'thoracic' and 'slumped' postures (Figure 4-4). Lumbopelvic posture was defined as neutral pelvis, lordosis confined to lumbar spine and relaxed thoracic musculature. Thoracic posture had a long lumbar lordosis which extended into the lower thoracic spine. Slumped posture occurred when back muscles were generally relaxed with sagittal spinal posture becoming flexed and the pelvis becoming posteriorly tilted.

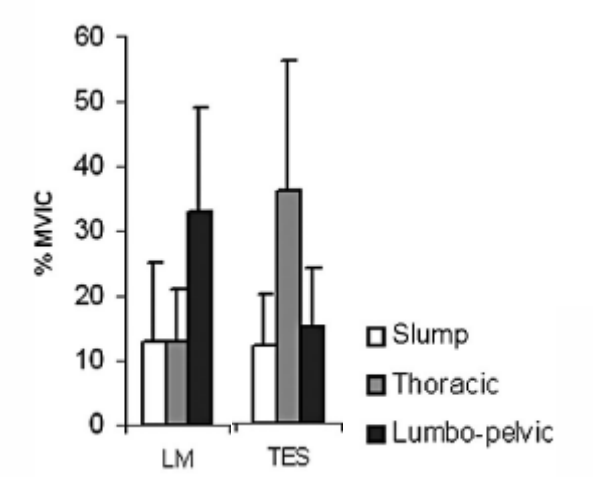


Figure 4-4 Graph from O'Sullivan et al. (2006) of muscle activity determined with EMG in various sagittal postures.

These findings were validated in a separate study using fine wire electromyography by Claus et al. (2009), who found the lumbopelvic posture also activated TrA, although this study was done in sitting. Overall, these findings suggest LM and TrA have a role in controlling sagittal lumbopelvic posture in addition to providing segmental stability. It appears that activity of deep muscles increases with steadily increasing anterior pelvic tilt accompanied by a lumbar lordosis which remains within the lumbar vertebrae, up to the thoracolumbar junction. At the point of lordosis extending into the thoracic spine, increasing superficial muscle recruitment (mostly erector spinae) occurs alongside,

decreasing LM and TrA muscle activity (Claus et al. 2009; O'Sullivan et al. 2006). The variation in spinal curves between the differing sagittal spinal postures is also well illustrated in Figure 4-5 from Kendall (2005).

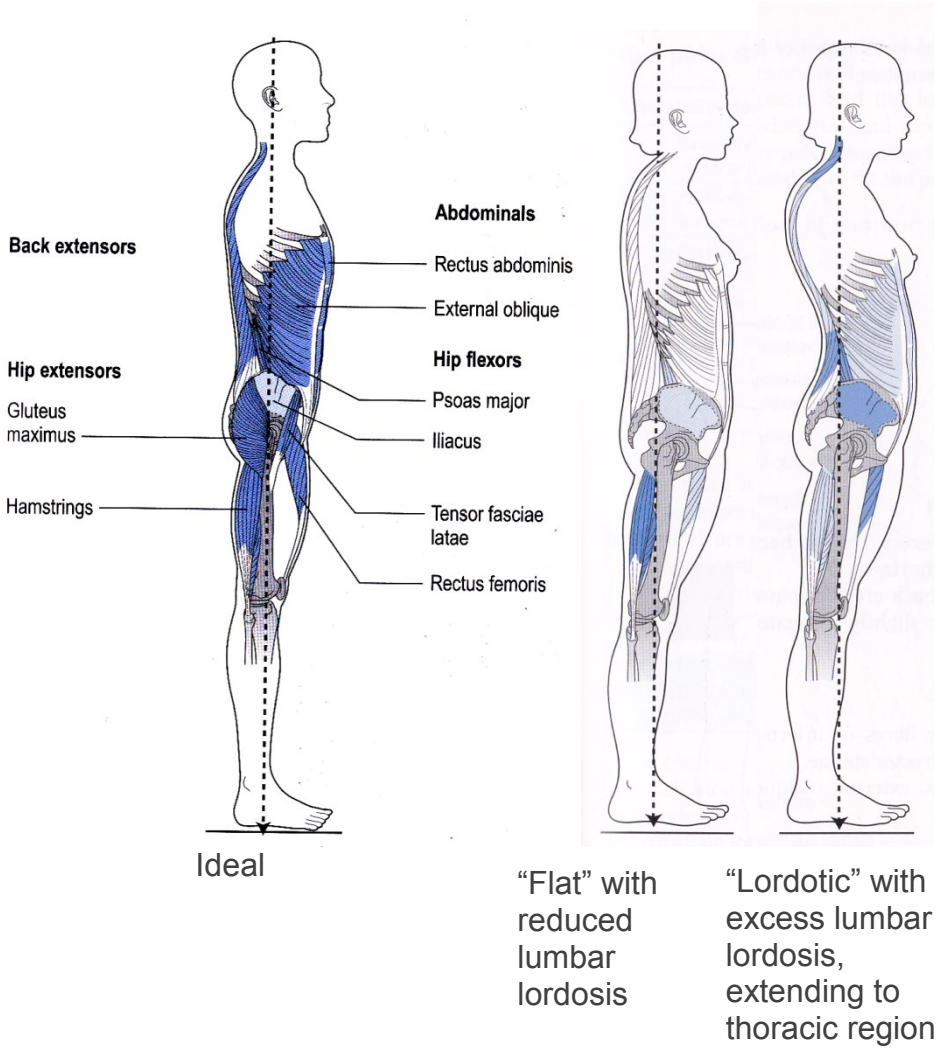


Figure 4-5 Various sagittal plane posture diagrams from Kendall (2005)

Atrophy of LM and TrA has also been associated with loss of lordosis, development of back pain and spinal injury, following periods of low activity and disuse of spinal muscles (Buckey 2006; Hides et al. 2011; Sayson and Hargens 2008). Loss of lordosis and atrophy of the LM muscle was also listed in chapter two as a physiological change resulting from periods of deconditioning during bedrest based space simulation studies.

The sum of the evidence presented above supports the definition of neutral posture for LBP interventions presented in section 1.8, which was based on an x-ray study of standing lumbopelvic posture across 160 participants by Roussouly et al. (2005). That definition stated that a balanced lumbopelvic posture exists when there is a degree of anterior pelvic tilt to the extent that the lumbar lordosis exists throughout the lumbar vertebrae up to the thoracolumbar junction. It appears, therefore, that poor motor control can lead to loss of balanced sagittal plane spinal kinematics resulting in hyper or hypo –lordotic lumbar spine postures. Therefore, rehabilitative interventions for lumbopelvic deconditioning should promote a sagittal plane pelvic tilt resulting in lumbar lordosis from L5 to the thoracolumbar inflection point and combined with deep muscle activity. This type of posture is also well linked to increased LM and TrA activity, which is considered an important element of motor control exercises. Traditional LM and TrA rehabilitation interventions involved progressive training, beginning with isolating muscle recruitment, followed by recruitment during upright functional positions while maintaining lumbar lordosis and thoracic kyphosis (Hides et al. 2008; O'Sullivan 2000).

Traditional training required conscious effort by the patient in order to recruit LM and TrA and maintain the required posture. FRED exercise has already been shown to automatically recruit both LM and TrA (Debuse et al. 2013) in a tonic contraction (Caplan et al. 2014) with no conscious input by the participants, as well increasing lumbopelvic stability when compared to over ground walking (Gibbon, Debuse and Caplan 2013). However, the effect of FRED exercise on promotion of ideal lumbopelvic kinematics for LM and TrA training has not been investigated, nor has the effect of FRED exercise on spinal kinematics in people with LBP.

Therefore, the lumbopelvic posture adopted by those using the device was assessed in this study. Comparison of lumbopelvic posture between asymptomatic individuals and a population with back pain was also conducted to highlight any potential differences. At the time of this study, the device had yet to be tested in any of the potentially relevant clinical populations. This study, therefore, was the first to consider the effect of exercise on the FRED in symptomatic individuals compared with no-LBP controls.

4.1.3. Aim and Objectives

This study aimed to determine the influence of FRED exercise on lumbopelvic kinematics in people with and without LBP. It was hypothesised that the device would automatically promote a sagittal plane lumbopelvic posture, which is consciously trained in traditional motor control interventions, and is linked to recruitment of LM and TrA muscles, and that similar kinematic postures would be facilitated in people with and without LBP. The objectives were as follows.

1. To observe participants' sagittal plane lumbopelvic posture during walking which is a similar functional movement to FRED exercise.
2. To observe participants' sagittal plane lumbopelvic posture during exercise on the device.
3. To assess any changes in the lumbopelvic posture between the two activities and between no-LBP and LBP participants.
4. To determine if exercise on the device promotes lumbopelvic postural changes compared with walking in both no-LBP and LBP populations.
5. To observe any differences in participants' ability to exercise in a slow and steady movement between LBP and no-LBP populations, and comment on any differences in lumbopelvic posture or exercise ability in the context of deep muscle activity and rehabilitation for lumbopelvic instability.

4.2. Methods

A within participant and two group, between group comparison study was used to investigate postural kinematics during over ground walking and exercise on the device. The study received ethics approval from the Faculty of Health and Life Sciences Ethics Committee at Northumbria University (see appendix J).

4.2.1. Recruitment

Data collection occurred at the Life Science Centre, Newcastle upon Tyne, as part of a "Meet the Scientist" programme, open to the general public. Participation was open to any members of the public attending the Centre over a four week period during July and August 2014. A data collection area titled "Meet the Scientist" was set up in the entrance to the "Body Worlds" anatomy exhibition already taking place at the centre. Meet the Scientist, European Space Agency and Northumbria University banners were displayed outside the data collection area. A screen displaying a repeating PowerPoint presentation displayed information about the study and invited people into the area. A cordoned space for the public to observe data collection activities was set up. Posters and information about the study were displayed within the cordoned area and indicated that volunteers, from the public, were being sought as participants. A large screen behind the research area showed the observing public either a live 3D kinematic avatar representation of study participants during data collection periods, or information on the FRED at all other times. Members of the data collection team were on hand and available to discuss the study with those observing. Participant information sheets (appendix C) detailing the study, and requirements to be a participant, as well as informed consent forms (appendix D) were readily available within the area.

Individuals volunteering to participate were screened for exclusion criteria based on previous FRED studies (Debuse et al. 2013). This included those aged under 18 and over 55 years, having history of neurological or neuromusculoskeletal problems or injuries resulting in scoliosis or inability to exercise safely on the device, heart disease, abdominal or spinal surgery in last three years, pregnancy and epilepsy.

Additionally, participants were required to complete and 'pass' the Physical Activity Readiness Questionnaire prior to being accepted. The Physical Activity Readiness Questionnaire identifies any persons for whom increased physical activity is contraindicated for medical reasons. The questionnaire has been shown to be 100% sensitive and 80% specific across all versions (Cardinal, Esters and Cardinal 1996). Those not having any exclusion criteria and passing the Physical Activity Readiness Questionnaire were accepted into the study.

4.2.2. Back pain screening

All included participants were screened for LBP on entry to the study to allow grouping of data into LBP and no-LBP populations for analysis. Questions 7 and 8 from the SF-36, standard, US version 2 (QualityMetric 2000) were used for this screening. The wording of the questions was edited to read "back pain" rather than "bodily pain", as follows:

"How much back pain have you had during the past 4 weeks? 1 – None, 2 – Very mild, 3 – Mild, 4 – Moderate, 5 – Severe, 6 – Very Severe"

Data from all participants who indicated a back pain score of two or above in the first question were later analysed as a LBP group. Remaining participants' data were analysed as a no-LBP group. To assess the impact any reported LBP

had on participants' activities, all those who indicated LBP were also asked to rate its impact on function using the following scale:

"During the past 4 weeks, how much did back pain interfere with your normal work (including both work outside the home and housework)? 1 – Not at all, 2 a little bit, 3- moderately, 4 Quite a bit, 5 – extremely".

This wording of this question was deliberately made similar to the back pain question and so is also based on the SF-36, standard US version 2.

To establish demographics, participants' gender, age, mass and height were recorded and they were asked to rate their normal activity levels on the following scale:

"Over the past 4 weeks, how active have you been?

1. Sedentary – General activities are confined to a few rooms. Slow walking pace and no running during the week. Most activity involves sitting.

2. Limited – Activities involve mostly walking or some slow running. Less than 10mins running per week. Less than 20mins brisk walking per week.

3. Moderate – Activities include golf, tennis, sailing, pleasure swimming, dancing, skiing etc. 10-30mins of running per week OR 20-24mins of walking at least three times a week.

4. Active – More than 30mins of sustained activity like jogging, swimming, football or tennis more than three times a week. 45-60mins of brisk walking at least three times a week.

5. Very active – At least 1.5hours of vigourous activity like competitive sports, weight training, mountain climbing etc. four times or more per week.

Demographics were recorded for gender, age, mass, height, BMI and activity score. Statistical differences between the LBP and no-LBP group demographics were assessed using MBI in relation to a minimal worthwhile change threshold of a 0.6 effect size. This threshold detected if any differences in demographics produced moderate effects between the groups (Hopkins et al. 2008), (see section 4.2.9).

4.2.3. Experimental Protocol and Data Collection

The FRED prototype version three was used throughout this study. The device was set in crank amplitude position 5 (smallest) and footplate position 1 (furthest forward) throughout. This setting was shown to be the least challenging in chapter three, therefore allowing participants to learn the movement skill required to exercise on the device quickly. This minimised the risk of varying levels of skill potentially confounding the results.

4.2.4. Measures

Kinematic data were recorded for anterior pelvic tilt, sagittal plane angles between spinal segments, measured as the angle between each segment at L5/S1, L3/L4, T12/L1, T8/T9 and centre of mass during walking and exercise on the device. Movement variability and frequency of the FRED exercise were also recorded.

4.2.5. Motion capture system and calibration

Kinematics were assessed using a wearable 3D motion capture system (MVN, XSens, Enschede) and MVN studio version 3.1 (XSens 2012). The motion capture suit consisted of seventeen inertial and magnetic sensors fixed to specific locations on all body segments (hands, forearm, upper arm, head, shoulder blades, pelvis, upper leg, lower leg and feet) with neoprene bands and Velcro (Figure 4-6).

Figure 4-6 Photograph from XSens MVN user manual (2012) showing tracker and neoprene band locations

The sensors contain accelerometers to determine direction of travel, 3D gyroscopes for determining orientation and magnetometers to sense the direction of the Earth's magnetic field as a reference for orientation to minimise drift errors (Rotenberg, Luinge and Slycke 2013). Data from each component combine to provide movement data. The sensors were placed over participant's clothing. However, jumpers and coats were removed prior to the placing of trackers to

avoid artefact noise from movement of multiple layers of clothing. Two packs were attached to the back to provide synchronised sensor sampling, battery power and a wireless link from the suit to a nearby computer. Data from the sensors were applied to a computer-generated 3D anatomical model to estimate full body kinematic data. The model assumes a participant's body is formed of 23 segments linked by joints (pelvis, L5, L3, T12, T8, neck, head, shoulders, arms, hands, legs, feet, toes) (Figure 4-7 and 4-8) (Roetenberg, Luinge and Slycke 2013).

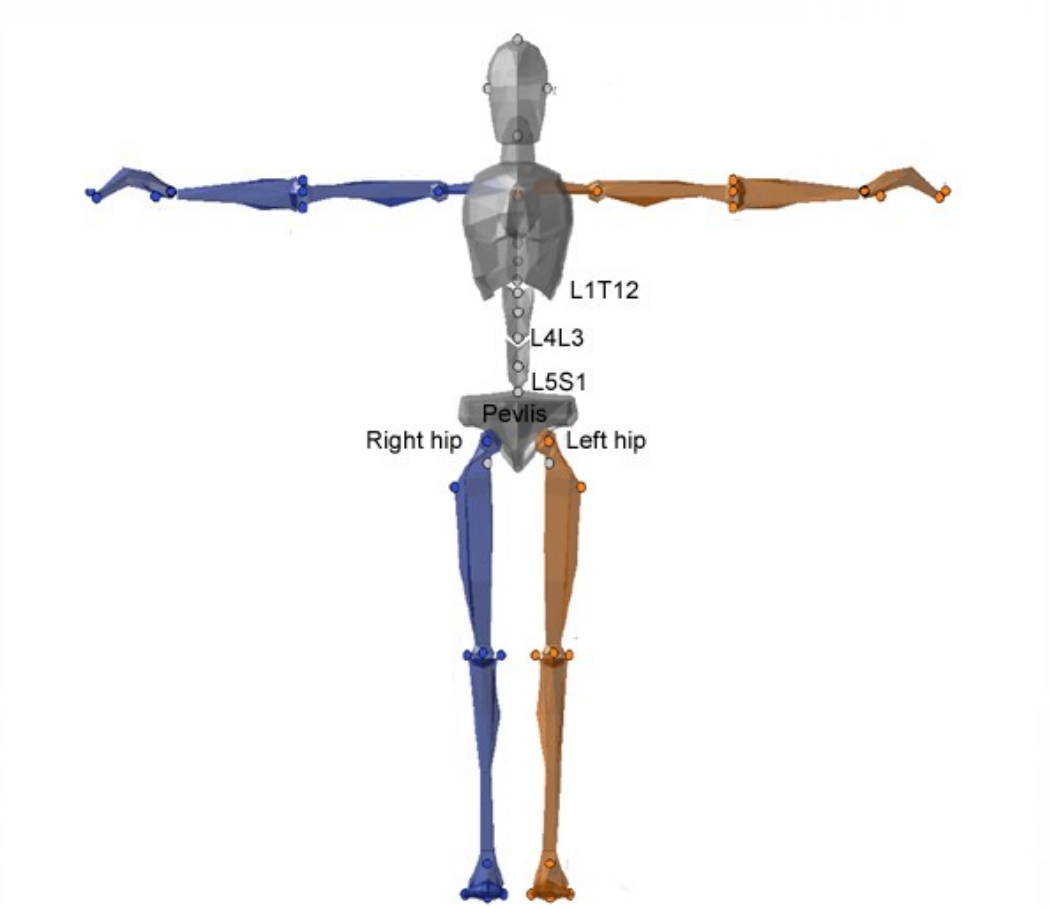


Figure 4-7 XSens kinematic model show in T-Pose front view from the XSens MVN user manual (2012 with labels added to sections relevant to this study)

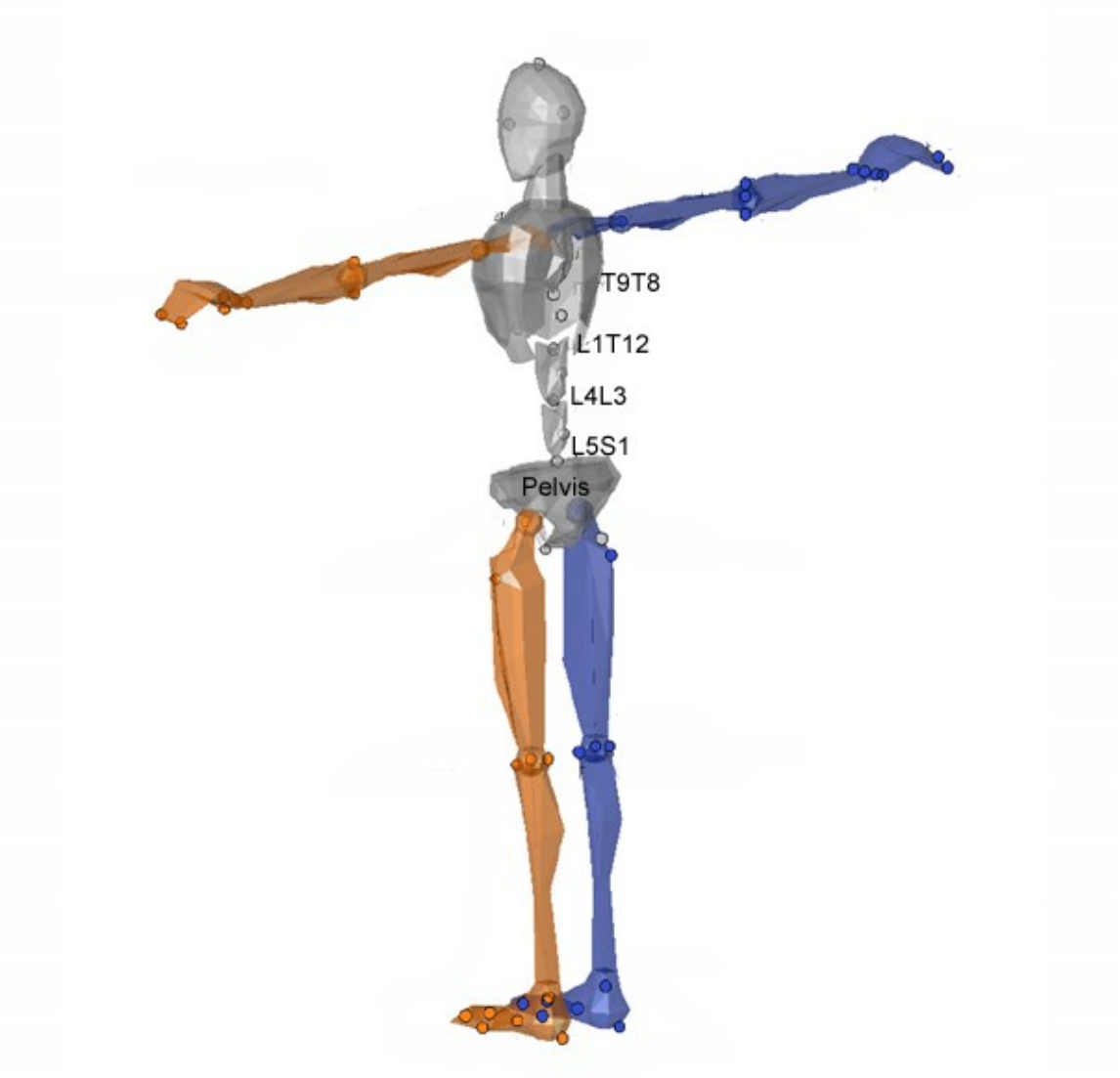


Figure 4-8XSens kinematic model shown in T-Pose from rear rotated view from the XSens MVN user manual (2012)

Full body kinematic data were collected at 120 Hz, using the default full body model and Kinematic Coupling Algorithm (KiC) fusion engine setting, without magnetometer data. Magnetometer data were not selected due to high potential for magnetic disturbance around the feet caused by a metal structural beam under the test area.

Calibration was performed in the same location for all participants, which was determined during pre-test mapping as having the lowest risk of magnetic disruption. Additionally, calibration was performed with participants standing on a

custom-made raised wooden platform (Figure 9) to further reduce risks of magnetic interference. Participant height and foot size were entered into the model to set avatar proportions. Two static calibration poses, T (arms out to the side in 90 degrees shoulder abduction) followed by N (arms by sides) pose, were then used to calibrate the system. Following calibration, participants were instructed to walk around the testing area to activate magnetic filters prior to data collection. In the event of any tracker drift being observed following calibration, a reset was performed to remove accelerometer data since calibration. If a reset failed to resolve any drift then repeat calibrations were performed.

Figure 4-9 Custom made wooden XSens calibration platform (top) and in use during a calibration (bottom)

4.2.5.1. Kinematic Data Collected

Kinematic data were collected during normal walking along a straight and level walkway 4.8m in length (Figure 4-10), allowing a minimum of two complete gait cycles to be captured. Twenty seconds of FRED exercise were collected, during which a minimum of five complete FRED cycles occurred. Data collection commenced following a five minute FRED exercise familiarisation period.

Figure 4-10 The 4.8m long motion capture track marked on the floor of the testing area with two white parallel lines - marks within the track related to other studies running in parallel

4.2.5.2. Centre of mass estimation

XSens calculates centre of mass from segment positions and orientations using a body mass distribution model (Roetenberg, Luinge and Slycke 2013). Data on the centre of mass are exported by MVN studio as an X,Y,Z vector relative to the origin (where calibration occurred). To make these data more meaningful, the X,Y,Z position of the pelvic midline relative to the origin was also exported. The difference between the pelvis segment and centre of mass vectors

was taken as the distance of the centre of mass from a midpoint segment of the avatar. This provides an estimate of the centre of mass relative to the pelvic midline in both anterior-posterior and lateral directions.

4.2.6. Movement variability and frequency of Movement

The FRED records data on the movement variability within one revolution of a foot plate per full FRED cycle, quantified as the difference (%) between the live angular speed of crank wheel during exercise and the average angular speed over the previous second. These data were collected using the same methods described in chapter three section 3.2.6. The FRED also records the frequency at which participants complete one rotation of the crank wheel.

The movement variability and frequency data were recorded live from the device on a Lenovo, Windows 8 PC running custom-created FRED software (Mazur Automation, Germany) which was connected directly to the exercise device. The data were then imported into Microsoft Excel 2010 for analysis.

4.2.7. Use of XSens during FRED exercise

XSens uses predicted contact points of the avatar with the floor to minimise drift of the avatar as a whole (Rotenberg, Luinge and Slycke 2013). During FRED exercise the model assumed the participant was performing the movement on a stable floor. This caused errors in the model resulting in dislocation of ankles and hips. To correct for this, contact point data for FRED exercise were ignored in post processing. While this resulted in restoration of accurate joint kinematics, the avatar as a whole drifted over time. The drift is constant for all avatar segments and, therefore, had no effect on joint angles, segment orientation or centre of mass data.

4.2.8. Reliability and Validity of XSens

The XSens setup used was reported as having up to two degrees 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 et al. 2013). The system has been validated previously against VICON for measuring kinematic data (Rotenberg, Luinge and Slycke 2013). The model uses sections of the spine which span several vertebrae, the data for the spinal movements come from trackers on the sacrum, scapulae and head, which is then averaged across the biomechanical model (XSens 2012). It is unable therefore, to report individual spinal segment kinematics, and instead, averages data across the spine from the sacral, scapulae and head trackers.

Movement variability and exercise frequency are novel outcome measures specific to the FRED. Therefore, no previous evidence of their validity and reliability as outcome measures of motor control existed. The data are recorded within the device using a rotary encoder (RP6010, ifm Electronic GmbH, Essen, Germany) which records angular velocity for analysis as movement variability and frequency using bespoke FRED software (Mazur Automation, Munich, Germany). No human error component exists and the device sensors are considered fit for purpose.

4.2.9. Minimal worthwhile change

To date, there is no reported valid minimal worthwhile change in the outcome measures which is clinically worthwhile. Therefore, mechanistic (physical) change in all variables was reported. To infer if the change was worthwhile a MBI approach was used. An effect size between comparisons of at least 0.2 was considered worthwhile as this shows that at least a small effect size existed between the two comparison groups (Batterham and Hopkins 2006). This

approach was chosen over traditional significance testing as it allows the direction of any change and the size of that change relative to the designated minimal worthwhile change to be reported. Traditional significance testing can miss small changes and does not provide information about the direction of change (Batterham and Hopkins 2006).

It was hypothesised that an individual with good motor control, exercising on the device would produce an even movement throughout. Conversely, an individual with poor motor control would likely produce uneven movements with rapidly varying movement velocities. Therefore, it was expected to see a low movement variability score in those with better motor control.

It was theorised that participants with good motor control and stability will be able to exercise at the target frequency without large variation, although this remains to be confirmed. Therefore, the mean variation of exercise frequency is also reported.

4.2.10. Ethics

The study recruited human participants, and their dignity, wellbeing and rights were protected at all times. A risk assessment was performed prior to any testing and steps to ensure appropriate health and safety were implemented. No lasting effects of the exercise were expected for any participants. Informed consent was provided in writing by all participants and they were informed they could withdraw from the study and remove their data at any time. No incentives or money for travel costs were provided to participants. Participant data were stored in a secure location in a site folder at all times and used solely for the purpose of this study. Any personal information will be destroyed after a maximum of three years following study completion. During data collection the site folder was kept in padlocked box with other sensitive equipment at the Life Science Centre,

following data collection and was moved to a filing cabinet in a swipe card access laboratory at Northumbria University.

4.2.11. Data Analysis

The mean change and standard deviation in raw units were calculated and presented for each comparison. Magnitude based inference statistics were then used to run multiple-pairwise comparisons of variables between the groups. These statistics provide the probability for each comparison that the true (population) change is positive, negative or trivial with reference to a pre-determined minimal worthwhile change. This method allows meaningful inferences about group difference to be made based on the measured effect sizes between the groups (Batterham and Hopkins 2006). It is useful to have a previously reported and validated minimal clinically meaningful change on which to base inferences. However, clinically relevant differences have yet to be determined and validated for the outcome measures assessed in this study, related to intersegmental spinal instability. This is in part due to the use of novel outcome measures determined by the device itself, which is still a prototype under development. Therefore, in line with Batterham and Hopkins' (2006) recommendations, an effect size of at least 0.2 was set as the minimal worthwhile change on which to base inferences, which shows the reported effect is at least small. Raw units were converted to standardised units (Cohen's D) for effect size using the following equation:

$$d = \frac{mean\ change}{standard\ deviation\ of\ the\ data}$$

The effect size, 90% confidence intervals and probabilities (%) that the true values were mechanistically positive, trivial or negative were then calculated and qualitatively defined 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*".

The following comparisons were made between over ground walking and the FRED within each group, and between the LBP and no-LBP groups:

- Differences in the angles between the XSens model's spinal segments in the sagittal plane, at L5-S1, L3-L4, T12-L1 AND T8-T9 positions;
- Differences in pelvic tilt (sagittal plane);
- Differences in centre of mass position;
- Differences in FRED reported outcomes of frequency (f) and movement variability.

The results are, therefore, reported as raw mean change with standard deviation and chance (%) that the true effect is greater than the smallest worthwhile change threshold. The 90% confidence interval of the effect size is reported in the results tables and presented graphically.

For Exercise frequency results, the variance within each group was calculated as follows:

$$Variance = \frac{\sum(x - mean\ x^2)}{(\mathrm{n} - 1)}$$

Where x is the point measure and mean x is the sample mean and n is the sample size.

XSens exports orientation using quaternions, based in a rotation matrix that is used to prevent singularities and gimbal lock errors in the orientation data and model animations (Kuipers 1998). Unfortunately, XSens fails to export these data as Euler angles in X, Y, Z vectors, essential for kinematic analysis in degrees. Therefore, pelvic orientation data were manually converted to Euler using the following 3x3 matrix from the XSens manual (XSens 2012):

$$\mathbf{R} = \begin{bmatrix} q_0^2 + q_1^2 - q_2^2 - q_3^2 & 2q_1q_2 - 2q_0q_3 & 2q_1q_3 + 2q_0q_2 \\ 2q_1q_2 + 2q_0q_3 & q_0^2 - q_1^2 + q_2^2 - q_3^2 & 2q_2q_3 - 2q_0q_1 \\ 2q_1q_3 - 2q_0q_2 & 2q_2q_3 + 2q_0q_1 & q_0^2 - q_1^2 - q_2^2 + q_3^2 \end{bmatrix}$$

$$= \begin{bmatrix} 1 - 2q_2^2 - 2q_3^2 & 2q_1q_2 - 2q_0q_3 & 2q_1q_3 + 2q_0q_2 \\ 2q_1q_2 + 2q_0q_3 & 1 - 2q_1^2 - 2q_3^2 & 2q_2q_3 - 2q_0q_1 \\ 2q_1q_3 - 2q_0q_2 & 2q_2q_3 + 2q_0q_1 & 1 - 2q_1^2 - 2q_2^2 \end{bmatrix}$$

XSens does not provide details on the conversion used by the system to go from the rotation matrix to Euler, therefore a mathematician (Lower 2014) was consulted to complete the conversion step using the following formulas.

With the 3x3 rotation matrix referenced as follows, and X being anterior/posterior tilt, Y being lateral tilt and Z being the direction vector:

$$\begin{matrix} m_{(0,0)} & m_{(0,1)} & m_{(0,2)} \\ m_{(1,0)} & m_{(1,1)} & m_{(1,2)} \\ m_{(2,0)} & m_{(2,1)} & m_{(2,2)} \end{matrix}$$

The conversion is therefore:

$$x = atan2\left(m_{(0,0)}, -m_{(2,0)}\right)$$

$$y = -atan2\left(m_{(2,1)}, m_{(2,2)}\right)$$

$$z = asin\left(m_{1,0)}\right)$$

The conversion steps were all solved in MS Excel 2010. A sample of the curves produced was visually checked against the Euler curves in XSens studio as validation.

4.3. Results

4.3.1. Participants and dropouts

A total of 130 participants volunteered to join the study and provided data. All differences between group demographics were found to be mechanistically *trivial* (Table 4-1). The number of LBP in each category is presented in Table 4-2.

Table 4-1 Participant Demographics and chance that any group differences are trivial using an inference threshold of effect size 0.6.

Group	n	Gender	Mean: Age	Mass (kg)	Height (m)	BMI	Activity Score
Entire population	130	62male / 68 female	35.2	76.8	1.72	25.5	3.6
LBP	56	30 male / 26 female	35.4	78.9	1.75	25.8	3.4
No-LBP	74	33 male / 41 female	35.2	74.7	1.72	25.3	3.7
Chance (%) that difference between groups is trivial			100%	99%	99%	100%	92%

Table 4-2 Low-back pain screening scale and numbers screened to each category

Question: "How much back pain have you had during the past 4 weeks?		n
1	None	74
2	Very mild	17
3	Mild	16
4	Moderate	17
5	Severe	4
6	Very severe	2

Figures 4-11 to 4-14 illustrate the raw change between walking and FRED exercise for the no-LBP and LBP groups individually and between the no-LBP and LBP groups, for lower spinal joint angles, sagittal pelvic tilt, centre of mass and FRED variables respectively. Tables 4-3 to 4-6 present the corresponding MBI

statistics using the effect size for each comparison and 90% confidence intervals. All tested differences in means use the smallest effect size (0.2, 0.6 or 1.2) which resulted in a clear inference, and is reported in all MBI table captions, as the threshold for a worthwhile change.

Lower spinal joint angles

Figure 4-11 shows that FRED exercise increased extension at all spinal joint angles compared to walking, with the highest increase occurring at the L5/S1 level. The increase in extension was 0.9-1.2 degrees at L5/S1 and 0.3-0.4 degrees at T8/T9. There was also a weak trend that the extension was less in the no-LBP group, by 0.3 degrees at L5/S1 and 0.1 degrees at T8/T9. Table 4-3 shows it was *very likely* that the mean extension angle during FRED exercise was positive compared to the mean during walking, at all spinal levels. It was at best *possible* that the mean extension angle in the no-LBP group was negative compared to the LBP group.

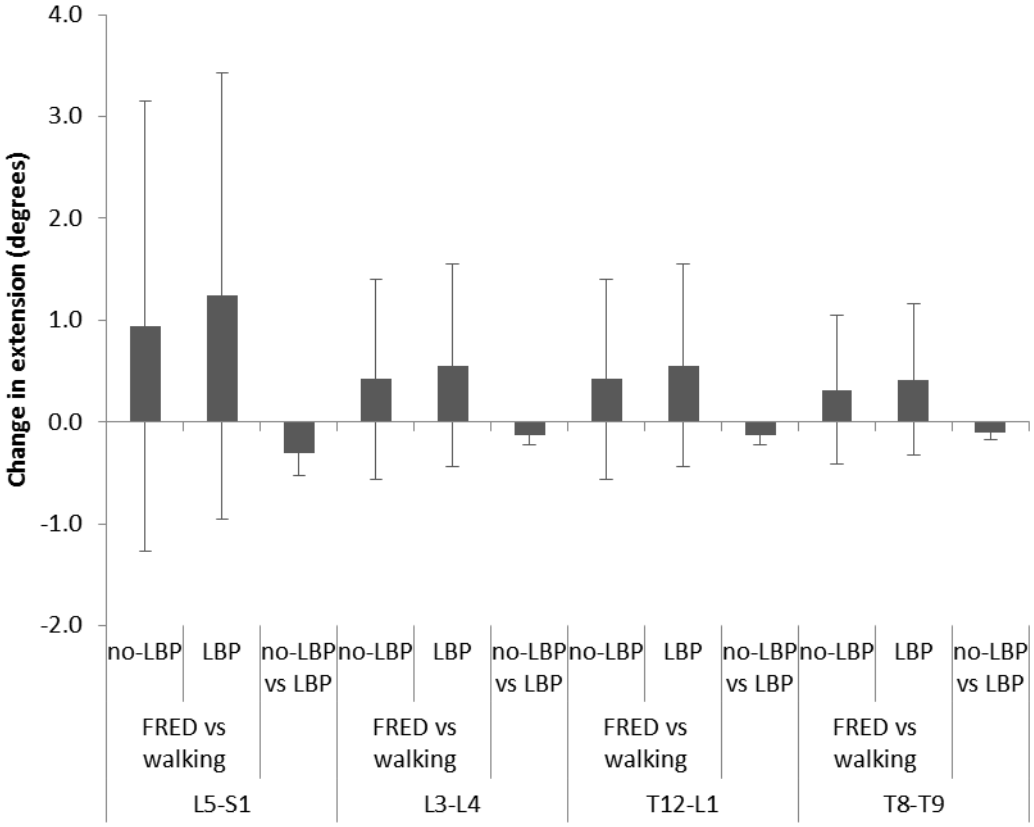


Figure 4-11. Raw change in lower spinal sagittal extension angles comparing walking and FRED exercise in the LBP and no-LBP groups individually and comparing the no-LBP and LBP groups for each joint angle.

Table 4-3. Difference in lower spinal sagittal extension angles for all comparisons, calculated with threshold for inferences of effect size 0.2.

Joint angle	Comparison	Effect size	90% Confidence limits		Mechanistic inference
L5-S1	FRED vs walking, no-LBP	0.4	0.2	0.6	Very likely +ve
	FRED vs walking, LBP	0.6	0.3	0.8	Most likely +ve
	No-LBP vs LBP	-0.1	-0.4	0.2	Possibly -ve
L3-L4	FRED vs walking, no-LBP	0.4	0.2	0.6	Very likely +ve
	FRED vs walking, LBP	0.6	0.3	0.8	Most likely +ve
	No-LBP vs LBP	-0.17	-0.5	0.2	Possibly -ve
T12-L1	FRED vs walking, no-LBP	0.4	0.2	0.6	Very likely +ve
	FRED vs walking, LBP	0.5	0.3	0.7	Very likely +ve
	No-LBP vs LBP	-0.2	-0.5	0.2	Possibly -ve
T8-T9	FRED vs walking, no-LBP	0.4	0.2	0.6	Very likely +ve
	FRED vs walking, LBP	0.6	0.3	0.8	Most likely +ve
	No-LBP vs LBP	-0.2	-0.5	0.2	Possibly -ve

Anterior pelvic tilt

Figure 4-12 shows that FRED exercise resulted in increased anterior pelvic tilt compared to walking, with the increase being 8.7 degrees in both the LBP and no-LBP groups. Table 4-4 shows it was *most likely* that the mean anterior pelvic tilt

angle was positive in both groups compared to the mean in walking and that any difference between the LBP and no-LBP group was *trivial*.

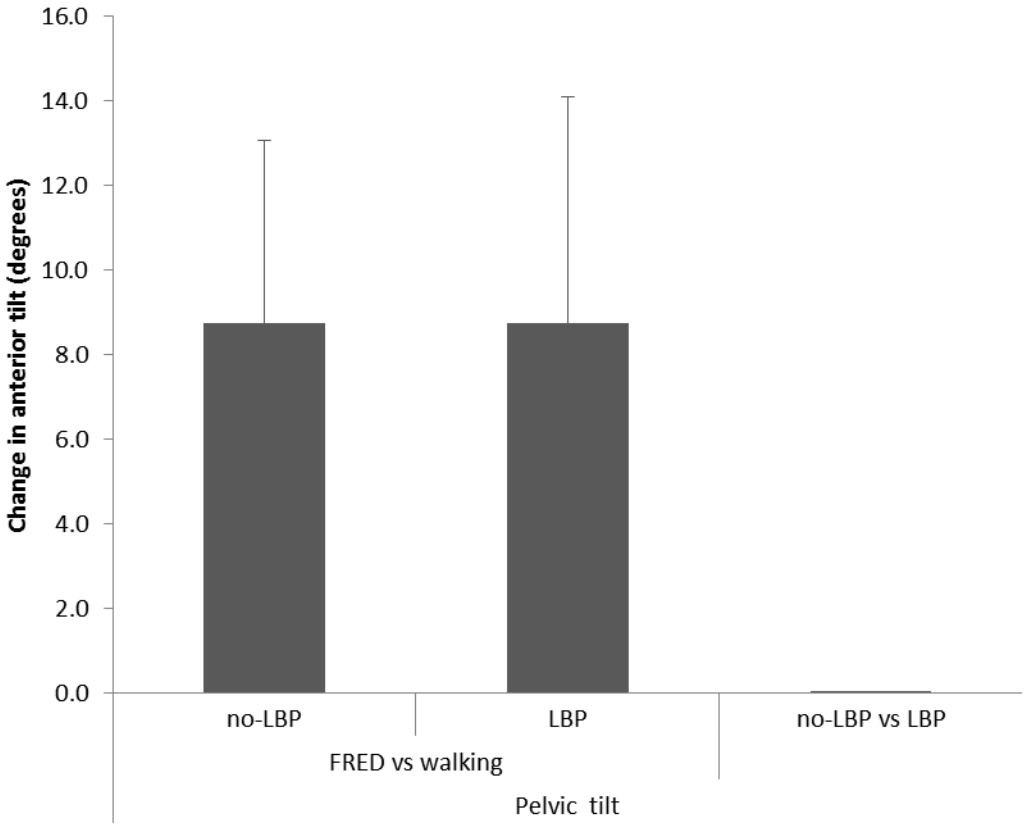


Figure 4-12. Raw change anterior pelvic tilt comparing walking and FRED exercise in the LBP and no-LBP groups individually and comparing the no-LBP and LBP groups for each joint angle.

Table 4-4. Difference in anterior pelvic tilt for all comparisons, calculated with threshold for inferences of effect size 0.2. [1] indicates threshold for inferences was set to effect size 0.6.

Comparison	Effect size	90% Confidence limits		Mechanistic inference
FRED vs walking, no-LBP	2.2	2.0	2.4	Most likely +ve
FRED vs walking, LBP	1.8	1.5	2.0	Most likely +ve
No-LBP vs LBP	0.0	-0.3	0.3	Most likely trivial[1]

Centre of mass variability

Figure 4-13 shows that FRED exercise resulted in greater centre of mass variability in both anteroposterior and lateral directions, with more variation in the lateral direction. The increase was by 0.7cm anteroposteriorly and 1 cm to 1.2 cm laterally. There may be a small trend suggesting that the LBP group had less lateral variability by 0.2 cm compared to the no-LBP group. Table 4-5 shows it was *most likely* that the mean centre of mass variability during FRED exercise

was positive compared to the mean during walking, in both directions. Any difference between the no-LBP and LBP groups was *trivial* in the anteroposterior direction, however, it was *possible* that the lateral variability mean was negative in the no-LBP group compared to the LBP group.

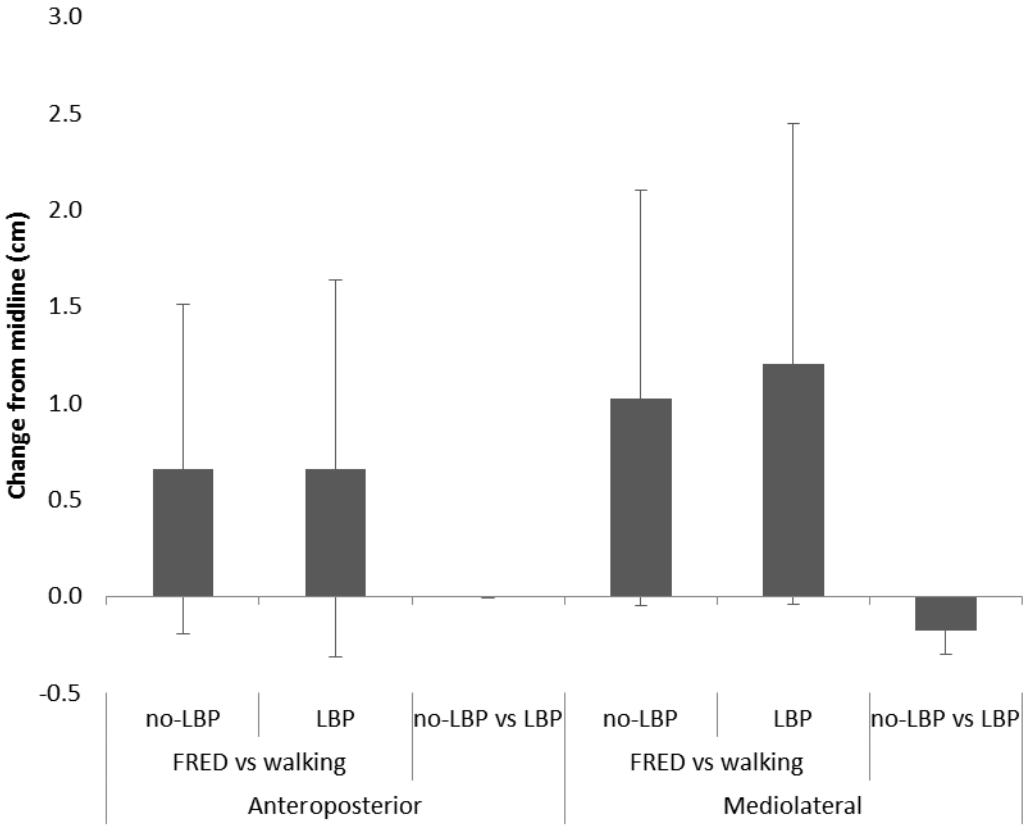


Figure 4-13. Raw change centre of mass variation comparing walking and FRED exercise in the LBP and no-LBP groups individually and comparing the no-LBP and LBP groups.

Table 4-5. Difference in centre of mass variation for all comparisons, calculated with threshold for inferences of effect size 0.2. [1] indicates threshold for inferences was set to effect size 0.6.

Direction	Comparison	Effect size	90% Confidence limits		Mechanistic inference
Antero-posterior	FRED vs walking, no-LBP	0.9	0.7	1.2	Most likely +ve
	FRED vs walking, LBP	0.8	0.5	1.0	Most likely +ve
	No-LBP vs LBP	0.0	-0.3	0.4	Most likely trivial[1]
Lateral	FRED vs walking, no-LBP	1.2	1.0	1.4	Most likely +ve
	FRED vs walking, LBP	1.2	1.0	1.4	Most likely +ve
	No-LBP vs LBP	-0.2	-0.5	0.2	Possibly -ve

Frequency and movement variability

Figure 4-14 shows that the no-LBP group had slightly decreased frequency while movement variability increased. The decrease in frequency was ~-0.5 and ~-0.011 Hz respectively and the increase in movement variability was ~4.9%. Table 4-6 shows that it was at best *possible* that the mean frequency was negative and the mean movement variability was positive in the no-LBP group compared to the means in the LBP group.

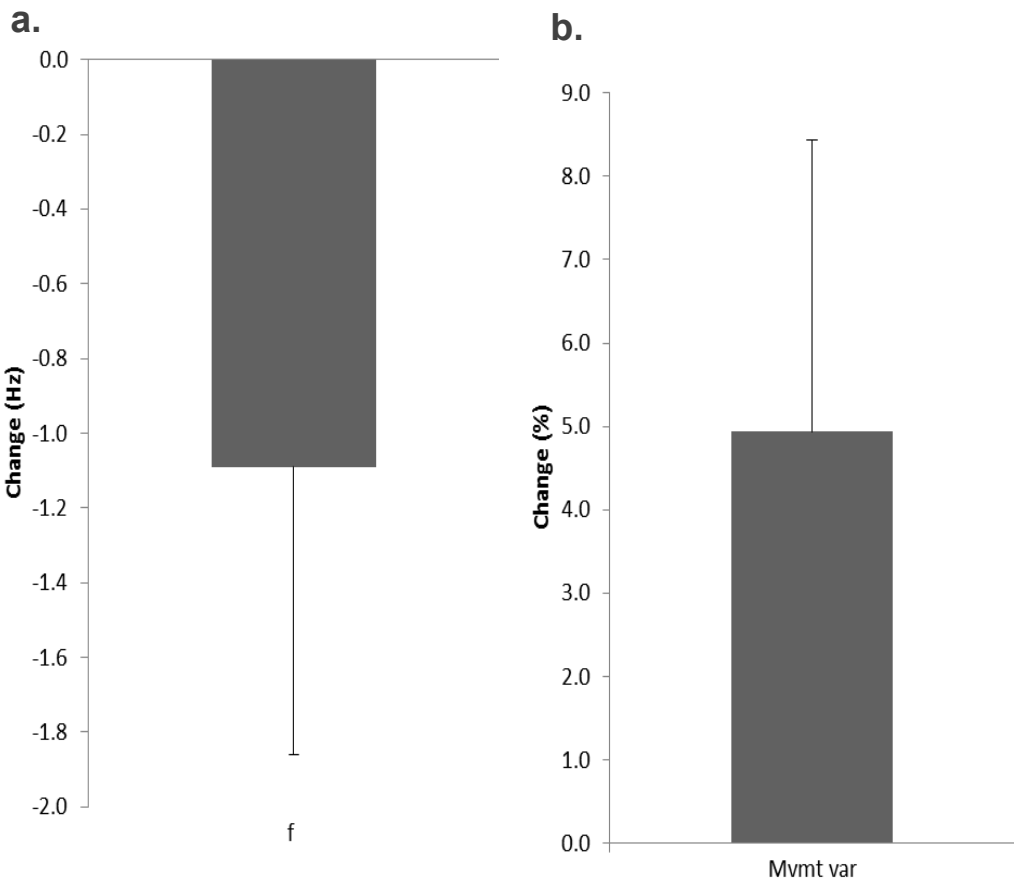


Figure 4-14 Illustrates the mean difference with standard deviation for a. exercise frequency (Hz) and b. movement variability between the no-LBP and LBP groups.

Table 4-6. Difference in anterior pelvic tilt for all comparisons, calculated with threshold for inferences of effect size 0.2. [1] indicates threshold for inferences was set to effect size 0.6.

Variable	Effect size	90% Confidence limits		Mechanistic inference
Frequency (f)	-0.2	-0.6	0.2	Possibly -ve
Movement variability	0.3	0.0	0.6	Possibly +ve

Figure 4-15 illustrates the results of all the MBI statistics for all comparisons and shows how pelvic tilt had the largest change compared to walking and all of the LBP vs no-LBP comparisons are *trivial* or small.

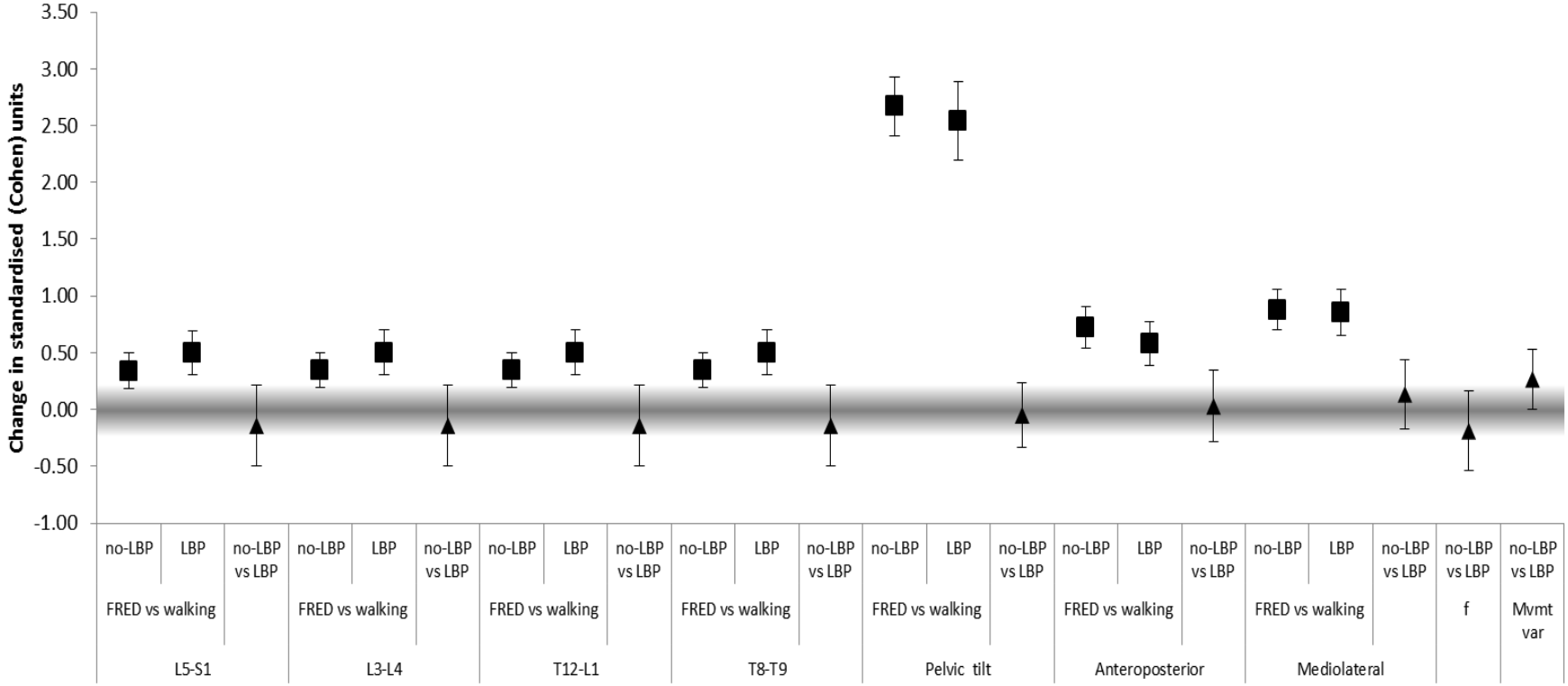


Figure 4-15 MBI results for all comparisons. Squares show effect size for FRED vs walking comparisons, triangles show LBP vs no LBP comparisons, tails show 90% confidence interval, shaded error represents inference threshold of effect size 0.2.

4.4. Discussion

The main finding of this study was that FRED exercise results in increased anterior pelvic tilt and spinal extension compared to over ground walking. Spinal extension is most increased in the lower lumbar spine around L5 and is increased by approximately 0.5 to 1 degree. The increase was slightly more (0.1-0.3 degrees) in the LBP group. FRED exercise also caused increased movement of the centre of mass away from pelvic midline in both the anteroposterior and lateral directions compared to walking with slightly more lateral movement in the LBP group. No instructions or information regarding pelvic tilt or spinal curves during exercise were given. Therefore the kinematic effects measured during FRED exercise occurred automatically, without participants consciously altering their posture.

The results showed that anterior tilt increased, along with spinal segment angles shifting towards increased extension at L5/S1, L3/L4 T12/L1 and T8/T9 joint angles. While the effect sizes were similar at all spinal angles, the raw change was 0.9-1.2 degrees in the lower lumbar spine, 0.4-0.6 in the upper lumbar spine 0.3-0.4 degrees in the lower thoracic spine. A shift of spinal segments towards being held in more extension, seen mostly in the lower lumbar spine, suggests lordosis angle was increasing and may have slightly reduced lower thoracic kyphosis. A shift of sagittal spine joint angles towards extension, seen mostly in the lower lumbar spine, suggests lordosis angle was increasing. O'Sullivan et al. (2006) and Claus et al. (2009), have reported this type of postural change as being associated with increased LM activity, provided the lumbar lordosis does not extend into the thoracic spine.

It is unknown from this study if an ideal posture of lordosis up to thoracolumbar junction occurred as the motion capture system used does not measure absolute position of the joints or relative to a normal or vertical reference. Small extension increases were seen in in the lower thoracic joints which may have resulted in a hyperlordotic posture. However, Debuse et al. (2013) previously demonstrated that FRED exercise recruits LM and TrA. Postures that increase anterior pelvic tilt and have increased lordosis, extending no further than the thoracolumbar junction, have been linked to increased LM and TrA recruitment (O'Sullivan et al. 2006; Roussouly et al. 2005). Additionally, hyperlordotic postures extending lordosis beyond the thoracolumbar junction have been shown to decrease LM and TrA activity (Claus et al. 2009). Therefore, the lordosis increase seen in FRED exercise is likely to be within the range that facilitates LM and TrA activation and is unlikely to have resulted in hyperlordosis. The small amount of increase in lordosis (0.5-1 degree), and it being mostly in the lower lumbar spine, further suggests the postural change was within the range required for LM and TrA to be active. Additionally, a small shift towards increasing lordosis may be a better result than a large shift, as larger shifts may be more likely to result in lordosis going beyond the lumbar into the thoracic spine.

Caplan et al. (2014) reported that LM activity during FRED exercise was tonic throughout the exercise, whereas walking resulted in peaks of activity during a phasic recruitment pattern. A continuous LM contraction in FRED exercise compared to phasic in walking may also partly explain why increased lordosis and anterior pelvic tilt was found throughout FRED exercise.

Training LM and TrA, while maintaining lumbar lordosis and thoracic kyphosis, is an element of traditional specific motor control intervention programmes (Hides et al. 2008; O'Sullivan 2000). FRED exercise has already been shown to automatically recruit LM and TrA, and this study suggests it also automatically

promotes a lumbopelvic posture beneficial to specific motor control training in people both with and without LBP. The ability of FRED exercise to automatically promote increased lordosis, therefore, suggests it may be a useful intervention for both training LM and TrA as part of a specific motor control programme and for improving lumbopelvic posture, including recovery of lumbar lordosis. The increase in lordosis in the LBP group was slightly higher than in the no-LBP group. This may indicate the device was producing a slightly larger effect in the LBP group which could occur if they had more varied spinal mechanics as is often found in populations with back pain (Panjabi 2006). While this may be an indication of device effectiveness as an intervention, the change was very small and this study was unable to assess absolute spinal postures.

Additionally, it is known that spaceflight results in a flexed posture (Buckey 2006; Pavy-Le Traon et al. 2007). Lordosis angle has also been seen to be lost in bed-rest study participants (Belavy et al 2010; Belavy et al 2011; Cao et al. 2005 and Maricias et al 2007, chapter two). Therefore, evidence of a shift towards increased lordosis being an acute effect of FRED exercise is further indication of its potential value in post spaceflight rehabilitation. This is seen alongside loss of cross sectional area and volume of LM (Belavy et al 2010; Belavy et al, 2008; Belavy et al 2011). This shows the potential for FRED exercise to aid with retraining spinal posture following long term deconditioning. These results show that FRED exercise may be a more suitable training modality for promoting deep muscle activity and increased lordosis angle than walking. A clinical trial would be needed to confirm this, and having evidence of acute effects which appear to beneficial will be useful for planning and applying for future research opportunities in spaceflight analogues, for example in bed-rest studies.

The results also show that centre of mass variability was greater in FRED exercise than during walking. While it is not possible to comment on the clinical relevance of this result, it may be part of the acute effects of FRED exercise. An increased variation of the centre of mass may be an element of challenging participants' balance and stability. Traditional motor control exercises often include reducing base of support as a part of training progression (Hides et al. 2008; O'Sullivan 2000).

This study also analysed movement variability of the feet, which showed a trend towards the no-LBP group exercising slightly slower with more uneven movements. However, the probability of the change in the true population was not high and the raw changes very small and therefore unlikely to be clinically relevant. However, these results were analysed in more detail by calculating the frequency variation across participants as within the no-LBP group was 0.47Hz in the no-LBP group and 0.53Hz in the LBP group. This additional analysis showed that while the LBP group was able to exercise with a more even movement, they had more variation away from the target frequency. Therefore, it appears that both no-LBP and LBP populations can exercise with an even movement on FRED during an initial short period of exercise. However, the LBP group was less able to achieve the target frequency. It might be found that as the groups exercise for longer, someone with LBP and segmental instability, who may not be used to activating the deep muscles and may have atrophied deep muscles (Hides et al. 2008), will possibly be unable to maintain these even movements for as long a period as the no-LBP group. This may be worth investigating in a future study as movement variability might then be a useful outcome for goal setting during clinical FRED training.

4.4.1. Limitations

XSens only provides data on the change from calibration pose, not from a reference “normal” posture, so it is also unknown if participants had poor posture and changed toward an improved one or not in this study. It was only possible to draw conclusions on the acute effects of FRED exercise compared to walking. Having a method of quantifying participants’ spinal posture to a normal reference would be useful for future studies as would the development of validated definitions of instability linked to valid and reliable outcomes. Additionally, the XSens model averages the spinal segment kinematics from sensors on the sacrum, both shoulder blades and the head. The movement data from the spinal reference sensors is applied to the kinematic model which then moves the spine appropriately, based on assumed joint angle stiffness (XSens 2015). It may be that this method results in a degree of averaging kinematics taking place across the spine, rather than reporting specifically within each segment.

This may also be a reason why small increases in extension where seen at all spinal segments rather than just in the lower lumbar region which would be the expected pattern based on the expected muscle activity. A study which validates the ability of XSens specificity to spinal levels producing the change may be useful. Also a future study of FRED exercise could assess lordosis with diagnostic imaging such as MRI as done by Belavy et al. (2010).

This study only considered the acute effects of FRED exercise and this may have been why no changes were seen between the LBP and no-LBP groups. It may be that during initial periods of exercise on the device individuals with back pain and potential instability can achieve as good a technique as their no-LBP counterparts. However over time, those with pain may not be able to sustain the

technique for as long a period. This is something that may be worth investigating in future studies.

4.4.2. Conclusion

It is expected that an acute effect of FRED exercise, compared to walking, is increased anterior pelvic tilt and lumbar extension. While no validated clinical worthwhile changes or cut offs for these variables exist to determine if these changes are clinically meaningful, the change does fit with patterns previously reported (Claus et al. 2009) (O'Sullivan et al. 2006) suggesting the posture promoted during exercise on the device correlates to the well balanced lumbopelvic type defined by Roussouly et al. (2005). This posture type is additionally most associated with activation of deep spinal muscles (Claus et al. 2009; O'Sullivan et al. 2006). This observation is strengthened when the overall pattern of posture change and deep muscle activity from previous research is considered together. The small increase in extension may also be part of the mechanism behind the LM and TrA muscle activation seen in previous FRED research (Debuse et al. 2013) into acute effects. The posture assumed on the FRED did not require any conscious trigger. Therefore, as with LM and TrA training, the device shows an ability to automatically promote elements which required conscious triggers in traditional specific stabilising exercises and can be a clinical challenge (Van, Hides and Richardson 2006).

It appears that all the reported acute effects of FRED exercise occur in both LBP and no-LBP populations. It may be worth observing if these acute effects remain the same between the groups over a longer period of FRED training.

5. Chapter Five: Feedback vs No Feedback

5.1. Introduction

The current FRED prototype (version 3) is the first to incorporate a visual feedback (FB) system which encourages users to exercise at an optimum frequency with minimal movement variability at the feet. The visual FB is presented throughout exercise and is comprised of two sections, a dial showing the current and target exercise frequency (Figure 5-1 right side) and a line graph showing changes in frequency in the live speed compared to the mean speed over the previous second, which has been termed “movement variability” in this thesis (Figure 5-1 left side). The angular velocity of the FRED crank wheel is measured using an integral rotary encoder (RP6010, ifm Electronic GmbH, Essen, Germany). The data output is analysed live using a PC connected to the FRED within bespoke software (Mazur Automation, Munich, Germany). Movement variability is calculated as the difference (%) between the live speed and the average speed of the previous second and frequency is the number of crank cycles in Hz. A movement variability result of 0% therefore indicates the device user is producing exercise movements at a constant speed and a frequency of 1Hz shows one crank revolution per second. It was assumed that a high movement variability result was an indicator of poor motor control. This assumption was supported by chapter three which found that more challenging device settings increased movement variability. Therefore, a user with good motor control during exercise is more likely to perform the exercise at a steady frequency and therefore have a low movement variability score. During exercise on the FRED, the movement variability is fed back to users as a line plot, showing the movement variability from -45% to +45% over the last 5 seconds of exercise. Increases and decreases in movement variability are represented by peaks and troughs in the plot. This FB is intended to help users maintain a level plot without any peaks and troughs by maintaining an even movement. A target frequency for

exercise is then set which deliberately creates a slow movement. Slow movements are more likely to be energy efficient (Taylor, Budds and Thomas 2003) and so preferentially recruit LM and TrA (Bergmark 1989). The target frequency was 0.42Hz as it has been shown that FRED exercise activates LM and TrA frequencies at less than 1 Hz (Debuse et al. 2013) and at 0.42 Hz (Weber et al. 2016). Version 3 of the FRED shows the target frequency as a "FRED Training Unit" or "FTU". The target frequency is reached when the FTU result is 50 and the dial visible in Figure 5-1 is at 50%. As the FB has high sensitivity any point between 25 and 75% was considered to be acceptable.

Figure 5-1 FRED control unit display showing FB with movement variability graph on left with live and target frequency dial (50% FTU) on the right, image shows display with FRED stopped, participants try to keep the graph and frequency dial within the green zones.

A review by Balzer et al. (1989) presented theories and initial research showing FB which provides live information on tasks being performed, while simultaneously linking this information with user's current achievement, and an ideal level of achievement, improves psychological elements of judgement and decision making relating to the performance of the task. More recently, computer-based sports training with effective feedback has been determined as a key strategy in motor skill learning (Iskander, Lester and Wills 2009). Feedback contents for motor skill learning should include speed and movement accuracy and reaction time via an appropriate interface (Iskander, Lester and Wills 2009).

Systems for improving rowing technique that included motor skill visual feedback on handle position have been shown to improve exercise technique by reducing speed variations, improving handle trajectory to be more energetically optimal and maintaining consistently good technique (Fothergill 2010; Ruffaldi et al. 2009). It was expected that similar principles applied to FRED feedback. As the FRED visual FB includes live information on both current and ideal task achievement, the evidence would suggest FRED users who have FB will make better judgements and decisions on their speed and movement variability improving their ability to perform the exercise correctly. This is further supported by a recent study into the use of visual FB to improve exercise technique during physiotherapy rehabilitation which found that patients who had FB were able to perform exercises more accurately and with better timing (Doyle et al. 2011). As the aim of FRED exercise is to train deep lumbopelvic muscles, which contract at lower power than superficial muscles and motor control of the lumbopelvic region during upright, weight baring, functional movement. It was therefore, expected that providing visual FB on user's speed and movement variability would improve FRED exercise performance by facilitating even movements, at a correct speed for deep muscle recruitment. This hypothesis was tested by creating two randomly assigned groups of participants exercising on FRED, one group exercising using the visual FB and the other without. The two groups were then compared for any measurable differences in variability and frequency of movement, lumbopelvic kinematics, and centre of mass position between the two groups.

5.1.1. Aim and Objectives

The aim of this study was to investigate the effect of FRED-generated visual FB on control of movement based exercise frequency, movement variability,

centre of mass variability and sagittal plane lumbopelvic position during exercise. The objectives were as follows.

1. To measure lumbopelvic kinematic data and assess if FB promotes postures linked to LM and TrA training as found in chapter four.
2. To measure movement variability and exercise frequency to assess if FB is needed to achieve even movements at the target frequency during exercise.
3. To assess centre of mass variation to determine the effect of FB on upright posture and balance during exercise.

5.2. Methods

This study was done in parallel with that described in chapter four, which documented the kinematics of the lumbopelvic region and variation of movement during FRED exercise compared to walking and compared no-LBP and LBP populations. Both studies used similar methods allowing data from participants without LBP who exercised on FRED, while receiving FB, in chapter four, to be compared with a small group of additional participants who exercised without FB. Therefore, participant recruitment, experimental protocol, outcome measure details for FRED recording measures, kinematics using the XSens MVN system and magnitude based inference statistics details are the same in both studies and can be read in detail in chapter four.

The differences in methods for this study are as follows. Participants entering the study in chapter four who did not have back pain were randomised, using a Microsoft Excel random number generator, into FB or no-FB groups until a no-FB group, totalling 18 participants, was acheived. The measures taken from the no-FB group were then compared with those assessed using the 74 participants from chapter four who had access to full visual FB and also indicated having no LBP. The no-FB group performed the same experimental protocol as that used in

chapter four, except that during FRED exercise, the visual FB was made not visible to the participants. All participants were shown how to perform FRED exercise including a live demonstration, as part of ensuring all individuals exercised in a safe way. The no-FB group was given a standardised set of verbal instructions explaining how to perform the exercise comprised of the following statements: “Exercise in upright posture”, “bend your hips and knees to help keep your trunk stable”, “fix your eyes on a point at eye level in front of you”, “try to keep your trunk stable”, “exercise at a slow and steady pace” and “keep the movement within one revolution as even as possible”. No other instructions or FB on exercise performance was provided.

Magnitude based inferences were used, in the same way as in chapter four comparing pain and no pain groups, to compare any differences between the FB and no-FB groups. For differences between tested outcome measures, a small effect size (at least 0.2) was set as the minimal worthwhile change, but increased to 0.6 or 1.2 if smaller effect size results were unclear, as per chapter four. The magnitude based inferences calculate the probability (%) of the true effect being at least the set effect size using 90% confidence intervals. This analysis method detects minimal worthwhile mechanistic differences. Participant demographics were tested for moderate effect sizes (at least effect size 0.6) existing between groups to check for any differences potentially confounding results. The study received ethics approval from the Faculty of Health and Life Sciences ethics committee at Northumbria University (see appendix J).

5.3. Results

Eighteen participants were successfully recruited to the no-FB group and compared to the 74 participants who had no back pain and exercised while receiving FB from chapter four. Group demographics are shown in Table 5-2.

Any differences between the groups were *trivial* for mass, height and activity score. The no-FB group appeared consistently two years older, however, a two-year age difference is not likely to have any clinical significance.

Table 5-1 Participant demographics with change that difference between groups is trivial using threshold for inferences of effect size 0.6.

Group	n	Gender	Mean: Age	Mass (kg)	Height (m)	BMI	Activity Score
FB	74	33 male / 41 female	35.2	74.7	1.72	25.3	3.7
No-FB	18	10male / 8 female	37.1	84.7	174.1	27.9	3.7
Chance (%) that difference between groups is trivial			48	90	98	85	83

No dropouts occurred and all planned measurements were taken. Data from one of the FB participants could not be calculated for pelvic tilt due to unresolvable singularities occurring in the data when converted to Euler vectors. All tested differences in means were determined using the smallest effect size (0.2, 0.6 or 1.2) which resulted in a clear inference, which are reported in all MBI table captions, as the threshold for a worthwhile change.

Lower spinal joint angles

Figure 5-2 shows that FRED exercise increased extension at all spinal joint angles compared to walking in both the FB and no-FB groups. There was also a weak trend of extension being greater in the no-FB group, by 0.5±0.6 degrees at L5/S1 and 0.2±0.1 degrees at T8/T9. Table 5-3 shows it was at least *likely* that the mean extension angle was positive during FRED exercise compared to the mean during walking, in both the FB and no-FB groups. However, the weak trend of increased extension when no-FB was provided was, at best, *unlikely*, and the highest probability was for any change between the groups to be *trivial*.

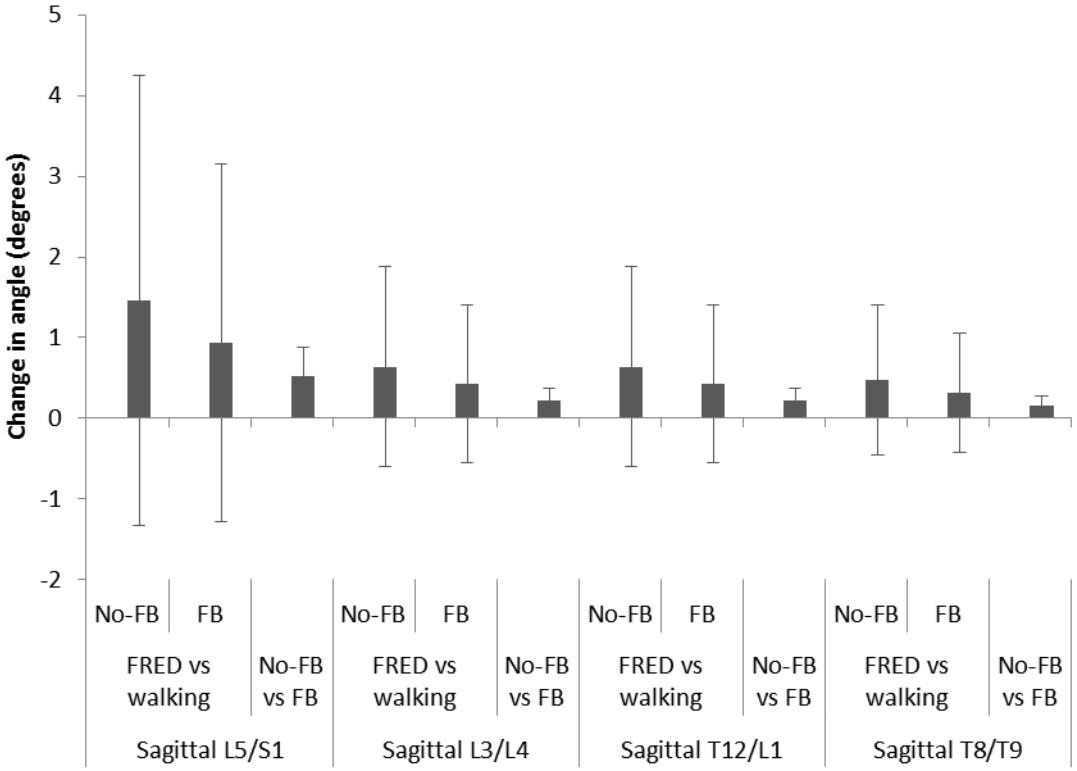


Figure 5-2. Raw change in lower spinal sagittal extension angles comparing walking and FRED exercise in the FB and no-FB groups individually and to each other.

Table 5-2. Difference in lower spinal sagittal extension angles for all comparisons, calculated with threshold for inferences of effect size 0.2. [1] indicates threshold for inferences was set to effect size 0.6.

Joint angle	Comparison	Effect size	90% Confidence limits		Mechanistic inference
L5/S1	No-FB	0.5	0.1	0.9	Likely +ve
	FB	0.4	0.2	0.6	Very likely +ve
	No-FB vs FB	0.1	-0.6	0.8	Unlikely +ve[1]
L3/L4	No-FB	0.5	0.1	0.9	Likely +ve
	FB	0.4	0.2	0.6	Very likely +ve
	No-FB vs FB	0.1	-0.6	0.8	Unlikely +ve[1]
T12/L1	No-FB	0.5	0.1	0.9	Likely +ve
	FB	0.4	0.2	0.6	Very likely +ve
	No-FB vs FB	0.1	-0.6	0.8	Unlikely +ve[1]
T8/T9	No-FB	0.5	0.1	0.9	Likely +ve
	FB	0.4	0.2	0.6	Very likely +ve
	No-FB vs FB	0.1	-0.6	0.8	Unlikely +ve[1]

Anterior pelvic tilt

Figure 5-3 shows that FRED exercise resulted in increased anterior pelvic tilt compared to walking, in both the FB and no-FB groups. There did not appear to be any change in pelvic tilt between the two groups. Table 5-4 shows it was *most likely* that the mean anterior tilt was positive both groups compared to the mean

during walking and showed any change between the groups to be *very likely trivial*.

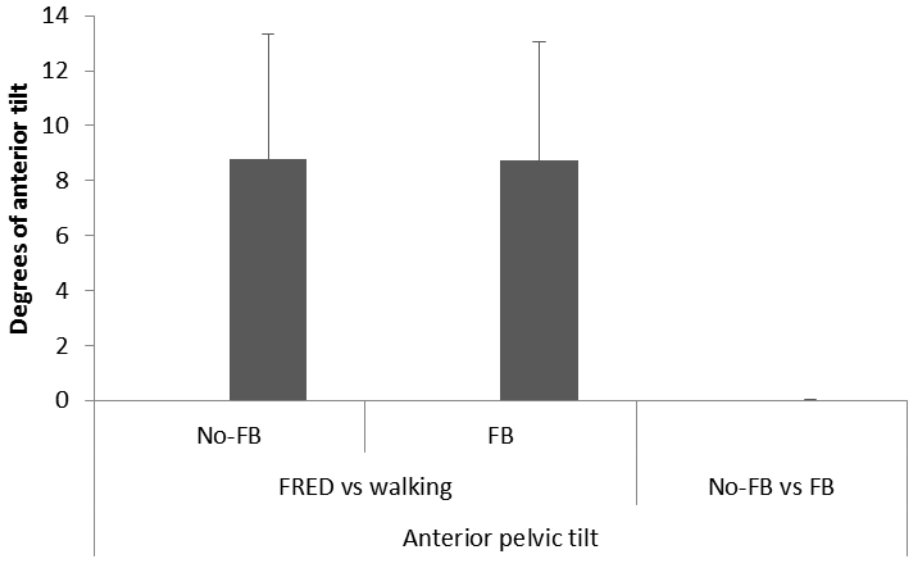


Figure 5-3. Raw change anterior pelvic tilt comparing walking and FRED exercise in the FB and no-FB groups individually and to each other.

Table 5-3. Difference in anterior pelvic tilt for all comparisons, calculated with threshold for inferences of effect size 0.2. [2] indicates threshold for inferences was set to effect size 1.2.

Comparison	Effect size	90% Confidence limits		Mechanistic inference
No-FB	1.5	1.2	1.8	Most likely +ve
FB	2.2	2.0	2.4	Most likely +ve
No-FB vs FB	0.0	-0.6	0.7	Very likely trivial[2]

Centre of mass variability

Figure 5-4 shows that FRED exercise resulted in increased centre of mass variation compared to walking in anteroposterior and lateral directions in both the FB and no-FB groups. There was a trend towards slightly less anteroposterior variability by 0.1±0.1 cm, and slightly more lateral variability by 0.3±0.2 cm, in the no-FB group. Table 5-5 shows the mean centre of mass variability during FRED exercise was at least *very likely* positive compared to the mean during walking in both groups. However, the trends between groups showed the mean variability in the no-FB group was *unlikely* negative anteroposteriorly, and *likely* positive mediolaterally, compared to the mean in the no-FB group.

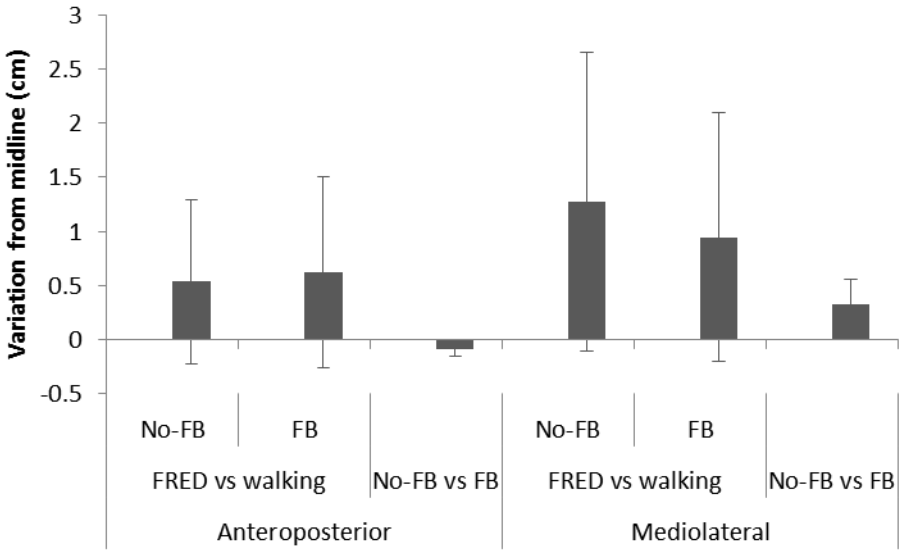


Figure 5-4. Raw change centre of mass variation comparing walking and FRED exercise in the FB and no-FB groups individually and to each other.

Table 5-4. Difference in centre of mass variation for all comparisons, calculated with threshold for inferences of effect size 0.2. [1] indicates threshold for inferences was set to effect size 0.6.

Direction	Comparison	Effect size	90% Confidence limits		Mechanistic inference
Anteroposterior	No-FB	0.5	0.2	0.9	Very likely +ve
	FB	0.9	0.7	1.2	Most likely +ve
	No-FB vs FB	0.2	-0.5	0.9	Unlikely +ve[1]
Mediolateral	No-FB	1.0	0.6	1.5	Most likely +ve
	FB	1.2	1.0	1.4	Most likely +ve
	No-FB vs FB	0.6	0.0	1.2	Likely +ve

Frequency and movement variability

Figure 5-5 shows that the no-FB group had an increase in frequency by 0.021±0.015 Hz and decrease in movement variability by -0.6±0.4%, compared to the FB group. Table 5-6 shows these between group changes to be *trivial* for frequency and at best *unlikely* for movement variability.

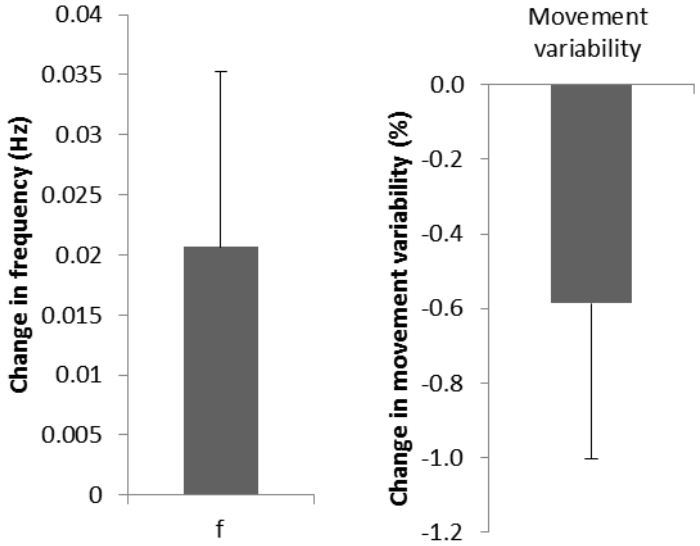


Figure 5-5 Illustrates the mean difference with standard deviation in raw units for frequency and movement variability between the FB and no-FB groups.

Table 5-5. Difference in frequency and movement variability, calculated with threshold for inferences of effect size 0.2. [1] indicates threshold for inferences was set to effect size 0.6 and [2] indicates effect size 1.2.

Variable	Effect size	90% Confidence limits		Mechanistic inference
Frequency (f)	0.0	-0.7	0.7	Very likely trivial[2]
Movement variability	-0.3	-0.9	0.3	Unlikely –ve[1]

The effect size and 90% confidence interval for each of the FB vs no-FB group comparisons was plotted in Figure 5- 6, with reference ranges indicating the 0.2 and 0.6 effect size minimal worthwhile change levels. The figure illustrates the large confidence intervals found in many of the between group comparisons which made inferences unclear using the 0.2 effect size threshold.

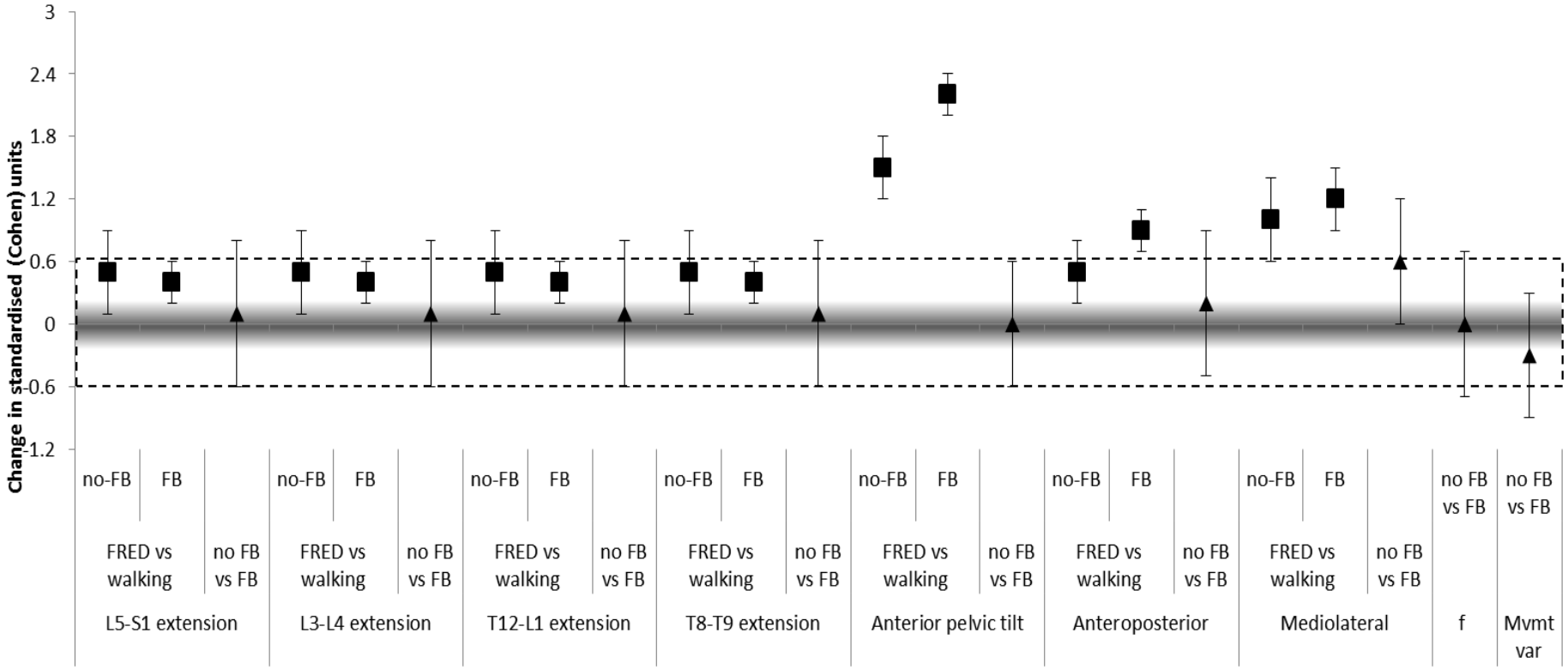


Figure 5-6 MBI results for all comparisons. Squares show effect size for walking vs FRED comparisons triangles show FB vs no-FB comparisons, tails show 90% confidence interval, shaded error represents inference threshold effect size of 0.2 and dashed line 0.6.

During analysis the frequency and movement variability standard deviations appeared to be consistently larger in the no-FB group. These values are not reported individually in the MBI results, therefore, individual group means and variation statistics for these measures are reported below. Table 5-6 illustrates that the variation, indicated by the standard deviation, was higher in the no-FB group for frequency and consistent between the groups for movement variability. In addition the FB group was able to exercise closer to the target frequency of 0.42 Hz

Table 5-6 mean and standard deviation (SD) for frequency and movement variability outcome measures

	Frequency (Hz)		Movement variability (%)	
Group	Mean	SD	Mean	SD
FB	0.47	0.07	9.79	3.76
No-FB	0.50	0.12	9.16	3.75

5.4. Discussion

The main findings of this study were that lower spinal joint angles, anterior pelvic tilt and centre of mass variation remained increased regardless of whether FB was provided. It was *unlikely* to see any differences in sagittal lumbopelvic position, centre of mass variation, frequency and movement variability whether FB is provided or not, except for mediolateral centre of mass variation which was increased in the no-FB group. However, frequency variation was higher in the no-FB group who also exercised at a mean frequency that 0.13Hz quicker than the FB group.

These results suggest that the posture adopted by FRED users during exercise and the frequency and movement variability is not affected by the visual FB. It appears that a demonstration and the standardised set of instructions resulted in similar sagittal plan lumbopelvic position, centre of mass variation, exercise frequency and movement variability. It may be that having had a demonstration of FRED exercise by a member of the research team who was already very familiar with how to exercise at the target frequency caused the no-FB group to adopt a similar exercise posture and frequency to the FB group. However, higher variation in mediolateral centre of mass was found in the no-FB group, which may indicate that device users were not maintaining a stable body position and demonstrated increased lateral position displacement, when FB was not provided.

The standard deviation of the frequency and movement variability data was consistently higher in the no-FB group. This suggests that while all participants exercised with even movements, the no-FB group were exercising at a much greater range of frequencies away from the target promoted by the FB. The range was 0.38-0.62 Hz in the no-FB group and 0.4-0.54 Hz in the FB group. In

addition the no-FB group also adopted a mean frequency that was 0.13 Hz faster. It appears, therefore, that the visual FB is useful for ensuring all participants exercise at the target frequency with minimal variation. It might be that the no-FB participants were focused on exercising in an even movement from the verbal instructions and maintained this. However, without a reference frequency provided by the FRED, the no-FB group had much greater frequency variation. This finding agrees with previous research (Fothergill 2010; Ruffaldi et al. 2009) that indicated motor skill visual feedback improves by reducing exercise speed variation as part of learning movement error correction. This explains why the frequency variation was a larger effect of having no-FB than the overall change in mean. This also links into the concept that having live FB during activities improves judgement within decisions of how to perform the task well (Balzer, Doherty and Raymond 1989). These findings also add evidence to support the framework for pedagogical feedback in the motor skill domain that states feedback elements should include speed and movement accuracy (Iskander, Lester and Wills 2009). As the results of this study show, these elements appeared to be more affected by the visual FB provided by the FRED than the kinematic measures, except for lateral centre of mass variation. However, the centre of mass result might be more specific to FRED and LM and TrA training principles than wider motor control learning theory which is not specific to deep spinal muscles.

Traditional training protocols for LM and TrA aim to promote low level, tonic contraction (O'Sullivan 2000; Richardson and Jull 1995). Exercising too fast may result in recruitment of superficial muscles, that have been shown to cause trunk movements, rather than recruiting deep muscles needed for segmental stability (Richardson and Jull 1995). Exercising too slowly on the FRED increases the time over which the front foot must be controlled vertically, as it drops throughout

the forward portion of the FRED cycle. Chapter three found that increasing the front foot drop time by increasing the amplitude resulted in a greater challenge to motor control. Going too slowly may have the same effect and could also result in too great a challenge and cause unstable trunk motion. The increase in lateral centre of mass variation found in the no-FB group may be a result of an increased motor control challenge from exercising at too low a frequency or from superficial muscle recruitment causing trunk movements when exercising too fast. However, both of these possibilities would need further investigation to be confirmed.

5.4.1. Limitations

This chapter shares some limitations discussed in chapter four section 4.4.1, including XSens not providing an absolute spinal position or one relative to a normal or vertical reference. Therefore, conclusions on the effect of the exercise, with and without FB, on exact spinal positioning and postural element such as lordosis angle are difficult to make.

The participants were given a demonstration of the FRED for safety purposes, which might have provided them with knowledge of the posture and frequency to assume while also showing that the movement should be consistent. This may explain why the technique was so comparable between the groups for many of the measures. However, speed did vary more within the no-FB group which might have affected trunk muscle recruitment patterns. It would be useful to assess this with ultrasound imaging or electromyography to test these theories.

5.5. Conclusion

Participants using FRED are able to perform even movements in the same posture whether they have FB or not, however, they exercise with less variation away from the target frequency and with a smaller amount of lateral body

displacement, when FB is provided. The lumbopelvic positioning of increased anterior pelvic tilt and lower spinal extension are similar to that in chapter four, which linked to LM and TrA activity. Therefore the deep muscles may still be active at the slow and fast frequencies, however, the exercise might lose its specificity to the deep muscles.

The visual FB provided during FRED exercise is required for users to achieve the correct frequency during exercise with less variation away from the target provided by the FRED visually. While those not provided with FB can exercise safely and adopt the same lumbopelvic posture, increased lateral centre of mass variation occurred, which might have been caused by superficial muscle recruitment. Should superficial muscles be recruited, the exercise would no longer be specific to the deep muscles. It is, therefore, recommended that visual FB be provided during exercise to aid participants in exercising at the correct frequency and refine their technique. These findings are in agreement with previous evidence determining the importance of, and recommended design of, visual feedback for motor skill learning.

6. Chapter Six: Investigation of Effect of Time on FRED Exercise, in a Large Population, Including Participants with Back Pain.

6.1. Introduction

To date, FRED studies have included exercise familiarisation periods of two to three minutes (Debuse et al. 2013), or five minutes (Caplan et al. 2014; Gibbon, Debuse and Caplan 2013). In chapters four and five, a five-minute familiarisation period was used. Familiarisation periods have been intended to give users time to understand the exercise and develop a good technique. All previous familiarisation periods have been arbitrary and it remains unknown if a quantifiable familiarisation period exists. As part of the series of studies to establish and document the underlying mechanisms of the FRED as an intervention, it was felt useful to attempt to quantify a standard familiarisation period. There has also been no investigation of how long first-time device users can maintain good technique during exercise. While fatigue is unlikely to occur due to physical effort, as FRED exercise is very low resistance, the high demand for coordination and balance to generate quality movements, linked to training motor control, might cause users to tire and loose technique. Generating evidence of familiarisation and also potential loss of technique points allows evidence-based training schedules to be developed for intervention trials based on empirical data. It was, therefore, considered useful to assess familiarisation and loss of technique periods and, if possible, recommend a standard time required to familiarise to FRED exercise.

Correct FRED exercise technique requires upright posture and a relatively stable lumbopelvic region, during slow and smoothly controlled lower limb functional movements (Debuse et al. 2013). Poor exercise technique may, therefore, be defined as movement, lumbopelvic kinematic and centre of mass variation, beyond the standard variation recorded once good technique has been attained. The standard variation for technique relevant measures can be determined from periods of familiarised exercise from previous studies. Any

mechanistic differences, greater than the familiarised variation, during exercise, indicate periods within which device users are either not familiarised or have lost technique. Periods of changing technique can then be used to infer familiarisation and loss of technique points.

As the device is expected to be used clinically in the rehabilitation of those with LBP and poor intersegmental control, which has been linked to increased incidence of LBP in space (Sayson and Hargens 2008; Pavy-Le Traon et al. 2007; Hides et al. 2007; Gernand 2004) and terrestrial populations (Panjabi 2006; Danneels et al. 2000; Hodges and Moseley 2003), it was also felt useful to test for any differences in potential familiarisation and loss of technique points between individuals with and without LBP.

6.1.1. Aim and Objectives

The aim was to observe the effect of time, during FRED exercise, on kinematic and device reported measures of exercise technique, to establish the time required for familiarisation to the exercise and observe for potential loss of technique, within a 600 second exercise period.

The objectives were as follows for first-time device users:

1. Determine if there is a familiarisation period during which poor exercise technique occurs while using the device.

2. Determine if there is loss of technique time when exercise technique on the device becomes poor. This will be observed for up to 600 seconds of exercise time.

3. Filter results by participants who indicated having LBP or not, to establish if any difference in times are found in objectives 1 and 2, between an asymptomatic and those with LBP.

4. Recommend a standard familiarisation time period for future FRED studies.

6.2. Methods

A within-participant, two group comparison design was used to investigate how postural kinematics and exercise control vary over a 600 second period of FRED exercise and determine the time required to familiarise with device use. The study received ethics approval from the Faculty of Health and Life Sciences ethics committee at Northumbria University (see appendix J).

6.2.1. Recruitment

The study was part of a "Meet the Scientist" outreach event at the Newcastle Life Science Centre, located in the Centre for Life Village in central Newcastle upon Tyne. Participants were recruited from the general public entering the Life Science Centre section of the village during a four-week period in summer 2015.

The recruitment strategy was designed to find participants aged between 18 and 55 years which are representative of the wider population and include individuals that are both asymptomatic and experience LBP (as a clinically relevant population). A dedicated study area was set up that included large screens to allow the public to observe live data collection. The live data collection screen showed the full body 3D avatar representation of the current participant or pre-recorded avatar movements between data collection periods. A large touch screen displayed an interactive PowerPoint that participants could use to independently learn about the study or watch informative videos about space medicine, astronaut training and life aboard the International Space Station. A separate section within the study area was setup to conduct an astronaut training themed exercise session for children, which provided a supervised and relevant activity, allowing accompanying adults to more easily participate in the study. Figures 6-1 shows the entire "Meet the Scientist" area and the FRED study

section, including the two large screens which can been seen in the background of Figure 6-2.

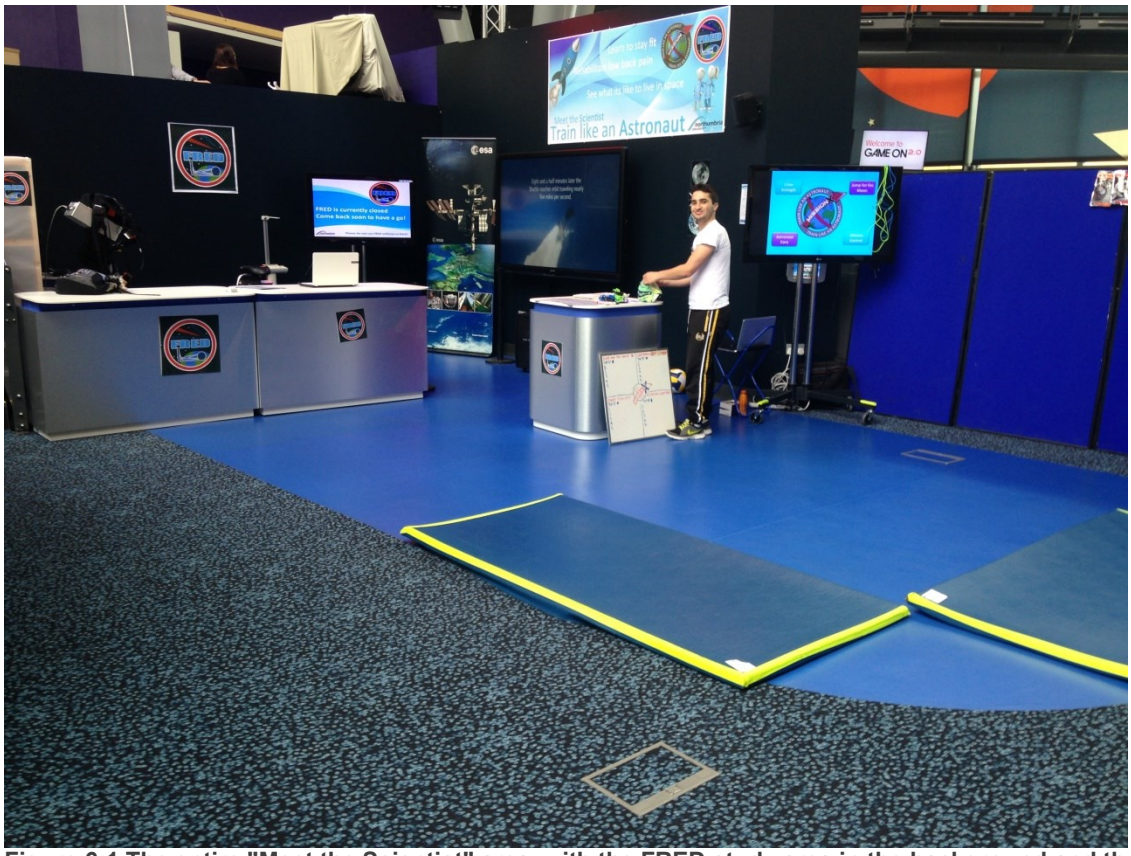


Figure 6-1 The entire "Meet the Scientist" area, with the FRED study area in the background and the children's astronaut training activity section in the foreground.

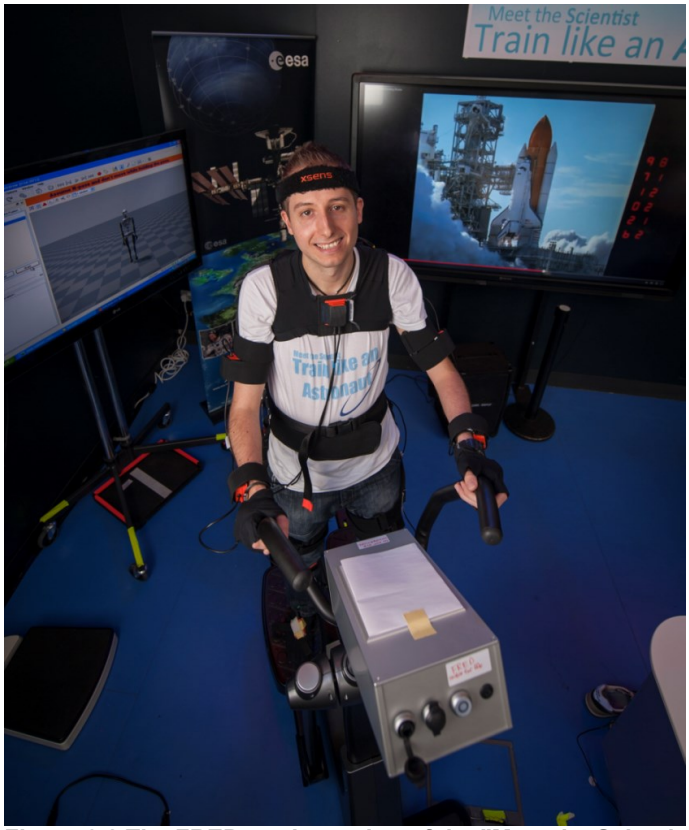


Figure 6-2 The FRED study section of the "Meet the Scientist" area showing the author wearing the XSens motion capture suit and exercising on the FRED. The live avatar can be seen on the screen to the left, while the screen to the right shows a space video

Individuals indicating an interest in participating in the study were given a participant information sheet (appendix E) to enable them to make an informed decision regarding participation. Those choosing to join the study were screened for exclusion criteria and LBP. Participants' demographics and normal activity levels were also noted. To ensure all participants were fit to engage in exercise, the Physical Activity Readiness Questionnaire (PARQ) (section 10) was completed by all individuals. Participants who answered no to all PARQ section 10 questions were considered fit and safe to participate. Any individual who answered yes to any question in the PARQ were excluded from the study, unless they had written evidence that a medical doctor had declared them safe to participate in gentle, upright exercise similar to walking for a period of up to 600 seconds. Other exclusion criteria were based on previous FRED studies (Debuse et al. 2013) and earlier chapters, including:

- Being below 18 or above 55 years of age.
- History of musculoskeletal or neurological problems/injuries affecting participants' ability to move.
- Heart disease.
- History of abdominal or spinal surgery within the previous three years.
- Epilepsy.
- Pregnancy.
- Diagnosed spinal scoliosis or other structural postural changes which may affect correct calibration of Xsens motion tracking software.

6.2.2. Screening and Demographics

Participants were screened on entry to the study for LBP using the same system as in chapter four (section 2.2 for details). Screening resulted in the creation of two groups, a LBP and no-LBP group. Data were analysed based on

this screening to establish the familiarisation time for both groups and identify any differences. Following screening a rating scale was used to record participants' physical activity over the previous four weeks. Physical activity data were required to monitor and correct for any potential confounding effects caused by variation in participants' normal activity. Physical activity ratings were collected using the same methods detailed in chapter four section 2.2. All participants were required to sign a consent form if they chose to participate (appendix F). Additional demographic data were also collected including gender, age and mass (to calculate BMI), as well as height and foot length required for equipment calibration. The number of participants screened into each category on the LBP scale is also indicated in Table 6-1, which shows there were 70 with LBP and 78 without.

Table 6-1 Participant demographics with Xsens exclusions accounted for

LBP screening question: "How much back pain have you had during the past 4 weeks?		n
1	None	78
2	Very mild	29
3	Mild	21
4	Moderate	14
5	Severe	4
6	Very severe	2

6.2.3. Experimental Protocol and Data Collection

The XSens MVN portable motion tracking system was used to collect kinematic data and the FRED prototype version three was used to collect exercise frequency and movement variability data. Six hundred seconds of kinematic and FRED data were simultaneously collected from the moment participants began exercising on the device until the end of the trial period. The FRED was set in crank amplitude position 5 (smallest) and footplate position 1 (furthest forward) to maintain similarity with, and comparability to, previous chapters. Chapter three also reported this device setting to be the least challenging to first-time users and recommended it as the initial setting in a progressive training protocol. This setting is therefore, likely to be the setting used by first-time device users and in the initial period of an intervention study. Participants were instructed on the correct use of the FRED device including the visual feedback it provides on exercise performance. During exercise, the following standardised verbal instructions were given which are required for safe use of the device:

- Exercise in an upright posture.
- Bend your hips and knees to help keep your trunk stable.
- Fix your eyes on a point at eye level, directly in front of you where you can see feedback on your performance.
- Try to keep the trunk stable.
- Exercise at a very slow and steady pace

- Try to keep the movement within one revolution as even as possible.

6.2.4. Kinematic and FRED Measures

Kinematic data were exported from the XSens full body kinematic avatar for anterior pelvic tilt, sagittal plane angles between spinal segments measured as the angle between each segment at L5-S1, L3-L4, T12-L1 and T8-T9 and centre of mass during exercise on the device. The XSens system information and calibration process was the same as that described in chapter four section 2.5. The only difference in this study was that full body kinematic data were collected at 80Hz for 600 seconds. The reduced frame rate used in this study enabled the large data files created during 600 seconds trials to be manipulated with the analysis software, as pilot studies demonstrated higher frame rates resulted in data files that were too large for the analysis software to process. Methodological issues of using XSens during FRED exercise were dealt with as per descriptions in chapter four section 2.8 and the reliability and validity of XSens is detailed in chapter four section 2.9. Movement variability and frequency of the FRED exercise were exported from the device control unit. Movement variability and frequency of movement were recorded using the same methods as detailed in chapter four section 2.7. Participants were allowed to hold on to the FRED handles during exercise while they felt they needed to, but were encouraged to let go as soon as possible and safe to do so. At the moment they stopped using the handles, they were instructed not use them again unless they felt unsafe or were about to fall. At least one FRED operator supervised participants closely throughout the exercise trial to ensure safety. The time at which participants stopped using the handles was determined visually from the kinematic avatar during data analysis to establish the average time at which participants felt able to let go. To facilitate observing the time point when the handles were no longer used during exercise from the avatar, participants were instructed to place their

hands by their sides once they felt safe to do so. The time at which this arm movement was completed by the avatar, using end of elbow extension as a reference, was determined to be point at which participants no longer needed to use the handles.

6.2.5. Data Analysis

All analysis was performed using Microsoft Excel 2010. Kinematic data were captured and exported using MVN studio 3.4.1 (MVN, XSens, Enschede). FRED data were captured and exported using the standard FRED software for device prototype three (Mazur Automation, Munich, Germany).

6.2.5.1. Demographics

Statistical differences between the LBP and no-LBP group demographics were assessed using magnitude based inferences. The mean difference with 90% confidence interval between the groups for each demographic was calculated. Magnitude based inferences were then used to investigate any differences between the groups in relation to a standardised minimal worthwhile change of effect size 0.6 (Cohen units), which shows if a moderate difference exists (Hopkins et al. 2008). Magnitude based inferences provide the probability (%) of the true population difference being more than the minimal worthwhile change. For identifying differences in demographics it was felt acceptable to set the minimal worthwhile change to the moderate, 0.6 level as smaller changes are not likely to confound the results.

6.2.5.2. Kinematic and FRED measures

For all measures, the mean and standard error of the mean (SEM), across each group's participants, were calculated for every data point. The mean ± SEM range was plotted as a function of time for angle of flexion at L5/S1, L4/L3, L1/T12

and T8/T9, anterior pelvic tilt, anteroposterior and mediolateral centre of mass, exercise frequency and movement variability.

$$Standard\ error\ of\ the\ mean = \frac{SD\ (sample)}{\sqrt{n}}$$

All data were filtered to reduce noise before analysis. A moving average filter was used so that each data point was recalculated as the mean of 26 data points either side of it. To ensure the level of filtering enabled 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.

All data appeared to have plateaued, indicating familiarisation by 150 seconds, and remained stable until at least 270 seconds, showing no loss of technique within this period. Therefore, the mean of each measure between 150 and 270 seconds was used as a familiarised reference. As the SEM is the smallest measurable change, any difference from the familiarised reference greater the mean SEM of the familiarised reference was considered to be familiarisation or loss of technique periods. These periods were determined to be familiarisation if they occurred before, or loss of technique if occurring after, reaching the familiarised reference. Therefore, the familiarised reference mean ± the mean SEM of each measure between 150 and 270 seconds was plotted on the graph as the measureable range beyond which data were considered familiarised or having lost technique.

Familiarisation and any loss points were determined in the data to the nearest 5 second interval and visually confirmed using the plots of the mean and SEM of each measure against time. Familiarisation was determined as the point at which mean ± SEM across all participants fully entered within the familiarisation

reference range. Loss points occurred if the mean ± SEM went fully outside of the familiarised reference, after the initial familiarisation point. Magnitude based inference was used to determine if a true worthwhile difference of at least the familiarised reference SEM existed before and after the estimated familiarisation and loss points. For all estimated familiarisation and loss points, the effect size, 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 in results. All mechanistic inferences were based on threshold changes of 5% for substantial magnitudes.

6.2.6. Ethics

The study recruited human participants, and their dignity, wellbeing and rights were protected at all times. A risk assessment was performed prior to any testing to ensure health and safety of all individuals involved in the study. No lasting effects of the exercise were expected for any participants. Informed consent was provided in writing by all participants and they were informed they could withdraw from the study and remove their data at any time. No incentives or money for travel costs were provided to participants. Participant data were stored in a secure location in a site folder at all times and used solely for the purpose of this study. During data collection the site folder was kept in a padlocked box, in a locked cupboard, with other sensitive equipment at the Life Science Centre. Following data collection the site folder was moved to a locking filing cabinet in a swipe card access laboratory at Northumbria University.

6.3. Results

6.3.1. Demographics

Table 6-2 presents the LBP and no-LBP group demographics. Four participants' kinematic data and seven sets of FRED data were excluded due to errors during testing. The group demographics and any differences found with MBI are therefore presented taking these exclusions into account. Table 6-2 shows that any differences between the groups were *trivial*.

Table 6-2 Participant demographics with Xsens exclusions accounted for

	n	Gender (M/F)	Age (years)	Mass (kg)	Height (m)	BMI	Activity Score
Kinematic data							
All participants	144	73/71	36.5	77.8	1.72	26.3	3.7
LBP	67	33/34	37.6	80.3	1.72	27.1	3.3
No-LBP	77	40/37	35.7	75.6	1.72	25.6	3.8
Chance (%) that difference between LBP and no-LBP groups is trivial			100	97	100	100	97
FRED data							
All participants	141	71/70	36.8	78.4	1.72	26.3	3.7
LBP	67	33/34	37.6	81.1	1.72	27.2	3.6
No-LBP	74	38/36	36.1	75.9	1.72	25.6	3.7
Chance (%) that difference between LBP and no-LBP groups is trivial			100	94	100	98	98

6.3.2. Measures

Filtering was performed on one kinematic set of data using a moving average period of 161, 241, 401 and 805 data points. As kinematic data were recorded at 80Hz this represents averaging data across 2, 3, 5 and 10 seconds respectively. Appendix E shows the resultant plots of each filtering option compared to the original data. A moving average of 401 data points or 5 seconds (2.5 seconds either side of the data point) for kinematic data, was considered to reduce noise sufficiently for analysis, without losing the overall pattern of the original data and was, therefore, used throughout the analysis (Figure 6-3). The FRED data were also filtered to reduce noise using the same time interval of 5 seconds. As the

FRED records at 5Hz, the moving average data point period was set to 26 data points.

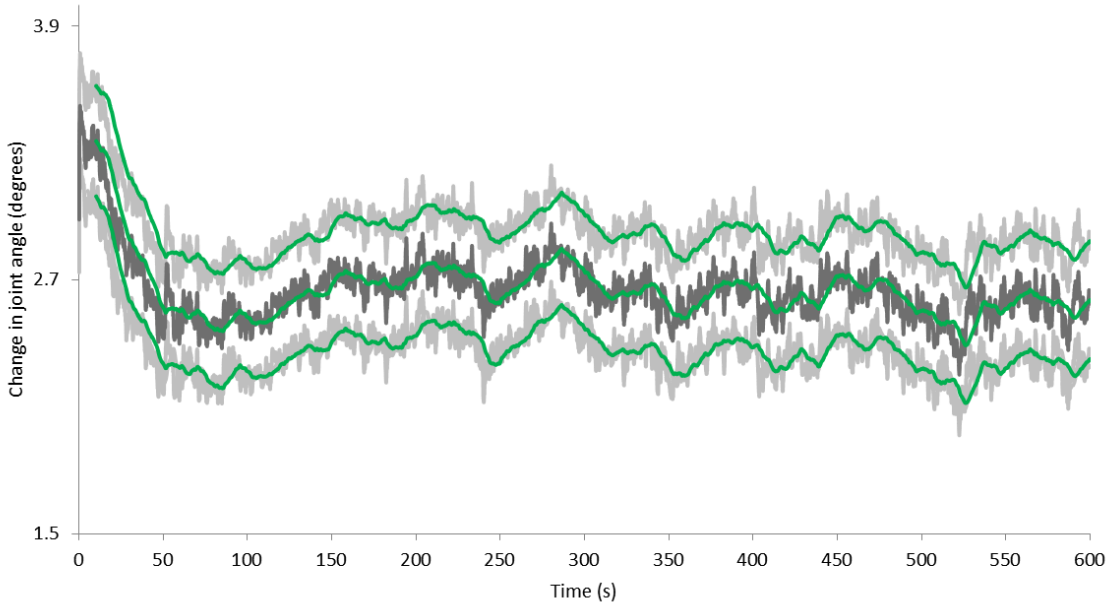


Figure 6-3 Data filtering options (green line) compared to original data (grey line) tested using mean L5/S1 flexion angle as a function of time, with moving average period of 401.

Figure 6-4 illustrates the Mean L5/S1 flexion angle across all participants throughout the 600 second trial, compared to the familiarised reference ranges, in both the LBP and no-LBP groups, as an example of variable. Familiarisation and loss of technique points are marked with vertical dotted lines on the plots. All other familiarisation figures can be found in appendix H. Tables 6-3 to 6-11 present the change in mean and 90% confidence limits of each measure, pre and post the estimated familiarisation and loss of technique points, and MBI. All tested differences in means use the SEM of the respective familiarised range as the threshold for a worthwhile change.

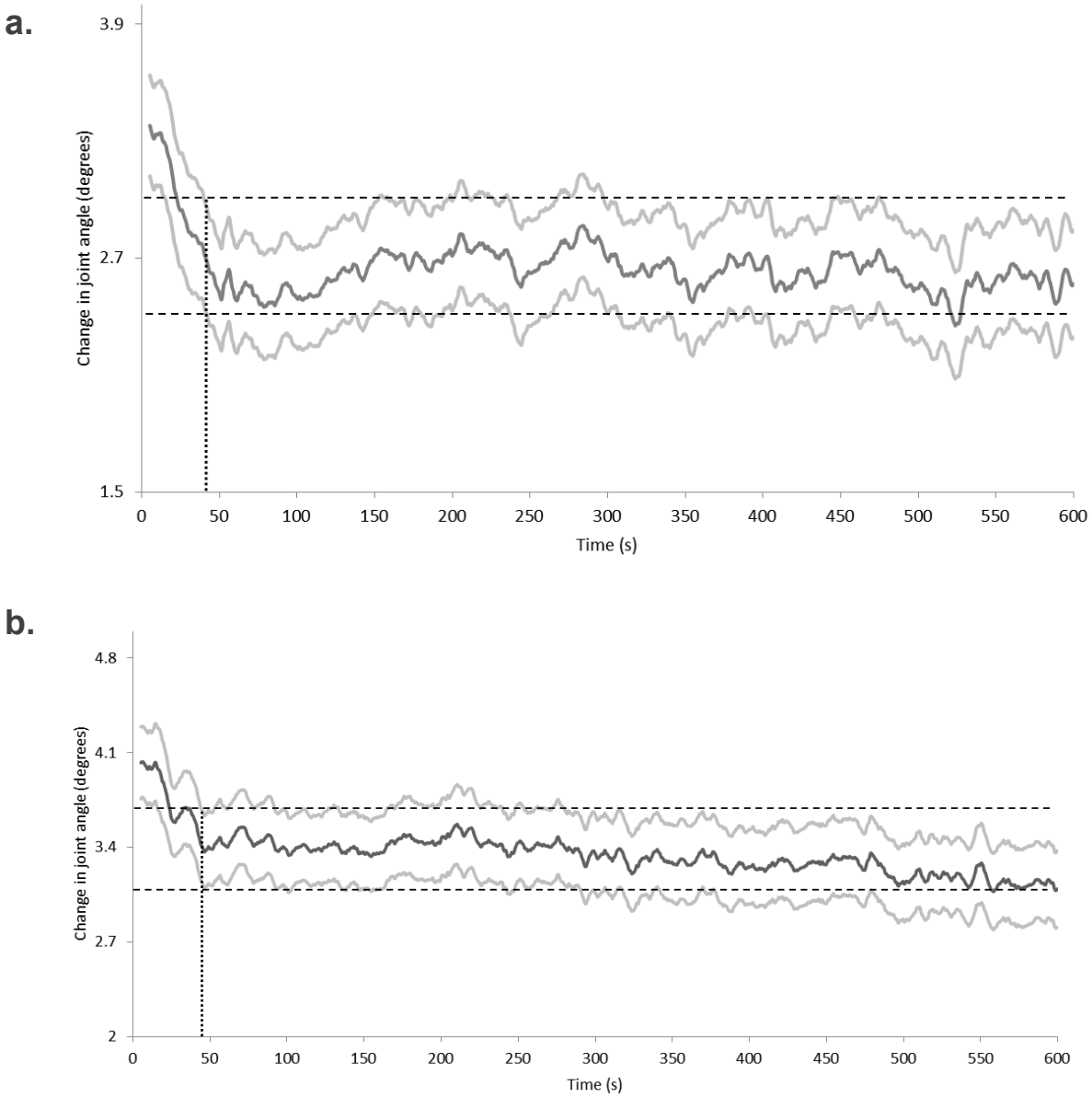


Figure 6-4 Mean L5/S1 flexion angle across all participants throughout the 600 second trial in; a. the no-LBP group and b. the LBP group. Familiarisation range shown on plots between dashed lines is no-LBP group: 2.7±0.3, LBP group: 3.4±0.3 (degrees).

Spinal flexion angles

Spinal positioning appeared familiarised by 40 seconds, in the no-LBP group and 45 seconds in the LBP group, and decreased during the familiarisation period in both groups. Tables 6-3 to 6-6 shows it was *likely* that the mean flexion angle before the estimated familiarisation points, were positive in both groups, compared to afterwards. No loss of technique points occurred.

Table 6-3. Differences in L5/S1 flexion angle, pre and post familiarisation point. Threshold for inferences using mean SEM, were 0.3 degrees in the no-LBP and LBP group

Comparison	Raw change in mean (degrees)	90% confidence limits		Mechanistic inference
No-LBP pre and post 40 s	0.4	0.6	0.2	Likely +ve
LBP pre and post 45 s	0.4	0.6	0.2	Likely +ve

Table 6-4. Differences in L3/L4 flexion angle, pre and post familiarisation point. Threshold for inferences using mean SEM, were 0.1 degrees in the no-LBP and LBP group

Comparison	Raw change in mean (degrees)	90% confidence limits		Mechanistic inference
No-LBP pre and post 40 s	0.2	0.3	0.1	Likely +ve
LBP pre and post 45 s	0.2	0.3	0.1	Likely +ve

Table 6-5. Differences in T12/L1 flexion angle, pre and post familiarisation point. Threshold for inferences using mean SEM, were 0.1 degrees in the no-LBP and LBP group

Comparison	Raw change in mean (degrees)	90% confidence limits		Mechanistic inference
No-LBP pre and post 40 s	0.2	0.3	0.1	Likely +ve
LBP pre and post 45 s	0.2	0.3	0.1	Likely +ve

Table 6-6. Differences in T8/T9 flexion angle, pre and post familiarisation point. Threshold for inferences using mean SEM, were 0.1 degrees in the no-LBP group and LBP group

Comparison	Raw change in mean (degrees)	90% confidence limits		Mechanistic inference
No-LBP pre and post 40 s	0.1	0.2	0.0	Likely +ve
LBP pre and post 45 s	0.2	0.2	0.1	Likely +ve

Anterior pelvic tilt

Anterior pelvic tilt appeared familiarised by 105 seconds in the no-LBP group and 110 seconds in the LBP group, decreasing during the familiarisation period in the no-LBP group and increasing in the LBP group. However, Table 6-7 shows that it was *unlikely* that the mean anterior pelvic tilt before the estimated familiarisation points was positive in the no-LBP group and negative in the LBP group compared to afterwards. No loss of technique points occurred.

Table 6-7. Differences in anterior pelvic tilt, pre and post familiarisation point. Threshold for inferences using mean SEM, were 0.5 degrees in the no-LBP and LBP group

Comparison	Raw change in mean (degrees)	90% confidence limits		Mechanistic inference
No-LBP pre and post 105 s	0.4	0.4	0.0	Unlikely +ve
LBP pre and post 110 s	-0.4	0.1	-0.9	Unlikely -ve

Centre of mass variation

Anteroposterior

Anteroposterior centre of mass variation appeared familiarised by 60 seconds in the no-LBP group and 40 seconds in the LBP group and decreased during the familiarisation period in both groups. Table 6-8 shows it was *most likely* that mean centre of mass variation before the familiarisation point was positive compared to aferwards. No loss of technique points occurred.

Mediolateral

Mediolateral centre of mass variation appeared familiarised by 80 seconds in the no-LBP group and 15 seconds in the LBP group. The variation decreased during the familiarisation period in both the no-LBP and LBP groups. Table 6-9 shows it was, at best, *unlikely* that the mean centre of mass variation before the familiarisation point was positive compared to the mean afterwards in the no-LBP

group. In the LBP group there was only a *trivial* difference before and after the familiarisation point

Loss of technique appeared to occur at 325 seconds in the no-LBP group and 480 seconds in the LBP group. The centre of mass variation increased after the loss of technique point. Table 6-9 shows it was *most likely* that the mean centre of mass variation before the loss of technique point was negative compared to afterwards in the no-LBP group, and *likely* negative in the LBP group.

Table 6-8. Differences in anteroposterior centre of mass variation, pre and post familiarisation point. Threshold for inferences using mean familiarised range SEM, were 0.2 cm in the no-LBP group and LBP group

Comparison	Raw change in mean (cm)	90% confidence limits		Mechanistic inference
No-LBP pre and post 60 s	0.7	0.9	0.5	Most likely +ve
LBP pre and post 40 s	0.9	1.1	0.7	Most likely +ve

Table 6-9. Differences in mediolateral centre of mass variation, pre and post familiarisation and loss point. Threshold for inferences using mean SEM, were 0.05cm in the no-LBP group and 0.1 cm in the LBP group

Comparison	Raw change in mean (cm)	90% confidence limits		Mechanistic inference
No-LBP pre and post 80 s	0.02	0.08	-0.03	Unlikely +ve
No-LBP pre and post 325 s	-0.11	-0.08	-0.15	Most likely –ve
LBP pre and post 15 s	0.03	0.09	-0.03	Very likely trivial
LBP pre and post 480 s	-0.13	-0.09	-0.17	Likely -ve

Frequency and movement variability

Exercise frequency appeared familiarised by 70 seconds in the no-LBP group and 15 seconds in the LBP group. Frequency decreased during the familiarisation period in the no-LBP group and increased in the LBP group. Table 6-10 shows it was *likely* that the mean frequency before the familiarisation point in

the no-LBP group was positive compared to afterwards. However, before the familiarisation point in the LBP group, it was only *possible* that the mean frequency was negative compared to afterwards.

Loss of technique appeared to occur at 580 seconds in the no-LBP group and 595 seconds LBP group with frequency increasing after the loss of technique point. Table 6-10 shows it was *most likely* that the mean frequency was negative before the loss of technique point compared to afterwards in the no-LBP group, but only *possibly* negative before the loss of technique point in LBP group.

Movement variability appeared familiarised by 130 seconds of exercise in the no-LBP group and 155 seconds in the LBP group. Movement variability decreased during the familiarisation period in both the no-LBP and LBP groups. Table 6-11 shows it was *most likely* that the mean movement variability was positive before familiarisation points in the no-LBP and LBP groups compared to afterwards. No loss of technique point occurred in the LBP group.

Loss of technique appeared to occur at 590 seconds in the no-LBP group. Movement variability decreased after the loss of technique point. Table 4 shows it was *most likely* that the mean movement variability was positive before the loss of technique point compared to afterwards.

Table 6-10. Differences in exercise frequency, pre and post familiarisation and loss point. Threshold for inferences using mean SEM, were 0.014 Hz in both the no-LBP and LBP group

Comparison	Raw change in mean (Hz)	90% confidence limits		Mechanistic inference
No-LBP pre and post 170 s	-0.024	-0.015	-0.033	Very likely -ve
No-LBP pre and post 580 s	-0.034	-0.021	-0.046	Most likely –ve
LBP pre and post 15 s	0.017	0.040	-0.007	Possibly +ve
LBP pre and post 595 s	-0.021	-0.024	-0.066	Possibly -ve

Table 6-11. Differences in movement variability, pre and post familiarisation point. Threshold for inferences using mean SEM, were 1.5% in the no-LBP group and 1.6% in the LBP group

Comparison	Raw change in mean (%)	90% confidence limits		Mechanistic inference
No-LBP pre and post 130 s	4.2	4.8	3.6	Most likely +ve
No-LBP pre and post 590 s	1.1	2.7	-0.5	Most likely +ve
LBP pre and post 155 s	3.2	3.6	2.7	Most likely +ve

6.3.3. FRED sampling error

During data analysis, it was observed that the FRED does not have a consistent sampling rate. Although the error is very small and therefore, was not observed during the 30 second trials from previous chapters, it amplifies across longer trials such as the 600 second sampling periods used in this study. The FRED frame rate is not set or reported live or recorded in the data, meaning it was not known what the frame rate was during each collection period. During analysis it was noted that the FRED data sets were smaller than the XSens sets and that variation was present in the lengths of the sets. Therefore, the sampling rate was calculated for each participant's FRED data set during the analysis, after the error was suspected. Across all data sets in this and chapter seven (including individuals which were recruited to chapter seven which shared data collection with this chapter) the average frame rate of FRED collection was 4.7fps with a standard deviation of 0.29fps. In seven participant's data the frame rate dropped below 4.5fps and four dropped below 4fps with the lowest frame rate calculated to be 2.5fps. During analysis all the data were tabulated in columns, for each participant, against time before being averaged during the analysis to plot the graphs and for copying to MBI spreadsheets. Therefore, the frame rates need to be closely matched between participants to be accurately representative of each time point in the analysis tables. The standard deviation was calculated with the four data sets with a frame rate less than 4fps excluded and then for all seven where it fell below 4.5fps. With only less than 4fps data excluded the standard deviation was still greater than 0.1 and resulted in a small error effecting the final 50 seconds of data. Therefore the full seven participants worth of data where the frame rate dropped below 4.5fps were excluded from the analysis. All the participants were in the no FB group, three had LBP and four did not. As the sample sizes of these groups was large and there was an even spread of

exclusions in both, this was considered to be an acceptable number of exclusions. The average sampling rate with all seven exclusions was 4.8Hz with a standard deviation of 0.06Hz. The remaining included data sets varied in length by a maximum of 8 seconds on the 600-second time scale used in the plots. Any findings from the final 8 seconds of the trials may, therefore, not be representative of the entire study population. Therefore caution must be taken when forming any conclusions based on changes in data during the final 8 seconds of the FRED data.

6.3.4. Summary of results

The average time taken to let go of the handles was 32±38 seconds in the no-LBP group and 35±24 seconds in the LBP group. Familiarisation and any loss of technique times are shown in Table 6-12 with bold times indicating a probability of the true mean difference between pre and post time points was at least *likely*.

Table 6-12 Time to familiarisation for each variable. Times in bold show that the inferences, based on the chance of the true mean change being mechanistically different between pre and post familiarisation times, are at least a *likely* difference.

Outcome	Sag L5S1	Sag L3L4	Sag T12L1	Sag T8T9	CoM X	CoM Y	Pelv tilt	FRED f	Movement variability
Time (s) familiarised in no-LBP group	**40**	**40**	**40**	**40**	**60**	80	105	**170**	**130**
Time (s) familiarised in LBP group	**45**	**45**	**45**	**45**	**40**	15	110	15	**155**

6.4. Discussion

The main finding of this chapter was that it took 170 seconds to familiarise to FRED exercise and this changed to 155 seconds in those with LBP. There was no loss of technique point at which loss of technique occurred at all measures. However, there was an increase in mediolateral centre of mass variation at 325 seconds, exercise frequency at 580 seconds and movement variability at 590

seconds in the no-LBP group. The only loss of technique in the LBP group was an increase in mediolateral centre of mass at 480 seconds.

6.4.1. Familiarisation in no-LBP individuals

In no-LBP individuals, full familiarisation happened by 170 seconds of exercise. Spinal posture was the first element to familiarise followed by anteroposterior centre of mass variation, movement variability, and finally exercise frequency. Spinal positioning started in a more flexed position and gradually extended for all segment angles while centre of mass variation, exercise frequency and movement variability all gradually decreased during familiarisation. No measurable change in pelvic tilt occurred throughout the 600-second trials. It is known from the chapter four results and Gibbon et al. (2013) that FRED exercise places the pelvis into increased anterior tilt compared to walking. The results of this study would seem to indicate that this pelvic positioning occurs immediately on initiating exercise. No loss of technique occurred within 600 seconds, however, there was a small increase in mediolateral centre of mass variation of 0.1cm at 325 seconds and an increase of 0.034Hz in exercise frequency at 580 seconds and a decrease of 1.1% in movement variability at 590 seconds. The change in mediolateral centre of mass was very small and happened 255 seconds before frequency and movement variability changed. Therefore, this is not considered an overall exercise loss of technique point. Changes in exercise frequency and movement variability were the only other measures which the no-LBP group lost technique. The FRED data error which might have affected data in the final 8 seconds may explain this variation in exercise frequency. While it is possible that increasing frequency could be the first sign of onset loss of technique, it might also be a result of participants possibly increasing exercise frequency in anticipation of the end of the training. Most pacing strategies in exercise involve an end spurt (Abbiss and Laursen

2008; Tucker, Lambert and Noakes 2006) and so it is possible that enough participants adopted a pacing strategy including this feature, which would appear as loss of technique point in the final few seconds. Increased movement variability is assumed to increase as technique is lost. Therefore, a decrease is unlikely to be linked to a loss of technique point and suggests this change was more likely due to the FRED data error. It is not clear from the overall results why frequency increased in the final 20 seconds, however, participants were aware how much training time remained and so it might be linked to the potential end spurt.

It is known from chapter three that the LM and TrA muscles were more active during FRED exercise compared to rest. 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 thoracolumbar junction (Claus et al. 2009; O'Sullivan et al. 2006; Roussouly et al. 2005). Chapter four found that FRED exercise promotes this type of posture more than walking. The pelvic and spinal kinematics were all familiarised and stable, having gone into a small amount of lumbar extension, by 40 seconds. It can therefore be assumed that LM activation had occurred and resulted in lumbopelvic position familiarisation by 40 seconds of exercise. The remaining familiarisation time then appears to be attempting to reduce movement variability and exercise at a steady frequency, most likely at the target frequency provided by the FRED visual feedback. Movement variability familiarised by 130 seconds followed by exercise frequency 40 seconds later. This suggests that device users focus first on achieving an even movement followed by doing this at the correct frequency. Therefore, it appears that FRED exercise places users into anterior pelvic tilt immediately, deep muscles appear to have activated by 40 seconds in order to achieve spinal positioning, after which it takes another 90 seconds to develop sufficient movement control to achieve controlled and even

movements, after which the target frequency is reached 40 seconds later. At this point, 170 seconds after initiating exercise, all measures were considered familiarised.

6.4.2. Differences in familiarisation in individuals with LBP

In individuals experiencing LBP full familiarisation occurred by 155 seconds of exercise, which was 15 seconds earlier than those without LBP. Spinal positioning was the second element to familiarise, by 45 seconds which was 5 seconds slower than the no-LBP group. Similarly to the no-LBP group pelvic tilt did not have a familiarisation point and, therefore, also appears to reach its exercise position immediately. Anteroposterior centre of mass variation familiarised 20 seconds quicker in the LBP group, by 40 seconds, becoming the first element to familiarise. There was no *likely* familiarisation point for exercise frequency, meaning participants appeared to reach a steady exercise frequency from initiating movement. However, full movement control was not reached until 155 seconds when movement variability familiarised which was the final element to familiarise. Similarly to the no-LBP group, mediolateral centre of mass variation did not have a familiarisation point, but did have a loss of technique point at 480 seconds which was 155 seconds later than in the no-LBP group. The patterns of change of all variables were the same in both the LBP and no-LBP groups with spinal positioning extending while centre of mass variation and movement variability decreased, whilst exercise frequency produced no measurable change throughout the 600 second trial, in the LBP group. The target frequency provided by the feedback was 0.42 Hz. 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 LBP had better motor control.

Additionally, despite the much quicker frequency familiarisation time which led to a faster overall familiarisation time, the LBP group took 25 seconds longer to develop sufficient motor control to reach familiarised movement variability. As people with LBP often have reduced motor control of deep lumbopelvic muscles including LM (Hides et al. 1994; Hodges and Moseley 2003; Hodges and Richardson 1996; Macdonald, Moseley and Hodges 2009; Panjabi 2006), it is not an unexpected finding that they took more time to develop the motor control required to control the movement, and showed reduced ability to exercise at the target exercise frequency. This finding may also support the potential use of the FRED as an intervention for challenging and training lumbopelvic motor control in people with LBP.

6.4.3. Limitations

Limitations of this study are similar to those of chapter four discussed in section 4.1. This includes the use of a generic LBP population which may include LBP caused by a multitude of factors. O'sullivan (2005) and Hodges, Cholewicki and Van Dieen (2013) advocate sub grouping LBP participants into groups which share common features. Failing to use subgrouping risks the heterogeneity of LBP features masking differences between the LBP and no-LBP group. FRED exercise is particularly relevant to the motor control sub group. Therefore, a system to recruit LBP individuals from that sub group may create a symptomatic group which is more representative of the target FRED clinical population. Also similar to chapter four limitations is the continued lack of clinically relevant minimal worthwhile changes and still only being able to report mechanistic differences in means which may not be clinically meaningful.

The LBP group consisted mostly of individuals who indicated experiencing very mild to moderate back pain. However, only six participants indicated

experiencing severe or very severe pain. Therefore, the LBP 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 low sampling rate available from the FRED to record movement variability suggests that the movement variability results should be treated with some caution. In future developments of the device, it would be useful to increase the sampling rate of FRED at which movement variability is recorded. Minimal clinically worthwhile changes in relevant outcome measures would also be useful to ascertain to use with MBI if FRED is trialled clinically.

6.4.4. Conclusion

First-time no-LBP users of the FRED in crank position 5 and footplate position 1 took 170 seconds to familiarise to the exercise in terms of pelvic and spinal positioning, centre of mass variation, frequency and movement variability. Overall familiarisation occurred 15 seconds earlier in the study participants with LBP as they moved at the target slow speed from initiating exercise. However, those with back pain took 20 seconds longer to develop sufficient motor control to make controlled movements and demonstrated less ability to modulate exercise frequency, suggesting the intervention might be useful as a motor control intervention. It is therefore recommended that future FRED studies include a familiarisation period of at least 170 seconds to allow correct lumbopelvic positioning and control of the movement to be reached. Loss of technique, including changes in lumbopelvic kinematics, frequency and movement variability, does not appear to occur in the first 600 seconds of FRED exercise.

7. Chapter Seven: Investigation of Effect of Using Handles, on Lumbopelvic Kinematics, During FRED Exercise

7.1. Introduction

The FRED currently being investigated as a possible intervention for training intersegmental control of the lumber spine and lumbopelvic stability, includes adjustable handles for users to steady themselves with. The handles can be seen in Figure 7-1. The FRED operating instructions (version 20131030) state that the handles are intended to enable safe mounting and dismounting and for steadying users during exercise if required. However, no specific guidance is available on the effect of handle use during exercise on intervention mechanisms and potential impact on exercise effectiveness or confounding of study results.

Chapters one and two highlighted that activity of the LM muscle is a key component of intersegmental control interventions. Increasing LM activity has been reported when progressively reducing base of support, challenging balance and loading the upper limbs, using surface electromyography (Calatayud et al. 2015). It is expected that use of FRED handles during exercise will aid balance and support the weight of the upper limbs. Therefore, holding on is likely to lower LM activity and reduce the effectiveness of the FRED exercise as an intersegmental control training intervention. Reduced intersegmental control training and balance challenge is also likely to affect FRED exercise technique. Lumbopelvic positioning during exercise may be changed due to the role of LM in lordosis maintenance (Macintosh et al. 1986; Musculino 2005) and centre of mass variation may decreased with reduced challenge to balance (Winter 1995). The effect of handle use during FRED exercise should, therefore, be investigated as part of studying the mechanisms of the exercise.

Previous studies investigating the FRED have varied regarding whether they allowed participants to use the FRED handles during exercise. Some studies have allowed participants to rest their hands lightly on the handles if required

(Debuse et al. 2013). Other studies have not specified handle usage in their methods but showed images of participants using the device with the hands resting lightly on the handles (Caplan et al. 2014; Gibbon, Debuse and Caplan 2013). In chapters three to six it was decided not to allow use of the handles during data collection periods, as it was unknown if such usage could alter exercise technique and results. However, in chapter six, the familiarisation period was included within data collection. Therefore in chapter six participants were allowed to use the handles when starting exercise for the first time if they felt unsafe, but once they let go, they were then instructed not to hold on again. Figure 7-1 shows a participant exercising on the FRED prototype version three without using the handles.

Figure 7-1 Exercise on FRED prototype three not using the handles

It remains unclear what effect use of the handles has on FRED exercise technique. It was, therefore, felt useful to assess any mechanistic differences in

technique between participants using and not using the handles during exercise. To investigate this, a parallel study using a small additional group of participants was conducted during the data collection period of chapter six. As chapter six was assessing technique over time, it was possible to compare the technique of the no-LBP group from that chapter who did not use the handles once familiarised, with another no-LBP group which did hold on throughout a full, 600 second, comparable trial. This comparison, therefore, allowed assessment of familiarisation and loss of technique point differences when using the handles and testing of any differences in technique relevant measures, throughout the trials, between the holding and no-holding groups. This study also forms part of the series of studies to establish the mechanisms of using the FRED as a complex intervention. Determining if use of the handles affects exercise technique will also allow evidence-based decisions to be made on handle usage during intervention studies using the device.

7.1.1. Aim and Objectives

The aim was to observe the effect of handle use during FRED exercise on technique relevant measures of movement variability, lumbopelvic posture and centre of mass and make recommendations on handle usage for future intervention studies using the device.

The objectives were for first-time no-LBP device users:

1. Determine if there is a difference in the exercise familiarisation period between groups using and not using handles during exercise.

2. Determine if there is a difference in the exercise technique relevant measures between groups using and not using handles during exercise.

3. Report any changes in exercise technique that occur if participants use the handles during exercise and make recommendations regarding handle usage for future studies.

7.1.2. Methods

The data collection for this study was done in parallel with chapter six which was investigating exercise technique changes over time in an asymptomatic and LBP population. This study used the same general methodology as chapter six with a relatively smaller group of additional no-LBP participants who exercised for the 600-second trial using the FRED handles throughout. The XSens MVN portable motion tracking system was used to collect kinematic data and the FRED prototype version three used to collect exercise frequency and movement variability data. See chapter six, section 2, for details of participant recruitment, experimental protocol, measures of exercise technique and magnitude based inference statistics. The study received ethics approval from the Faculty of Health and Life Sciences ethics committee at Northumbria University (see appendix J).

Participants entering the study in chapter six who were screened to the no-LBP group, were randomised using a Microsoft Excel random number generator into a holding or no-holding group until the holding group had 16 participants. From that point on remaining no-LBP participants were all assigned to the study reported in chapter six. The only protocol difference from chapter six was that the holding on group was instructed to use the FRED handles at all times throughout the exercise trial and not let go. The same analysis as used in chapter six was performed to determine familiarisation and loss of technique points using the same moving average settings to filter the data.

Additional analysis performed in this chapter included direct comparisons using magnitude based inference to compare the mean of all measures across the entire trial period between the holding and no-holding groups. This additional analysis identified if any measurable changes existed between the holding and no-holding groups. For all magnitude based inference calculations the mean

standard error of the mean across the full 600 seconds of all the holding group participants was used as the smallest worthwhile change.

$$Standard\ error\ of\ the\ mean = \frac{SD\ (sample)}{\sqrt{n}}$$

The holding group SEM was used to make conservative comparisons. As there were less in the holding group resulting in the SEM of this group being the largest as these values are inversely proportional. Therefore, any difference of at least the holding group SEM, would also exist using the smaller SEM of the no-holding group, with its higher number of participants.

7.2. Results

Tables 7-1 and 7-2 present the holding and no-holding group demographics. One participant's kinematic data were excluded from analysis due to problems with the equipment or electromagnetic interference resulting in poor quality data. Four sets of FRED recorded data (frequency and movement variation) from the no-holding groups were excluded due to a frame rate error during FRED data collection discussed in chapter six section 6.3.3. The group demographics and any differences found with MBI are therefore presented taking these exclusions into account. The no-holding group had a slightly higher activity score of 3.8 compared to 3.3 in the holding group. Although this was a consistent difference, it is likely to be small enough not to confound results.

Table 7-1 group demographics and chance of differences being trivial with kinematic data exclusions taken into account

	n	Gender (M/F)	Mass(kg)	Height (cm)	BMI	Activity score	Age (years)
All participants	93	50/43	76.8	172.6	25.7	3.7	36.7
No-holding group	77	40/37	75.6	1.72	26.6	3.8	35.7
Holding group	16	10/6	82.5	174.9	26.8	3.3	41.6
Chance (%) that difference between the groups is trivial			87	81	79	67	68

Table 7-2 group demographics and chance of differences being trivial with frequency and movement varation data exclusions taken into account

	n	Gender	Mass (kg)	Height (cm)	BMI	Activity score	Age (years)
All participants	90	48/42	77.1	172.5	25.7	3.7	37.1
No-holding group	74	38/36	75.9	172.0	25.6	3.7	36.1
Holding group	16	10 /6	82.5	174.9	26.8	3.3	41.6
Chance (%) that difference between the groups is trivial			83	85	79	49	74

Figure 7-2 shows the mean L5/S1 flexion angle across all participants throughout the 600 second trial for the holding and no-holding groups, as an example variable. All other familiarisation figures can be found in appendix I. Familiarisation and loss of technique points were identified in the data, confirmed on the plots and marked accordingly. The corresponding MBI results are presented in Tables 7-3 to 7-11. The familiarised reference ranges are also displayed on the plots. The dark lines on the plots show the mean and light lines show the SEM range. All tested differences in means use the SEM of the respective familiarised range as the threshold for a worthwhile change.

Spinal flexion angles

All spinal positioning appeared familiarised by 40 seconds in the no-holding group and between 170 -205 seconds in the holding group. Flexion decreased during the familiarisation period in the no-holding group and decreased before increasing back to baseline values in the holding group. Tables 7-3 to 7-6 shows it was *likely* that the mean flexion angles before the familiarisation point, were positive compared to afterwards in the no-holding group. However, the pre-familiarisation point means were only *possibly* negative in the holding group. No loss of technique point occurred.

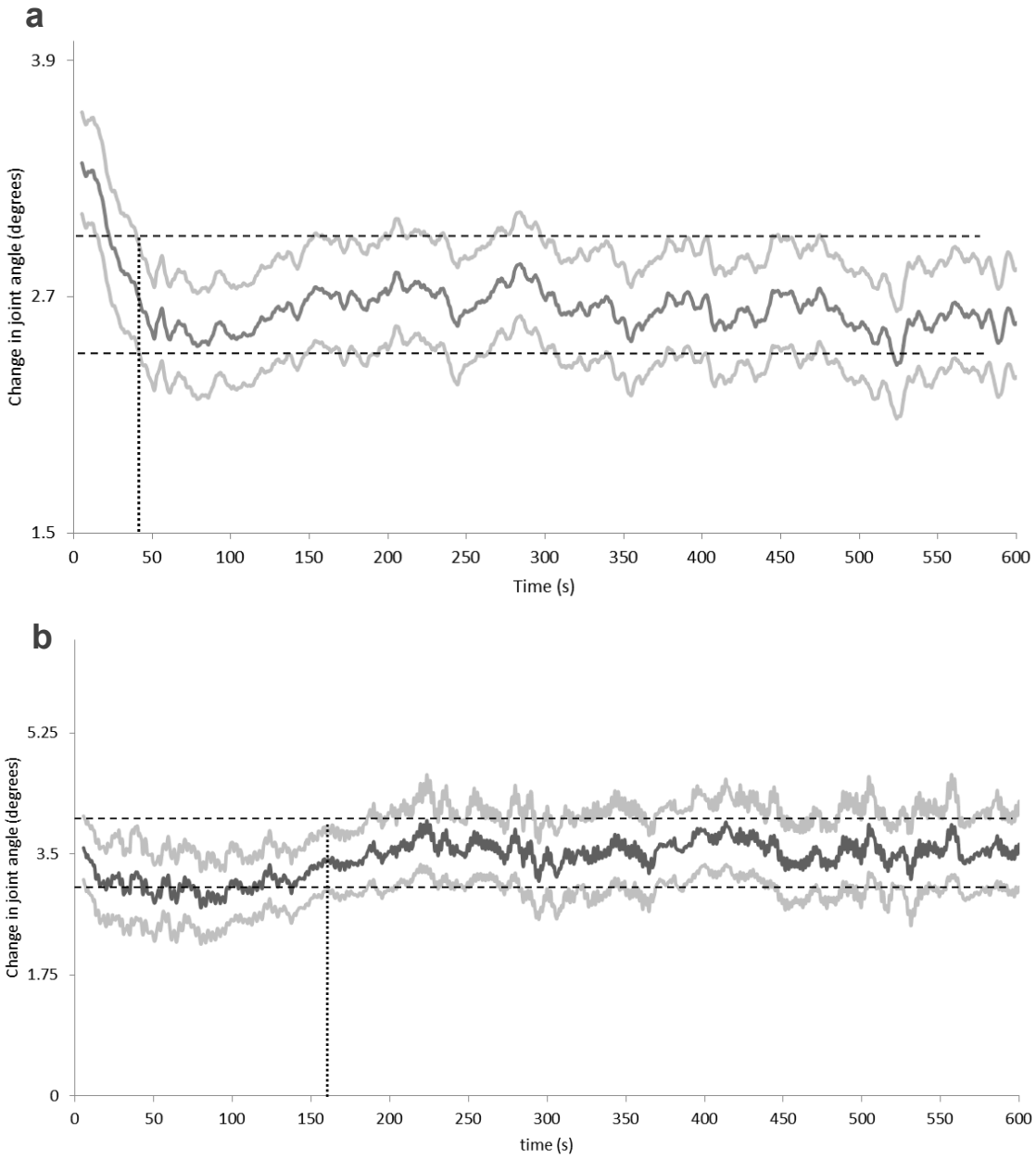


Figure 7-2 Mean L5/S1 flexion angle across all participants throughout the 600 second trial in; a. the no-holding group and b. the holding group. Familiarisation range shown on plots between dashed lines is 2.7 ± 0.3 in the no-holding group and 3.5 ± 0.5 in the holding group (degrees).

Table 7-3 Differences in L5/S1 flexion angle, pre and post familiarisation point. Threshold for inferences using mean SEM, were 0.3 degrees in the no-holding group and 0.5 degrees in the holding group

Comparison	Raw change in mean (degrees)	90% confidence limits		Mechanistic inference
No-holding pre and post 40 s	0.4	0.6	0.2	Likely +ve
Holding pre and post 170s	-0.5	0.0	-0.9	Possibly -ve

Table 7-4 Differences in L3/L4 flexion angle, pre and post familiarisation point. Threshold for inferences using mean SEM, were 0.1 degrees in the no-holding group and 0.2 degrees in the holding group

Comparison	Raw change in mean (degrees)	90% confidence limits		Mechanistic inference
No pain pre and post 40 s	0.2	0.3	0.1	Likely +ve
Pain pre and post 185 s	-0.2	0.0	-0.4	Possibly -ve

Table 7-5 Differences in T12/L1 flexion angle, pre and post familiarisation point. Threshold for inferences using mean SEM, were 0.1 degrees in the no-holding group and 0.2 degrees in the holding group

Comparison	Raw change in mean (degrees)	90% confidence limits		Mechanistic inference
No pain pre and post 40 s	0.2	0.3	0.1	Likely +ve
Pain pre and post 185 s	-0.2	0.0	-0.4	Possibly -ve

Table 7-6 Differences in T8/T9 flexion angle, pre and post familiarisation point. Threshold for inferences using mean SEM, were 0.1 degrees in the no-holding group and 0.1 degrees in the holding group

Comparison	Raw change in mean (degrees)	90% confidence limits		Mechanistic inference
No-holding pre and post 40 s	0.1	0.2	0.0	Likely +ve
Holding pre and post 205 s	-0.1	0.0	-0.3	Possibly -ve

Anterior pelvic tilt

Anterior pelvic tilt appeared familiarised by 100 seconds in both the holding and no-holding group, decreasing during the familiarisation period in both groups. However, Table 7-7 shows the mean anterior pelvic tilt before the familiarisation point was at best *unlikely* positive in the no holding group compared to afterwards and *possibly* positive in the holding group. No loss of technique point occurred.

Table 7-7 Differences in anterior pelvic tilt, pre and post familiarisation point. Threshold for inferences using mean SEM, were 0.5 degrees in the no-holding group and 1.8 degrees in the holding group

Comparison	Raw change in mean (degrees)	90% confidence limits		Mechanistic inference
No-holding pre and post 105 s	0.4	0.4	0.0	Unlikely +ve
Holding pre and post 100 s	1.7	3.0	0.3	Possibly +ve

Anteroposterior centre of mass variation

Anteroposterior centre of mass variation appeared familiarised by 60 seconds in the no-holding group and that no familiarisation point was estimated in the holding group. Table 7-8 shows it was *most likely* that the mean centre of mass variation was positive compared to afterwards in the no-holding group. To confirm no change occurred in the holding group, the first and second 300 seconds were compared and any change was *most likely trivial*. No loss of technique point occurred.

Mediolateral centre of mass variation

Mediolateral centre of mass variation appeared familiarised by 75 seconds in the no-holding group and by 60 seconds in the holding group. The variation decreased during the familiarisation period in the holding group and fluctuated without clear direction of change in the holding group. Table 7-9 shows that the mean centre of mass variation before the familiarisation point was *possibly*

positive in the no-holding group and *possibly* negative in the holding group, compared to afterwards.

Loss of technique appeared to occur at 325 seconds in the no-holding group and 570 seconds in the holding group. The centre of mass variation increased after the loss of technique point in both groups. Table 8 shows it was *most likely* that the mean centre of mass variation before loss technique centre of mass variation was negative in the no-holding group, and *likely* negative in the holding group.

Table 7-8 Differences in anteroposterior centre of mass variation, pre and post familiarisation point. Threshold for inferences using mean SEM, were 0.2 cm in the no-holding group and 0.6 cm in the holding group

Comparison	Raw change in mean (cm)	90% confidence limits		Mechanistic inference
No-holding pre and post 60 s	0.7	0.9	0.5	Most likely +ve
Holding pre and post 300 s	0.0	0.0	0.0	Most likely trivial

Table 7-9 Differences in mediolateral centre of mass variation, pre and post familiarisation and loss point. Threshold for inferences using mean SEM, were 0.05cm in the no-holding group and 0.1 cm in the holding group

Comparison	Raw change in mean (cm)	90% confidence limits		Mechanistic inference
No-holding pre and post 75 s	0.05	0.11	0	Possibly +ve
No-holding pre and post 325 s	-0.11	-0.08	-0.15	Most likely –ve
Holding pre and post 60 s	-0.1	0.1	-0.3	Possibly -ve
Holding pre and post 570 s	-0.2	-0.1	-0.4	Likely -ve

Frequency and movement variability

Exercise frequency appeared familiarised by 170 seconds in the no-holding group and 70 seconds in the holding group. Frequency increased during the familiarisation period in the no-holding group and decreased in the holding group. Table 7-10 shows it was *likely* that the mean frequency before the familiarisation point was negative compared to afterwards in the no-holding group and *possibly* positive in the holding group.

Loss of technique appeared to occur at 580 seconds in the no-holding group and at 350 seconds in the holding group with frequency increasing after the loss of technique point in both groups. Table 8 shows it was *most likely* that the mean frequency was negative before the loss of technique point compared to afterwards in the no-holding group but only *possibly* negative in the holding group.

Movement variability appeared familiarised by 130 seconds of exercise in the no-holding group and 60 seconds in the holding group. Movement variability decreased during the familiarisation period in both groups. Table 7-11 shows it was at least *very likely* that the mean movement variability was positive before the familiarisation point, compared to afterwards in both groups.

Loss of technique appeared to occur only in the no-holding group at 590 seconds with movement variability decreasing after the loss of technique point. Table 7-11 shows it was *most likely* that the mean movement variability was positive before the loss of technique point compared to afterwards.

Table 7-10 Differences in exercise frequency, pre and post familiarisation and loss point. Threshold for inferences using mean SEM, were 0.014 Hz[1] in the no-holding group and 0.021 Hz in the holding group

Comparison	Raw change in mean (Hz)	90% confidence limits		Mechanistic inference
No pain pre and post 170 s	-0.024	-0.015	-0.033	Very likely -ve
No-holding pre and post 580 s	-0.034	-0.021	-0.046	Most likely –ve
Holding pre and post 70 s	0.017	0.050	-0.016	Possibly +ve
Holding pre and post 350 s	-0.021	-0.008	-0.034	Possibly -ve

Table 7-11 Differences in movement variability, pre and post familiarisation point. Threshold for inferences using mean SEM, were 1.5% in the no-holding group and 1.7% in the holding group

Comparison	Raw change in mean (%)	90% confidence limits		Mechanistic inference
No holding pre and post 130 s	4.2	4.8	3.6	Most likely +ve
No holding pre and post 590 s	1.1	2.7	-0.5	Most likely +ve
Holding pre and post 60 s	3.5	4.8	1.3	Very likely +ve

7.2.1. Results summary

Table 7-12 shows the estimated times taken to familiarise from each plot. Bold entries in the table show when the probability of the true difference between the time points being changed by more than smallest worthwhile amount was at least *likely* (≥75%).

Table 7-12 Summary of familiarisation times across all measures

Outcome	Sag L5S1	Sag L3L4	Sag T12L1	Sag T8T9	CoM X	CoM Y	Pelv tilt	f	Movement variability
Time (s) familiarised in no holding group	**40**	**40**	**40**	**40**	**60**	80	105	**170**	**130**
Time (s) familiarised in holding group	170	185	185	205	0	60	100	70	**60**

Table 7-13 shows the mean difference in each variable between the holding and no-holding groups across the entire 600 second trials. Results where the magnitude of true change was at least *likely* (≥75%) to be the smallest worthwhile change are again shown in bold.

Table 7-13 Comparisons of all measures across the full 600 second trials for all comparing the holding with the no-holding group, using the corresponding no-holding group SEM as the minimal worthwhile change threshold for MBI, all in raw unites (flexion angle and pelvic tilt: degrees, centre of mass: cm, frequency: Hz and movement variability: %)

Outcome	Raw change	90% confidence intervals		Inference
L5/S1 flexion angle	1.2	0.1	2.3	**Likely +ve**
L3/L4 flexion angle	0.5	0.0	1.0	**Likely +ve**
T12/L1 flexion angle	0.5	0.1	1.0	**Likely +ve**
T8/T9 flexion angle	0.4	0.0	0.7	**Likely +ve**
Anteroposterior centre of mass	1.6	0.4	2.7	**Likely +ve**
Mediolateral centre of mass	-0.2	-0.4	0.0	Unclear
Anterior pelvic tilt	3.3	-0.7	7.4	Unclear
Frequency	-0.003	0.03	-0.02	Unclear
Movement variability	-2.2	-3.6	-0.9	**Likely -ve**

7.3. Discussion

The main findings of this chapter were that there is no *likely* familiarisation period when holding on. Individuals who exercised holding on were also *likely* to have a more flexed spinal position, increased variation in anteroposterior centre of mass and lower movement variability score.

7.3.1. Familiarisation time

The details of familiarisation in the no-holding group are detailed in chapter six section 6.4.1. In summary, familiarisation had begun by 40 seconds of exercise and took a further 130 seconds to complete across all measures, with full familiarisation reached by 170 seconds of exercise. Spinal mechanics familiarised first and exercise frequency last.

Holding on during FRED exercise results in no *likely* worthwhile change existing between the pre and post estimated familiarisation periods in all measures, except for movement variability which familiarised by 60 seconds. It therefore appears that the holding on group did not have, and therefore need, an overall familiarisation period. A 60 second period is still required to develop enough motor control to successfully manage movement variability. However, the following familiarisation points were still *possible*. Spinal position was no longer the first element to familiarise and became the final element to do so with familiarisation occurring after 170 seconds at L5/S1, 185 seconds at L3/L4 and T12/L1, and 205 seconds at T8/T9. Movement variability became the first element to familiarise after 60 seconds of exercise. Mediolateral centre of mass and exercise frequency were the second and third elements to *possibly* familiarise after 60 and 70 seconds of exercise, respectively. Pelvic tilt familiarised at 100 seconds, before spinal positioning began familiarising at 170 seconds. There was

a 100% probability that any change in anteroposterior centre of mass variation between the first and second half of the trial was *trivial*. Therefore, while it is not like *likely* that a familiarisation period longer than 60 is required to reach the target frequency while exercising holding on, it is possible that some variation in exercise may be present until as late as 205 seconds. However, the probability of this variation beyond 60 seconds is not great enough to warrant a familiarisation time recommendation.

7.3.2. Mean difference across entire trial in all measures

It appears that the spine is held in a more flexed position, the movement variability score lower (resulting in smoother movements) and variation in anteroposterior centre of mass increased, when holding on. Although the 90% confidence interval shows there could be a small decrease in anterior pelvic tilt, most of the interval showed an increase. While the potential to increase and decrease makes the magnitude based inference result unclear, when taken alongside the increasingly flexed spinal angles, it appears that participants using the handles positioned their entire trunk in a more forward flexed and forward leaning position. A possible reason for this is that the handles are positioned anteriorly to device users. Therefore, participants might have been leaning towards the handles in order to hold them and reduce the need to reach far with the arms.

Lumbar spinal extension that does not place the inflection point above thoracolumbar junction is associated with increased LM activity (Claus et al. 2009; O'Sullivan et al. 2006; Roussouly et al. 2005). Therefore, the shift towards flexed spinal angles suggests the LM muscle activity was decreased when holding on. It is also known that the LM muscle has a role in controlling and maintaining lumbar

lordosis (Macintosh et al. 1986; Moseley, Hodges and Gandevia 2002). Therefore, increasing lumbar flexion which in turn decreases lumbar lordosis, is also likely to be associated with decreased activity of the LM muscle. Ultrasound imaging or electromyography could be used to test this theory. The reduced movement variability also suggests that use of handles during exercise results in a reduced challenge to motor control as it appears participants were more easily able to exercise with smoother movement. It is possible that this might be due to trunk stability being gained passively through the arms, using the support of the handles rather than actively through use of the LM and TrA muscles. Although increased anteroposterior centre of mass variation from midline could indicate an increased balance challenge when holding on, it is more likely that the centre of mass was moved anteriorly due to the increased flexed and anteriorly positioning trunk. It has also been shown that decreasing support results in increased challenge to balance (Winter 1995). Therefore, it is also unlikely that balance would be challenged more when a participant is able to steady themselves with stable handles during the exercise.

7.3.3. Limitations

As the methodology of this chapter is based on that from chapter six, the limitations are also the same. Therefore, please see chapter six section 4.3 for the limitations of this methodology.

7.4. Conclusion

It appears that holding on during FRED exercise resulted in a more flexed spine with increased anterior pelvic tilt, suggesting a more anteriorly slanted and leaning trunk/pelvis orientation. There also appears to be a reduced challenge to motor control as device uses are able to exercise with smoother and more

controlled movements with less variation. Holding on also resulted in device users no longer having a *likely* familiarisation period, except for requiring 60 seconds to establish a smooth movement pattern. These changes are likely to result in reduced demands for motor control and less LM muscle activity. As FRED is intended to train both these elements, it is suggest that use of the handles during exercise is likely to make the exercise a less effective intervention. It is recommended that intervention studies do not allow participants to hold on to the handles except for mounting/dismounting, breaking a possible fall and during the familiarisation period established in chapter six.

8. Conclusion

8.1. Introduction

This thesis explored the underlying mechanisms of FRED exercise from the perspective of its potential as a future intervention in the rehabilitation of lumbopelvic deconditioning, which often results in LBP linked with LM and TrA muscle atrophy and control deficiencies, both on Earth and following human spaceflight. The overarching aim was to develop evidence that informs a decision on whether a clinical trial of the FRED is justified in both terrestrial and human spaceflight simulation settings. The study began by synthesising the evidence for effectiveness of interventions for lumbopelvic deconditioning during and after microgravity exposure, to inform future research and enable comparison of emerging interventions, such as FRED exercise, with current practice. Such synthesis, while common in terrestrial medicine, was lacking within aerospace medicine. The mechanistic kinematic and motor control effects caused by FRED exercise, compared to walking, were determined in participants with and without LBP, to assess the exercise mechanisms in relation to current LM and TrA rehabilitation theory. Additional mechanistic studies identified the effect of altering FRED settings on motor control and key muscle recruitment, established the time needed to familiarise with the exercise in LBP and asymptomatic groups, and assessed the impact of visual feedback and handle use, on kinematics and motor control during exercise, to inform the future creation of a standardised and evidence based exercise protocol for use in a clinical trial. The thesis sought to answer three key questions: Do the underlying mechanisms of FRED exercise indicate that it may be a useful intervention to trial in the rehabilitation of lumbopelvic deconditioning resulting from microgravity exposure in astronauts and a sedentary lifestyle in the general population? What are the requirements for a standard and progressive training protocol using the FRED? What current

inventions are used to treat and rehabilitate lumbopelvic deconditioning in a spaceflight context and what are their effects?

8.2. Original experimental findings and implications

The main experimental findings are chapter specific and are summarised in the opening discussion paragraph of chapters three through seven. In this section, the findings are synthesised in relation to how they answer the main three research questions.

1. Do the underlying mechanisms of FRED exercise indicate that it may be a useful intervention to trial in the rehabilitation of lumbopelvic deconditioning resulting from microgravity exposure in astronauts and a sedentary lifestyle in the general population?

a. The FRED automatically recruits LM and TrA automatically and more than rest: All of the FRED version 3 settings were tested and recruited LM and TrA automatically. A large body of evidence has linked these muscles to lumbopelvic deconditioning and LBP (Panjabi 2006; Danneels et al. 2000; Hodges et al. 2006; Hides et al. 1994; Hodges and Richardson 1996). These muscles are difficult to recruit consciously (Van, Hides and Richardson 2006) and so their apparent automatic recruitment during FRED exercise would appear to be particularly beneficial over current practice.

b. The FRED promotes increased lumbar extension, mostly in the lumbar region, and anterior pelvic tilt compared to over ground walking: Attaining a lordosis throughout the lumbar spine below the thoracolumbar junction is a common goal of current interventions (O'Sullivan 2000) and is the sagittal spinal position where LM tends to be most active (Claus et al. 2009; Moseley, Hodges

and Gandevia 2002; O'Sullivan et al. 2006). Although this finding alone does not indicate that the correct lordosis is promoted by FRED exercise, when combined with finding a. there is increased likelihood that the spinal position promoted during FRED exercise is more conducive to LM recruitment than walking. A clinical trial including imaging of the lumbar spine to accurately determine lordosis change, with methods similar to Roussouly et al. (2005) or Belavy et al. (2010) which are likely to have better accuracy than surface measurements, and could correlate lordosis changes with a patient reported and clinically relevant outcome such as a pain score, is needed to test if these mechanisms will be effective at normalising lumbopelvic position in a LBP population.

c. The FRED causes increased anteroposterior and mediolateral centre of mass variation compared to walking: This suggests an increased challenge to balance and, therefore, control of the FRED exercise movement. This may form part of the motor control mechanism of FRED exercise which promotes the increased LM and TrA activity and lumbar lordosis found in finding b. This adds to the overall evidence that the FRED works in line with current motor control interventions and when combined with the automatic recruitment in finding a. adds weight to the justification for a clinical trial.

Overall, the experimental findings of this thesis validated previous findings that FRED exercise recruits LM and TrA automatically and may be very beneficial in people with LBP. The mechanisms underpinning this effect are now understood to be the upright lumbopelvic posture, including increased lumbar lordosis, which FRED exercise promotes, alongside an increased balance challenge compared to walking, which is a similar upright functional exercise. These findings support an argument that FRED exercise appears to have potential to be beneficial in the rehabilitation of lumbopelvic deconditioning and,

therefore, should be trialled as an intervention for those with LBP terrestrially and/or following microgravity exposure, to determine the clinical effects which result from these mechanistic findings.

Alongside the mechanistic justification for a clinical trial of the FRED, chapter two reviewed the current evidence base for effectiveness of interventions used in, and after, microgravity exposure. The lack of any current countermeasure effectively preventing lumbopelvic deconditioning during microgravity, and only one trial assessing rehabilitation, demonstrates a clear need for additional research to find better countermeasure interventions and assess post exposure interventions effectiveness to inform clinical guidelines for microgravity operations.

2. What are the requirements for a standard and progressive training protocol using the FRED?

a. Increasing crank amplitude increases movement variability, ΔTrA_{max}, ΔLM_{max} and TrA muscle recruitment: These outcomes are all measures of motor control of either the global movement or muscle recruitment. Increasing the crank amplitude increased the motor control demand, which can be considered a more difficult setting and therefore a progression of the exercise.

b. There is more variation away from the target exercise frequency if visual feedback is not provided: The target frequency of FRED exercise was chosen as it is expected to preferentially recruit deep lumbopelvic muscles rather than superficial, as explained in the introduction to chapter five. Therefore, achieving the target frequency is considered important in the potential role of FRED exercise as an intervention to train these muscles and should form part of a standard exercise protocol.

b. It took 170 seconds for asymptomatic individuals to familiarise to FRED exercise and 155 for those with LBP: The main reason for the difference was that those with LBP exercised at the target frequency from initiating movement. It was recommended to use at least the upper limit of familiarisation time, 170 seconds, as the standard familiarisation period for those with and without LBP, as this ensures the majority of users will be familiarised. A short additional period could be considered to allow for some natural variation.

c. There was no likely familiarisation period and spinal positioning become more flexed with reduced movement variability when the handles were used during exercise: These findings strongly suggest that the lumbopelvic posture promoted by the FRED which likely links to LM and TrA recruitment is disrupted when the handles are used. Increased lumbar flexion is opposite to the posture promoted when not holding on that is expected to be linked to increased LM and TrA activity. This is combined with reduced movement variability that suggests there was also reduced challenge to motor control when holding on. The changes seen when holding on are all ones that are likely to reduce the effectiveness of FRED exercise as an intervention to recruit LM and TrA and challenge motor control.

These findings result in a recommendation that a standard FRED training protocol include a 170 second familiarisation time, include visual feedback of the live and target exercise frequency and that the handles should not be used once device users are safe to let go. These findings provide evidence to inform creation of an evidence-based standardised training protocol that can be used within future FRED studies.

What current interventions are used to treat lumbopelvic deconditioning and what are their effects?

The literature review in chapter one explored the current interventions and reported effectiveness of terrestrial interventions. Synthesis of the terrestrial evidence had already been performed through use of systematic review and showed that motor control theory had effects in LBP when used within a wider biopsychosocial model and with subgrouping of clinical patients, that also considered and treated wider problems including those beyond the basic musculoskeletal model. However, synthesis was lacking in the field of clinical operational spaceflight and so chapter two performed this for lumbopelvic deconditioning.

a. Current countermeasures are unlikely to fully protect against all lumbopelvic changes occurring due to microgravity exposure: This finding demonstrates a need for further research into new interventions to better protect the spine during microgravity exposure. It might be possible to translate ground-based interventions into new countermeasures or develop new ones based on the current lumbopelvic deconditioning rehabilitation theory. Any new interventions will need testing in ground based microgravity simulations before incurring costs associated with actual spaceflight testing. Lower body negative pressure treadmill was the most effective currently researched countermeasure against lumbopelvic deconditioning. As this countermeasure is not yet used in operational spaceflight and no countermeasure is fully effective, there remains a need for rehabilitation.

b. Research into post microgravity rehabilitation interventions for lumbopelvic deconditioning is lacking: From the research that is available from trials of rehabilitation following human spaceflight, specific motor control followed

by general trunk strengthening appears to be the most effective rehabilitation intervention. However, with this being based on only one rehabilitation trial, with no other trials exploring other rehabilitation interventions, this finding must be treated with caution. However, the fact that motor control exercise has shown effects in post spaceflight and in terrestrial rehabilitation, combined with FRED exercise automatically recruiting key muscles, provides justification for proposing the device be considered for operational use. A recommendation for operational use could also only occur following a clinical trial showing it to be safe and effective.

The systematic review provided the required synthesis of current evidence of effectiveness of interventions for treating lumbopelvic deconditioning in microgravity exposure. It found that more research into this area is required. The review can be used to benchmark emerging interventions, such as FRED exercise, against current interventions. This will however, require new research to use at least some of the same outcome measures as the studies in the review. One of the other findings was a lack of patient reported outcome measures in microgravity exposure research. Therefore it is recommended that future trials use a combination of both comparable measures to previously synthesised research to enable direct comparison of effect, and include patient reported outcomes. This combination would enable operational decisions regarding intervention use by having direct evidence of comparable effectiveness with previous interventions and evidence for new interventions at least, of clinical worthwhile effects as reported by patients. If a clinical trial of FRED exercise occurs terrestrially, and it appears effective as an intervention for lumbopelvic deconditioning, then a trial using terrestrially simulated microgravity exposure, such as using a bed-rest study is recommended to assess the effects of the

device for informing operational decisions on its potential use in rehabilitation following human spaceflight. In the longer term, initial investigations could begin to consider if FRED exercise theory and mechanisms could be utilised as a countermeasure during microgravity exposure. Initially this could be through computer modelling, as already begun by Lindenroth et al. (2015), potentially followed by suspension studies which could use similar methods to Cao et al. (2005) and Marcias et al. (2007) who used a vertically aligned treadmill and participant suspension systems to eliminate the normal gravity vector for ground based studies.

8.3. Methodological contributions

The use of a local science museum within which to conduct a study including participation being open to the public has proven itself to enable large population studies that include a clinical group. While such a method will only work with short duration participant involvement protocols, it should be considered useful for creating a high study power and for enabling quick and easy clinical population recruitment, for any condition which has high incidence such as LBP, which the NHS reports as affecting one third of the UK adult population each year (NICE 2009).

Systematic reviews in aerospace medicine were found to be lacking in chapter two. This resulted in the need to create novel quality scoring tools and statistical tests for this field or review. These tools, should they be shown to be valid and reliable, could make original contributions to future aerospace medicine system review teams. It has since been acknowledged by both the European Space Agency's Medical Operations Office and the Aerospace Medicine Association that

it would be useful to consider developing an aerospace systematic review group in the future, to build on the tools and methods developed in this thesis.

8.4. Theoretical implications

Due to the mechanistic nature of this thesis, being very specific to FRED exercise, the wider theoretical implications are limited. However, the FRED has been conceived as a specific motor control intervention to promote intersegmental stability in lumbopelvic deconditioning, and initial trials successfully showed it has potential in this area (Debuse et al. 2013). Therefore, the findings that FRED exercise, recruits LM and TrA, appears to promote lordosis consistent with recruitment of these key muscles and challenges balance and control of movement, can be compared with current theory relating to if these elements should be present in such interventions. The muscle recruitment finding is consistent with current motor control theory commonly presented in the literature both in terrestrial environments (Hodges and Richardson 1996; Hides et al. 1994; Hodges and Cholewicki 2007; Hides, Richardson and Jull 1996; Panjabi 2006) and following human spaceflight (Evetts 2015; Hides et al. 2015; Hides et al. 2011). Therefore, the studies may give a small level of limited validation to the theories. However, the theoretical implications are far more useful when transferred from the literature to FRED exercise, in that it shows that the device mechanisms appear to link very well to current motor control theory. Using the theoretical implications in this way adds support that FRED exercise appears suitable for clinical trial as a motor control intervention.

8.5. Policy implications

The majority of this thesis is again limited in its wider policy implication due to the mechanistic and specific to FRED nature of the studies. However, the

methodological contributions may already be showing potential to impact policy regarding synthesis of aerospace medicine research. The systematic review showed that both synthesis and use of patient reported outcome measures are both lacking in aerospace medicine. These findings have been included in European Space Agency report by the Topical Team for Post Flight Reconditioning with recommendations for inclusion of patient reported outcomes in future research and for additional aerospace medicine research synthesis in the future. An initial proposal has also been drafted to form a systematic review group for aerospace medicine which will collect current and develop future review tools and methods for this field, in order to guide and encourage high standards of synthesis in the future. This proposal, while still draft, has been viewed positively by the Aerospace Medical Association, European and UK Space Agencies and experts from the Cochrane Collaboration. Should this proposal develop further, it could result in a significant contribution to the future of aerospace medicine research synthesis.

8.6. Limitations of study

The mechanistic nature of the studies within this thesis, while able to highlight the underlying mechanisms and show the potential effectiveness of FRED exercise as a LBP intervention, are unable to provide any estimate or measure of the true effectiveness. Therefore, while the effects found in these studies support the argument that sufficient mechanistic study of FRED exercise has been completed to show it is likely to have beneficial effects, the effectiveness of FRED exercise has yet to be examined in people with LBP and/or in relationship to current rehabilitation interventions. The FRED is a large piece of equipment and some have argued that interventions should not require large or expensive equipment (Airaksinen et al. 2004), and therefore the FRED will need to

demonstrate clear effectiveness over traditional exercises if it is to become a mainstream intervention. Should future evidence show this effectiveness, then having a wide body of additional evidence of beneficial mechanisms that underpin the exercise will be helpful in promoting use of the device. No clinically meaningful changes in any outcomes were used in the studies undertaken as part of this PhD, due to the short nature of participant engagement time and again, the mechanistic nature of the studies. For a clinical trial, including minimal worthwhile changes over time, such as a change of at least 2 points on a ten point pain numerical rating scale (Salaffi et al. 2004) would be useful to generate evidence relating to the clinical worth of the device.

The LBP population in the studies expressed LBP as a symptom, but was not verified as having LM or TrA deconditioning, and in all studies was formed predominantly from those with mild to moderate pain. Therefore, the findings must be treated with caution for LBP populations whose symptoms are severe or worse. It has long been established that LBP is a heterogenic with respect to potential causes and that subgrouping is likely to aid clinical diagnosis and selection of most appropriate treatments (Bouter, van Tulder and Koes 1998; Hancock, Herbert and Maher 2009). It has been argued that considering LBP as a homogenous symptom itself is too simplistic an approach to a condition often labelled non-specific by nature and when applying a biopsychosocial approach to practice (O'Sullivan 2005). This is a view further supported by a systematic review that found individual treatments have limited effect compared to multi-lateral approaches with combinations of interventions (Ferreira et al. 2006). However, Hides et al. (1994) found LM atrophy in a study of 26 LBP patients compared to asymptomatic controls and validated this finding in a further study of 21 LBP patients (Hides, Richardson and Jull 1996). Therefore, those expressing

LBP may be considered likely to have LM deconditioning and so may allow LBP to be considered without sub grouping during initial mechanistic studies, as done in this thesis. It will be useful in future studies to use LBP subgrouping strategies such as proposed by Brennan et al. (2006) which included a stabilisation group, or specifically screen for, and recruit, those with LBP and known LM or TrA changes as reported previously (Hides et al. 1994; Danneels et al. 2000; Ferreira, and Hodges 2004; Hides et al. 2007). Sub-grouping in this manner is a method which has been advocated by those who argue for more multi-lateral approaches to LBP (O'Sullivan 2012).

8.7. Recommendations for future research

A clinical trial of the effectiveness of FRED exercise, in both terrestrial LBP patients who have deconditioning of LM or TrA and in humans that are deconditioned following exposure to microgravity, is justified based on the mechanistic studies reported in this thesis and previously that show that FRED exercise has potential to be of benefit. Such a trial should consider sub-grouping of LBP in its recruitment strategy as mentioned in section 8.6. Comparable outcome measures to current interventions, reported in chapter two, should be included for direct benchmark comparisons, as well as outcomes that are both patient reported or have known minimally clinically worthwhile changes. A future trial is also likely to be assessed for quality in future synthesis using similar tools to those used in chapter two, including tools such as Cochrane Risk of Bias (Higgins, Altman and Sterne 2011) and PEDro scores (PEDro 1999). Many of the intervention studies assessed in chapter two failed in blinding, resulting in automatic loss of three points out of the eleven available from PEDro and being considered to have high overall risk of bias on the Cochrane tool. Assessor blinding might be achieved through coding of data and removal of all identifying

elements, which would then be analysed without knowing which participant data belongs to. A sham exercise could take the form of normal elliptical training exercise with resistance at a faster frequency than promoted with the FRED. Participants, who agreed to join blind study testing function upright exercise for LBP rehabilitation, would be assigned randomly to each exercise, producing blinding. A cross over design could also be used to ensure all patients had access to the potentially beneficial FRED intervention and retain ability to compare the randomly assigned groups. Therapist blinding would still be a challenge to overcome, but this method would at least allow blinding of participants and assessors, blinding of outcome assessment, random sequence generation and allocation concealment. Provided other criteria which were commonly met by most included studies in chapter two, were also fulfilled, PEDro scores as high as 10 and low risk of bias results might be achievable.

Early development stage computer modelling or basic suspension studies to begin evaluating the FRED as a countermeasure for lumbopelvic deconditioning during microgravity exposure could also be considered. More widely, additional synthesis of aerospace medicine research is also recommended.

8.8. Conclusion

In agreement with initial studies (Debuse et al. 2013; Caplan et al. 2014; Gibbon, Debuse and Caplan 2013) which suggested that FRED exercise may be beneficial in the rehabilitation of LM and TrA in those with lumbopelvic deconditioning, the underlying mechanisms of FRED exercise have been validated, agreed with and provided further evidence in support of the original suggestion. The underlying mechanisms of FRED exercise have shown that it automatically recruits LM and TrA, promotes correct lordosis and challenges

motor control. The body of evidence in existence is considered sufficient to justify a clinical trial of FRED exercise to establish its effectiveness in relevant clinical populations both terrestrially and following microgravity exposure.

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Appendix

A. Chapter three participant information sheet

Participant Information Sheet

Project Title: Development of an exercise intervention for low back pain – Phase 1

Principal Investigator: Dr Dorothée Debuse
Investigator contact details: Telephone: 0191 215 6292
Email: dorothée.debuse@northumbria.ac.uk

1. What is the purpose of the project?

The purpose of the study is to assess the effect of 14 different combinations of movement amplitude and foot position when using a new exercise device. This exercise device was developed to train key muscles that provide spinal stability in the lower back and pelvis. Based on the results from our initial studies we are confident that the new exercise device could be a very useful tool in the rehabilitation of people with muscle atrophy and dysfunction in the lower back area, including those with low back pain, astronauts and people following long-term bed rest.

However, to date we have not yet investigated which of the possible combinations of exercise parameters (amplitude and foot position) is the most effective at recruiting these muscles. We also want to find out more about the forces that act on the body during exercise on the new device in different combinations of exercise parameters and how people feel about using the exercise device. Therefore, we need to undertake this study, in order to develop an effective and feasible and evidence-based exercise intervention using the new exercise device. This study will be the first in a series of studies which are funded by the European Space Agency.

2. Why am I invited to take part?

You have been invited because you are likely to meet the inclusion criteria for the study which are being fit and healthy, and between 18 and 55 years of age. Unfortunately, we cannot offer you any financial incentives or reimburse your travel expenses to take part in this study.

3. Do I have to take part, and can I withdraw from the project later?

It is up to you whether or not you take part. You can also leave the study at any time without need for explanation or justification, and this will not affect your future studies or employment at Northumbria University. If you do want to withdraw your data from this project at any time, simply contact the principal investigator by telephone, email or in person and let her know.

4. What does taking part involve?

You will be asked to visit one of our laboratories at City Campus for no more than two hours on two consecutive days. During the first visit you will be asked to

fill in a brief questionnaire about your general health and fitness, including how often you exercise.

For all exercise sessions reflective markers will be applied to your body in key areas on your legs and trunk, so that your movement during exercise can be captured by our VICON movement analysis system.

During each of your visits you will be asked to exercise on the new device in seven different combinations of amplitude of movement and foot position. In each of these seven combinations (14 overall), at rest, and in one control position, your transversus abdominis and lumbar multifidus muscle thickness will be measured using ultrasound imaging (see Table 1). We will take three images of your transversus abdominis (on the side of your abdominal wall) during each of these conditions and six images (at two different spinal levels) of your lumbar multifidus (in your back).

Table 1:

Session	Conditions		
	rest	control	Exs. conditions
1	✓	✓	7
2	-	-	Another 7

Rest = You will be asked to lie on a standard physiotherapy examination bench.

Control = Standing on the exercise device, but not moving.

Ultrasound imaging uses sound waves to produce an image of the tissues beneath the skin. This is a safe technique and used on a daily basis worldwide. The technology is identical to that which is used for checking on the development of foetuses within the womb during pregnancy.

The actual exercise will be at a very low intensity, and you can have a rest between the different conditions if you like. The total anticipated exercise duration is expected to be less than 70 minutes, with individual exercise conditions lasting no more than 8 minutes. We will ask you to rate your level of comfort in each condition, and we will not ask you to exercise beyond what you are comfortable with.

Exercise sessions will be arranged to take place over two consecutive days. We will also assess your comfort level 24hours after exercise, to check how you are feeling after exercise. We can check these face to face when you attend your second visit. Twenty for hours after the second visit we will contact you via email or telephone, whichever you prefer, to assess your comfort level after the second visit. The comfort level allows us to find out how you are feeling following the sessions, so we can get a sense of whether you have any after-exercise muscle soreness.

5. What are the exclusion criteria, i.e. are there any reasons why I should not take part?

- Being below 18 or above 55 years of age
- History of musculoskeletal or neurological problems/injuries affecting your ability to move normally or exercise, including low back pain
- History of abdominal or spinal surgery within the last three years

- Any heart conditions that would affect your ability to exercise safely
- Epilepsy
- Pregnancy

6. Will my participation involve any physical discomfort?

Ultrasound transmission gel will be applied to your flank and on your lower back during each of the combinations of parameters. The gel tends to feel cold initially, but soon you'll not notice it any more. Surplus gel will be removed using alcohol free tissue.

The exercise is designed to be gentle and will not involve any range of movement beyond what you are likely to experience in your normal daily activities. However, as you are not likely to be used to working your muscles in quite this way, you may experience a slight ache in your leg and/or tummy muscles during the exercise and/or on the day or two after. However, the level of exercise activity is not likely to be above what you are likely to experience during everyday activities. We will not ask you to exercise for any longer than you are comfortable with, and you can stop exercising if you wish.

7. Will my participation involve any psychological discomfort or embarrassment?

For us to be able to access the relevant areas on your flank and back to capture your movement and take the ultrasound images, we will ask you to expose your skin and to wear shorts and a crop top (if applicable) for the occasion. Nobody other than the researchers will have access to the lab where the ultrasound imaging is done, and screens will be placed around the exercise device to ensure privacy. The researchers will treat you with dignity and respect at all times.

8. How will confidentiality be assured?

You will be allocated a participant ID code that will always be used to identify any data that you provide. Your name or other personal details will not be associated with your data; for example, the consent form that you sign will be kept separate from your data.

Only the research team will have access to any identifiable information; and all identifiable information (other than the consent forms which are legally required to keep for the duration of the study) will be destroyed as soon as an ID code has been assigned to you. Paper records will be stored in a locked filing cabinet and electronic information will be stored on a password-protected computer. All data will be treated in accordance with the Data Protection Act.

9. Who will have access to the information that I provide?

Information you provide and the data we collect will be seen only by the principal investigator, Dr Dorothée Debuse and her research team. All records will be kept confidential except for potential auditing (that the correct procedures have been followed) by Northumbria University Ethics Committee and/or regulatory authorities.

10. How will my information be stored / used in the future?

Your information will be stored on a password-protected computer or in a locked filling cabinet. Any personal information will be destroyed after 3 years. Data may be published in peer-reviewed journals or presented as posters/abstracts at conferences; however all data will be anonymised and any personal information will not be referred to at any time.

11. Has this investigation received appropriate ethical clearance?

The study has received full ethical approval from the Faculty of Health and Life Sciences Ethics Committee. If you require confirmation about this, please contact the chair of the committee, stating the title of the research project and the name of the principal investigator:

Dr Nick Neave, Chair of the Faculty of Health and Life Sciences Ethics Committee, Northumberland Building, Northumbria University, Newcastle Upon Tyne, NE1 8ST

nick.neave@northumbria.ac.uk

You can also contact him if you would like to discuss the study with somebody other than the principal investigator or if you want to register an official complaint about the study.

12. If I want any further information who should I contact and how?

If you have any further questions, please feel free to contact the *principal investigator*:

Dr Dorothée Debuse,
Senior Lecturer in Physiotherapy,
Department of Sport, Exercise and Rehabilitation
Northumbria University
Newcastle-upon-Tyne
NE7 7XA
E:mail: dorothee.debuse@northumbria.ac.uk

13. What happens next?

If, after reading this information sheet, you decide that you would like to take part, please get in touch with Andrew Winnard, PhD student, via e-mail at andrew.winnard@northumbria.ac.uk. He will then contact you to answer any further questions you may have about the study and arrange a convenient time for you to come to the lab. Before the start of testing, you will be asked to sign a consent form. A copy of the consent form and this information sheet are yours to keep.

Many thanks for taking the time to read this information sheet.

B. Chapter three informed consent form

Consent Form

Title of Study: Development of an exercise intervention for low back pain – Phase 1

Name of Principal Investigator: Dr Dorothée Debuse

Please initial boxes

	YES	NO
1. I confirm that I have read and understand the participant information sheet dated 29.10.13 version 1 for the above study. I have had the opportunity to consider the information and ask questions which have been answered fully.	☐	☐
2. I confirm that none of the exclusion criteria stated in the participant information sheet apply to me.	☐	☐
3. I understand that my participation is voluntary and that I am free to withdraw from the study at any time without giving any reason. Withdrawing will not affect my future studies at Northumbria University or legal rights.	☐	☐
4. I am happy to be involved in the above study as outlined in the participant information sheet dated 29.10.13 version 1.	☐	☐
5. I understand that any data created from this study will be kept safe on a password protected computer for four years after the end of the study, at which point it will be destroyed. All data collected will be made anonymous and kept confidential. Only the Principal Investigator and her research team will have access to this information.	☐	☐
6. I would like to receive a summary of the overall results following completion of data analysis and/or a copy of my individual data (please delete as appropriate). I am aware that the personal data will contain no interpretation of the data.	☐	☐

Name of Participant	Date	Signature
Principal Investigator	Date	Signature

C. Chapter four and five participant information sheet

Can you take part?

Yes, if you want to – provided:

1. You don't have heart disease or epilepsy.
2. You are not pregnant.
3. You have not had abdominal or spinal surgery in the last three years.
4. You don't have an abnormal spinal curve that prevents you from standing up straight.
5. You can answer no to ALL of the important medical questions below.
6. You sign a consent form.

Age restrictions may apply to some of the activities.

Important Medical Questions

So we are sure you will be okay to do exercise with us today, **we can only let you take part if you can honestly answer no to all the following questions**:

1. Has your doctor ever said that you have a heart condition *and* that you should only do physical activity recommended by a doctor?
2. Do you feel pain in your chest when you do physical activity?
3. In the past month, have you had chest pain when you were not doing physical activity?
4. Do you lose your balance because of dizziness or do you ever lose consciousness?
5. Do you have a bone or joint problem that could be made worse by a change in your physical activity?
6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
7. Do you know of *any other reason* why you should not do physical activity?

It is up to you whether or not you take part. You can also leave the study at any time without explanation or justification, and this will not affect you in any way. If you do want to withdraw your data from this project at any time, simply contact us by email or in person.

You can contact us at the following emails:
Andrew.Winnard@northumbria.ac.uk
Sian.Lawson@northumbria.ac.uk

FRED

northumbria
UNIVERSITY NEWCASTLE

What does it involve?

FRED: You will be asked to do a short period of over ground walking, followed by around three minutes of exercise on the device (FRED). You may also have the option of wearing a motion capture suit. The suit collects detailed information about how you move. FRED also collects information on how fast and how even your movements are during exercise.

We will show you how to use the device safely. The exercise involves moving your feet in a slow and controlled circular motion while standing upright on the device. There is no resistance, so you have to control the movement accurately yourself. It should not feel excessively tiring, but you will be able to stop at any time if you feel you need to. The exercise is designed to be gentle and will not involve any range of movement beyond what you are likely to experience walking. However, as you are probably not used to working your muscles in quite this way, you may experience a slight ache in your leg and/or tummy muscles during the exercise and/or on the day or two after.

Other people at the Centre for Life will be able to see the testing taking place. The researchers will treat you with dignity and respect at all times.

Data and Ethical Information

Confidentiality: You will be allocated a participant number that will be used to identify any data that you provide. Your name or other personal details will not be associated with your data; for example, the consent form that you sign will be kept separate from your data. All data will be stored anonymously and securely, and deleted within three years.

Information you provide and the data we collect will be seen only by the research team. All records will be kept confidential except for potential auditing (to check that the correct procedures have been followed) by Northumbria University Ethics Committee and/or regulatory authorities.

Data may be published in peer-reviewed journals or presented at conferences; however all data will be anonymised and any personal information will not be referred to at any time. Additionally the study and its results will be written up as a chapter of a PhD study looking into rehabilitation of pelvic and spinal stability on Earth and in space. The PhD chapter will also be anonymised and contain no data related to the identity of participants.

Ethical approval: The study has received full ethical approval from the Faculty of Health and Life Sciences Ethics Committee. If you require confirmation about this, please contact the chair of the committee, stating the title of the research project:

Dr Nick Neave, Chair of the Faculty of Health and Life Sciences Ethics Committee, Northumberland Building, Northumbria University, Newcastle upon Tyne, NE1 8ST

nick.neave@northumbria.ac.uk

You can also contact him if you would like to discuss the study with somebody other than the research team or if you want to register an official complaint about the study.

If, after reading this information sheet, you decide that you would like to take part, speak to us at the stand. You will need to sign a consent form and get your participant number.

Many thanks for taking the time to read this information sheet

FRED

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D. Chapter four and five informed consent form

Meet the Scientist – SMALL Project 2014

Consent Form

V.1.0

Participant 1

I have read and understood the participant information sheet "Meet the Scientist – SMALL project 2014 v1.0". I have had chance to ask questions and these have been answered.

I confirm that I do not have any of the exclusion criteria.

I understand my participation is voluntary and that I am free to withdraw from the study at any time without needing to give any reason.

I am happy to be involved in the studies outlined in the participant information sheet "Meet the Scientist – SMALL Project 2014 v1.0"

I am happy for anonymised data to be collected and analysed from my participation in the studies. I understand this will be kept safe and confidential.

I understand and agree to video and images of my movements possibly being recorded during the studies.

Name of Participant | Date | Signature

If you would like to receive a summary of the overall results after the studies are complete, then please provide an email address below.
We are only able to provide a summary of the raw data with no interpretation.

Email:

FRED

northumbria UNIVERSITY NEWCASTLE

Participant number
Tear off corner and carry with you to all studies

1

E. Chapter five and six participant information sheet

Can you take part?

Yes, if you want to – provided:

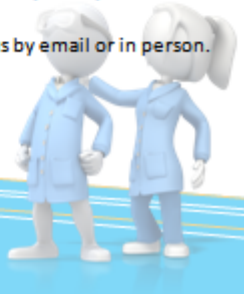
1. You don't have heart disease or epilepsy.
2. You are not pregnant.
3. You have not had abdominal or spinal surgery in the last three years.
4. You don't have an abnormal spinal curve that prevents you from standing up straight.
5. **You can answer no to ALL of the important medical questions below.**
6. You sign a consent form.

Age restrictions apply to FRED – only 18-55 year olds can join in this activity!

To check you can safely do exercise with us today, we can only let you take part if you can honestly answer no to all the following questions:

1. Has your doctor ever said that you have a heart condition *and* that you should only do physical activity recommended by a doctor?
2. Do you feel pain in your chest when you do physical activity?
3. In the past month, have you had chest pain when you were not doing physical activity?
4. Do you lose your balance because of dizziness or do you ever lose consciousness?
5. Do you have a bone or joint problem that could be made worse by a change in your physical activity?
6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
7. Do you know of *any other reason* why you should not do physical activity?

It is up to you whether or not you take part. You can also leave the study at any time without explanation or justification, and this will not affect you in any way.
If you do want to withdraw your data from this project at any time, simply contact us by email or in person.



You can contact us at the following email:
Andrew.Winnard@northumbria.ac.uk

FRED

northumbria
UNIVERSITY NEWCASTLE

Data and Ethical Information

Confidentiality: You will be allocated a participant number that will be used to identify any data that you provide. Your name or other personal details will not be associated with your data; for example, the consent form that you sign will be kept separate from your data. All data will be stored anonymously and securely, and deleted within three years.

Information you provide and the data we collect will be seen only by the research team. All records will be kept confidential except for potential auditing (to check that the correct procedures have been followed) by Northumbria University Ethics Committee and/or regulatory authorities.

Data may be published in peer-reviewed journals or presented at conferences; however all data will be anonymised and any personal information will not be referred to at any time. Additionally the study and its results will be written up as a chapter of a PhD study looking into rehabilitation of pelvic and spinal stability on Earth and in space. The PhD chapter will also be anonymised and contain no data related to the identity of participants.

Ethical approval: The study has received full ethical approval from the Faculty of Health and Life Sciences Ethics Committee. If you require confirmation about this, please contact the chair of the committee, stating the title of the research project:

Dr Nick Neave, Chair of the Faculty of Health and Life Sciences Ethics Committee, Northumberland Building, Northumbria University, Newcastle upon Tyne, NE1 8ST

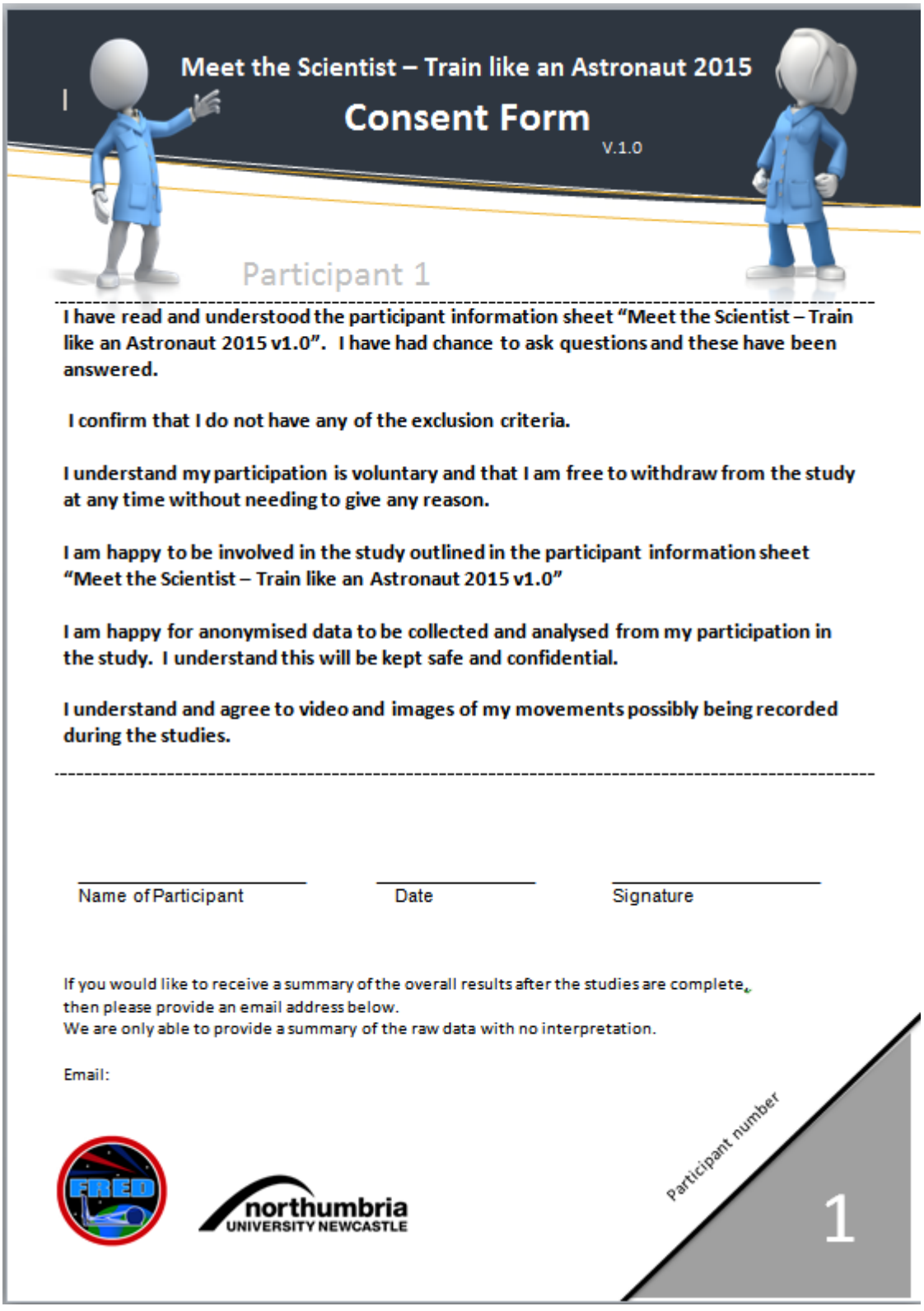
nick.neave@northumbria.ac.uk

You can also contact him if you would like to discuss the study with somebody other than the research team or if you want to register an official complaint about the study.

If, after reading this information sheet, you decide that you would like to take part, speak to us at the stand. You will need to sign a consent form and get your participant number.

Many thanks for taking the time to read this information sheet

F. Chapter five and six informed consent form



Meet the Scientist – Train like an Astronaut 2015

Consent Form

V.1.0

I

Participant 1

I have read and understood the participant information sheet "Meet the Scientist – Train like an Astronaut 2015 v1.0". I have had chance to ask questions and these have been answered.

I confirm that I do not have any of the exclusion criteria.

I understand my participation is voluntary and that I am free to withdraw from the study at any time without needing to give any reason.

I am happy to be involved in the study outlined in the participant information sheet "Meet the Scientist – Train like an Astronaut 2015 v1.0"

I am happy for anonymised data to be collected and analysed from my participation in the study. I understand this will be kept safe and confidential.

I understand and agree to video and images of my movements possibly being recorded during the studies.

Name of Participant _____ Date _____ Signature _____

If you would like to receive a summary of the overall results after the studies are complete, then please provide an email address below.
We are only able to provide a summary of the raw data with no interpretation.

Email:

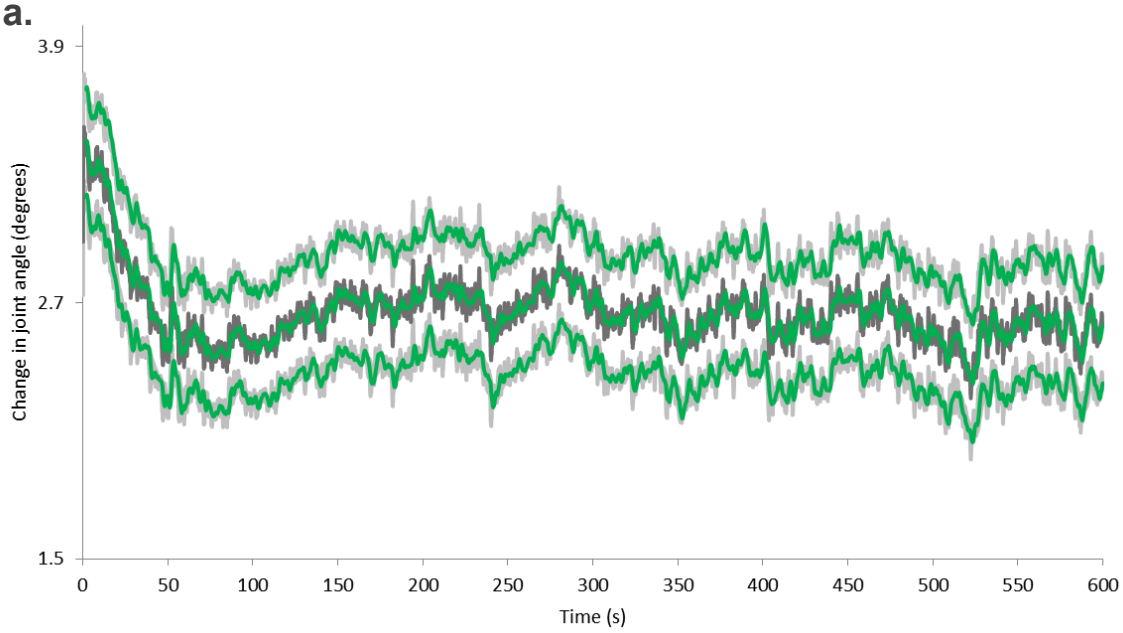
FRED

northumbria UNIVERSITY NEWCASTLE

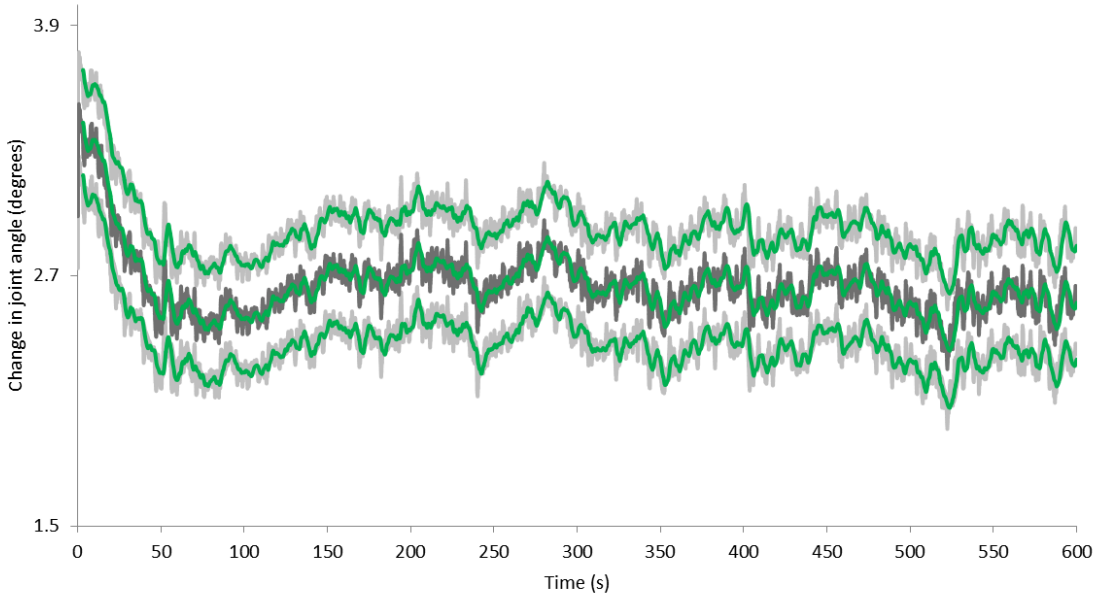
Participant number 1

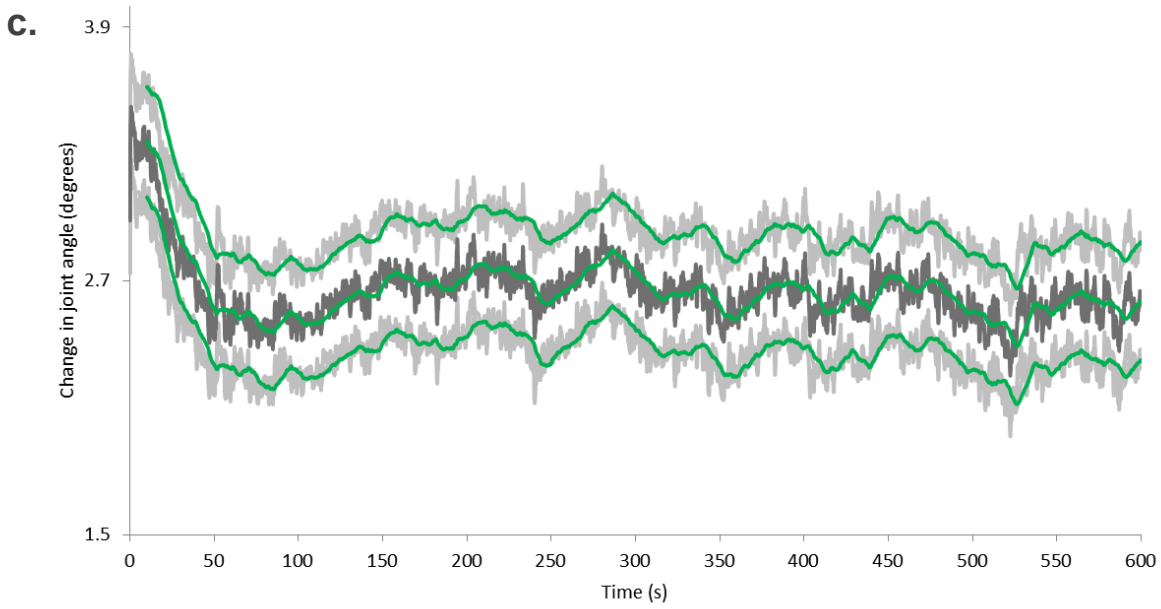
G. Data filtering results for chapters 6 and 7

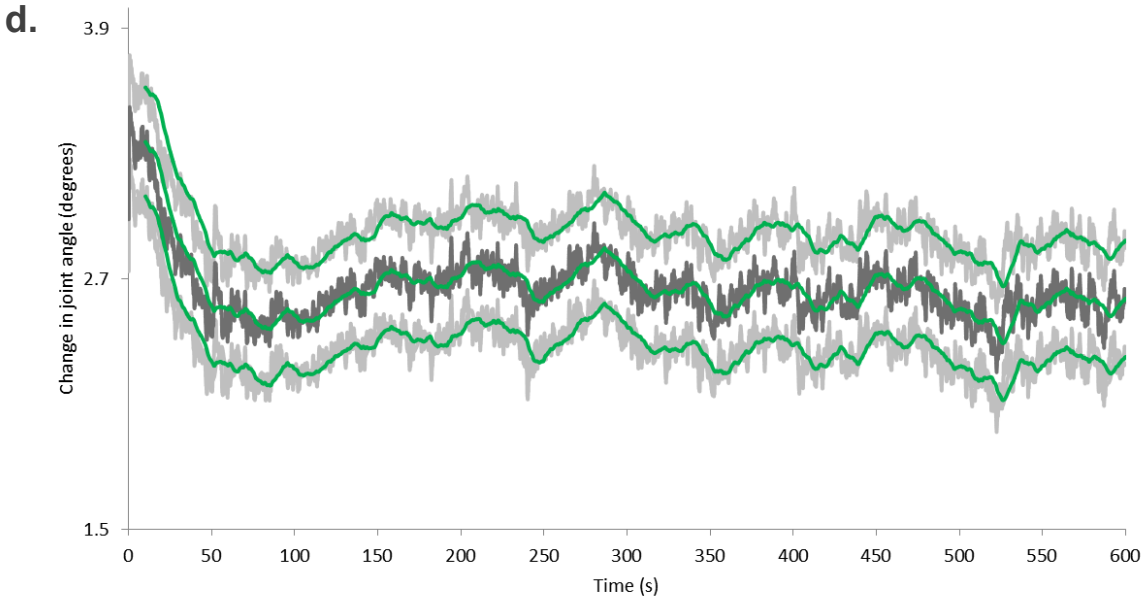
a.



b.







Figures showing various data filtering options (green lines) compared to original data (grey lines) tested using mean L5/S1 flexion angle as a function of time, with moving average periods of; a. 161, b. 241, c. 401 and d. 801.

H. Familiarisation figures for chapter 6

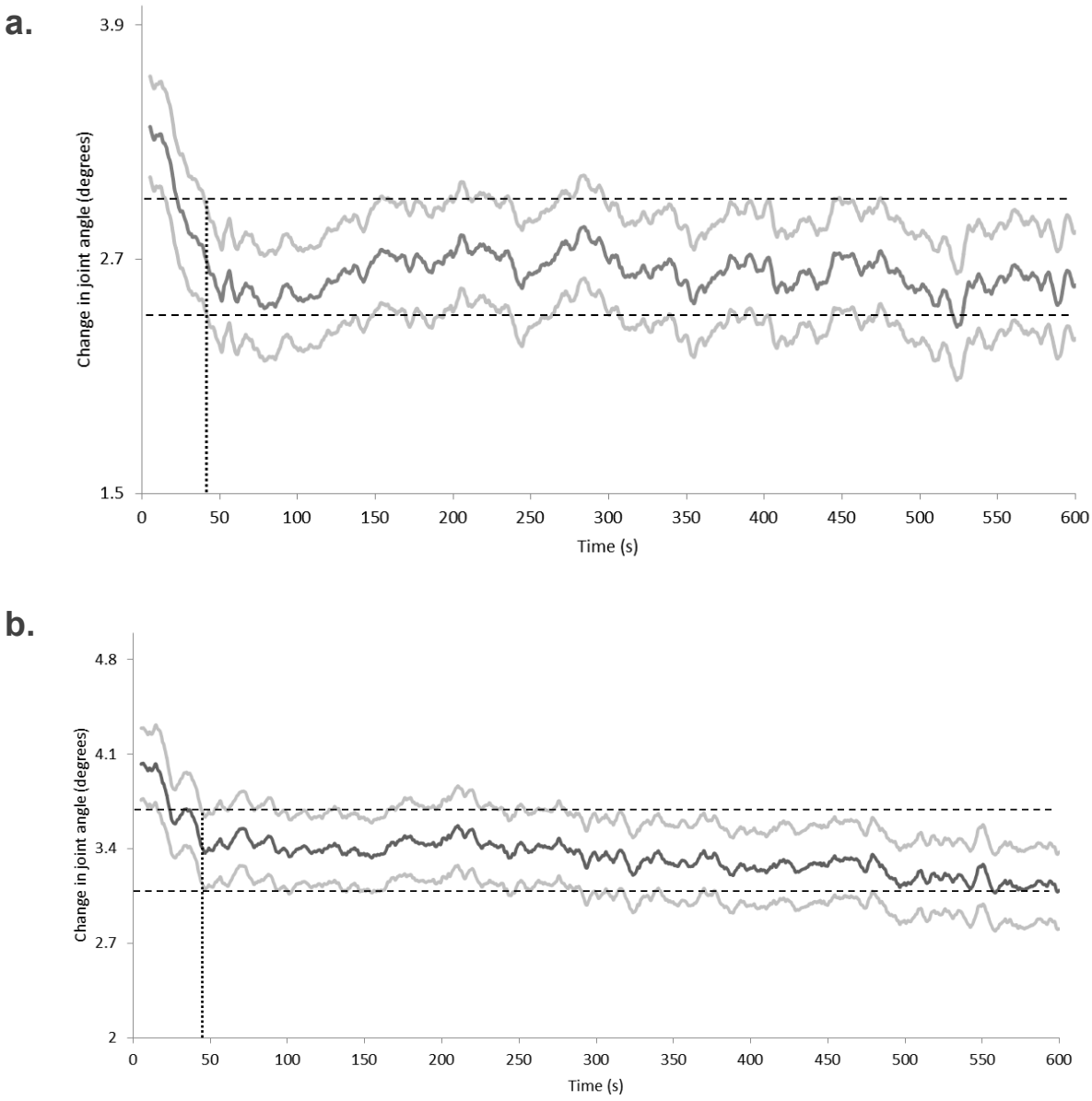


Figure H-1 Mean L5/S1 flexion angle across all participants throughout the 600 second trial in; a. the no-LBP group and b. the LBP group. Familiarisation range shown on plots between dashed lines is no-LBP group: 2.7±0.3, LBP group: 3.4±0.3 (degrees).

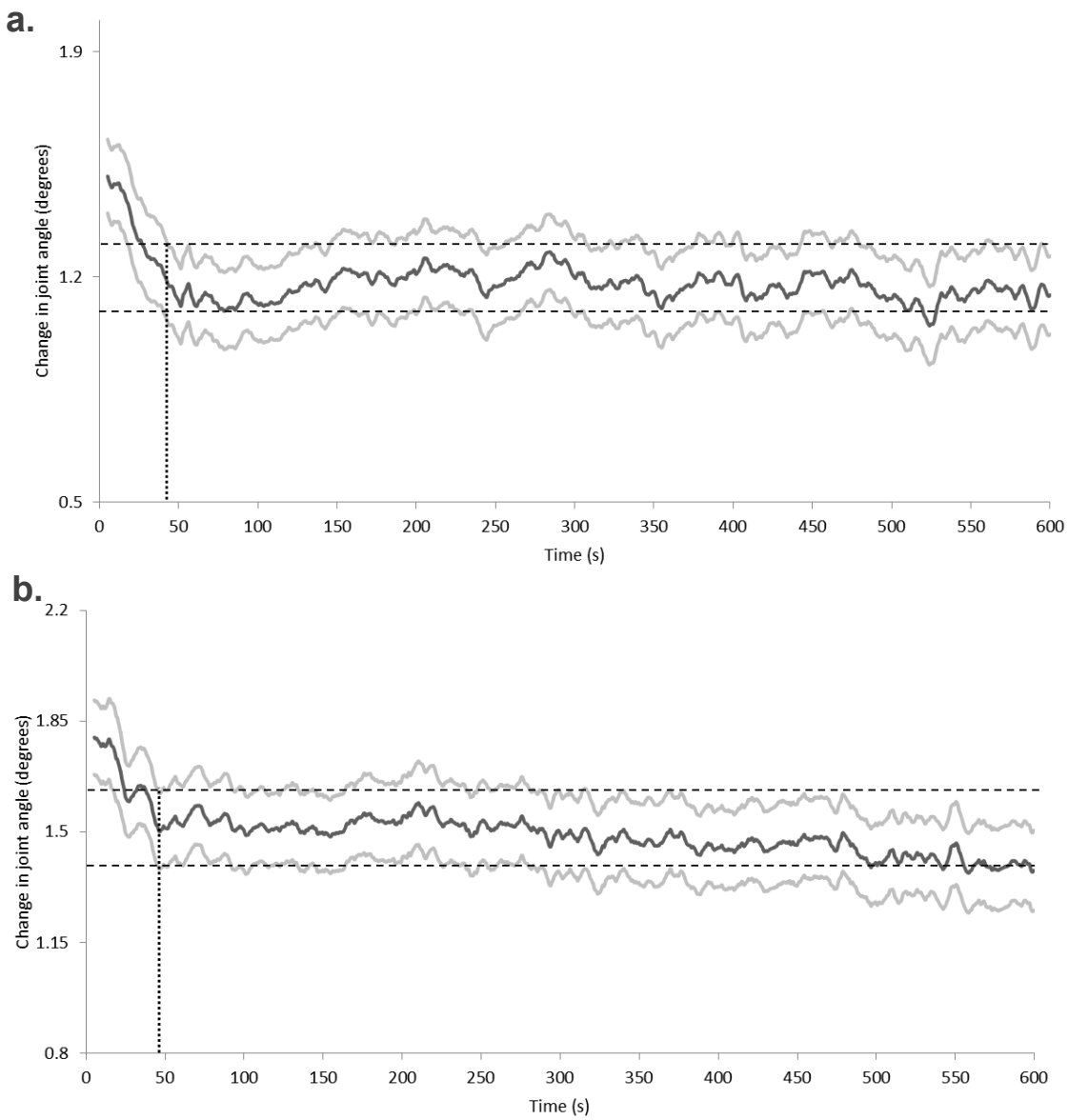


Figure H-2 Mean L3/L4 flexion angle across all participants throughout the 600 second trial in; a. the no-LBP group and b. the LBP group. Familiarisation ranges shown on plots between dashed lines is no-LBP group: 1.2±0.1, LBP group: 1.5±0.1 (degrees)

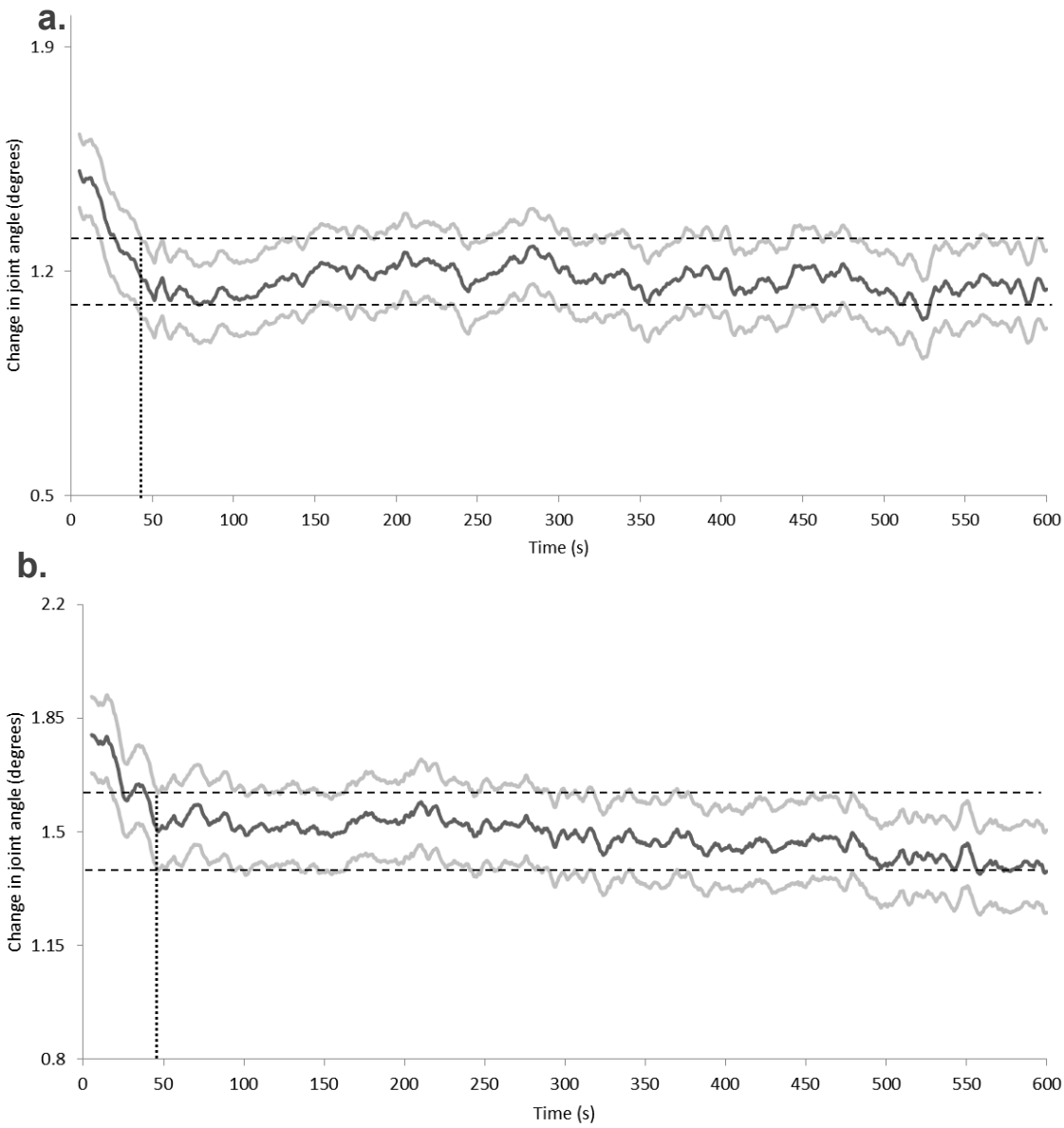


Figure H-3 Mean T12/L1 flexion angle across all participants throughout the 600 second trial in; a. the no-LBP group and b. the LBP group. Familiarisation ranges shown on plots between dashed lines is no-LBP group: 1.2±0.1, LBP group: 1.5±0.1 (degrees)

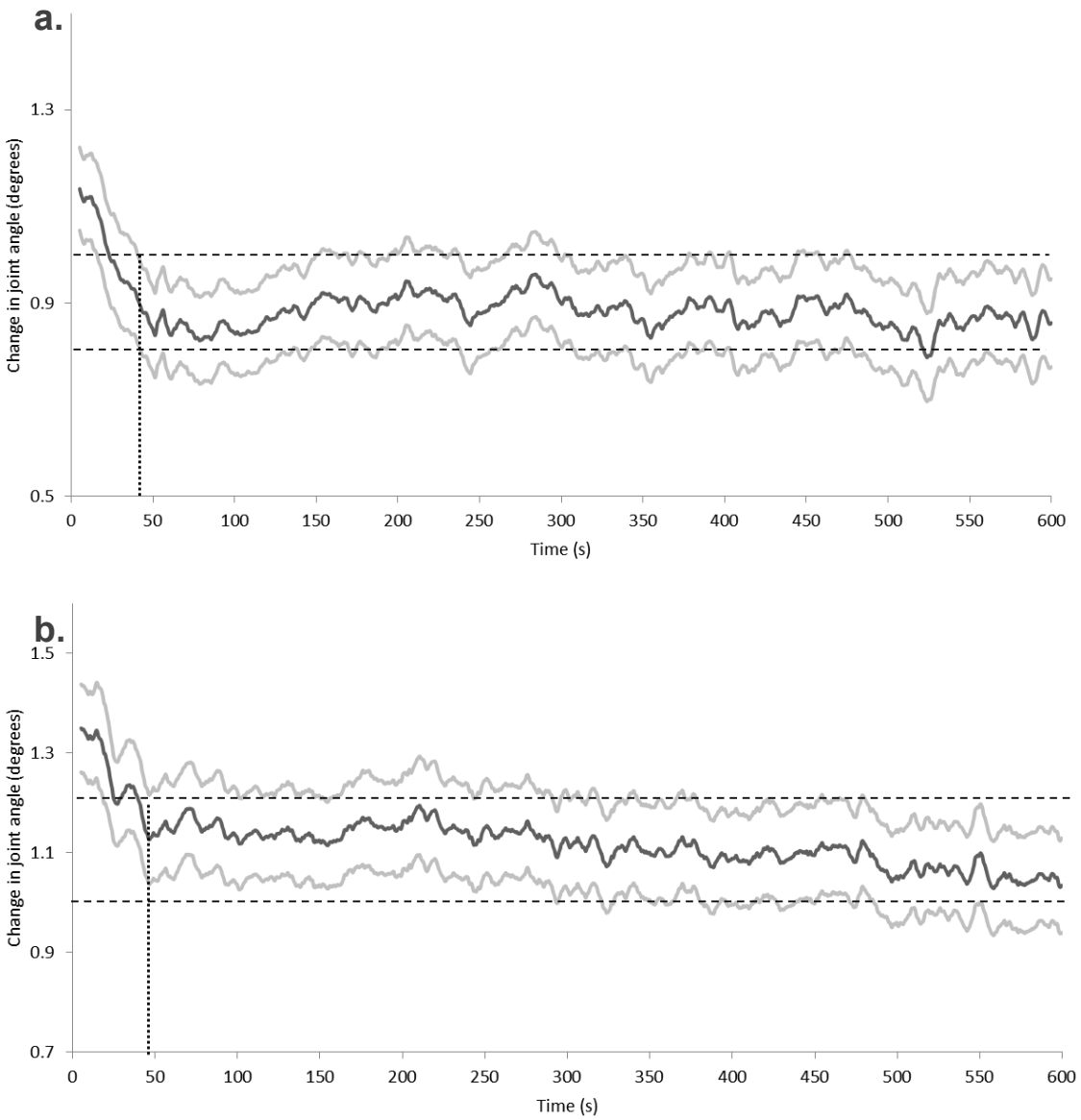


Figure H-4 Mean T9/T8 flexion angle across all participants throughout the 600 second trial in; a. the no-LBP group and b. the LBP group. Familiarisation ranges shown on plots between dashed lines is no-LBP group: 0.9±0.1, LBP group: 1.1±0.1 (degrees)

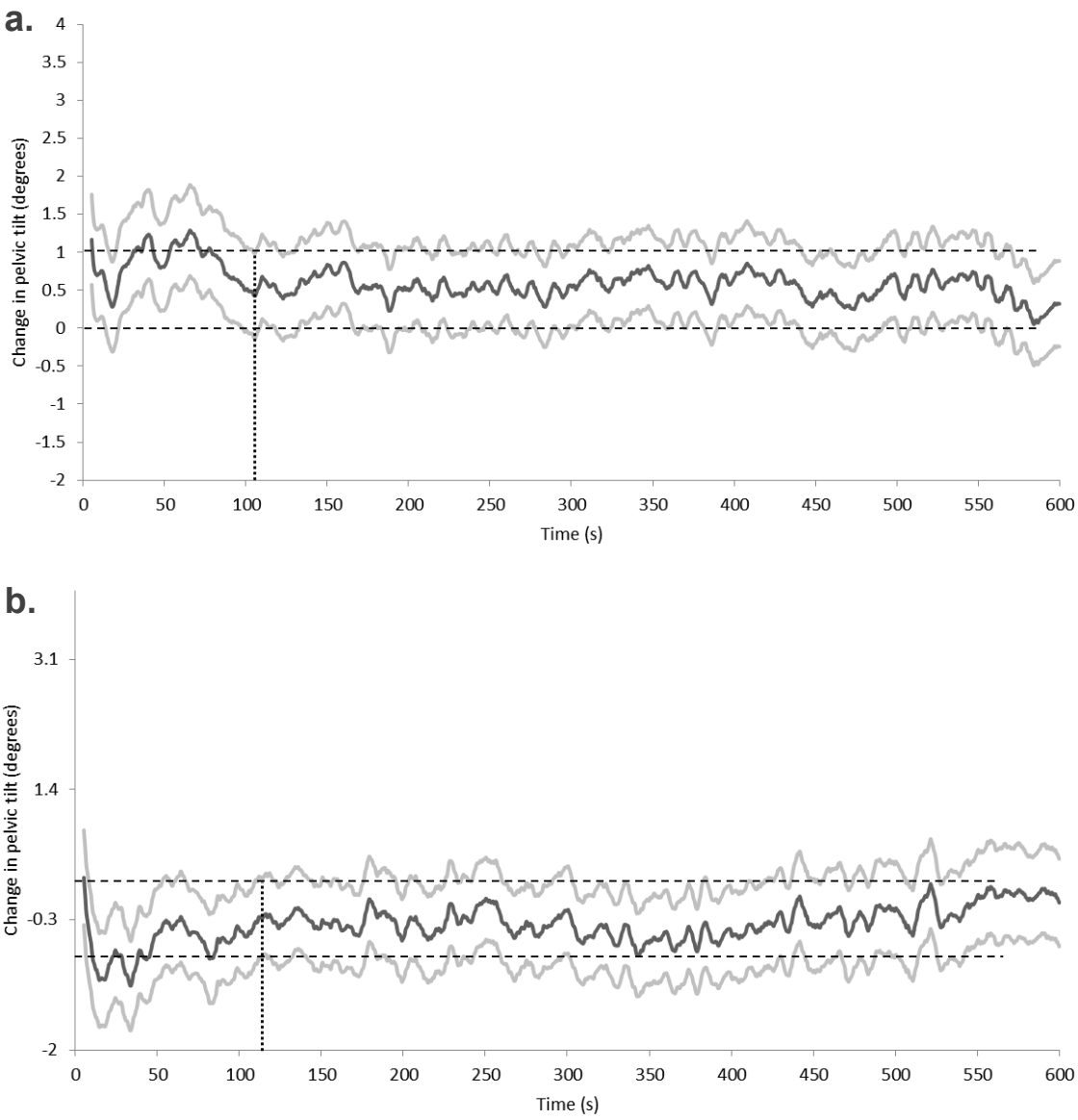


Figure H-5 Mean sagittal plane (anterior) pelvic tilt across all participants throughout the 600 second trial in; a. the no-LBP group and b. the LBP group. Familiarisation ranges shown on plots between dashed lines is no-LBP group: 0.5±0.5 LBP group: -0.3±0.5 (degrees)

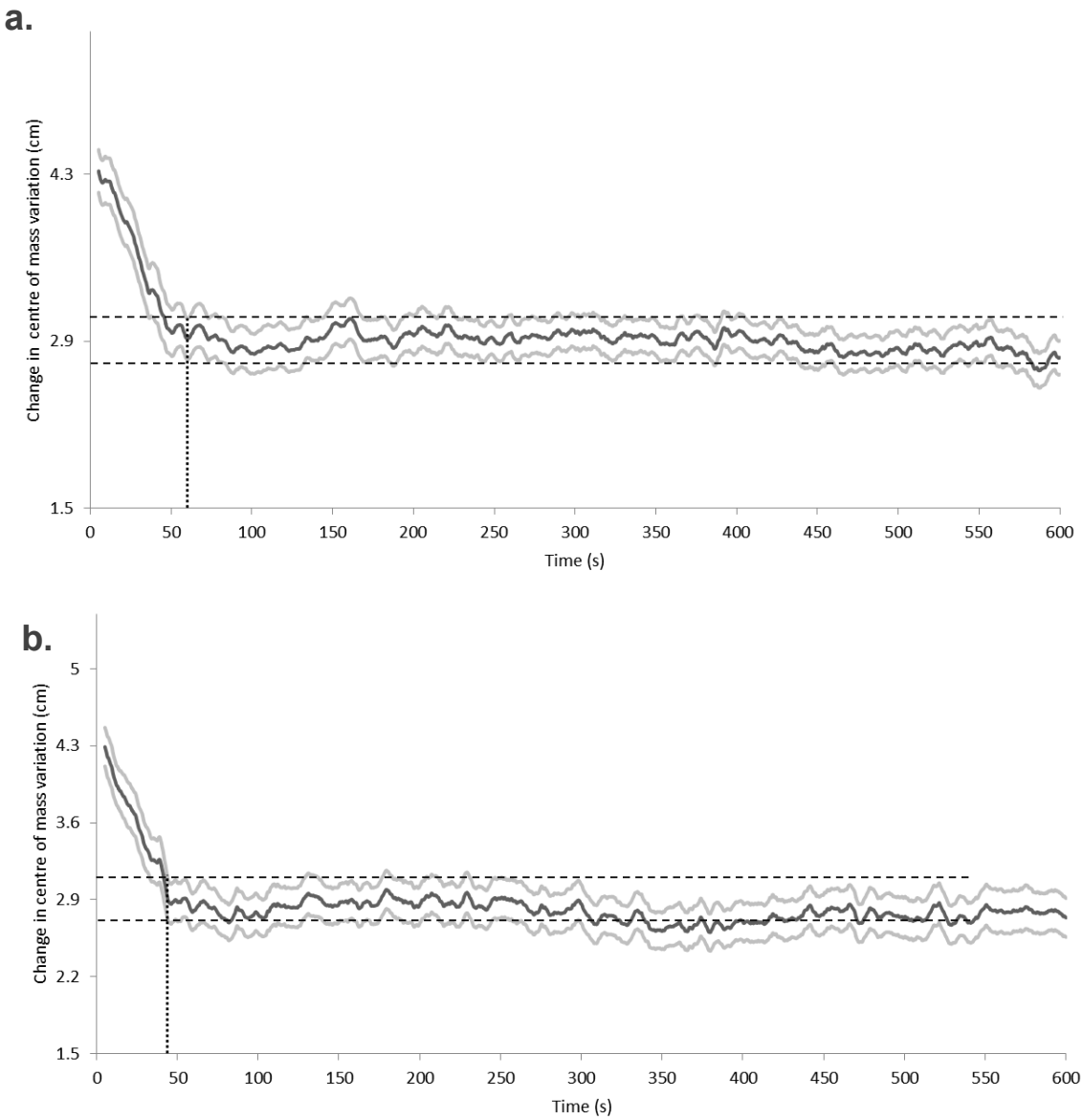


Figure H-6 Mean anteroposterior centre of mass variation across all participants throughout the 600 second trial in; a. the no-LBP group and b. the LBP group. Familiarisation ranges shown on plots between dashed lines is no-LBP group: 2.9±0.2,LBP group: 2.9±.0.2 (cm)

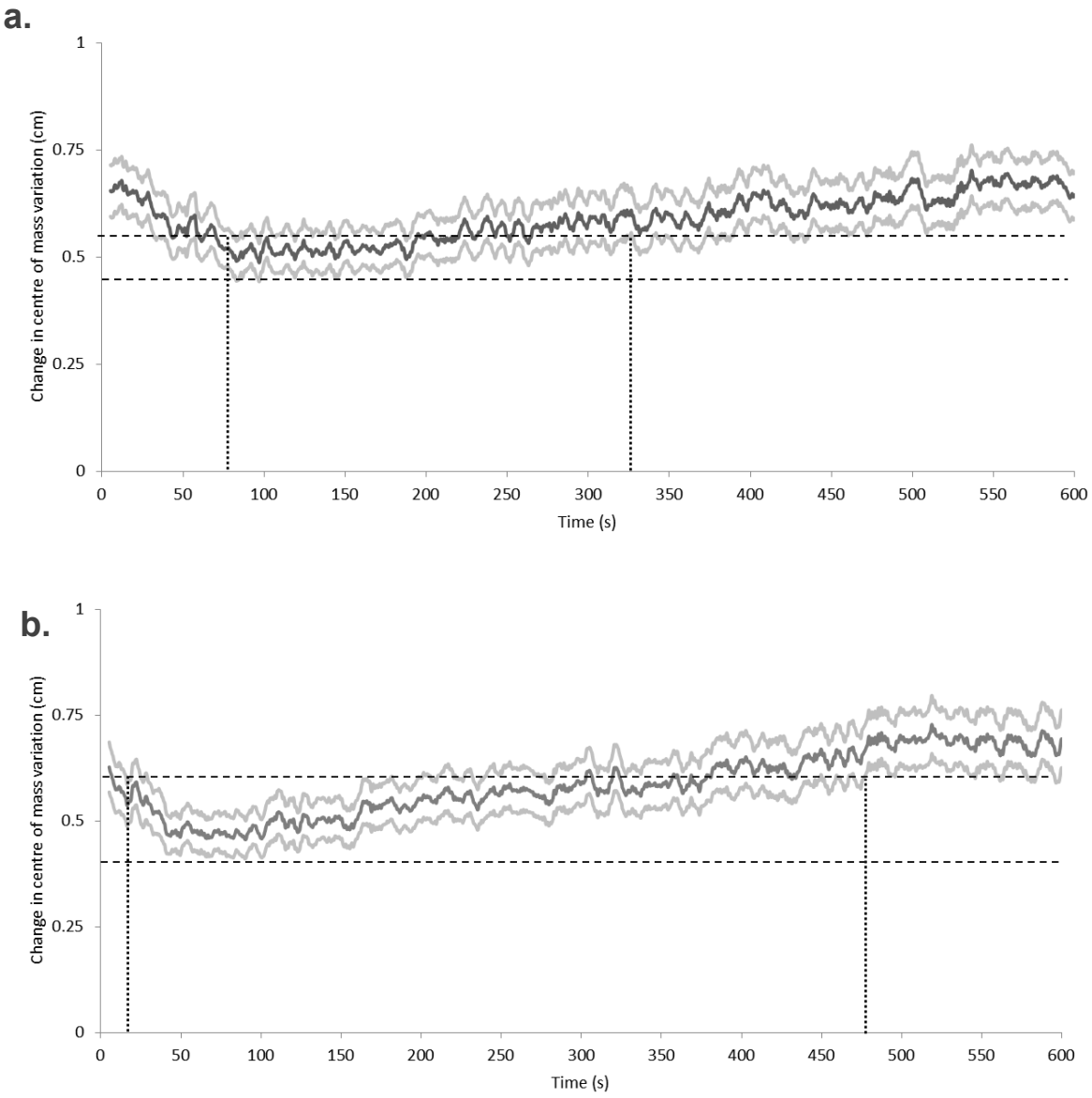


Figure H-7 Mean mediolateral centre of mass variation across all participants throughout the 600 second trial in; a. the no-LBP group and b. the LBP group. Familiarisation ranges shown on plots between dashed lines is no-LBP group: 0.5±0.05, LBP group: 0.5±0.1 (cm)

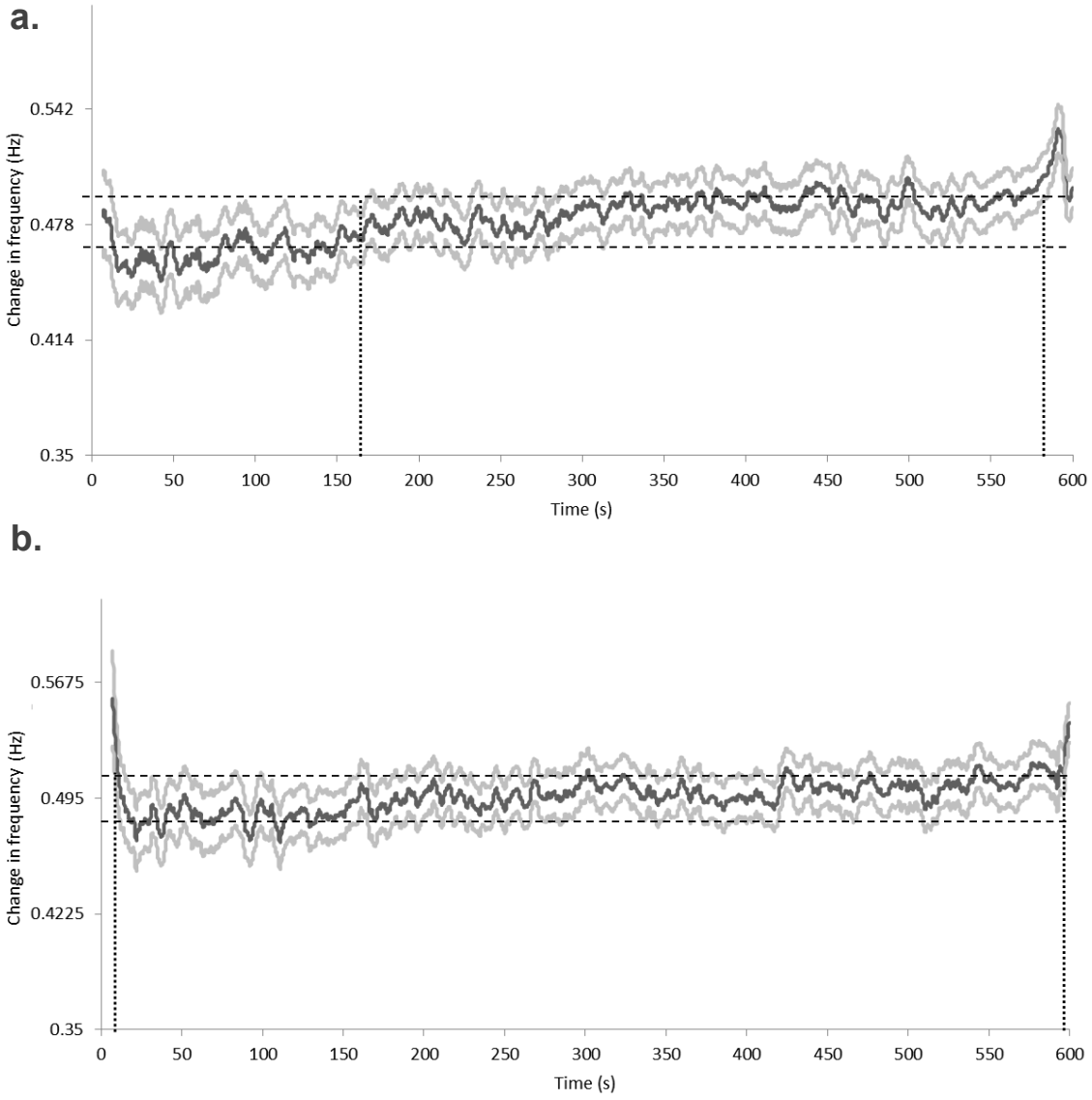


Figure H-8 Mean exercise frequency (f) across all participants throughout the 600 second trial in; a. the no-LBP group and b. the LBP group. Familiarisation ranges shown on plots between dashed lines is: no-LBP group: 0.478±0.014, LBP group: 0.495±0.014 (Hz)

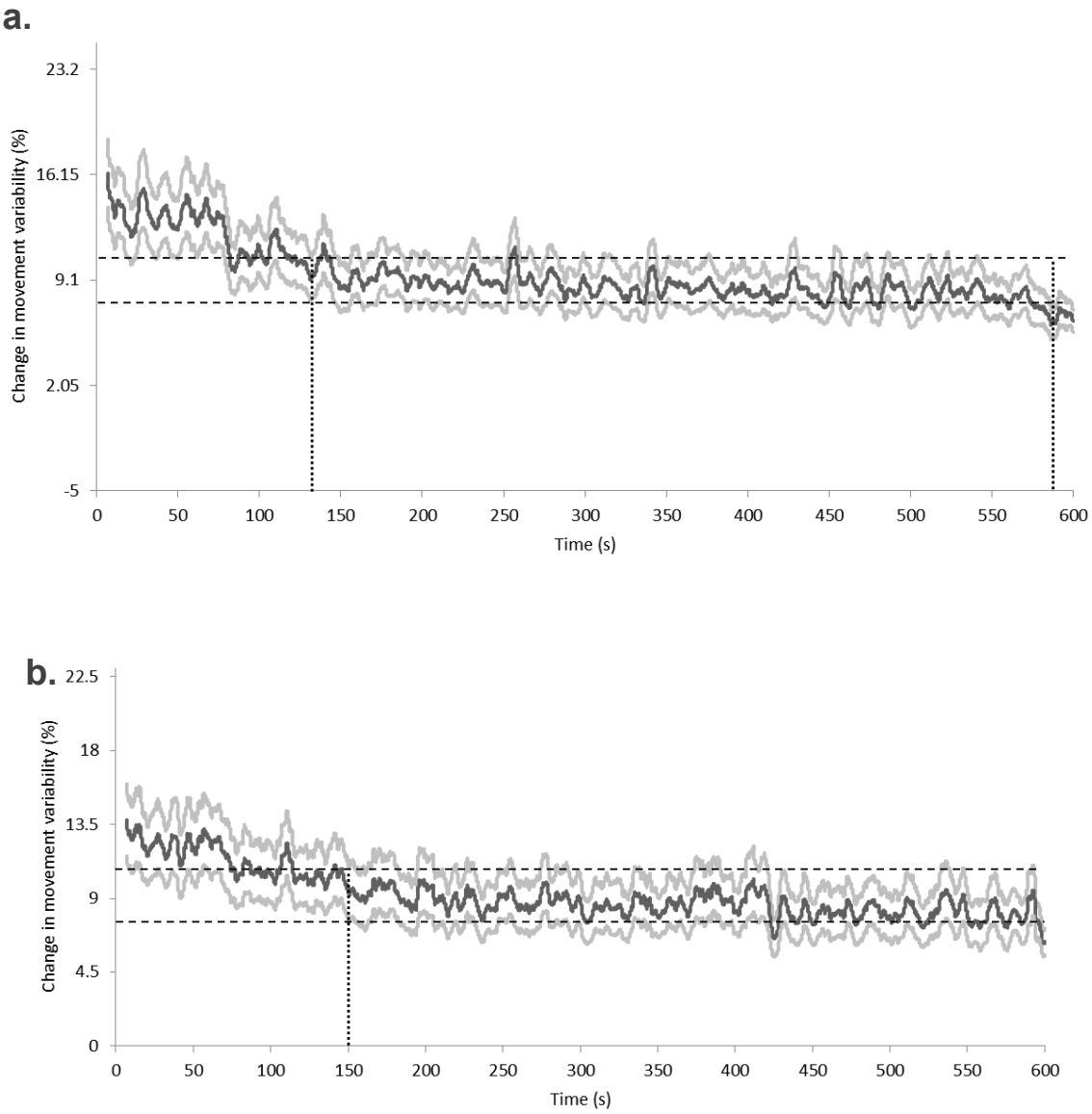


Figure H-9 Mean FRED movement variability across all participants throughout the 600 second trial in; a. the no-LBP group and b. the LBP group. Familiarisation ranges shown on plots between dashed lines is no-LBP group is: 9.1±1.5 LBP group: 9.0±1.6 (%)

I. Familiarisation figures for chapter 7

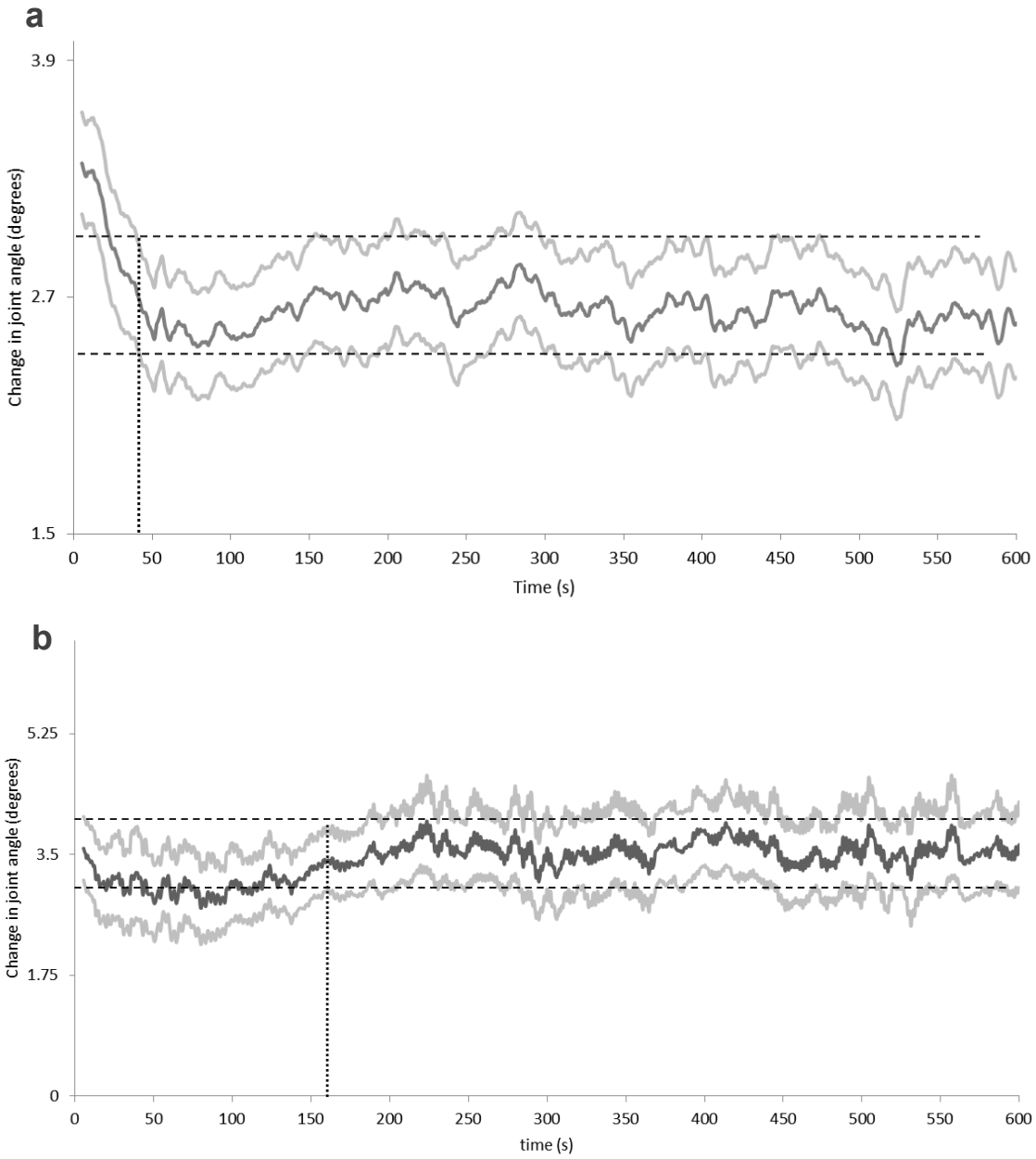


Figure I-1 Mean L5/S1 flexion angle across all participants throughout the 600 second trial in; a. the no-holding group and b. the holding group. Familiarisation range shown on plots between dashed lines is 2.7 ± 0.3 in the no-holding group and 3.5 ± 0.5 in the holding group (degrees).

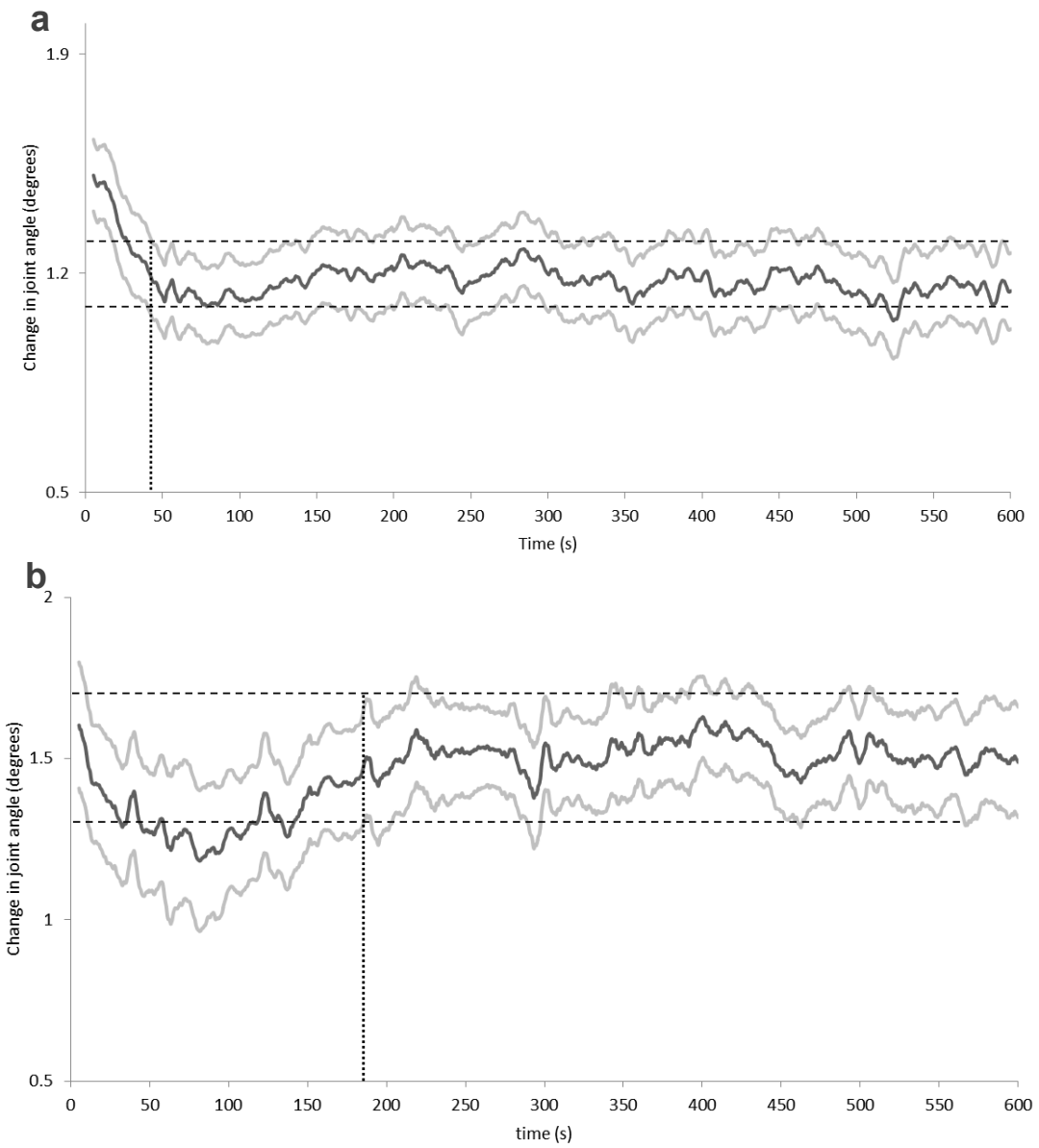


Figure I-2 Mean L3/L4 flexion angle across all participants throughout the 600 second trial in; a. the no-holding group and b. the holding group. Familiarisation ranges shown on plots between dashed lines is 1.2 ± 0.1 in the no-holding group and 1.5 ± 0.2 in the holding group (degrees)

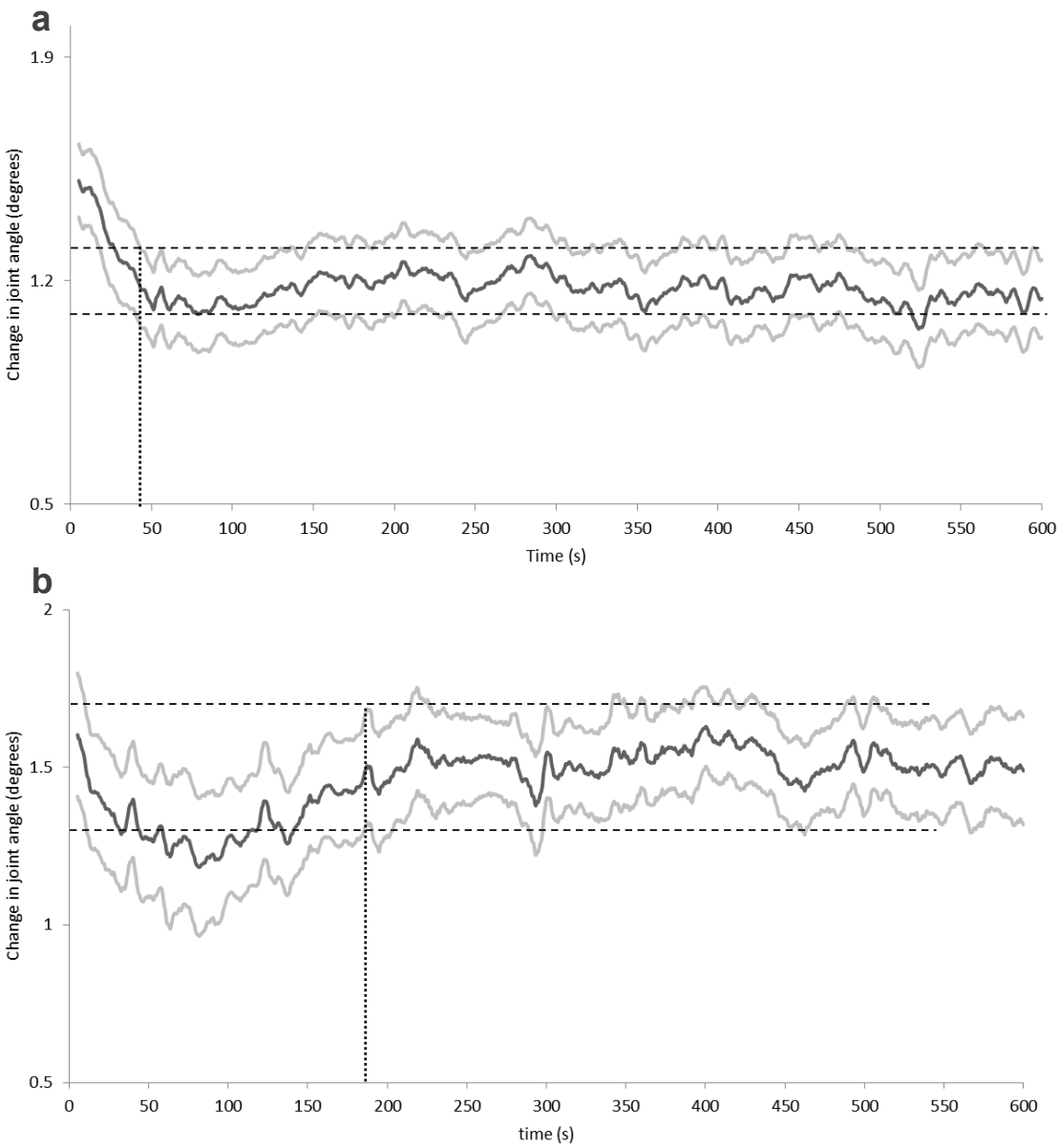


Figure I-3 Mean T12/L1 flexion angle across all participants throughout the 600 second trial in; a. the no-holding group and b. the holding group. Familiarisation ranges shown on plots between dashed lines is 1.2 ± 0.1 in the no-holding group and 1.5 ± 0.2 in the holding group (degrees)

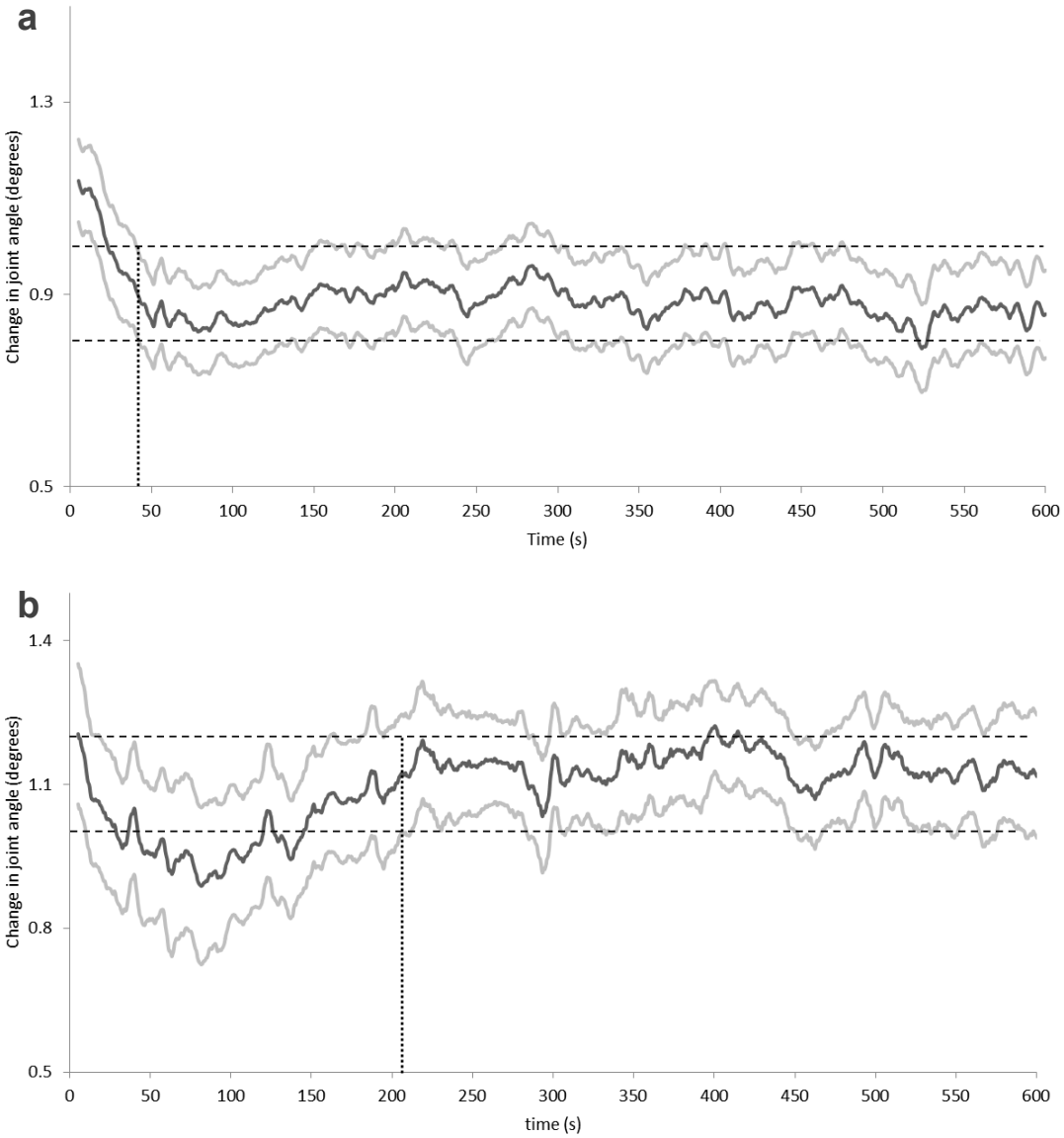


Figure I-4 Mean T8/T9 flexion angle across all participants throughout the 600 second trial in; a. the no-holding group and b. the holding group. Familiarisation ranges shown on plots between dashed lines is 0.9 ± 0.1 for the no-holding group and 1.1 ± 0.1 for the holding group (degrees)

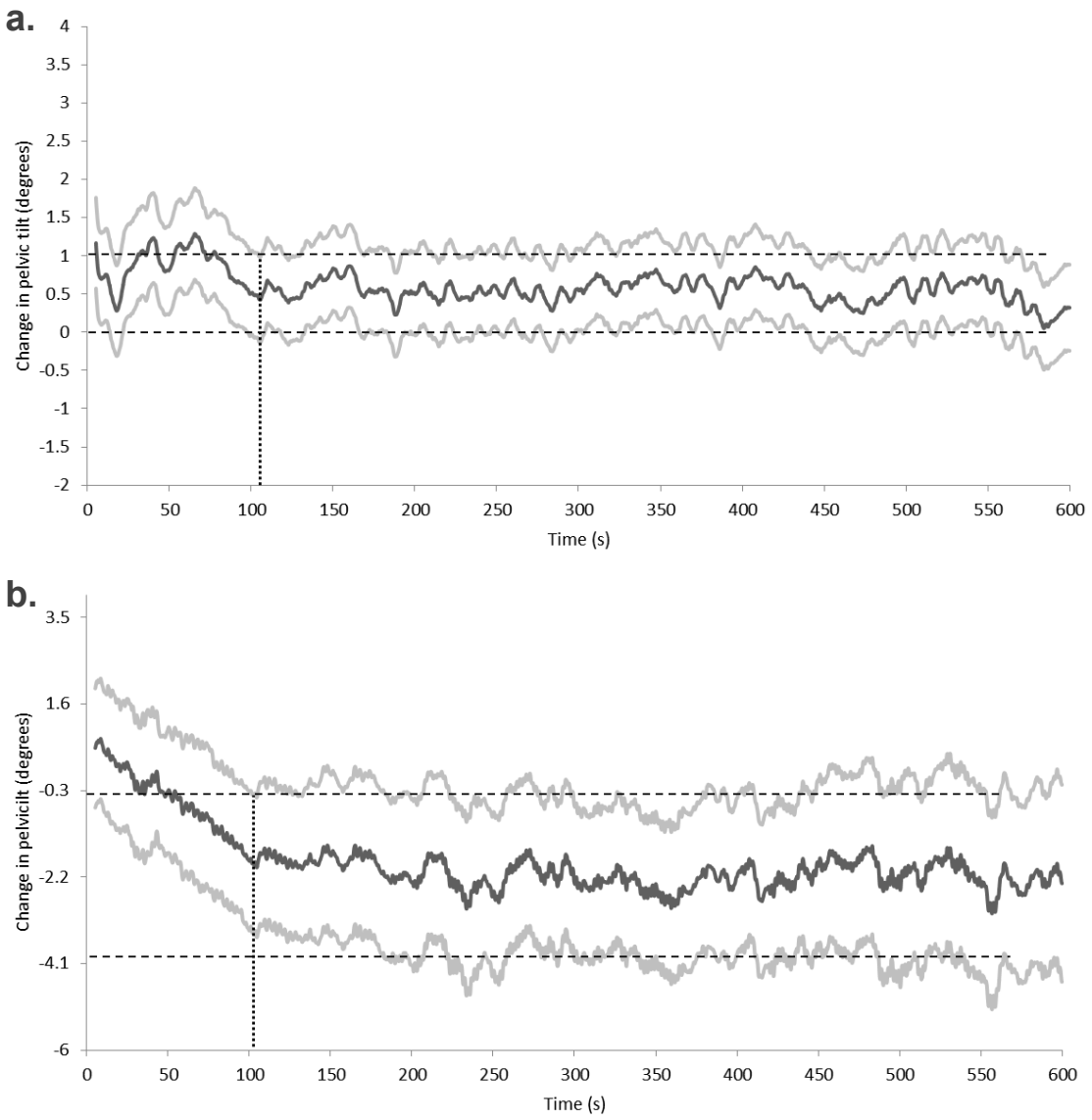


Figure I-5 Mean sagittal plane (anterior) pelvic tilt across all participants throughout the 600 second trial in; a. the no-holding group and b. the holding group. Familiarisation ranges shown on plots between dashed lines is 0.5 ± 0.5 in the no-holding group and -2.1 ± 1.8 in the holding group (degrees)

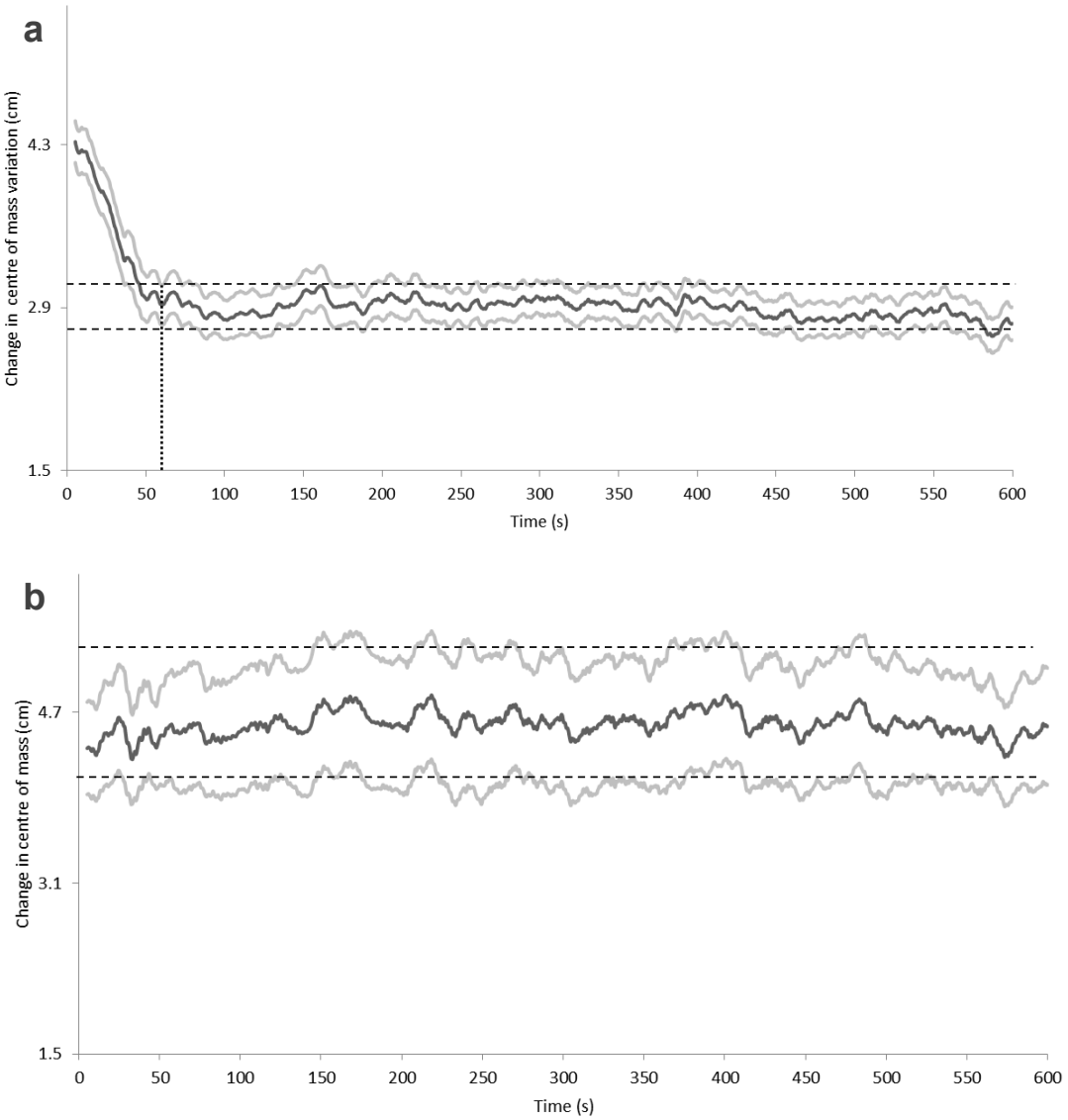


Figure I-6 Mean anteroposterior centre of mass variation across all participants throughout the 600 second trial in; a. the no-holding group and b. the holding group. Familiarisation ranges shown on plots between dashed lines is 2.9 ± 0.2 for the no-holding group and 4.7 ± 0.6 (cm)

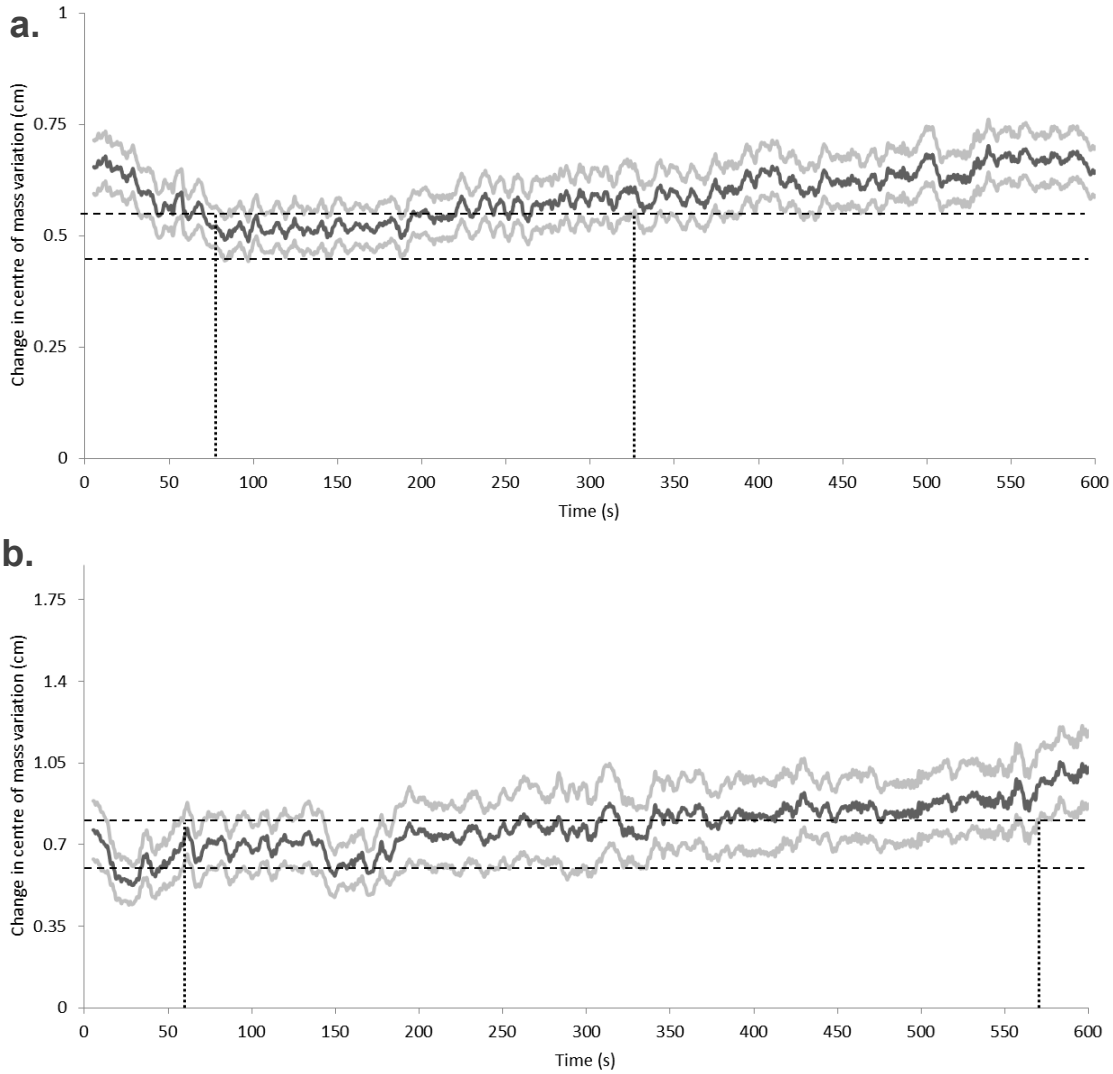


Figure I-7 mean mediolateral centre of mass variation across all participants throughout the 600 second trial in; a. the no-holding group and b. the holding group. Familiarisation ranges shown on plots between dashed lines is 0.5 ± 0.05 in the no-holding group and 0.7 ± 0.1 in the holding group (cm)

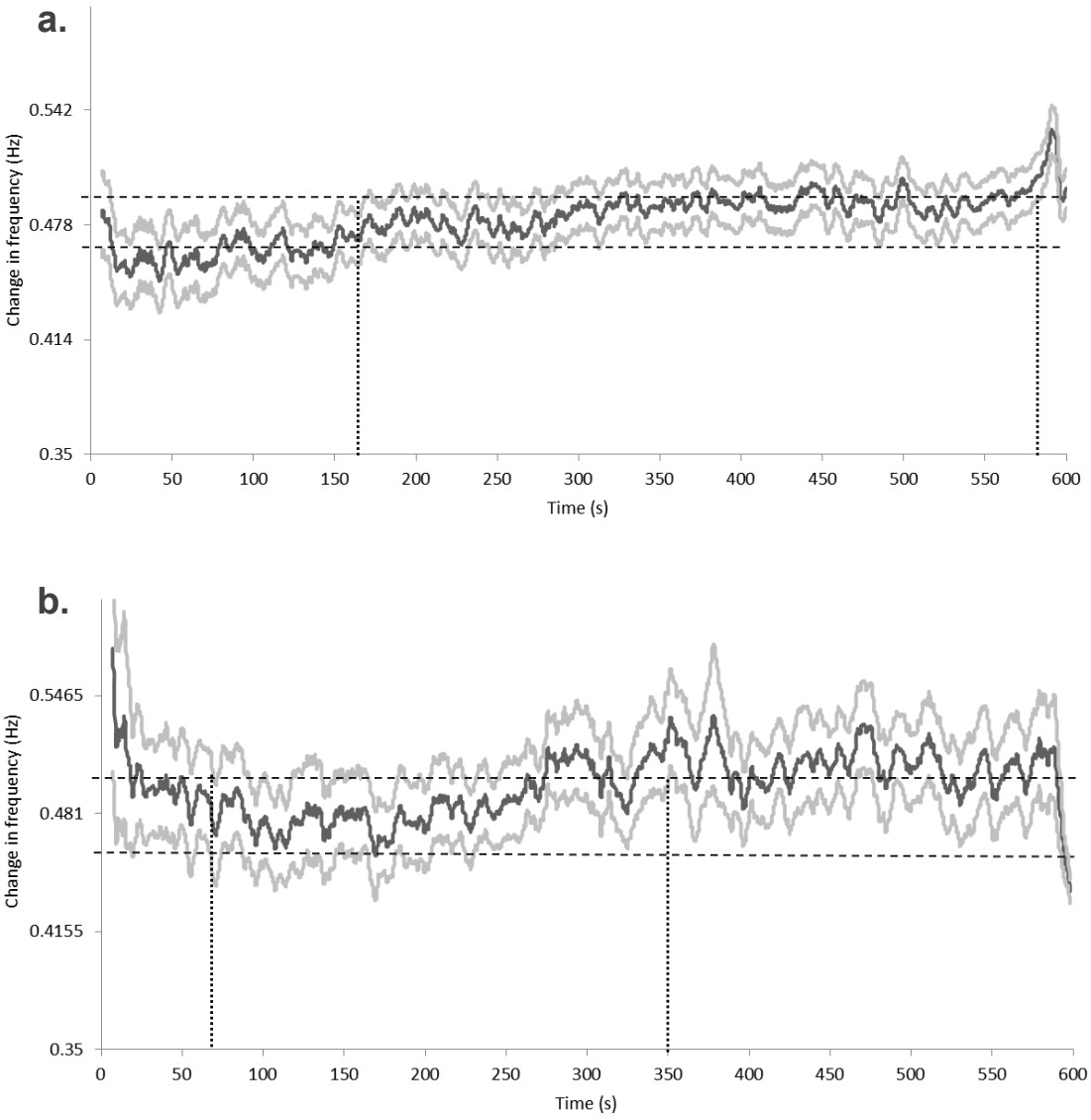


Figure I-8 Mean exercise frequency (f) across all participants throughout the 600 second trial in; a. the no-holding group and b. the holding group. Familiarisation ranges shown on plots between dashed lines is 0.478 ± 0.014 Hz in the no-holding group and 0.481 ± 0.021 Hz in the holding group.

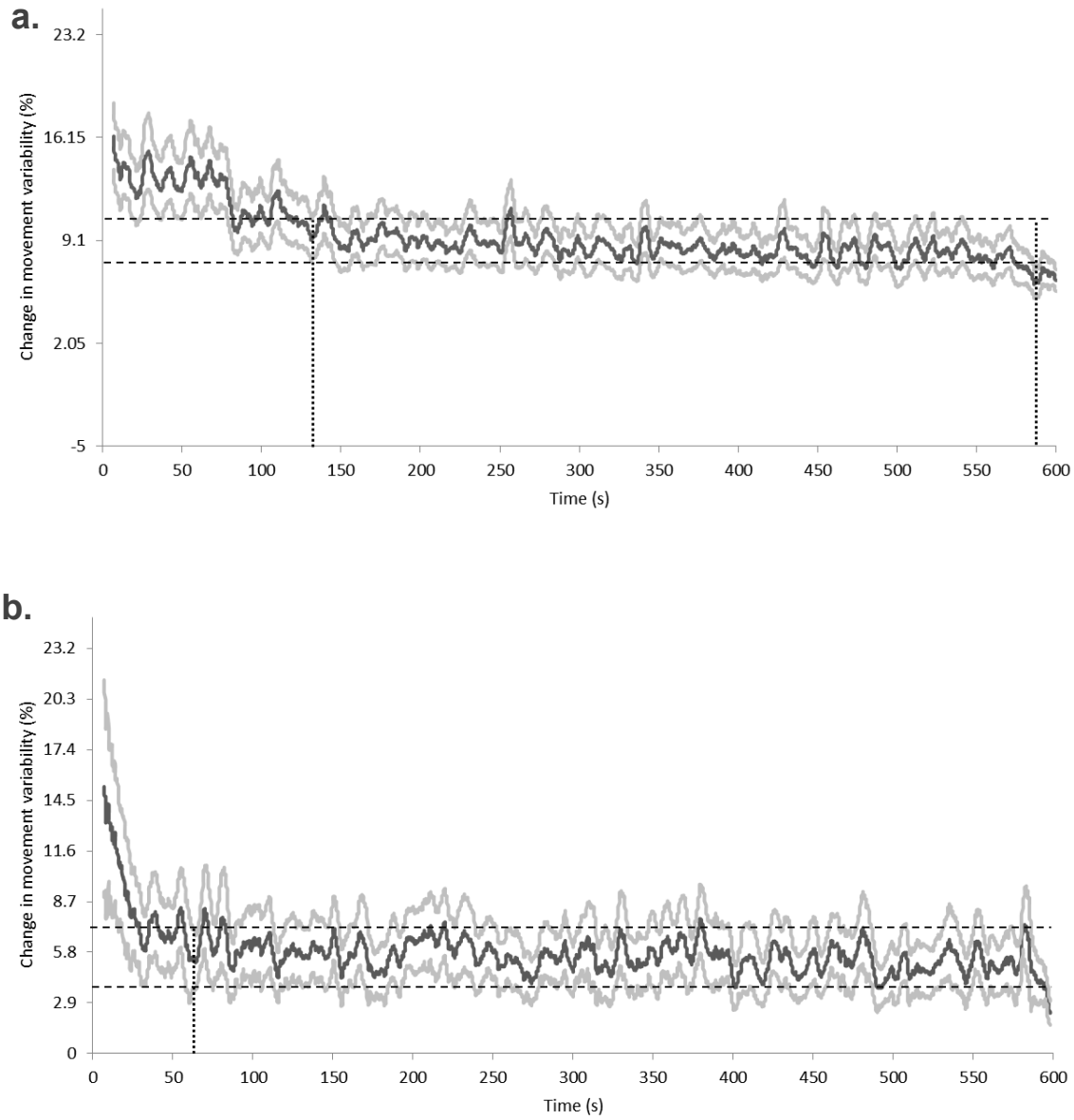


Figure I-9 Mean FRED movement variability across all participants throughout the 600 second trial in; a. the no-holding group and b. the holding group. Familiarisation ranges shown on plots between dashed lines is 9.1 ± 1.5 in the no-holding group and 5.8 ± 1.7 in the holding group (%)

J. Ethics approval notifications

For the study in chapter three, the ethical approval process was handled by PhD supervisor Dr Dorothee Debuse and notification sent via emails as below

Dorothee Debuse <dorothee.debuse@northumbria.ac.uk> 04/12/2013

to me

Hi Andrew,
The number is: RE-HLS-12-130828-521e020c6e066
Approval was granted on 29.10.13.

Will find out for you when it was initiated. Will have to go into the system tomorrow morning (nothing on paper any more, not even an approval letter!).

BW,
Dorothée

Dr Dorothée Debuse, PhD
Senior Lecturer in Physiotherapy
Room H014, Coach Lane Campus
Faculty of Health and Life Sciences
Northumbria University

Dorothee Debuse <dorothee.debuse@northumbria.ac.uk> 04/12/2013

to me

Hi Andrew,
The number is: RE-HLS-12-130828-521e020c6e066
Approval was granted on 29.10.13.

Will find out for you when it was initiated. Will have to go into the system tomorrow morning (nothing on paper any more, not even an approval letter!).

BW,
Dorothée

Dr Dorothée Debuse, PhD
Senior Lecturer in Physiotherapy
Room H014, Coach Lane Campus
Faculty of Health and Life Sciences
Northumbria University

For the studies in chapters four and five:

Staff/PGR research ethics review

Project title:	*Study of the effect of visual feedback on posture and control of movement during exercise on the FRED exercise device*
Investigator name:	*Andrew Winnard*
Ethics code:	*RE-HLS-13-140226-530daf3adf083*
General	
Project risk level:	*Amber*
Decision:	*APPROVED WITH MINOR AMENDMENTS: There are some minor ethical issues to be addressed. These have been outlined in attached review*

For the studies in chapters six and seven:

from:	Mic Wilkinson <mic.wilkinson@northumbria.ac.uk>
to:	"Andrew Winnard (ajwinnard@gmail.com) (ajwinnard@gmail.com)" <ajwinnard@gmail.com>
date:	30 April 2015 at 11:29
subject:	Ethics decision
mailed-by:	northumbria.ac.uk

Hi Andrew,

The project listed below has now received approval. Please keep this message for your records.

best wishes,
Mick

HLSAW130415
Effect of time on functional readaptive exercise device training

Mick Wilkinson, PhD
Senior Lecturer
Sport, Exercise and Rehabilitation
Northumbria University
Newcastle-upon-Tyne
England
NE1 8ST
mic.wilkinson@northumbria.ac.uk
Tel: 0191 243 7097